

VG Somani
Drugs Controller General of India
Central Drugs Standard Control Organization
Ministry of Health and Family Welfare
FDA Bhavan, ITO
Kotla Road
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17 June 2021

Via e-mail: dcni@nic.in

Dear Dr Somani:

I'm writing on behalf of People for the Ethical Treatment of Animals (PETA) India and our more than 2 million members and supporters to share concerns about the use of newborn calf serum (NBCS) in cell culture media for the production of the COVID-19 vaccine and to request that you direct vaccine manufacturers in India to replace it with the animal-free, chemically defined media that are already commercially available.

We've received numerous queries from members of the public about news articles published yesterday,¹ expressing concern over the use of NBCS in the indigenous production of the COVID-19 vaccine, COVAXIN, which was developed by Bharat Biotech in collaboration with the Indian Council of Medical Research. Through a separate news release yesterday,² the Ministry of Health and Family Welfare clarified that the "Newborn Calf Serum is used only for preparation/ growth of vero cells" and that "in the final vaccine formulation no calf serum is used".

The use of animal-derived components – including serums such as foetal bovine serum (FBS) and NBCS – has numerous scientific limitations. These contribute to the reproducibility crisis in research, owing to their complex mixtures of undefined ingredients and significant batch-to-batch variation,³ undesirable and unexpected outcomes,⁴ and risk of contamination by animal-derived proteins and pathogens for human biologics.^{5,6} Moreover, the extraction of NBCS is associated with the suffering and death of newborn calves, as it's extracted from the blood of slaughtered calves fewer than 20 days of age.⁷ They're taken away from their mothers shortly after birth, which traumatises and distresses both mother and calf.

So far, only 3.7% of India's population has been fully vaccinated with the COVID-19 vaccine.⁸ This is critically important, because as the government scales up the drive to vaccinate the entire population, a

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serum shortage could delay vaccine production – a concern easily avoided by using serum-free media for culturing Vero cells. As you know, the Indian people hold religious and ethical beliefs about cows and calves and might hesitate to take a vaccine after learning that calves were slaughtered in order to extract the serum used to produce it.

The central legislation, the Prevention of Cruelty to Animals (Slaughter House) Rules, 2001,⁹ prohibits the slaughter of pregnant animals and animals under 3 months of age. Numerous states in the country have already banned the slaughter of cows and sometimes calves, bulls, and buffaloes.¹⁰ In a country where killing cows and calves is prohibited by law, it would be considered inappropriate and unethical by most to import and use NBCS manufactured by killing those same animals in other countries.

The use of NBCS/FBS as a supplement to cell culture media to maintain and grow Vero cells can be easily replaced with chemically defined media. This would avoid the ethical and scientific issues associated with NBCS/FBS and optimise the reliability and reproducibility of vaccine production. Multiple chemically defined serum free media are already commercially available and can be used to grow Vero cells for virus production instead of using NBCS extracted by slaughtering calves.^{11,12,13,14,15,16} Studies have documented the use of these animal-free, chemically defined media for the efficient production of several viruses.^{17,18,19,20,21}

The use of chemically defined media is also aligned with government authorities encouraging the elimination of animal-derived components in cell culture media.²² PETA India and its affiliate scientists have been leading scientific efforts in this area (see <https://www.thepsci.eu/our-work/fbs/>), and we'd be happy to provide you with more information, as needed.

Out of respect for the religious and cultural beliefs about cows and calves that the people of India hold and to comply with the laws of the country, it's extremely important that vaccine manufacturers be directed to end the use of NBCS and FBS and instead adopt the scientifically robust methods of cultivating Vero cells and developing vaccines using chemically defined media that are already commercially available.

May I please hear from you regarding this important matter? I can be contacted on +91 9910317382 or at AnkitaP@petaindia.org. Thank you for your time and consideration.

Sincerely,



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PETA India

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