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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

Date of Decision: 14th August, 2023

\+ W.P.(C) 12660/2018 & CM APPLs. 49163/2018, 49164/2018, 36282/2019, 36284/2019, 36285/2019

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS, (PETA) INDIA ..... Petitioner

Through: Mr. Rajshekhar Rao, Senior Advocate with Ms. Pritha Srikumar Iyer, Ms. Vishakha Gupta and Mr. Abhyudaya Shishodia, Advocates.

versus

THE UNION OF INDIA & ORS ..... Respondents

Through: Mr. Manish Mohan, CGSC with Mr. Vikram Chandravanshi and Mr. Jatin Teotia, Advocates for R-1.
Ms. Manisha T. Karia, Ms. Nidhi Nagpal, Mr. Rohan Trivedi and Mr. Aditya Kesar, Advocates for R-4.
Mr. A. Tiwari, Mr. Tuhin and Mr. Anam Sahar, Advocates for R-7.
Mr. Rohan P. Shah, Ms. Anusha Nagarajan and Mr. Sri Sabri Rajan, Advocates for R-8, 10 & 12.
Mr. Nitin S. Tambwekar and Mr. Seshatalpa Sai Bandaru, Advocates for R-13.
Mr. Sunil Fernandes and Ms. Priyasha Sharma, Advocates for R-15 & 16.
Mr. Varun Kumar, Advocate for R-23.

CORAM:
HON'BLE THE CHIEF JUSTICE
HON'BLE MR. JUSTICE SANJEEV NARULA

JUDGMENT

SANJEEV NARULA, J. (Oral):

1. This public interest litigation (PIL) has been initiated by People for the Ethical Treatment of Animals (PETA), an esteemed organization dedicated to cause of animal welfare and rights. The Petitioner spotlights our attention to the grave concerns surrounding the treatment of equines—namely, horses, mules, donkeys, and the like—in the commercial production of antibody products and anti-venin. Central to this concern is the procedure that necessitates bleeding of these animals to extract blood serum. The Petitioner thus *inter alia* seeks directions towards adoption of non-animal-based methods for production of antibody products; rigorous inspection of current equine facilities to ensure they align with prevailing laws and regulations; prompt punitive measures against those found in contravention; and transparent public disclosure of findings of such inspections.

2. The motivation prompting the Petitioner to appeal to our extraordinary jurisdiction is articulated as follows:

2.1. The products such as anti-toxins and anti-venoms derive from the 'sera' extracted from the blood of animals previously immunized against specific toxins or venoms. This immunization process involves administering antigens—essentially cultured versions of specific toxins or venoms—to healthy animals, predominantly equines. These animals then produce antibodies in response. The immunization schedule incorporates primary doses followed by booster doses. Administered intermittently and at multiple sites, this regimen poses significant risks to the animals. Alarmingly, it can precipitate conditions like haemophilic shock induced by the toxin, with dire outcomes including death. Once an adequate immune response is achieved, substantial quantities of blood are drawn from the animals. From this blood,

the serum fraction undergoes processing to separate the antibodies. The resultant 'sera' carries specific 'immunoglobulins' with therapeutic properties, invaluable for individuals exposed to, or affected by, diseases linked to the respective toxin or venom.

2.2. Numerous establishments in the antibody product industry favor equines for production, primarily because they are manageable, can endure large antigen doses, and can offer substantial quantities of 'hyperimmune sera'. However, a concerning majority of these establishments employ methods that are neither scientifically sound nor ethically grounded to extract this sera. Such questionable practices, paired with the compromised health of equines, not only jeopardize the quality of the antibody product but also pose health risks to humans who receive the sera. These health complications range from serum sickness and hypersensitivity reactions to inflammation, rashes, and fever.

2.3. Central to the Petitioner's argument is reliance upon Prevention of Cruelty to Animals Act, 1960 [henceforth "***PCA Act***"] and the rules framed under its purview, governing animal experimentation. The Petitioner highlights that the Central Government, in February 1991, set up the Committee for the Purpose of Control and Supervision of Experiments on Animals [hereinafter "***the CPCSEA***"] under Section 15(1) of the PCA Act. The primary aim of this Committee is to mitigate unnecessary pain or suffering experienced by animals before, during, or after experiments. The CPCSEA, which is reconstituted periodically, framed the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 [hereinafter "***1998 Rules***"], laying down regulations for animal experimentation. These rules demand, among other things, the mandatory registration of establishments involved in animal breeding, trade, or experimentation, along

with routine inspections by the CPCSEA. However, the Petitioner raises concerns regarding the inspection checklist, pointing out the absence of specific criteria to gauge equine health, welfare, or the detection of equine injuries. Furthermore, these rules instituted the formation of the Institutional Animals Ethics Committee [hereinafter "***the IAEC***"], comprised of CPCSEA-nominated individuals, tasked with overseeing animal experimentation within these establishments. In February 2001, the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2001 saw light, which extended the definition of "experiments" under the 1998 Rules to encompass the utilization of animals in reagent, antigen, or antibody production. A significant shift occurred in 2006, with the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006 [henceforth "***2006 Rules***"], which further broadened the term "experiments" to include contributions to the well-being of the nation's populace.

2.4. Moreover, the CPCSEA, in its pursuit of humane treatment of animals, laid out the **"Guidelines for the Care and Management of Equines used in the Production of Biologicals, 2001"** [henceforth "***CPCSEA Protocol***"]. These guidelines meticulously detail the recommended care and management practices for equines involved in antibody production.

2.5. The Petitioner also refers to historical context to espouse their case in the present petition. There arose concerns when it came to light that aged horses from the armed forces, deemed unfit for military service, were being repurposed by specific establishments for serum production. This led to the filing of W.P.(C) No. 216/2001 before the Supreme Court. Acting upon the plea, the Court commissioned the CPCSEA to inspect the implicated establishments and assess their adherence to the CPCSEA Protocol. The inspections, conducted in December 2001, painted a grim picture.

Establishments were found to be in gross violation: veterinarians overlooked basic treatment standards, bleeding procedures were conducted in open sheds against the CPCSEA's guidelines, and improperly sized metallic cannulas were used, leading to open wounds on the animals. Despite receiving directives from the CPCSEA to halt their bleeding operations, four of these establishments continued their practices unabated. Recognizing the gravity of these infractions, on 18th January, 2002, the Supreme Court empowered the CPCSEA and Central Government to take action against these violators. The issue reached a resolution on 23rd September, 2002, with the Supreme Court acknowledging the CPCSEA's efforts against the erring establishments. The Court, in its final remarks, entrusted the Ministry of Environment and Forests with the ongoing responsibility of vigilance and enforcement in such matters. Recognizing the need for further clarity, the CPCSEA Protocol underwent an amendment in 2005. This revision introduced age specifications for equines. Interestingly, while it set clear guidelines on the age of equines and the bleeding schedule, it also removed the prior stipulation that prohibited retaining any animal beyond three years. Additionally, the amendment clearly defined the permissible amount of blood that could be drawn from the animals. In a subsequent chapter of this unfolding narrative, the Animal Welfare Board of India [*hereinafter* "***the AWBI***"] - a statutory body birthed by Section 4 of the PCA Act - initiated a comprehensive examination in 2015. Their goal was clear: inspect nine establishments, known for their involvement in the production of antibody and anti-snake venom derived from horses within India. This endeavour was spurred by a desire to gauge both the mental and physical well-being of equines in these establishments and scrutinize the standards of their housing, upkeep, and overall maintenance. What transpired during these inspections, carried out between July and

September of that year, was deeply unsettling. They unveiled stark transgressions of both the CPCSEA Protocol and the PCA Act. These observations were meticulously documented and subsequently presented to the CPCSEA in December 2015, [collectively referred to as "***AWBI Inspection Report(s)***"]. A detailed exposition of the findings from this report has been encapsulated in paragraph 27 of the current petition:

> *"27. During the inspections, inter alia it was found that animals were being procured without permission from the CPCSEA's Central Committee as required, that veterinary findings and reports were not being accurately documented and licensed farriers were not available at the establishments, in violation of the Prevention of Cruelty to Animals (Licensing of Farriers) Rules, 1965. Further, it was found that several animals were bled multiple times in a month and that more than a permitted quantity of blood was withdrawn. 36% of the animals in these establishments were found to be suffering from some form of anemia, indicating poor nutrition and/or excessive bleeding. It was also found that the frequent injection of toxins into the animals for production of antibody products was resulting in a host of adverse local health effects on the animals, including injection site oedema, thrombosis, phlebitis, abscesses, fistulas, fibrosis and other problems. A large percentage of the animals in these establishments also suffered from systemic infections, lack of grooming, improper wound and pain management, lack of dental care and poor body condition scores. Animals with untreatable conditions which warrant euthanasia under law, unfit, lame and pregnant animals were all found to be used in the bleeding programme, in blatant violation of the law. The reports inter alia recommended that the licenses of establishments that violated animal protection laws be cancelled, that seriously sick and injured animals be euthanized, and that other sick/injured animals be rehabilitated at a sanctuary. Certain amendments were proposed to the CPCSEA Protocols to strengthen them and it was further recommended that regular surveillance for infectious and contagious diseases in equines at these establishments be carried out. The inspection report of the establishments inspected were duly submitted to CPCSEA in December, 2015."*

2.6. The petition also sheds light on the conscientious actions of the AWBI inspection team's veterinarians during their inquiry. Guided by their commitment to Veterinary Professional and Ethical Duties, these professionals reached out to the establishment's veterinarians. Their intent was clear - to elucidate the protocols surrounding equine pain management

and recommend potential remedial measures. Yet, their earnest efforts were met with an unsettling silence; no actionable response emerged from the establishments. In a subsequent revelation in October 2015, the Petitioner procured a list of entities sanctioned by the CPCSEA for equine antibody production. This list highlighted a mere 12 registered establishments, which notably included Respondents No. 7 to 14, 22, and 23. Alarmingly, the Petitioner asserts that Respondents No. 15 to 18, and 21 — previously inspected by the AWBI in 2015 — were absent from this list, suggesting their illegal operation. The fact that certain establishments were functioning without registrations was also documented by AWBI and presented to the CPCSEA, astonishingly, it did not trigger any corrective action. Further casting doubt on the diligence of oversight bodies, the Petitioner points out that the CPCSEA's subsequent inspection of these establishments in 2015-16 produced reports that largely zeroed in on infrastructure, rather than holistically gauging the welfare of the ensnared animals. In a perplexing development, the AWBI was abruptly side-lined from its role in the CPCSEA by way of a notification dated 17th February 2016, issued by the Ministry of Environment, Forest and Climate Change, formalized this exclusion.

2.7. The Petitioner also endorses recent technological advancements that have ushered in novel methods for the production of antibody products. One such notable advance is the emergence of ‘recombinant technologies’ that facilitate the production of these products without the need for equine ‘immunoglobulins’. A case in point is the availability of rabies anti-serum in India that's derived from non-equine and non-animal sources. This technological shift is further evidenced by the introduction of several commercially available recombinant antibody drugs, including raxibacumab (for anthrax treatment), palivizumab (targeting respiratory syncytial virus),

belimumab (for various immune diseases), and adalimumab (aimed at autoimmune diseases).

2.8. Given the aforementioned advancements and the alarming findings detailed in the AWBI Inspection Reports, the Petitioner underscores its persistent efforts to advocate for equine welfare. They have forwarded multiple representations, emphasizing the urgency of adopting non-animal-based technologies to develop standardized and safer antibody products. These appeals were directed to various authorities including the CPCSEA, Ministry of Health, and Drug Controller General of India. Regrettably, despite these earnest appeals for remedial actions, the Petitioner's concerns remain unaddressed by the Respondents.

2.9. In 2017, the CPCSEA undertook an initiative to address concerns related to equines used in the production of antibodies. They formed a committee consisting of equine specialists named the "CPCSEA Equine Expert Committee". This committee carried out inspections across all establishments registered with the CPCSEA that house equines for antibody production purposes. Come January 2018, the Petitioner came to know of the committee's concerning discoveries in a meeting organised by the CPCSEA on demand and supply of anti-snake venom in India. These findings highlighted several areas of negligence and mistreatment. Key issues reported included the absence of trained veterinarians attending to the equines, the use of inappropriate needle sizes for drawing blood from the horses, unmeasured blood withdrawals, prevalent hoof problems, neglected skin and coat hygiene, and the glaring absence of meticulous record-keeping, among other discrepancies.

2.10. Later in 2018, acting on their concern for the welfare of these equines, the Petitioner embarked on a personal, eyewitness investigation. Focusing on

the conditions at the premises of Respondent No. 11, the findings were disheartening, revealing deplorable living conditions for the equines. The Petitioner promptly communicated the results of this investigation to the government and all members of the CPCSEA. Disappointingly, their efforts were met with silence, as no response or acknowledgment was forthcoming.

2.11. Set against the backdrop of these revelations, the Petitioner articulates a strong contention. Primarily, the repeated bleeding of equines for the purpose of antibody product development unequivocally qualifies as cruelty under the provisions of the PCA Act. Moreover, it's evident that a significant number of establishments have failed to adhere to the stipulated CPCSEA Protocol and the mandates of the 2006 Rules. Such negligence is not just a breach of legal and regulatory obligations but also culminates in the production of medical products of inferior quality. These substandard products have been known to trigger adverse reactions in humans.

2.12. Additionally, the Petitioner emphasizes the availability of non-animal biotechnological alternatives, both domestically and internationally. These alternatives not only exhibit superior efficacy but also significantly reduce the instances of adverse effects. In light of these considerations, the Petitioner urges the adoption of such advanced methods. Doing so would not only promote better health outcomes, but would also prevent blatant transgressions against animal rights, as enshrined in the Constitution of India and detailed in the PCA Act. The Petitioner's plea to the Court is encapsulated in the following reliefs:

> *"a. Issue a writ, order or direction in the nature of a mandamus, directing the Respondents 7 to 21 to ensure proper rehabilitation and care of the equines who are diseased/ aged/ unhealthy/physically unfit, currently in these establishments, including euthanasia to relieve the suffering of the animals in appropriate cases;*
>
> *b. Issue a writ, order or direction to the Respondents 1 to 3 to*

ensure/encourage development of non-animal-based production techniques of anti-toxins/anti-venin/antibodies, so as to phase out animal based production techniques, within a reasonable timeframe;

c. Issue a writ, order or direction constituting an independent committee including representatives of reputed organizations working for animal rights and welfare including the Petitioner herein, equine veterinarians and the Respondents 4 and 23, to inspect establishments housing equines for the production of biologicals, and to submit a report regarding compliance with the applicable laws and the CPCSEA Protocol.

d. Issue a writ, order or direction in the nature of a mandamus, directing the Respondents 7 to 21 to ensure proper rehabilitation and care of the equines who are diseased/ aged/ unhealthy/physically unfit, currently in these establishments, including euthanasia to relieve the suffering of the animals in appropriate cases;

e. Issue a writ, order or direction in the nature of a mandamus, directing the Respondents 1 and 5 to take immediate steps for cancellation of the licenses of all establishments found to be in violation of the applicable laws and the CPCSEA Protocol;

f. Issue a writ, order or direction in the nature of a mandamus, directing the Respondent 5 to inspect equine establishments on an annual basis, with specific reference to the requirements of the CPCSEA Protocol and the parameters stipulated thereunder, and to publish the inspection-reports on their website, along with details of actions taken in the case of errant establishments;"

3. We have carefully evaluated the submissions advanced by the counsel for both sides. In any democratic polity, the bedrock of its foundation is the equitable and just treatment of its constituents. This includes not only human beings, but also the environment they inhabit and the diverse species within the animal kingdom. Our Constitution, while conferring rights on individuals, also emphasizes duties towards animals, as can be discerned from the Directive Principles of State Policy. Cruelty to animals not only disregards these principles but also challenges our moral fabric. The PCA Act was constituted with a primary objective to prevent unnecessary suffering of animals. This Act, along with its subsequent amendments and rules, underscores the state's responsibility to ensure the welfare of animals. Thus

the immediate question that beckons our consideration is whether the current practices of establishments, as claimed by the Petitioner, indeed amount to cruelty under the PCA Act. Further, we must also examine if there is merit in Petitioner's contention regarding tangible dissonance between legislative intent and its manifestation on the ground.

4. Mr. Manish Mohan, speaking for the Union of India, staunchly asserts that comprehensive actions have been set into motion addressing the Petitioner's grievances. He bolsters his claim by pointing to the status report dated 03rd December, 2022, submitted by the CPCSEA. Countering this, Mr. Rajshekhar Rao, Senior Counsel for the Petitioner, articulates a contrasting viewpoint. He challenges the adequacy of the measures taken and accentuates the gaping chasm between official documentation and the tangible reality on the ground.

5. Mr. Rao, while acknowledging the wide scope of the reliefs sought in the petition, focuses on two pivotal concerns. The first is a probing critique of the CPCSEA's alleged lapses, asserting that the body has been remiss in exercising its proactive mandate against established violators under the PCA Act. The second contention revolves around the incongruity between the narratives painted by the CPCSEA's status report and the AWBI Inspection Reports appended to the petition, with specific reference to Respondent No. 10 (documented in Annexure P-23, page 461 of the petition).

6. Responding to our probing for contemporaneous evidence that might spotlight persistent infringements of animal rights or potential inaction on the part of the government, Mr. Rao navigates us back to the inspection reports annexed to the petition.

7. CPCSEA, which operates as a government oversight body, holds the onerous responsibility of ensuring that experiments on animals align with

humanitarian principles. It is a consortium of experts spanning veterinary science, pharmaceuticals, and bio-medical research, and operates with the express endorsement of the Ministry of Environment, Forest, and Climate Change. There is no doubt, that presently there exists a robust system committed to ensuring equine welfare. This assertion is reinforced by the comprehensive roles earmarked for the CPCSEA, the guiding parameters of the 2006 Rules, and the underlying ethos of the CPCSEA Protocol. Mandated by the 2006 Rules and CPCSEA Protocol, the CPCSEA routinely embarks on inspections of those establishments that are engaged in deriving antibody products from equines. The CPCSEA not only conducts an annual overview *via* nominees designated in the IAEC but also mandates intermittent mid-term reviews. The status report dated 03rd December, 2022, proffered by the CPCSEA, paints a contrasting picture to the narrative projected by the Petitioner. As a Court, our duty is to weigh the evidence and ascertain the veracity of the claims, and in that endeavour, we have meticulously examined the report submitted by CPCSEA dated 03rd December, 2022. It indicates that CPCSEA has been relentless in its endeavour to uplift and preserve the health and welfare standards of equines. The report elucidates that out of 17 Equines Holding Facilities affiliated with the CPCSEA, 4 establishments voluntarily sought cancellation of their registration. Notably, the registration of Respondent No. 2 with the CPCSEA was annulled as it ceased to house equines. Moreover, the registrations of Respondent Nos. 23 and 7 with the CPCSEA were terminated on grounds of their non-reliance on equines for producing hyperimmune plasma. It is noteworthy to mention that Respondent No. 21 had never been officially affiliated with the CPCSEA for equine housing purposes. On an encouraging note, the report indicates that the remaining 9 facilities have garnered satisfactory remarks as per the most

recent evaluation reports. An elucidative chart, annexed to the status report, delineates the current statuses of Respondents No. 7 to 23 and additionally includes the precise dates of their inspections.

8. Thus, the recent status report evidences that during the period of 2021 to 2022, the CPCSEA actively invalidated the registrations of certain establishments, while concurrently conducting targeted inspections. Additionally, for a select few establishments, recommendations for enhancements were made. It mandated that the establishments align with these improvements, which subsequently was corroborated through ensuing inspections. This sequence of events indicate that post the filing of the petition, the CPCSEA has exhibited due diligence, through systematic inspections, and consequential actions, be it annulment of registrations or endorsing requisite enhancements, as the case may have dictated.

9. Mr. Rao's submission leans prominently on historical evidence, drawing from past inspection reports, witness testimonies, and earlier actions like the AWBI Inspection Reports. The inspection reports from 2015 and 2018 undeniably provide a lens into past discrepancies, but with the year now being 2023, the Court must discern the current status of the establishments under scrutiny. It's essential to recognize the temporal distance between the reports relied on by the Petitioner and the present, which carries with it– changes and improvements. While past violations can offer vital insights, possibly unveiling a persistent trend or culture that warrants rectification, we cannot solely rely on them without examining recent developments. The status report presented reflects positive strides taken by the CPCSEA between 2021 and 2022, evident in their systematic inspections, and consequent actions.

10. The dedication displayed by the CPCSEA post the filing of the petition

is commendable, yet it is imperative to underline that their mission must not pause and should remain ongoing. The objectives they were established for remain as pertinent as ever, and their pursuit should be relentless. Recognizing their efforts is one thing, but substantial ground is yet to be covered. The envisioned future should be a system that is not only more compassionate but is technologically advanced, efficient, and, most importantly, truly resonates with both the letter and spirit of the PCA Act.

11. While the steps depicted in the status report are steps in the right direction, there is discernible room for amplification and enhancement. In fact, the existence of a positive status report does not provide full assurance. There exists a need to probe beyond the surface. The historical data, while invaluable, must be supplemented with fresh, comprehensive inspections to aptly gauge the current scenario and bridge the gap between past allegations and current realities. Mr. Rao has argued that he has valuable suggestions and data that provides for an impelling need to delve deeper. These suggestions can serve as a constructive roadmap for the CPCSEA, prompting further introspection and corrective action as may be deemed necessary. Therefore, we allow the Petitioner to submit their representations to CPCSEA for appropriate action, if it is so warranted.

12. It is important to bear in mind the nature of products emanating from these establishments, like anti-venom and anti-rabies serums, which are indispensable life-savers, vital for preserving the health and safety of our nation’s populace. CPCSEA has the mandate to ensure that the well-being of the animals involved in the process of preparation of the products, is taken care of, without impeding the production of such life-saving products. However, we can also not be oblivious the dawn of cutting-edge, non-animal-centric techniques for antibody generation. Such advancements suggest a

trajectory that these establishments might, and arguably should, consider in the right earnest. Given our non-expertise in this niche, our observation remains broad-stroked. Yet, we must emphasize that the responsibility clearly rests on supervisory bodies to not just delve into these contemporary methodologies but to earnestly integrate them, thereby diminishing reliance on equines.

13. We direct CPCSEA and other Government bodies to continue to conduct routine inspections to assess animal welfare and well-being, and initiate action against defaulting establishments under extant laws and regulations. In this vein, CPCSEA is also directed to consider the recommendations/ suggestions made by the Petitioner in the present petition and implement the same, wherever possible. Specifically, the adoption of the latest scientific methodologies for antibody production be encouraged wherever feasible. The CPCSEA is hereby directed to consider the proposals put forth by the Petitioner in this petition, effectuating them where deemed appropriate.

14. With the above directions we close the present proceedings.

15. Disposed of.

SANJEEV NARULA, J

SATISH CHANDRA SHARMA, CJ

AUGUST 14, 2023
as
[Corrected and released on 23rd august, 2023]