EXD568(BT)(E)

Department for Environment, Food and Rural Affairs

The Bluetongue Regulations 2008 S.I 2008/962 (as amended) -
Regulation 19

Bluetongue-3 inactivated Vaccine: General Licence for Using Inactivated Bluetongue 3 Vaccine in England

Applies to England only

Valid from: 12:00 on 18 October 2024.

In accordance with Regulation 19(1) of the Bluetongue Regulations 2008 (as amended) ("the 2008 Regulations") the Secretary of State grants this general licence, subject to compliance with the conditions in the Schedule.

1. This licence allows the vaccination of ruminating animals or camelids pursuant to Regulation 19(1) of the 2008 Regulations with inactivated bluetongue 3 vaccine, provided that the vaccine is covered by:
    a. a marketing authorisation granted by the Veterinary Medicines Directorate; or
    b. a permit granted by the Secretary of State under Schedule 4 (4) of the Veterinary Medicines Regulations 2013.

2. A specific risk assessment has been carried out in accordance with regulation 19 (4) of the 2008 Regulations.

3. This general licence applies in England only.

4. The general licence which came into force at 09:00 on 26 September 2024 is hereby revoked and replaced by this general licence with effect from 12:00 on 18 October 2024.

5. This general licence may be amended, suspended or revoked in writing at any time by the Secretary of State.

Signed by: Gordon Hickman

Authorised by the Secretary of State

Date: 18 October 2024

Schedule of Conditions:

1. The vaccine shall be administered by a private veterinary surgeon, or the animal keeper may administer the prescribed bluetongue 3 vaccine and must do so according to the manufacturer's instructions and veterinary instruction.
2. The person administering vaccine under this licence must only vaccinate the animals with bluetongue 3 vaccine which has been prescribed by the vet normally responsible for caring for the animals.
3. Written or digital records must be kept of every animal vaccinated and must be provided to an inspector on request. The record must be retained for at least five years and contain the following:
    a. Species vaccinated,
    b. Individual permanent ID number (ear tag or other permanent official animal ID mark),
    c. Date of 1st dose,
    d. Date of any further doses,
    e. Vaccine product name and batch number,
    f. Name and job title of the person who administered the vaccine,
    g. Dose administered (ml),
    h. Route of administration (i.e. intramuscularly or subcutaneously),
    i. The stated withdrawal period of the vaccine used,
    j. Any excess doses and the amount (ml), to be returned as per condition 6 below.
    k. CPH and address of the holding where vaccination took place,
4. The animal keeper is responsible for making and retaining an accurate record as stipulated in Condition 3.
5. The licensee must complete the record required in condition 3 above at: Animal keeper reports of BTV-3 vaccination activity (office.com) as soon as possible and no more than 48 hours from the date vaccination took place.
6. Any person in possession of BTV3 vaccine must store the vaccine according to the manufacturer's instructions.
7. The animal keeper must ensure all excess doses (opened or otherwise) are returned to the prescribing vet.
8. Any adverse side effects associated with the vaccine, including suspected lack of efficacy, should be reported by the animal keeper within 7 calendar days of the adverse effects first being observed to the relevant pharmaceutical company (as detailed on the package leaflet) or the Veterinary Medicines Directorate (Report a suspected problem with an animal medicine or microchip: https://www.gov.uk/report-veterinary-medicine-problem.

Notes:

1. The general licence only permits the use of permitted or authorised vaccines to be administered in England.
2. Vaccinated animals must comply with the same movement controls and bluetongue regulations as unvaccinated animals.
3. “Veterinary surgeon” means a suitably qualified person registered with the Royal College of Veterinary Surgeons (RCVS).
4. “Animal” means a ruminating animal or camelid. Ruminating animals includes but is not limited to cattle, sheep, goats and deer. Camelid includes camels, llamas and alpacas.
5. If you suspect notifiable disease, you must report this immediately:
    a. England - Defra Rural Services Helpline on 03000 200 301
6. Nothing in this licence removes your obligation to comply with relevant legislation.
7. Contact Animal and Plant Health Agency (APHA) on the details provided above or your Local Authority (LA) for further advice on biosecurity measures and any other legislation that may apply.
8. Bluetongue legislation can be found at: Bluetongue: how to prevent it and stop it spreading - GOV.UK (www.gov.uk)
9. Vaccinated animals should not be tested as part of pre-movement testing within 7 days of receiving a vaccination dose to minimise the risk of false positives.
10. Information on how we use your personal data is set out in APHA’s Personal information charter: Personal information charter Personal information charter - Animal and Plant Health Agency - GOV.UK (www.gov.uk) and Privacy notices: Animal and Plant Health Agency privacy notices - GOV.UK (www.gov.uk). Animal and Plant Health Agency privacy notices - GOV.UK (www.gov.uk)

Any person who contravenes a provision of this licence made under the Bluetongue Regulations 2008 (as amended) shall commit an offence and is liable on summary conviction to a fine not exceeding level 5 on the standard scale or to imprisonment not exceeding 3 months or to both.