**SPF Animal Specifications**

Embryonated eggs and primary cultured cells to be used for production of seed lot products must conform to the specifications provided below. This does not apply for embryonated eggs to be used in the production process after bulk material of inactivated seed lot products.

1 Embryonated eggs

1.1 Embryonated chicken eggs

Embryonated chicken eggs to be used for the production of seed lot products must be derived from SPF chicken flocks that meet 1.1 in the Materials for Live Vaccine Production.

1.2 Embryonated quail egg

Embryonated quail eggs to be used for the production of seed lot products must be derived from SPF quail flocks that meet 1.2 in the Materials for Live Vaccine Production.

1.3 Embryonated duck egg

Embryonated duck eggs to be used for the production of seed lot products must be derived from SPF duck flocks that meet 1.3 in the Materials for Live Vaccine Production.

2 Primary cultured cells

2.1 Cattle

Cattle used to prepare primary cultured cells for the production of seed lot products must be derived from SPF cattle herds as confirmed to be free of pathogens listed in Table 1 by the tests and treatment provided therein or inspections and treatment approved as equivalent thereof. However, cattle herds that are managed in regions with no recorded outbreaks of the listed infectious disease may be considered free from infection with the pathogen.

2.2 Sheep

Sheep used to prepare primary cultured cells for the production of seed lot products must be derived from SPF sheep flocks as confirmed to be free of pathogens listed in Table 2 by the tests and treatment provided therein or inspections and treatment approved as equivalent thereof. However, sheep flocks that are managed in regions with no recorded outbreaks of the listed infectious disease may be considered free from infection with the pathogen.

2.3 Goat

Goats used to prepare primary cultured cells for the production of seed lot products must be derived from of SPF goat flocks as confirmed to be free of pathogens listed in Table 3 by the tests and treatment provided therein or inspections and treatment approved as equivalent thereof. However, goat flocks that are managed in regions with no recorded outbreaks of the listed infectious disease may be considered free from infection with the pathogen.

2.4 Horse

Horses used to prepare primary cultured cells for the production of seed lot products must be derived from SPF horse herds as confirmed to be free of pathogens listed in Table 4 by the tests and treatment provided therein or inspections and treatment approved as equivalent thereof. However, horse herds that are managed in regions with no recorded outbreaks of the listed infectious disease may be considered free from infection with the pathogen.

2.5 Swine

Swine used to prepare primary cultured cells for the production of seed lot products must be derived from SPF swine herds as confirmed to be free of pathogens listed in Table 5 by the tests and treatment provided therein or inspections and treatment approved as equivalent thereof. However, swine herds that are managed in regions with no recorded outbreaks of the specified infectious disease may be considered free from infection with the pathogen.

2.6 Chicken

Chickens to be used for preparing the primary cultured cells for the production of seed lot products must be derived from SPF chicken flocks that meet 1.1 in the Materials for Live Vaccine Production.

2.7 Quail

Quail to be used for preparing the primary cultured cells for the production of seed lot products must be derived from SPF quail flocks that meet 1.2 in the Materials for Live Vaccine Production.

2.8 Duck

Ducks to be used for preparing the primary cultured cells for the production of seed lot products must be derived from SPF duck flocks that meet 1.3 in the Materials for Live Vaccine Production.

2.9 Dog

Dogs used to prepare primary cultured cells for the production of seed lot products must be derived from SPF dog groups as confirmed to be free of pathogens listed in Table 6 by the tests and treatment provided therein or inspections and treatment approved as equivalent thereof. However, dog groups that are managed in regions with no recorded outbreaks of the listed infectious disease may be considered free from infection with the pathogen.

2.10 Cat

Cats used to prepare primary cultured cells for the production of seed lot products must be derived from SPF cat groups as confirmed to be free of pathogens listed in Table 7 by the tests and treatment provided therein or inspections and treatment approved as equivalent thereof. However, cat groups that are managed in regions with no recorded outbreaks of the listed infectious disease may be considered free from infection with the pathogen.

2.11 Rabbit

Rabbits used to prepare primary cultured cells for the production of seed lot products must be derived from SPF rabbit colonies as confirmed to be free of pathogens listed in Table 8 by the tests and treatment provided therein or inspections and treatment approved as equivalent thereof. However, rabbit colonies that are managed in regions with no recorded outbreaks of the listed infectious disease may be considered free from infection with the pathogen.

2.12 Mouse

Mice used to prepare primary cultured cells for the production of seed lot products must be derived from SPF mouse colonies as confirmed to be free of pathogens listed in Table 9 by the tests and treatment provided therein or inspections and treatment approved as equivalent thereof. However, mouse colonies that are managed in regions with no recorded outbreaks of the listed infectious disease may be considered free from infection with the pathogen.

2.13 Rat

Rats used to prepare primary cultured cells for the production of seed lot products must be derived from SPF rat colonies as confirmed to be free of pathogens listed in Table 10 by the tests and treatment provided therein or inspections and treatment approved as equivalent thereof. However, rat colonies that are managed in regions with no recorded outbreaks of the listed infectious disease may be considered free from infection with the pathogen.

2.14 Hamster

Hamsters used to prepare primary cultured cells for the production of seed lot products must be derived from SPF hamster colonies as confirmed to be free of pathogens listed in Table 11 by the tests and treatment provided therein or inspections and treatment approved as equivalent thereof. However, hamster colonies that are managed in regions with no recorded outbreaks of the listed infectious disease may be considered free from infection with the pathogen.

2.15 Guinea pig

Guinea pigs used to prepare primary cultured cells for the production of seed lot products must be derived from SPF guinea pig colonies as confirmed to be free of pathogens listed in Table 12 by the tests and treatment provided therein or inspections and treatment approved as equivalent thereof. However, guinea pig colonies that are managed in regions with no recorded outbreaks of the listed infectious disease may be considered free from infection with the pathogen.