Recommended Changes and Draft Clauses for the Draft Prevention of Cruelty to Animals (Control and Supervision of Experiment, Breeding and Trading of Laboratory Animals) Rules, 2026

Submitted to:
The Member Secretary, Committee for Control and Supervision of Experiments on Animals (CCSEA), Office of CCSEA, Near State Bank of India, Delhi Milk Scheme Complex, Shadipur, Delhi – 110008, in response to Notification G.S.R. 864(E) dated 30.09.2026 inviting objections and suggestions on the Draft Rules (by e-mail to cpcsea-mef@gov.in)

Submitted by:
India Legal Research Foundation (ILRF)

Contributors:

Aaditya Bajpai, Legal Research Associate, ILRF

Devang Anand, Legal Consultant, ILRF

Gautami Seth, Manager: New Initiatives, ILRF

Kunwarinder Pal Singh Bamrah, Legal Consultant, ILRF

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The Committee has invited objections and suggestions on the draft Prevention of Cruelty to Animals (Control and Supervision of Experiment, Breeding and Trading of Laboratory Animals) Rules, 2026 (hereinafter "the 2026 Draft Rules") within thirty days of their publication in the Gazette of India on 7 October 2026 (G.S.R. 864(E), dated 30 September 2026). This submission is made in response to that invitation. It is respectfully placed before the Committee as follows: a summary of the principal requests, followed by Part I (provisions of the draft that are welcomed, with suggestions to strengthen them), Part II (critical provisions requiring amendment, with a comparative matrix), Part III (further rule-wise recommendations), Part IV (a summary table of Part III), Part V (drafting errors and inconsistencies in the Gazette text) and Part VI (the concluding submission).

Unless otherwise stated, references to "the Act" are to the Prevention of Cruelty to Animals Act, 1960; references to "the 1998 Rules" are to the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 as amended by S.O. 134(E) dated 15 February 2001 ("the 2001 Amendment") and S.O. 1818(E) dated 23 October 2006 ("the 2006 Amendment"); and references to "the EU Directive" are to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes, on which several provisions of the 2026 Draft Rules are modelled. References to "the IAEC SOP" are to the Committee's Standard Operating Procedures for Institutional Animal Ethics Committees, under which, in current practice, protocols on animals other than small laboratory animals are referred to the Committee.

SUMMARY OF PRINCIPAL REQUESTS

- **Central approval for larger animals:** Restore prior CCSEA approval for every experiment on animals above rodents and lagomorphs, whatever its severity category (Rule 11), require prior CCSEA approval for severe experiments on rodents and lagomorphs (which no rule currently assigns to any authority), and leave other experiments on rodents and lagomorphs with the IAEC, subject to a CCSEA power to call in any protocol.
- **Independent IAEC:** Ensure that external CCSEA nominees form at least half of every IAEC and its quorum, and that severity classification is not left to an in-house veterinarian (Rules 11(10), 16 and 17).
- **Sourcing:** Delete open-market and unregistered sourcing (Rule 21(2)), the stray-animal exception (Rule 5(3)) and the waiver of the duty to relieve the suffering of wild-caught animals (Rule 5(2)(c)).
- **Primates:** Protect all non-human primates irrespective of their Wild Life (Protection) Act schedule, with a mandatory F2 or self-sustaining colony requirement and prior CCSEA approval, and redraft Rule 6(2), whose reference to the 2022 Amendment Act is uncertain in scope (Rules 5 and 6).

- **Restore lost safeguards:** Reinstate the 1998 prohibitions (debarking, eye-irritancy, paralysants without anaesthesia, demonstrations, repetition of known experiments), the 2006 duties of aftercare, rehabilitation and lifetime-care funding, and the 3Rs standard of Rule 9(bb).
- **Prohibited procedures:** Move the most extreme procedures listed in Annexure-I (Section III, item 4) to a list of prohibited procedures, and correct the classification examples so that they follow the effect-based criteria in Sections I and II of Annexure-I.
- **Enforcement:** Permit unannounced inspections (Rule 24(4)), restore powers to give directions for the care and custody of animals on suspension (1998 Rule 14(c) and (d)), and remove the limit on the Committee's power to seek information (Rule 11(8)).
- **Transparency and accountability:** Make the appeal mechanism available to CCSEA nominees and animal welfare organisations, provide for public Non-Technical Project Summaries and annual statistics, and place core welfare standards in the Rules themselves instead of in guidelines that bypass prior publication and Parliamentary scrutiny.
- **Cosmetics and other prohibited testing:** State expressly that no experiment shall be performed for testing cosmetics or their ingredients, or for any purpose for which another law has prohibited animal use (Rules 4(3) and 15(3)).
- **Drafting corrections:** Correct the statutory references, cross-references and numbering errors listed in Part V, several of which change the meaning of the provision concerned.

I. WELCOMED PROVISIONS IN THE 2026 DRAFT

1. Codification of the four-tier severity classification: Rule 7

- **Statutory Alignment with International Standards:** The formal categorisation of experimental procedures into 'Non-recovery', 'Mild', 'Moderate', and 'Severe' aligns Indian regulatory frameworks with global best practices, notably the European Union Directive 2010/63/EU.
- **Harmonization of Scientific Metrics:** Historically, the absence of an objective severity matrix in Indian law created administrative ambiguity. Defining expected pain, distress, and lasting harm allows protocols to be calibrated with tailored analgesia, humane endpoints, and scientific justification.
- **Suggested Strengthening:** The examples in Section III of Annexure-I should be revised so that they are consistent with these effect-based criteria (see Recommendation 14 below).

2. Creation of a Mandatory Institutional Euthanasia Registry: Rule 15(4)(c)

- **Traceability and Accountability:** Mandating an institutional Euthanasia Registry plugs an administrative loophole where undocumented terminations of research subjects occurred without oversight.

- **Data Integrity:** This requirement establishes an auditable chain of custody regarding the true mortality and distress indices of laboratory animals, preventing retrospective protocol alterations.
- **Suggested Strengthening:** As drafted, the registry requirement appears as clause (c) under Rule 15(4), whose opening words apply to experiments in which "death as the endpoint is unavoidable". It may therefore be read as applying only to such experiments. The registry should be made a stand-alone sub-rule covering every animal euthanised in the establishment for any reason, the entries should be open to inspection by CCSEA nominees, and a consolidated figure should be reported annually in Schedule IX.

3. **Welfare Standards in Housing and Care: Rules 2(k), 2(r), 3(3) and 19(1)(e)(f)**
   - **Humane Endpoints and Refinement:** The definition of "Humane Endpoint" in Rule 2(k) and the requirement in Rule 3(3) of environmental enrichment, best veterinary practice and validated humane endpoints are welcome additions to the statutory framework.
   - **Preference for Non-Invasive Methods:** Rule 2(r) states that non-invasive experiments "shall be employed wherever the scientific objective can be achieved without invasive procedures". This is a valuable refinement principle.
   - **Species-Specific Needs:** Rule 19(1)(e) (species-specific environmental enrichment and ethological needs) and Rule 19(1)(f) (exercise and rehabilitation areas for large animals) give binding effect to standards that were earlier found only in guidelines.
   - **Suggested Strengthening:** The preference for non-invasive methods in Rule 2(r) should be moved into Rule 3, since a definition clause does not ordinarily impose obligations.
4. **Monitoring of IAEC Approvals and Periodic Inspections: Rules 11(4) and 24(1)**
   - **Staged Reporting:** Rule 11(4) requires the IAEC to report mild and moderate experiments on animals above lagomorphs to the Committee at study initiation, at an interim stage and at completion. Rule 24(1) makes it binding on the Main Nominee and the Socially Aware Nominee to inspect the animal house at least twice a year, apart from IAEC meetings.
   - **Suggested Strengthening:** Reporting after approval does not replace prior review. The Committee should be expressly empowered to suspend, modify or call for re-examination of any protocol on the basis of a report received under Rule 11(4) (see Recommendation 1 below)
5. **Complaint-Based Action and Emergency Suspension: Rule 25(1).**
   - **Access for the Public:** Rule 25(1) allows action on the basis of complaints made by any person or organisation once verified through inspection. Rule 25(1)(c)

preserves the Committee's power to order immediate suspension or revocation where there is an imminent risk to the life, health or welfare of animals.

- **Suggested Strengthening:** These powers should be accompanied by the power to issue binding directions for the care and custody of the affected animals (see Recommendation 17 below).

II. CRITICAL PROVISIONS REQUIRING AMENDMENT

1. Re-establishing Central Oversight for Large Animals and High-Severity Protocols

- **The Flaw:** Rule 11(3) devolves the sole authority to approve 'mild' and 'moderate' experiments on all species of animals including large animals such as dogs, cattle, equines, and pigs to the local Institutional Animal Ethics Committee (IAEC), and expressly provides that "such experiment shall not be referred to the Committee". Under the existing framework, which rests on the IAEC SOP rather than on the text of the 1998 Rules, the IAEC gives final approval only to experiments on small laboratory animals such as rodents and rabbits, while protocols on larger animals are forwarded to CCSEA for approval on the IAEC's recommendation. The 2026 Draft Rules would be the first time this division is placed in the Rules, and they place it there in a weaker form.
- Rule 11(4) requires the IAEC to report such approvals for animals above lagomorphs to the Committee at three stages. However, these reports are made after approval has been granted, and the Rules give the Committee no express power to refuse, modify or stop a protocol on the basis of them.
- **Legal Grounding:** Section 17(2)(e) of the Act directs that experiments on larger animals be avoided where the same results can be achieved with small laboratory animals; that direction is not served by a system in which the institution alone decides whether a larger animal is needed. Section 17(1) also places on the Committee itself the duty to ensure that animals are not subjected to unnecessary pain or suffering. A sub-rule directing that such experiments "shall not be referred to the Committee" shuts the Committee out of the very protocols on which that duty bears most heavily.
- **Recommended Change:** Substitute sub-rules (2) and (3) of Rule 11 as set out below. This restores the existing division for larger animals, closes the gap for severe experiments on rodents and lagomorphs (Recommendation 10), and keeps routine work on rodents and lagomorphs with the IAEC, so that the Committee's workload remains manageable:

  "*(2) Every establishment shall, after the recommendation of its IAEC, apply to the Committee through the online portal, with the details in Schedule III, for prior approval of –*

(a) every experiment, of whatever severity, on animals above the category of rodents and lagomorphs;

(b) every experiment classified as 'severe' under Rule 7, on any species; and

(c) every experiment on non-human primates,

and the Committee shall decide every such application within thirty working days.

(3) Every other experiment shall be submitted in Schedule III to the IAEC for decision:

Provided that the Committee may, on the report of its nominee, on a report received under sub-rule (4), or of its own motion, call for, examine, modify, suspend or revoke any approval granted by an IAEC."

2. Absolute Ban on Sourcing from the Open Market and Unregistered Sources

- **The Flaw:** Rule 21(2) permits establishments to procure livestock, farm animals (above the level of Lagomorpha), fishes and birds from "non-registered establishments or open market" with only the prior approval of their own IAEC. The requirement of a veterinarian-certified quarantine and stabilisation period addresses the health of the animal on arrival; it does not establish where the animal came from or the conditions in which it was kept and transported before arrival.
- **Legal Grounding:** Contrary to the mandate of Section 17(1) and Section 17(2)(g) of the Act, which require that animals are not subjected to unnecessary pain or suffering before, during or after experiments and are properly looked after before and after experiments; unmonitored commercial sourcing involves undocumented transit conditions (see also Section 11(1)(d)) and compromises physiological states. It destroys the regulatory chain of custody. It is also a step back from Rule 10(b) of the 1998 Rules (as substituted in 2006), under which alternate legal sources could be used only with the written permission of the competent authority.
- **Recommended Change:** Strike out Rule 21(2). All animals, regardless of species, must be sourced exclusively from CCSEA-registered breeding establishments complying with mandatory welfare standards. *Where purpose-bred animals are not available, the experiment must be deferred until they are, rather than permitting a sourcing route that compromises the welfare and dignity of the animals.* In the alternative, and only for livestock, poultry and fish used in agricultural or veterinary research, procurement from a non-registered source may be permitted with the prior written approval of the Committee (not the IAEC), on documentary proof of lawful origin, a transport record complying with the Transport of Animals Rules, 1978, and a quarantine period fixed in the Rules themselves. This would restore the substance of Rule 10(b)(iii) of the 1998 Rules, as substituted by the 2006 Amendment.

3. Complete Prohibition on the Experimentation of Stray and Community Animals

- **The Flaw:** Rule 5(3) carves out a discretionary exception permitting undefined 'competent authorities' to allow the use of stray and feral animals of domestic species where there is an "essential need" for studies on animal health or welfare or on "serious threats to the environment or to human or animal health", and where the purpose can be achieved only by using such animals. The provision reproduces Article 11 of the EU Directive, but India's community animals are governed by a different statutory scheme (see Recommendation 11 below).
- **Legal Grounding:** Under the Animal Birth Control Rules, 2023, framed under the same Act, community dogs are to be sterilised, vaccinated and returned to the same locality. Rule 5(3) would allow the same animals to be diverted to laboratories, so that two sets of rules under one Act would point in opposite directions. In *Animal Welfare Board of India v. A. Nagaraja, (2014) 7 SCC 547*, the Supreme Court read the "five freedoms" into Sections 3 and 11 of the Act. The expression "competent authorities" is not defined anywhere in the draft, so the exception would be administered by an unnamed authority applying no stated standard.
- **Recommended Change:** Substitute Rule 5(3) as follows: "(3) No stray, free-ranging, community or feral animal of a domestic species, and no companion animal that has been lost, abandoned or surrendered, shall be captured, acquired or used in an experiment." In the alternative, and without prejudice to the foregoing, confine any exception to non-invasive studies of the health or welfare of such animals themselves, require the prior approval of the Committee itself rather than of an undefined "competent authority", record the locality from which each animal is taken, and require its return to that locality, as the Animal Birth Control Rules, 2023 require.

4. Expansion of Non-Human Primate Protections to Cover Macaca mulatta

- **The Flaw:** Rule 6(2) bars only those non-human primates that are "listed in the Wildlife (Protection) Amendment Act, 2022", and Rule 5(1)(c) takes all non-human primates out of the general rule on protected species. Protection therefore depends on the schedule in which a species happens to be placed. The Rhesus Monkey (Macaca mulatta) was removed from Part I of Schedule II by the 2022 Amendment Act and now appears only in Schedule IV, which implements CITES and regulates international trade. The Standing Committee of the National Board for Wildlife recommended its re-inclusion in Schedule II in 2025, on a request from the Animal Welfare Board of India, but protection under these Rules should not turn on such changes. The reference is also uncertain in scope. The Wild Life (Protection) Amendment Act, 2022 did not itself list any species; it substituted the Schedules to the Wild Life (Protection) Act, 1972. If "listed" includes Schedule IV, every non-human primate is covered, since all primates appear in Appendix I

or II of CITES, and Rule 6(2) would make Rule 6(1) a dead letter. If it does not, Rule 6(2) leaves out the rhesus macaque, one of the principal primate species used in Indian research. Either way the sub-rule must be redrafted. Rule 5(2)(d) only requires the Committee to "review" the sourcing of primates from self-sustaining colonies, without any binding requirement.

- **Legal Grounding:** Ties protection to a criterion foreign to the Act, which aims at preventing cruelty irrespective of conservation status; Section 2(a) of the Act defines "animal" as any living creature other than a human being. Sentient animals require protection regardless of endangerment. Article 10 of the EU Directive, read with its Annex II, requires non-human primates to be offspring of animals bred in captivity or obtained from self-sustaining colonies.
- **Recommended Change:** Substitute Rule 6 as follows:

"*6. Non-human primates.– (1) No non-human primate, of any species and whether or not listed in any Schedule to the Wild Life (Protection) Act, 1972, shall be used in an experiment unless–*

(a) the experiment is undertaken for the avoidance, prevention, diagnosis or treatment of a life-threatening or seriously debilitating clinical condition in human beings;

(b) there is scientific justification that the purpose cannot be achieved by the use of any other species or of any non-animal method;

(c) the animal is the offspring of non-human primates bred in captivity, of the second or a later generation, or is obtained from a self-sustaining colony registered with the Committee; and

(d) the prior approval of the Committee has been obtained under Rule 11(2).

(2) No non-human primate taken from the wild, and no great ape, shall be used in an experiment.

Explanation.– A clinical condition is "seriously debilitating" if it substantially limits a person's ability to carry out the ordinary activities of daily life."

5. Restricting Animal Use for Vocational Skills and Manual Training

- **The Flaw:** Draft Rule 4(6) permits the use of animals for "higher education, or professional training for the acquisition, maintenance or improvement of vocational skills", and Annexure-I (Section III, item 1) lists laparoscopic, robotic and invasive surgery training on animals as its only examples of non-recovery experiments.
- **Legal Grounding:** Section 17(2)(f) of the Act directs that, as far as possible, experiments are not performed merely for the purpose of acquiring manual skill, and Section 17(2)(d) directs that experiments be avoided in medical schools, hospitals, colleges and the like where books, models, films and the like may equally suffice. Under Rule 9(g) of the 1998 Rules, as substituted by the 2001

Amendment, manual-skill experiments outside schools and colleges required programme-specific scrutiny and permission by the Committee. Rule 4(6) makes vocational training a free-standing purpose with neither limit, and Rule 11(11) lets the IAEC approve curriculum-based teaching for up to five years. The provision also runs against the move to non-animal teaching already made by the UGC (guidelines of November 2011 for the phased discontinuation of dissection and animal experimentation in zoology and life sciences, extended in 2014), the Medical Council of India, now the NMC (amendment of 19 March 2014 to its Minimum Standard Requirements, directing that undergraduate physiology and pharmacology be taught through computer-assisted modules), and the Pharmacy Council of India (notification of 25 August 2014 to the same effect for pharmacy curricula).

- **Recommended Change:** Substitute Rule 4(6) as follows:

"*(6) professional training, at the postgraduate level or of qualified veterinary or medical practitioners, for the acquisition of a specific surgical or clinical skill that cannot be acquired through validated non-animal methods, including simulators, models, ethically sourced cadavers and supervised clinical practice, where–*

(a) the trainee has first demonstrated competence on such non-animal methods;

(b) the procedure is performed entirely under general anaesthesia from which the animal does not recover; and

(c) the prior approval of the Committee has been obtained:

Provided that no animal shall be used in an experiment for teaching or training in any school or undergraduate course, or to demonstrate a result that is already known."

Consequentially, omit curriculum-based teaching from the five-year approvals permitted by Rule 11(11)."

COMPARISON: 1998 FRAMEWORK, 2026 DRAFT AND RECOMMENDED REVISIONS

REGULATORY DOMAIN	1998 RULES (AS AMENDED) AND CURRENT PRACTICE	2026 DRAFT PROPOSAL	RECOMMENDED FINAL PROVISION	LEGAL JUSTIFICATION
Approval Jurisdiction	Rules allow approval by CCSEA or the IAEC (Rule 8); under the IAEC SOP, the IAEC gives final approval only for small laboratory animals, and protocols on larger animals go to CCSEA on IAEC recommendation.	Local IAEC empowered to approve 'Mild' and 'Moderate' studies across all species (Rule 11(3)); post-approval reporting only (Rule 11(4)).	Prior CCSEA approval for all experiments above rodents and lagomorphs, all 'Severe' experiments on any species and all primate work; IAEC decides the rest, subject to CCSEA call-in.	Section 17(1) (the x) and Section 17(2)(e) of the Act.
Animal Sourcing	Registered breeders; alternate legal sources only with written permission of competent authority (Rule 10(b), as substituted in 2006).	Purchase of livestock, farm animals, fish and birds from 'non-registered establishments or open market' with IAEC approval (Rule 21(2)).	Absolute prohibition on open-market sourcing. All species must come from CCSEA-registered breeders.	Sections 17(1) and 17(2)(g); Section 11(1)(d) on cruel conveyance.
Stray / Free-Ranging Animals	No exception permitting stray animals; sourcing confined to registered breeders or permitted alternate legal sources.	Prohibited under Rule 5(3), but with exemptions by undefined 'competent authorities'.	Absolute, non-derogable statutory prohibition on the use of stray and community animals.	Sections 3 and 11 as read in *AWBI v. Nagaraja*; Animal Birth Control Rules, 2023.

Non-Human Primates	No species-specific rule; experiments on primates required CCSEA approval as large animals.	Protection tied to Wild Life (Protection) Act listing (Rules 5(1)(c), 6(2)); *Rule 6(2) uncertain: read with Schedule IV it bars all primates, otherwise it leaves out Macaca mulatta*; colony sourcing only 'reviewed' (Rule 5(2)(d)).	Comprehensive protection for all non-human primates, mandating F2 captive-bred verification and CCSEA sign-off; no wild-caught primates; life-threatening or seriously debilitating human conditions only.	Section 2(a) of the Act; EU Directive Art. 10 and Annex II.
Education & Training	Manual-skill experiments barred except in schools, colleges and programmes scrutinised and permitted by the Committee (Rule 9(g), as substituted in 2001); schools up to higher secondary level outside the definition of "establishment" (Rule 2(d)).	Rule 4(6) permits animal use for vocational skill training; Annexure-I lists surgical training as non-recovery.	No animal use in schools or undergraduate courses; postgraduate and professional skills training only where non-animal methods cannot suffice, under non-recovery anaesthesia, with prior CCSEA approval.	Sections 17(2)(d) and 17(2)(f) of the Act; 1998 Rule 9(g), as substituted in 2001.

III. ADDITIONAL PROVISIONS REQUIRING AMENDMENT

6. Loss of Existing Protections and Partial Adoption of the EU Directive

- **The Flaw:** The 2026 Draft Rules supersede the 1998 Rules and, in doing so, drop a number of safeguards that have governed laboratory animal use in India for close to thirty years (see Recommendations 7, 8 and 13). Much of the new text,

notably Rules 1, 3 to 7, 12, 13 and Annexure-I, follows the EU Directive closely. Several of the most permissive provisions, including the stray-animal exception in Rule 5(3) and the waiver of the duty to relieve the suffering of wild-caught animals in Rule 5(2)(c), are taken almost word for word from Articles 11 and 9 of the Directive. However, the protective provisions of the same Directive have not been adopted: coverage of live cephalopods (Article 1(3)(b)), limits on reuse (Article 16), project evaluation and authorisation by an impartial competent authority (Articles 36 to 38), retrospective assessment (Article 39), Non-Technical Project Summaries (Article 43), unannounced inspections (Article 34) and annual statistics (Article 54).

- **Legal Grounding:** The object of the Act, as stated in its Preamble and reflected in Section 17(1), is the prevention of unnecessary pain and suffering. Rules framed under Section 17 must further that object and should not lower the level of protection already secured. In *Animal Welfare Board of India v. A. Nagaraja, (2014) 7 SCC 547*, the Hon'ble Supreme Court read the Act alongside Article 51A(g) of the Constitution and stressed the duty to show compassion to animals.
- **Recommended Change:** No safeguard of the 1998 Rules should be dropped unless the 2026 Rules put in place an equivalent or higher standard. Where the draft relies on the EU Directive, its corresponding safeguards (Articles 1(3)(b), 16, 34, 36 to 39, 43 and 54) should be adopted as well.

7. Aftercare, Rehabilitation, Lifetime Care Funding, Euthanasia and Reuse

- **The Flaw:** Clauses (cc) and (ff) of Rule 9, inserted by the 2006 Amendment, made investigators responsible for aftercare and rehabilitation, treated aftercare as part of research costs, required rehabilitation to continue until the animal could resume a normal existence (supported by a lump-sum amount for its expected life span), and permitted euthanasia only in three situations: where the animal is paralysed or cannot perform its natural functions, where recurring pain persists after a procedure, or where keeping the animal alive would endanger humans or other animals. The 2026 Draft Rules contain neither clause. Instead:
  a. Rule 1(6) treats euthanasia and rehabilitation as equal alternatives at the end of an experiment.
  b. Rule 15(1) leaves rehabilitation and reuse entirely to orders or guidelines to be issued by CCSEA, without any standard in the Rules themselves.
  c. Rule 15(4) accepts death as an endpoint where it is "unavoidable".
  d. Schedule III (Part B, item 12(a)) asks only for the "scope for reuse", and item 11(d) contemplates major survival surgery being performed more than once on the same animal. Section II(viii) of Annexure-I also assumes reuse.

- The draft does refer to rehabilitation in Schedule I (item 10), Schedule III (item 12(b)), Rule 19(1)(f) and Schedule IX. However, none of these imposes a binding duty to rehabilitate or a duty to fund lifetime care.
- **Legal Grounding:** The Committee's duty under Section 17(1) extends to suffering "after the performance of experiments", and Section 17(2)(g) specifically requires that animals be properly looked after after experiments.
- **Recommended Change:** Insert the following as **Rule 15A**, which carries forward clauses (cc) and (ff) of Rule 9 of the 1998 Rules (inserted by the 2006 Amendment) and the limits on reuse in Article 16 of the EU Directive, so that animals are not euthanised merely for convenience or cost and lifetime care remains a mandatory budget head. Items 11(d) and 12(a) of Schedule III, Part B should be amended to correspond:

  "*15A. Aftercare, rehabilitation, euthanasia and reuse.– (1) The investigator shall be responsible for the aftercare and rehabilitation of every animal after the experiment. The cost of aftercare and rehabilitation, including a lump-sum amount sufficient for the care of the animal for its expected remaining life span, shall form part of the cost of the project and shall be stated in the application under Schedule III.*

  (2) No animal shall be euthanised on completion of an experiment except where–

  (a) it is paralysed or unable to perform its natural functions, has become incapable of independent locomotion, or can no longer perceive its environment in an intelligible manner;

  (b) it has been left with recurring pain and shows obvious signs of pain and suffering;

  (c) keeping it alive would endanger human beings or other animals; or

  (d) the approved protocol is a non-recovery experiment, or specifically requires post-mortem examination of the animal and the approving authority has recorded why that examination is necessary.

  (3) No animal that has undergone a procedure classified as 'severe' shall be reused. Any other animal may be reused only if the Designated Veterinarian certifies in writing that it has fully recovered its general state of health and well-being, and the reuse forms part of the approved protocol.

  (4) Not more than one major survival surgery shall be performed on the same animal, except with the prior approval of the Committee on scientific justification that the surgeries are related components of a single project."

8. Restoring the 1998 Prohibitions and Prohibiting Extreme Procedures

- **The Flaw:** Rule 9 of the 1998 Rules contained specific prohibitions and safeguards that find no place in the 2026 Draft Rules:

a. operative procedures more severe than simple inoculation or superficial venesection to be carried out under anaesthesia throughout, with the person administering it present until completion (clause (d));

b. animals so injured under anaesthesia that recovery would involve serious suffering to be destroyed while still under anaesthesia (clause (e)), and animals in severe or abnormal pain to be painlessly destroyed (clause (f));

c. no experiments for illustration or public demonstration (clauses (h) and (i));

d. no curare or similar paralysing agents without deep anaesthesia (clause (j));

e. no repetition of experiments whose results are conclusively known, without prior justification (clause (k));

f. no application of chemicals to the eye solely to cause pain (clause (l)); and

g. no debarking of dogs held for experiments (clause (m)).

- In addition, item 10(g) of Schedule III, Part B contemplates protocols that "prohibit use of anaesthetics or analgesics for the conduct of painful procedures". Rule 7(2) bars only experiments involving severe pain that is both long-lasting and incapable of amelioration. Within that limit, item 4 ("Severe") of Section III of Annexure-I lists, among others, the following procedures: single-dose acute toxicity testing (4(i)); tumours allowed to ulcerate or cause cachexia (4(n)); unstable fractures, thoracotomy without adequate analgesia and trauma producing multiple organ failure (4(o)); inescapable electric shock (4(s)); prolonged complete isolation of dogs and primates (4(t)); immobilisation stress to induce ulcers or cardiac failure (4(u)); and exercise to exhaustion (4(v)). Item 4(o) contradicts item 4(j) of the same list, which describes thoracotomy "under general anaesthesia and appropriate analgesia".
- **Legal Grounding:** Section 17(2)(b) of the Act requires experiments involving operations to be performed, as far as possible, under anaesthetic sufficient to prevent pain. Section 17(2)(c) requires animals whose recovery would involve serious suffering to be ordinarily destroyed while still insensible. Section 11 prohibits unnecessary pain or suffering.
- **Recommended Change:** Restore clauses (d), (e), (f), (h) to (m) of Rule 9 of the 1998 Rules. Clause (g) is addressed separately under Recommendation 5. Provide in the Rules that no surgical procedure shall be performed without general anaesthesia, and substitute item 10(g) of Schedule III, Part B so that any proposal to withhold analgesia from a painful procedure must be justified and requires the prior approval of the Committee. Remove the procedures in items 4(i), (n), (o), (s), (t), (u) and (v) of Section III of Annexure-I from the "Severe" examples and

list them in a new Schedule of prohibited procedures, to which a new Rule 7(3) should give effect, in the following terms:

"*Schedule X – Prohibited procedures {See Rule 7(3)}. The following shall not be performed on any animal:*

1. any toxicity test in which the death of the animal is the intended endpoint, including the classical LD50 test, unless such a test is expressly required by a law for the time being in force in India and no alternative is accepted by the regulator concerned, in which case it shall require the prior approval of the Committee;

2. allowing a tumour to ulcerate, or to progress to cachexia, invasive bone involvement or metastatic spread, before the humane endpoint is applied;

3. major surgery, including thoracotomy, without adequate analgesia; the production of unstable fractures; and trauma intended to cause multiple organ failure;

4. inescapable electric shock, including to produce learned helplessness;

5. complete isolation of dogs, non-human primates or other social species for prolonged periods;

6. immobilisation stress to induce gastric ulcers or cardiac failure;

7. exercise tests with exhaustion as the endpoint;

8. debarking of dogs; and

9. the use of any neuromuscular blocking agent without general anaesthesia sufficient to produce loss of consciousness."

In the alternative, if the Committee is not inclined to prohibit any of these procedures outright, each should be permitted only with the prior approval of the Committee, with humane endpoints defined so as to end the procedure before death or exhaustion, and with a retrospective assessment of the kind required by Article 39 of the EU Directive.

9. Independence of the IAEC and Severity Certification

- **The Flaw:** This point develops Recommendation 1.

a. **Severity certified in-house:** Under Rule 11(10), the IAEC Veterinarian, an officer of the establishment, certifies the severity of the experiment. That classification decides whether the protocol goes to CCSEA at all. The "Moderate" examples in Annexure-I (Section III, item 3), which the IAEC alone may approve, include tumour induction, sub-lethal irradiation and chemotherapy, creation of genetically altered animals through surgery, five days in metabolic cages, 48-hour food withdrawal and inescapable aversive stimuli (item 3(m)).

b. **Internal majority:** Under Rule 16(2) and (4), five of the nine members, including the Chairperson and Member Secretary, are internal members of the establishment. Since the Link Nominee attends only when the Main Nominee

is unavailable (Rule 17(3)), internal members are always in the majority at a meeting. Rule 17(2) makes the presence of the Main Nominee and the Socially Aware Nominee mandatory for quorum, but neither can prevent a protocol from being approved.

c. **Long-term approvals:** Rule 11(11) permits approvals of up to five years for repetitive or curriculum-based teaching experiments, subject to conditions and periodic reviews "as may be specified". The Rules do not themselves require a review of available alternatives during that period. A five-year approval would also outlast both the IAEC that grants it and the establishment's registration, each of which is valid for only three years (Rules 10(1)(g), 16(1) and 23(1)).

d. **Meetings:** Rule 17(1) requires only two IAEC meetings a year, although the IAEC is now to be the final approving authority for most experiments.

- **Legal Grounding:** Section 17(2)(e) of the Act (preference for small laboratory animals) and Section 17(2)(d) (avoidance of experiments wherever possible) cannot be effectively applied where the establishment classifies, reviews and approves its own protocols.
- **Recommended Change:** (i) Entrust final severity classification to the Main Nominee or CCSEA, and require reasons to be recorded. (ii) Amend Rules 16 and 17 so that external CCSEA nominees form at least half of the IAEC and of its quorum, the Chairperson is an external member, and any protocol objected to in writing by the Main Nominee or the Socially Aware Nominee is referred to CCSEA for decision. (iii) Require, in Rule 11(11) itself, an annual review of alternatives and a maximum approval period of three years. (iv) Require quarterly IAEC meetings for establishments using animals above rodents and lagomorphs.

10. Gap in Approval for Severe Experiments on Rodents and Lagomorphs, and Limits on the Committee's Information Powers

- **The Flaw:** Rule 11(2) sends to CCSEA only severe and non-recovery experiments "on animals above the category of rodent and lagomorph", and Rule 11(3) sends mild and moderate experiments to the IAEC. Neither sub-rule deals with severe or non-recovery experiments on rodents and lagomorphs, which make up the overwhelming majority of animals used. Rule 11(1) says only that permission is to be obtained from the Committee or the IAEC "as the case may be". Separately, Rule 11(8) allows the Committee to seek information after completion of experiments, but "limited to the welfare of the animals". Rule 8(d) of the 1998 Rules contained no such limit.
- **Legal Grounding:** Section 17(1A)(b) of the Act empowers the Committee to make rules for "the reports and other information which shall be forwarded to the Committee". Confining that power to welfare information alone limits the

Committee's ability to examine scientific justification, numbers used and compliance with the 3Rs.

- **Recommended Change:** Provide expressly that all severe experiments, on any species, require prior CCSEA approval after IAEC recommendation, as in the substituted Rule 11(2) proposed under Recommendation 1. Non-recovery experiments on rodents and lagomorphs, which are performed entirely under general anaesthesia, may remain with the IAEC. Delete the words "but limited to the welfare of the animals" from Rule 11(8).

11. Wild-Caught and Protected Animals, Stray Animals and the Primate Provisions

a. **Protected species:** Rule 5(1) permits experiments on species protected under wildlife law for the purposes in Rule 4(2)(a), 4(3) or 4(5), on scientific justification and permission. Clause (b) refers to "endangered species", a narrower expression than the "protected" species covered by the opening words.

b. **Waiver of the duty to relieve suffering:** Rule 5(2)(a) allows animals to be taken from the wild on an exemption from an undefined "Competent authority of the relevant department". The second sentence of Rule 5(2)(c) allows competent authorities to waive the requirement of acting to minimise the suffering of an animal found injured or in poor health during or after capture.

c. **Unclear primate exception:** Rule 5(1)(c) ("sub-rule (1) shall not apply to any species of non-human primates") is placed as one of the conditions of an exception, between clauses (b) and (d). Its effect is unclear: it may be read as allowing protected primates to be used without satisfying the other conditions.

d. **Primates in basic research:** Rule 6(1)(b) permits primates to be used in basic research under Rule 4(1), with no link to any serious human condition. The Note to Rule 6(1) defines a "debilitating clinical condition" so broadly ("a reduction in a person's normal physical or psychological ability to function") that almost any ailment qualifies.

- **Legal Grounding:** A waiver of the duty to minimise suffering is inconsistent with Section 3 of the Act (duty of persons in charge of animals) and Sections 17(1) and 17(2)(b).

- **Recommended Change:** Prohibit the capture of wild animals for invasive experiments; delete the second sentence of Rule 5(2)(c); define "competent authority" in Rule 2 for each case in which it is used; replace clause (c) of Rule 5(1) with a separate proviso stating that non-human primates shall be governed exclusively by Rule 6; and, through the substituted Rule 6 proposed under Recommendation 4, remove basic research as a purpose for which primates may be used and narrow the definition of a debilitating condition.

12. Expansion of the Purposes for Which Animals May Be Used

- **The Flaw:** Rule 2(h) of the draft defines "Experimentation" by reference to saving or prolonging life, alleviating suffering, significant gains in well-being, or combating disease "of human beings or animals". Rule 4, however, permits experiments for purposes going well beyond that definition:
  a. Rule 4(2)(a) and (b) extend to diseases and physiological conditions of "plants".
  b. Rule 4(1) permits basic research for the advancement of knowledge without reference to Rule 2(h).
  c. Rule 4(2)(c) permits experiments to improve production conditions for animals reared for agriculture, while Rule 1(10)(d) excludes "recognised animal husbandry" from the Rules.
  d. Rule 2(i) omits the express exclusion of schools up to the higher secondary level found in Rule 2(d) of the 1998 Rules.
  e. Rule 4(8) ("Process of bleeding/blood products") and item 5(vi) of Schedule I (production of hyperimmune plasma and serum) recognise blood and serum production as independent purposes, but set no limits on volume or frequency of bleeding, no restriction on PMSG (Pregnant Mare Serum Gonadotropin) extraction, and no provision for the retirement and lifelong care of equines and sheep used for bleeding.
- **Legal Grounding:** Sections 17(2)(d) and 17(2)(f) of the Act. Section 14 of the Act does refer to knowledge useful for combating diseases "of human beings, animals or plants", but Section 17(2)(d) still requires animal experiments to be avoided wherever possible. That requirement should be applied with particular rigour where the subject of the research is not an animal. The internal inconsistency between Rules 2(h) and 4 should in any event be resolved.
- **Recommended Change:** (i) Delete "or plants" from Rule 4(2)(a) and (b) or, in the alternative, require prior CCSEA approval and proof that no non-animal method can achieve the objective. (ii) Make Rule 4(1) subject to Rule 2(h). (iii) Make Rule 4(2)(c) experiments subject to the Rules notwithstanding Rule 1(10)(d). (iv) Provide expressly that no experiment shall be performed in any school up to the higher secondary level. Restoring the 1998 wording alone would not achieve this, because that wording excluded such schools from the definition of "establishment" and so took them outside the Rules rather than prohibiting animal use in them. (v) Prescribe limits on the volume and frequency of bleeding, prohibit the bleeding of pregnant mares for PMSG (eCG) production, and require lifelong care for equines and other animals retired from serum and antivenom production. Require the Committee to review, at least once every two years, the

availability of recombinant or other non-animal methods for each such product, and to fix a timeline for transition once such a method has been approved by the Central Drugs Standard Control Organisation. Antivenom remains essential in India, and the transition should follow, not precede, the approval of alternatives.

13. The 3Rs and New Approach Methodologies (NAMs)

- **The Flaw:** Rule 9(bb) of the 1998 Rules (inserted in 2006) required that animals lowest on the phylogenetic scale capable of giving valid results be considered first. It also required the minimum number of animals needed for statistically valid results at a 95% confidence level, and sound justification where available alternatives were not used. Rule 3 of the draft does not carry forward the phylogenetic preference or the 95% standard, and limits Replacement to "wherever possible". The draft is also silent on non-animal methods such as organ-on-a-chip and microphysiological systems, human organoids, 3D bioprinting and *in silico* toxicology. The only check on alternatives in Schedule III is a question whether similar studies have been done "on in vitro models" (Part B, item 9(b)) and the Principal Investigator's own declaration (Part C, item 3).
- **Legal Grounding:** Sections 17(2)(d) and 17(2)(e) of the Act. The New Drugs and Clinical Trials Rules, 2019 were amended in 2023 (G.S.R. 175(E), dated 9 March 2023) to enable the use of non-animal methods in drug development; the 2026 Draft Rules should be consistent with that position.
- **Recommended Change:** Restore the substance of Rule 9(bb) of the 1998 Rules, define NAMs and require a verified search for alternatives, by amending Rules 2 and 3 as follows:

  "2(pa) 'New Approach Methodologies' means methods, technologies and approaches, used alone or in combination, that do not involve the use of live animals, including in vitro, in chemico and in silico methods, organoids, organ-on-chip and other microphysiological systems, and three-dimensional bioprinted tissues;"

  "3(1) that no experiment is performed where a scientifically satisfactory method or testing strategy not entailing the use of live animals, including a New Approach Methodology accepted for the relevant purpose by any Indian regulator or under an OECD Test Guideline, can achieve the objective, and that, where animals must be used, the species lowest on the phylogenetic scale that can give scientifically valid results is considered first;"

  "3(2) that the number of animals is the minimum necessary, justified in the application by a power calculation or other recognised statistical method;"

  "3(4) that every application under Schedule III is accompanied by a record of a search for non-animal alternatives in at least two recognised databases, stating the

search terms, dates and results, which the IAEC or the Committee, as the case may be, shall verify."

14. Inconsistencies in the Severity Examples in Annexure-I

- **The Flaw:** Sections I and II of Annexure-I classify experiments by the pain, suffering, distress or lasting harm expected for the individual animal. Several examples in Section III instead classify by the type of agent or study, and so conflict with those criteria:
  a. all use of radioactive materials, recombinant DNA or GMOs, and all Risk Group III/IV pathogen studies are "Severe" (items 4(c) and (d)), while all testing of "phyto-formulations" and "established pharmacological compounds" is "Moderate" (item 3(d)), whatever their actual effects;
  b. "Lethal endpoint studies or euthanasia-based protocols" are "Severe" (item 4(e)), although a procedure ending in euthanasia under anaesthesia may be non-recovery;
  c. the only "Non-recovery" examples are surgical training (item 1); and
  d. inescapable aversive stimuli producing moderate distress are "Moderate" (item 3(m)), and so within the IAEC's sole approval.
- Because the category determines who approves the protocol, misclassification directly affects oversight.
- **Recommended Change:** Revise Section III of Annexure-I so that every example is based on the expected effect on the animal, in line with Annex VIII of the EU Directive. State expressly that the examples are illustrative and that, where in doubt, the higher category applies. Move item 3(m) to "Severe".

15. Commercial Traders, Alternative Sources and Mobile Facilities

- **The Flaw:** Rules 2(u) and 8 create a new category of registered "Traders", and item 5(vii) of Schedule I permits registration for "Housing of animals in Transit". Rule 16(6) dispenses with an IAEC for traders who supply animals without housing them. Yet Rule 8(4) requires breeders and traders to submit quarterly reports to the IAEC, without saying which IAEC a trader without one is to report to. Rule 14(1) requires a Designated Veterinarian only for breeders and users, not for traders who house animals in transit. Separately, Rule 2(i) extends "Establishment" to "a place that is not wholly enclosed or covered and mobile facilities". This sits uneasily with item 8 of Schedule I (fixed GIS coordinates) and Rule 19(1)(a) (a quiet location undisturbed by traffic and protected from weather).
- **Legal Grounding:** Sections 11(1)(d) and 17(2)(g) of the Act, and the Transport of Animals Rules, 1978.
- **Recommended Change:** Remove the category of traders, or at minimum require every trader to be attached to the IAEC of a registered breeder or user, to have a

Designated Veterinarian, and to comply with the Transport of Animals Rules, 1978. Without prejudice to Recommendation 2, require prior written approval of CCSEA for any procurement from an alternative legal source. Delete the reference to unenclosed places and mobile facilities in Rule 2(i), or confine it to field studies specifically approved by CCSEA.

16. Qualifications and Competence of Personnel

- **The Flaw:** Rule 9(a) of the 1998 Rules, as substituted by the 2001 Amendment, required experiments to be performed by, or under the supervision of, a person holding a specified qualification: a degree in medicine or veterinary science, a postgraduate qualification in the life, pharmaceutical or other natural sciences, a degree or diploma in pharmacy, or a diploma or certificate in laboratory animal techniques from an institution identified by the Committee. Rule 14(2) of the draft requires all experiments to be supervised by a veterinarian, which is welcome. However:
  a. Rule 12(2) says only that staff "should" be adequately educated and trained.
  b. Rule 12(4) allows untrained staff to perform procedures, care and euthanasia under supervision.
  c. Rule 12(6) leaves each establishment to publish its own minimum requirements. Article 23(3) of the EU Directive, from which the provision is taken, places that duty on the Member State, that is, on the regulator.
- **Legal Grounding:** Section 17(2)(a) of the Act places responsibility for experiments in an institution on the person in charge of it and requires individuals experimenting outside an institution to be qualified in that behalf, and Section 17(2)(b) requires experiments to be performed with due care and humanity. Neither object is secured if each establishment sets its own standard of competence and untrained staff may perform procedures.
- **Recommended Change:** Replace "should" with "shall" in Rule 12(2). Restore the qualification requirement of Rule 9(a) of the 1998 Rules (as substituted in 2001) for the person performing or directly supervising each procedure. Provide that CCSEA shall prescribe uniform national standards of training and competence. Require competence to be first demonstrated on non-animal training models.

17. Inspection and Enforcement Powers

- **The Flaw:** Rule 24(4) requires CCSEA inspection teams to visit "with prior intimation". Rule 25(1)(c) permits immediate suspension where there is imminent risk to animals, which is welcome. Otherwise, however, Rule 25(1) proceeds by a 15-day deficiency notice, or waits for repeated violations within six months, and permits suspension to be confined to a single project or unit. Rule 14(b) of the

1998 Rules permitted suspension pending a final decision on a *prima facie* finding of non-compliance, whether or not there was an imminent risk. Rule 14(c) and (d) enabled the Committee to give directions for the care of the affected animals and required the establishment to stop experiments and the acquisition or transfer of animals immediately on receiving the order. These provisions have no counterpart in Rule 25.

- **Legal Grounding:** Section 18 of the Act authorises entry and inspection "at any time considered reasonable" by the authorised person, and a rule requiring advance notice narrows that power. Section 19 empowers the Committee to prohibit experiments where its rules are not complied with. Article 34 of the EU Directive requires an appropriate proportion of inspections to be carried out without prior warning.
- **Recommended Change:** Delete "with prior intimation" from Rule 24(4) and provide for unannounced inspections. Add to Rule 25 the power of interim suspension on a *prima facie* finding, the power to give binding directions for the care, custody and rehabilitation of animals held by a suspended or de-registered establishment, and an obligation to stop experiments and transfers of animals immediately on receipt of the order. Because Section 19 of the Act requires an opportunity of being heard before experiments are prohibited, the Rules should provide that an interim suspension is followed by a hearing within fifteen days, and that the final decision is taken after that hearing.

18. Exclusion of Cephalopods, Decapod Crustaceans and Veterinary Field Trials

- **The Flaw:** Rules 1(8) and 2(n) confine the Rules to vertebrates, so cephalopods and decapod crustaceans are excluded, although Article 1(3)(b) of the EU Directive covers live cephalopods. Rule 1(10)(c) excludes veterinary clinical field trials required for marketing authorisation, other than batch testing, so that those trials face no review by an IAEC or CCSEA.
- **Legal Grounding:** Section 2(a) of the Act defines "animal" as any living creature other than a human being, without limiting it to vertebrates.
- **Recommended Change:** Extend Rules 1(8) and 2(n) to live cephalopods and decapod crustaceans, and delete Rule 1(10)(c), or require such trials to be reviewed by an IAEC.

19. Definitions of "Invasive" and "Non-Invasive" Experiments

- **The Flaw:** Rule 2(m) treats restraint, blood collection and injection as "invasive", while Rule 2(r) treats as "non-invasive" anything that involves no breach of the skin or surgery. The two definitions overlap; restraint, for example, falls within both. Neither definition is used in the operative rules, except that Rule 11(10) uses "non-invasive" in place of "non-recovery" as a severity category. Procedures such

as food or water deprivation, social isolation, inescapable shock and forced exercise fall outside Rule 2(m) and may be described as "non-invasive" under Rule 2(r), although Annexure-I treats several of them as moderate or severe.

- **Recommended Change:** Replace "non-invasive" with "non-recovery" in Rule 11(10). Reconcile Rules 2(m) and 2(r), and add a proviso that no procedure causing psychological distress, deprivation of food, water or sleep, restriction of natural behaviour, or physiological stress shall be treated as non-invasive.

20. Contract Research on Behalf of Foreign and Unregistered Entities

- **The Flaw:** Rule 12 of the 1998 Rules, as originally made, prohibited contract research, which Rule 2(g) of those Rules defined as research undertaken on behalf of a foreign person for consideration. The 2001 Amendment permitted contract research only with the prior permission of the Committee. The 2006 Amendment removed that condition, but still required contract research to be carried out in accordance with the Act and the Rules. Rule 2(g) of the draft now covers research undertaken by any domestic or foreign person on behalf of any other person, and nothing in the draft requires the sponsor to be identified. Rule 22 allows "any research institutions or agency not defined under the rules" to outsource animal research to a registered establishment, without any condition at all. Taken with the IAEC's sole approval of moderate experiments on larger animals, and the absence of a funded aftercare duty, this may encourage outsourcing of animal testing to India in order to avoid stricter regulation abroad.

- **Recommended Change:** Make all contract research subject to: (i) disclosure of the sponsor and the regulatory purpose in Schedule III; (ii) prior CCSEA approval for every contract protocol on animals above rodents and lagomorphs, and for all severe protocols, restoring in part the position under the 2001 Amendment; (iii) a bar on testing for a foreign regulatory purpose where that regulator accepts a validated non-animal method; and (iv) a bar on contract research for unregistered or undisclosed sponsors.

21. Appeals and Public Transparency

- **The Flaw:** Under Rule 26(1), only an aggrieved establishment may appeal, and the appeal lies to the Secretary of the administrative Ministry. That officer's decision is final under Rule 26(3). Rule 26(2) states that the Secretary, "if so desire, shall … hear the grievance", which leaves it unclear whether a hearing is mandatory. CCSEA nominees, Socially Aware Members and animal welfare organisations have no remedy where a protocol is wrongly approved or enforcement is not taken. The draft also contains no provision for publication of Non-Technical Project Summaries or national statistics (Articles 43 and 54 of the EU Directive).

- **Legal Grounding:** Sections 15 and 17 of the Act place regulatory functions in a statutory, multi-member Committee. Leaving final decisions to a single officer, on an appeal open to one side only, is difficult to reconcile with that scheme.
- **Recommended Change:** Make the right of appeal available to CCSEA nominees, Socially Aware Members and registered animal welfare organisations, before an independent multi-member appellate body including a retired Judge of a High Court, an animal welfare ethicist and an expert in non-animal methods or, at the least, before the full Committee against decisions of the Member Secretary or an IAEC, and before the Central Government, after a mandatory hearing, against decisions of the Committee. Make the hearing mandatory. Require CCSEA to publish (a) Non-Technical Project Summaries of approved protocols, (b) IAEC minutes and inspection reports, after redaction of confidential information, and (c) annual national statistics, for which Schedule IX should be extended from large animals to all species and should record the actual severity experienced by each animal.

22. Core Welfare Standards Left to Guidelines

- **The Flaw:** Rule 1(4) states that the Rules "lay down guidelines". Many essential matters are left to orders or guidelines to be issued by CCSEA from time to time (Rule 2(j)):
  a. procedures to minimise pain and suffering, including rehabilitation and reuse (Rule 15(1));
  b. welfare standards for housing during and after experiments (Rule 15(2));
  c. technical parameters for stocking and housing (Rule 19(1));
  d. sourcing of primates from self-sustaining colonies (Rule 5(2)(d));
  e. the quarantine period for open-market animals (Rule 21(2)); and
  f. periodic reviews of five-year approvals (Rule 11(11)).
- **Legal Grounding:** Section 17(1) of the Act requires rules on the conduct of experiments to be made "subject to the condition of previous publication", and Section 38A requires rules made by the Committee to be laid before each House of Parliament. Guidelines issued administratively are subject to neither safeguard. Standards that determine the treatment of animals should therefore be set out in the Rules or their Schedules, so that they are open to public comment and Parliamentary scrutiny and are clearly binding.
- **Recommended Change:** Replace "guidelines" with "requirements" in Rule 1(4). Set out minimum standards for rehabilitation, reuse, housing and stocking, primate sourcing and quarantine in new Schedules to the Rules. Provide that any

guideline issued under Rule 2(j) shall be published in draft for public comment before adoption and shall not dilute any requirement in the Rules.

23. **Cosmetics and Testing Already Prohibited by Other Laws**

- **The Flaw:** Rule 4(3) permits experiments for testing the quality, effectiveness and safety of "drugs, food and feed stuffs and other substances or products". The words "other substances or products" are wide enough to include cosmetics and their ingredients. Testing cosmetics on animals has been prohibited since 2014 (Rule 148-C of the Drugs and Cosmetics Rules, 1945, inserted by G.S.R. 346(E) dated 21 May 2014), and the prohibition now appears in Rule 39(7) of the Cosmetics Rules, 2020. Rule 18(4) of those Rules bars the import of cosmetics tested on animals after 12 November 2014. Rule 15(3), which bars experiments with agents "banned by any authority and not required for testing", is too obscure to fill the gap.
- **Legal Grounding:** Section 17(2)(d) of the Act directs that experiments be avoided wherever it is possible to do so. Rules framed by the Committee should not appear to permit what another law in force prohibits.
- **Recommended Change:** Insert the following proviso at the end of Rule 4: "Provided that no experiment shall be performed for the testing of cosmetics or their ingredients, or for any other purpose for which the use of animals is prohibited by any law for the time being in force."

24. **CCTV and Retention of Records**

- **The Flaw:** Schedules II and VIII require inspectors to check "CCTV cameras" and the "CCTV footage record", but no rule requires an establishment to install CCTV or to retain footage. The Schedules therefore check compliance with an obligation that the Rules never impose. Rule 18 also does not say for how long records are to be kept.
- **Legal Grounding:** Section 17(2)(h) of the Act requires suitable records to be maintained, and Section 18(b) empowers an authorised person to require the production of records.
- **Recommended Change:** Insert the following sub-rules in Rule 18: "(3) Every establishment shall install closed-circuit television cameras covering every animal room, procedure room and euthanasia area, retain the footage for not less than ninety days, and make it available on demand to the Committee, its nominees and any person authorised under section 18 of the Act. (4) All records maintained under these Rules shall be retained for not less than five years after the completion of the experiment to which they relate."

25. **Imported Animals**

- **The Flaw:** Rule 21(3) allows animals not available in India to be imported "as per the provisions of the extant Import-Export policies/guidelines". It sets no welfare condition on the source facility or on transport, and does not require the Committee's approval. Under Rule 10(e) of the 1998 Rules, as substituted by the 2006 Amendment, import was confined to genetically defined animals not available from registered breeders or alternate legal sources (a condition that did not apply to genetically defined rats and mice), and required the permission of the Directorate General of Foreign Trade.
- **Legal Grounding:** Sections 17(1) and 17(2)(g) of the Act.
- **Recommended Change:** Substitute Rule 21(3) as follows: "(3) An animal that is not available from a registered breeder in India may be imported only with the prior approval of the Committee, from a facility that meets standards of housing and care not lower than those prescribed under these Rules, and with transport complying with the IATA Live Animals Regulations; no animal taken from the wild shall be imported for use in experiments."

IV. SUMMARY TABLE (*Numbers correspond to the Recommendations in Part III*)

Rec. No. OF ADDITIONAL PROVISIONS REQUIRING AMENDMENT	RULES OF 2026 DRAFT	CONCERN	RECOMMENDED CHANGE
6	Rules 1, 3-7, 12, 13; Annexure-I	EU exceptions adopted without EU safeguards; 1998 protections dropped	Retain 1998 safeguards; adopt EU Arts. 1(3)(b), 16, 34, 36-39, 43, 54
7	Rules 1(6), 15(1), 15(4); Sch. III items 11(d), 12(a)	No binding aftercare duty or lifetime funding; reuse and repeat surgery permitted	Restore 2006 Rule 9(cc) and 9(ff); limit reuse and repeat surgery
8	Rule 7(2); Sch. III item 10(g); Annexure-I Sec. III item 4	1998 Rule 9 safeguards omitted; extreme procedures listed as "Severe"	Restore 1998 Rule 9(d)-(f), (h)-(m); Schedule of prohibited procedures
9	Rules 11(10), 11(11), 16, 17	In-house severity certification; internal majority; long approvals; two meetings a year	External classification; independent IAEC; 3-year cap; quarterly meetings

10	Rules 11(1)-(3), 11(8)	No approving authority named for severe rodent work; CCSEA information power limited	CCSEA approval for all severe work; delete limiting words in 11(8)
11	Rules 5(1), 5(2), 5(3), 6(1)	Wild capture; waiver of duty to relieve suffering; unclear primate exception; broad Note	Bar wild capture; delete waiver; define competent authority; restructure 5(1)(c)
12	Rules 2(i), 4(1), 4(2), 4(8), 1(10)(d); Sch. I item 5(vi)	Purposes beyond Rule 2(h); schools no longer excluded; unregulated bleeding	Align Rule 4 with Rule 2(h); bar animal use in schools; regulate bleeding
13	Rule 3; Sch. III items B9, C3	3Rs diluted; NAMs absent; alternatives self-certified	Restore 2006 Rule 9(bb) with a power-calculation standard; define NAMs; verified alternatives search
14	Annexure-I Sec. III	Examples classified by agent, not effect; inescapable stimuli "Moderate"	Effect-based examples; higher category where in doubt
15	Rules 2(i), 2(u), 8, 14(1), 16(6), 21(2); Sch. I item 5(vii)	Traders without IAEC or veterinarian; mobile facilities	Remove or regulate traders; CCSEA approval for alternative sources
16	Rules 12(2), 12(4), 12(6)	Training optional; establishments set own standards	Mandatory qualification; national standards by CCSEA
17	Rules 24(4), 25	Prior notice of inspections; no custody directions; no interim suspension	Unannounced inspections; restore 1998 Rule 14(b)-(d)
18	Rules 1(8), 2(n), 1(10)(c)	Cephalopods, decapods and veterinary field trials excluded	Extend coverage; review of field trials
19	Rules 2(m), 2(r), 11(10)	Overlapping definitions; wrong category in 11(10)	Reconcile definitions; correct Rule 11(10)
20	Rules 2(g), 22	Unconditional contract research for any agency, including foreign	Disclosure, CCSEA approval and other conditions

21	Rule 26	One-sided appeal to a single officer; no transparency	Independent appellate body; publication of summaries and statistics
22	Rules 1(4), 2(j), 5(2)(d), 11(11), 15(1)-(2), 19(1), 21(2)	Core standards left to guidelines outside Sections 17(1) and 38A	Move standards into Schedules; consultation on guidelines
23	Rules 4(3), 15(3)	Cosmetics testing not excluded	Express proviso excluding cosmetics and other prohibited testing
24	Rule 18; Schs. II, VIII	CCTV checked but never required; no retention period	Mandatory CCTV; 90-day footage and 5-year record retention
25	Rule 21(3)	Imports without welfare conditions or CCSEA approval	CCSEA approval; equivalent standards; IATA transport; no wild-caught imports

V. DRAFTING ERRORS AND INCONSISTENCIES IN THE GAZETTE TEXT

The following errors in the English text should be corrected before the Rules are finalised. Several of them affect the meaning or enforceability of the provision concerned and are not merely typographical.

S. No.	PROVISION	ERROR	SUGGESTED CORRECTION
1	Preamble	Recites that the Committee, "in supersession of" the 1968 and 1998 Rules, has "decided to amend" them; cites "sub-section (1), 1(A) and (2) of Section 17".	Recite that the Committee "hereby makes the following rules" in supersession of the earlier Rules; cite "sub-sections (1), (1A) and (2) of section 17".
2	Notice inviting objections	The English text says "within a period of thirty days" without stating from when; the Hindi text runs the period from publication in the Official Gazette.	Align the English text with the Hindi text in any republished draft and in the final notification.
3	Rules 5(1), 6(2)	Refer to species listed in the "Wildlife (Protection) Amendment Act, 2022", an amending Act with no list of its own.	Refer to the Schedules to the Wild Life (Protection) Act, 1972 (53 of 1972), and state which Schedules are meant (see Recommendation 4).
4	Rule 1(6)	"euthanized, rehabilitated" lacks a conjunction, and the Rules cease to apply on rehabilitation, leaving its outcome unmonitored.	"euthanised, or rehabilitated …", with the Rules continuing to apply until the rehabilitation is reported in Schedule IX.

5	Rule 1(8)	"as from the last third stage of their normal development".	"as from the last third of their normal development" (Article 1(3)(a)(ii) of the EU Directive).
6	Rule 2(l)	IAEC "constituted and operated in accordance with experiments specified for the purpose by the Committee".	"in accordance with the procedures specified for the purpose by the Committee" (as in Rule 2(f) of the 1998 Rules).
7	Rule 2(r)	A definition that imposes an obligation ("shall be employed wherever …"); "mean" for "means".	Move the obligation to Rule 3 and correct the grammar.
8	Rule 5(1)(b)	The opening words cover "protected" species, but clause (b) refers to "endangered species".	Use "such protected species" in clause (b).
9	Rule 6(1)	Clauses (a) and (b) are joined by "or" and clause (c) by "and", so it is unclear whether the justification requirement in (c) applies to experiments under (b).	Make justification a separate requirement applying to every experiment (see the substituted Rule 6 in Recommendation 4).
10	Rule 7(2)	"likely to be long period".	"likely to be long-lasting".
11	Rules 8(4), 20	Annual report "for each financial year … on or before 31st March": the financial year ends on 31 March, so the report falls due on the last day of the period it covers. Rule 20 repeats the duty for an undefined "breeder-trader"; Schedule IX uses the calendar year.	One reporting rule with one reporting period and a due date after the period ends (for example, 30 June for the year ending 31 March); delete Rule 20 or define "breeder-trader".
12	Rule 8(4) with Rule 16(6)	Traders must report quarterly to an IAEC, but traders who do not house animals need not have one.	Specify the IAEC, or the Committee, to which such traders report (see Recommendation 15).
13	Rule 11(10)	Lists "non-invasive" as a severity category in place of "non-recovery".	Substitute "non-recovery".
14	Rule 11(11)	Five-year approvals outlast the three-year validity of the IAEC and of registration (Rules 10(1)(g), 16(1), 23(1)).	Cap approvals at three years and require re-approval by the reconstituted IAEC.
15	Schedule IV heading	Refers to Rule 11(8); the provision on Schedule IV is Rule 11(9).	"{See Rule 11(9) and Rule 18(1)}".

16	Rules 12(3) to (6)	Refer to "clause (b)", "clause (a), (c) or (d)", "this paragraph" and "paragraph 2", terms carried over from Article 23 of the EU Directive.	"clause (b) of sub-rule (2)", "clauses (a), (c) or (d) of sub-rule (2)", "this rule" and "sub-rule (2)".
17	Rule 15(3)	"banned by any authority and not required for testing": read conjunctively, a banned agent may still be used if "required for testing".	"No establishment shall perform any experiment prohibited by any law for the time being in force, or use in an experiment any substance whose use is so prohibited."
18	Rule 19(1)(a)	"protected from drought", carried over from Rule 7(a) of the 1998 Rules.	"protected from draughts".
19	Rule 25	Two clauses numbered (b); the second says "Notwithstanding anything contained in sub-rule (1)" although it is itself a clause of sub-rule (1); clause (c) refers to "Rule 25" from within Rule 25.	Renumber as sub-rules (1) to (3) and correct the internal references.
20	Rule 26	"if so desire" in sub-rules (1) and (2); sub-rule (2) makes the hearing appear optional.	Delete "if so desire" in both places and make the hearing mandatory (see Recommendation 21).
21	Schedule II	Item 5 is missing (items run 4, 6, 7, 8).	Renumber.
22	Schedule III, Part B	Item 10(c) "tropical applications"; item 15(a) "Radio nucleotides".	"topical applications"; "radionuclides".
23	Schedule V	The attendance sheet has eight rows, but the IAEC has nine members and may also have the Link Nominee and a co-opted specialist present.	Provide rows for all members, the Link Nominee and co-opted members.
24	Annexure-I, Section III	Item 4(o) ("thoracotomy without adequate analgesia") contradicts item 4(j) (thoracotomy "under general anaesthesia and appropriate analgesia").	Delete those words from item 4(o) (see Recommendation 8).

VI. CONCLUDING SUBMISSION

The 2026 Draft Rules contain welcome advances, notably the four-tier severity classification, the euthanasia registry and binding standards on enrichment. Taken as a whole, however, they would reduce independent oversight of experiments on larger animals, widen the sources from which animals may be obtained, and drop safeguards that have applied in India since 1998, 2001 and 2006.

It is therefore respectfully requested that the Committee:

- consider and incorporate the recommendations in Parts II and III, and correct the drafting errors listed in Part V;
- in view of the number and extent of the changes required, publish a revised draft for a further round of public consultation before the Rules are finalised;
- publish, with the final Rules, a summary of the objections and suggestions received and the Committee's reasons for accepting or rejecting them; and
- afford ILRF an opportunity to be heard, in person or virtually, before the Rules are finalised.

ILRF would be glad to assist the Committee with drafting or technical input on any of the matters raised in this submission.

Respectfully submitted,

Aaditya Bajpai, Legal Research Associate, ILRF
Devang Anand, Legal Consultant, ILRF
Gautami Seth, Manager: New Initiatives, ILRF
Kunwarinder Pal Singh Bamrah, Legal Consultant, ILRF

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