DAHD

CCSEA drafts rules for lab animal breeders, traders and users

Draft G.S.R. 864(E) would supersede the 1968 and 1998 animal experiment rules and require CCSEA registration to use, house, breed or trade lab animals.

THE COMMITTEE FOR Control and Supervision of Experiments on Animals (CCSEA), under the Department of Animal Husbandry and Dairying of the Ministry of Fisheries, Animal Husbandry and Dairying, issued notification G.S.R. 864(E), dated September 30, 2026, setting out draft rules to be called the Prevention of Cruelty to Animals (Control and Supervision of Experiment, Breeding and Trading of Laboratory Animals) Rules, 2026. It was published on October 6, 2026 in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 793. It cites the powers in sub-section (1), 1(A) and (2) of section 17 of the Prevention of Cruelty to Animals Act, 1960, and the rules would supersede the Experiments on Animals (Control and Supervision) Rules, 1968 and the Breeding of and Experiments on Animals (Control & Supervision) Rules, 1998, except as respects things done or omitted to be done before the supersession. Rule 1(2) says the rules shall come into force on the date of their publication in the Official Gazette. The notification is signed by Dr. Sujit Kumar Dutta, Member Secretary, under F. No. V-11011(14)/4/2021-CPCSEA-DADF.

KEY FACTS

AUTHORITY

DAHD

PUBLISHED

September 30, 2026

ISSUED BY

Committee for Control and Supervision of Experiments on Animals (CCSEA), Department of Animal Husbandry and Dairying, Ministry of Fisheries, Animal Husbandry and Dairying

DOCUMENT

Notification G.S.R. 864(E): draft Prevention of Cruelty to Animals (Control and Supervision of Experiment, Breeding and Trading of Laboratory Animals) Rules, 2026

CCSEA drafts rules for lab animal breeders, traders and users

DAHD · September 30, 2026

The Committee for Control and Supervision of Experiments on Animals (CCSEA), under the Department of Animal Husbandry and Dairying of the Ministry of Fisheries, Animal Husbandry and Dairying, issued notification G.S.R. 864(E), dated September 30, 2026, setting out draft rules to be called the Prevention of Cruelty to Animals (Control and Supervision of Experiment, Breeding and Trading of Laboratory Animals) Rules, 2026. It was published on October 6, 2026 in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 793. It cites the powers in sub-section (1), 1(A) and (2) of section 17 of the Prevention of Cruelty to Animals Act, 1960, and the rules would supersede the Experiments on Animals (Control and Supervision) Rules, 1968 and the Breeding of and Experiments on Animals (Control & Supervision) Rules, 1998, except as respects things done or omitted to be done before the supersession. Rule 1(2) says the rules shall come into force on the date of their publication in the Official Gazette. The notification is signed by Dr. Sujit Kumar Dutta, Member Secretary, under F. No. V-11011(14)/4/2021-CPCSEA-DADF.

The rules apply to live non-human vertebrate animals used or intended to be used in experiments, including independent feeding larval forms of fishes, embryonated eggs and fetal forms of mammals as from the last third stage of their normal development. They do not apply to non-experimental agricultural and clinical veterinary practices, veterinary clinical field trials required for the marketing authorization of a legally approved veterinary medicinal product (except test batch and quality control trials for batch manufacturing), recognized animal husbandry, identification of an animal, or practices not likely to cause pain, suffering, distress or lasting harm equal to or greater than that caused by the introduction of a needle in accordance with good veterinary practice. No establishment may perform any experiment on animals, or house, breed or trade any animal for experiments, unless it is registered with CCSEA. It applies in Schedule I through CCSEA's online portal to the Member Secretary, with specified fees, and receives a unique registration code and number for each purpose. The registration certificate of an establishment maintaining an animal house facility, including its Institutional Animal Ethics Committee (IAEC), is valid for three years, and registration is to be renewed every three years along with the reconstruction of the IAEC, on review of three years of IAEC minutes, annual inspection reports and, where relevant, annual statements of large animal use. The IAEC has nine members, five internal and four nominated by CCSEA, and meets at least twice in each calendar year; a trader that supplies animals from breeders to users without housing them needs none.

A trader is a person registered with CCSEA who supplies animals to establishments registered with it. Traders must ensure that animals are traded only to CCSEA-registered establishments, on approval of the receiving establishment's IAEC or of CCSEA, as the case may be. Breeders and traders submit a quarterly report to the IAEC and an annual report for each financial year, in Schedule VII, to CCSEA on or before March 31 of each year; rule 20 also requires the breeder-trader to submit trading information in Schedule VII annually before March 31. Registered

breeders, users and establishments may transfer, sell or acquire animals only from CCSEA-registered breeders, establishments or traders. Livestock and farm animals above the level of Lagomorpha, fishes and birds not available from them may be procured from non-registered establishments or the open market with the IAEC's prior approval and maintenance of documents, provided they undergo a veterinarian-certified quarantine and stabilization period before experimentation. Animals not available in the country may be sourced from outside it under the extant import-export policies or guidelines. Contract research is defined as research undertaken by a domestic or foreign individual, company, firm, corporation or institution on behalf of an individual, company, firm, corporation or institution, for consideration, for profit or not, and research institutions or agencies not defined under the rules may outsource research involving animals to a CCSEA-registered establishment.

Every registered establishment needs permission from CCSEA or its IAEC before an experiment. Experiments are classed as non-recovery, mild, moderate or severe under Annexure-I. Severe and non-recovery experiments on animals above rodents and lagomorphs go to CCSEA in Schedule III after the IAEC's recommendation, and CCSEA decides within thirty working days; mild and moderate experiments are decided by the IAEC and not referred to CCSEA, though for animals above lagomorphs the IAEC reports to CCSEA at study initiation, interim progress and completion. Among the purposes allowed is, for the aims of translational or applied research, the development, manufacture or testing of the quality, effectiveness and safety of drugs, food and feed stuffs and other substances or products. Among Annexure-I's examples, assessed case by case, a single-dose pharmacokinetic study with limited blood samples (under 10% of circulating volume) of a substance not expected to cause any detectable adverse effect is mild; testing of established pharmacological compounds is moderate; and acute dose-range finding studies and chronic toxicity or carcinogenicity tests with non-lethal endpoints, toxicity testing where death is the endpoint, first-in-animal or uncertain-risk models, and testing of a device whose failure may cause severe pain, distress or death, such as cardiac assist devices, are severe. Schedule III asks whether research is basic, educational, regulatory or contract research and, for a new chemical entity (NCE), its chemical characteristics, likely reaction to the biological system and in vitro study details.

Where an inspection report by CCSEA's nominees, or a complaint verified through inspection, gives reason to believe the Act or rules have been contravened, CCSEA issues a deficiency notice requiring corrective action within 15 days. If the establishment fails to comply within 15 days, or violations recur within six months, CCSEA may, after a reasonable opportunity of being heard, suspend or revoke the registration, in whole or for a project, protocol, unit or facility, and it may order immediate suspension or revocation where it is satisfied there is an imminent risk to the life, health or welfare of the animals. An appeal lies to the Secretary of CCSEA's Administrative Ministry within thirty days of receipt of the decision, and the Secretary's decision is final. Objections and suggestions go to the Member Secretary (CCSEA), Office of CCSEA, Near State Bank of India, Delhi Milk Scheme Complex, Shadipur, Delhi – 110008, or cpcsea-mef@gov.in, "within a period of thirty days". The English text does not say from which date the thirty days run; the Hindi text counts them from the date of the notification's publication in the

Official Gazette. The issue is dated October 6, 2026; its e-Gazette ID, CG-DL-E-07102026-276913, and its digital signature date the copy October 7, 2026. The draft does not state the registration fees, does not say whether CCSEA or the IAEC decides severe and non-recovery experiments on rodents and lagomorphs, and does not mention CDSCO, the New Drugs and Clinical Trials Rules, 2019 or the Medical Devices Rules, 2017.

Issued by	Committee for Control and Supervision of Experiments on Animals (CCSEA), Department of Animal Husbandry and Dairying, Ministry of Fisheries, Animal Husbandry and Dairying
Document	Notification G.S.R. 864(E): draft Prevention of Cruelty to Animals (Control and Supervision of Experiment, Breeding and Trading of Laboratory Animals) Rules, 2026
Dated	September 30, 2026
Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 793, October 6, 2026
Gazette ID	CG-DL-E-07102026-276913; the e-Gazette copy is dated October 7, 2026
Would supersede	Experiments on Animals (Control and Supervision) Rules, 1968; Breeding of and Experiments on Animals (Control & Supervision) Rules, 1998
Applies to	Establishments that experiment on, house, breed or trade live non-human vertebrate animals for experiments
Registration	With CCSEA, in Schedule I through its online portal, with specified fees; certificate valid three years; renewed every three years
Breeder and trader reports	Quarterly to the IAEC; annually, in Schedule VII, to CCSEA on or before March 31
Severe and non-recovery experiments	On animals above rodents and lagomorphs: CCSEA permission, decided within thirty working days
Animals not available in India	May be sourced from outside the country under the extant import-export policies or guidelines
Appeal	To the Secretary of the Administrative Ministry, within thirty days of receipt of the decision
Comments	Within thirty days: the English gives no start date, the Hindi counts from publication in the Official Gazette (issue dated October 6, 2026); to the Member Secretary (CCSEA), Shadipur, Delhi, or cpcsea-mef@gov.in

Takes effect	On the date of publication in the Official Gazette, as rule 1(2) of the draft reads
Signed by	Dr. Sujit Kumar Dutta, Member Secretary
File number	F. No. V-11011(14)/4/2021-CPCSEA-DADF

Who must do what under the draft rules

Who	What the draft requires	Rule
Every establishment that experiments on, houses, breeds or trades laboratory animals	Register with CCSEA in Schedule I through its online portal, with specified fees; renew every three years along with the reconstruction of the IAEC	8, 9, 10, 23
Establishment conducting experiments	Obtain permission from CCSEA or the IAEC before each experiment; severe and non-recovery experiments on animals above rodents and lagomorphs go to CCSEA	11
Establishment	Constitute a nine-member IAEC, valid for three years (not needed by a trader that supplies animals from breeders to users without housing them); its Chairperson convenes at least two meetings a calendar year, one in each half, and submits minutes within fifteen days	16, 17
Breeder and user	Appoint a veterinarian; all experiments are performed under a veterinarian's supervision	14
Establishment	Keep records of animals used (Schedule IV), bred or acquired (Schedule VI), and sold or transferred (Schedule VII), open to inspection	18
Breeder, user or establishment	Transfer, sell or acquire animals only from CCSEA-registered breeders, establishments or traders, except as rule 21 allows	21
Trader	Trade animals only to CCSEA-registered establishments, on approval of the receiving establishment's IAEC or of CCSEA	8(3)
Breeder and trader	Quarterly report to the IAEC; annual report for each financial year in Schedule VII to CCSEA on or before March 31	8(4), 20

The notification (draft rules) (PDF, 1.2 MB)

Source: Gazette of India, CG-DL-E-07102026-276913.

Checked against the official copy on October 27, 2026.

IndusDesk

hello@indusdesk.com · +91 11 4141 3939

9th Floor, Hemkunt House, Rajendra Place, New Delhi, Delhi 110008, India

Read online: indusdesk.com/dahd/insights/ccsea-drafts-rules-for-lab-animal-breeders-traders-and-users/