Japan's Comments on

The Biological Standards Commission Report of the September 2019 meeting

Japan would like to express its appreciation to the Biological Standards Commission (BSC) and other relevant Commissions, Working Groups and ad hoc Groups for all the works they have done. Japan also appreciates the BSC for providing us the opportunity to comment on the proposed revisions to the texts of Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

Content

1. CHAPTER 3.1.7. EPIZOOTIC HAEMORRHAGIC DISEASE

Specific comments

(1) Proposal of amendment to the 2nd paragraph of "C. REQUIREMENTS FOR VACCINES"(L417-426) (amendment)

Japan proposes to exclude the description of the outbreak in 1997.

C. REQUIREMENTS FOR VACCINES

In Japan, both live modified and inactivated vaccines have been developed to control Ibaraki disease. The live attenuated vaccine derived from the Ibaraki-2 strain was used following the outbreaks in 1980s and has been demonstrated to be safe and effective for prevention of Ibaraki disease caused by EHDV-2 until now~~, at least up to 1997 (Ohashi et al., 1999)~~. The vaccine has to be administered once subcutaneously during the low vector season. ~~National surveillance efforts and intensive monitoring of yearlings as sentinel cattle in place for a number of years did not reveal either Ibaraki disease or seroconversion until 1997, when new cases of the disease were observed (Ohashi et al., 1999). It is worthwhile to point out that the 1997 outbreak was characterised by abortion and stillbirths, clinical signs not observed in the previous outbreaks.~~ The inactivated vaccine includes bovine ephemeral fever and Ibaraki viruses grown in cell cultures and inactivated by formalin, as an aluminium-gel adjuvanted vaccine. In Japan both vaccines are used on a voluntary basis according to the epidemiological situation.

Rationale

- The outbreak in 1997 had been considered to be Ibaraki disease caused by a variant of EHDV-2 Ibaraki strain, happened under the vaccination control. However, it was revealed that the outbreak was caused by EHDV-7, not by EHDV-2 Ibaraki strain (Shirafuji et al., 2017).

[References]

Shirafuji H, Kato T, Yamakawa M, Tanaka T, Minemori Y, Yanase T. (2017) Characterization of genome segments 2, 3 and 6 of epizootic hemorrhagic disease virus strains isolated in Japan in 1985-2013: Identification of their serotypes and geographical genetic types. Infect Genet Evol. 2017 Sep;53:38-46

(2)Proposal of amendment to the table in page 7 to 8 (L288-296)

Specific comments

Japan proposes to add the information on the favorable combination of primers and probes to detect eastern/western topotype as indicated in the table in the original article by Viarouge et al.

(e.g.)

Draft	Amendment
EHDV-2_Seg2_F_1642-1665	EHDV-2_Seg2_F_1642-1665 (W)
EHDV-2_Seg2_F'_1640-1666	EHDV-2_Seg2_F'_1640-1666 (E)

2. CHAPTER 3.3.4. Avian influenza (infection with high pathogenicity avian influenza viruses)

Specific comments

Proposal of amendment to the pH of PBS (L509-510)

2.3. Haemagglutination and haemagglutination inhibition tests

Variations in the procedures for HA and HI tests are practised in different laboratories. The following recommended examples apply to the use of V-bottomed microwell plastic plates in which the final volume for both types of test is 0.075 ml. The reagents required for these tests are isotonic PBS (0.01 M), pH 7.0–7.4~~7.2,~~ and red blood cells (RBCs) taken from a minimum of three SPF or SAN chickens and pooled into an equal volume of Alsever's solution. Cells should be washed three times in PBS before use as a 1% (packed cell v/v) suspension. Positive and negative control antigens and antisera should be run with each test, as appropriate.

Rationale:

- PBS reagents commercially available are pH 7.2 or 7.4 (Gibco or Sigma-Aldrich) and PBS used for sample preparation in this chapter is pH 7.0-7.4.(L160)

- PH of PBS doesn't affect HA and HI titers as long as pH for PBS is between 6.8 - 7.6 (our unpublished data, available by request).