

Minimum Requirements for Veterinary Biological Products Volume 1 新旧对照表

Page	Line	Item	修正後	修正前
13	4	1 Definition	<u>Seed Lot Specifications</u>	<u>seed lot specifications</u>
21	5		<u>Bovine</u>	<u>bovine</u>
21	6		<u>Seed Lot Specifications</u>	<u>seed lot specifications</u>
29	5		<u>Seed Lot Specifications</u>	<u>seed lot specifications</u>
44	9		<u>Seed Lot Specifications</u>	<u>seed lot specifications</u>
70	4		<u>Seed Lot Specifications</u>	<u>seed lot specifications</u>
78	4		<u>Seed Lot Specifications</u>	<u>seed lot specifications</u>
84	4		<u>Seed Lot Specifications</u>	<u>seed lot specifications</u>
13	5		that meet <u>the said</u> specifications	that meet <u>these</u> specifications
21	6		that meet <u>the said</u> specifications	that meet <u>these</u> specifications
29	6		that meet <u>the said</u> specifications	that meet <u>these</u> specifications
44	9		that meet <u>the said</u> specifications	that meet <u>these</u> specifications
70	5		that meet the <u>said</u> specifications	that meets <u>the</u> specifications
84	4		<u>Rabies</u>	<u>rabies</u>
84	5		that meet the <u>said</u> specifications	that meet the specifications
13	17	2 Production methods	<u>The dispensed</u>	<u>Dispensed</u>
21	10		<u>Bovine</u>	<u>bovine</u>
21	13		<u>virus strain</u>	<u>virus</u>
21	14		<u>the strain</u>	<u>this virus</u>
21	15		<u>virulent strain</u>	<u>virulent virus</u>
29	13		<u>virus strain</u>	<u>virus</u>
30	12		<u>The strain</u>	<u>This virus</u>
31	6		<u>The strain</u>	<u>This virus</u>
31	36		<u>The strain</u>	<u>This virus</u>
44	18		<u>virus strain</u>	<u>virus</u>
44	20		<u>The strain</u>	<u>This virus</u>
45	19		<u>virus strain</u>	<u>virus</u>
45	21		<u>The strain</u>	<u>This virus</u>
46	14		<u>virus strain</u>	<u>virus</u>
46	16		<u>The strain</u>	<u>This virus</u>
47	9		<u>virus strain</u>	<u>virus</u>

47	10		<u>The strain</u>	<u>This virus</u>
48	4		virus <u>strain</u>	virus
48	5		<u>The strain</u>	<u>This virus</u>
70	4		Japanese	<u>the Japanese</u>
78	6		<u>Bacterial</u>	<u>Virus</u>
78	10		<u>bacterial</u>	<u>virus</u>
78	14		<u>The master</u>	Master
84	11		virus <u>strain</u>	virus
84	12		<u>the strain</u>	<u>this virus</u>
84	15		<u>The strain</u>	<u>This virus</u>
18	9	Properties test	, <u>and no</u> foreign	. <u>No</u> foreign
26	11		, <u>and no</u> foreign	. <u>No</u> foreign
80	26		, <u>and no</u> foreign	. <u>No</u> foreign
92	8		, <u>and no</u> foreign	. <u>No</u> foreign
165	8,13,18	1Embryonated eggs	<u>tests</u>	<u>inspection</u>
168		Table 1	ページ全体 (次ページ)	

Table 1 Inspection and Treatment of SPF Chicken Flocks

Pathogen	Antigen under inspection ¹⁾	Inspection timing and number of chickens inspected				Inspection method ²⁾	Treatment
		1st		2 nd and subsequent			
		Timing	Number of chickens (%)	Timing	Number of chickens (%)		
Newcastle disease virus	Ishii strain	8–12 weeks old	20	Every 3 months	10	HI	All the positive group and cohabitant group ³⁾ culling
Avian infectious bronchitis virus	M-41 strain	"	"	"	"	ELISA	
Avian leukosis virus	Sub-A, B	"	"	"	"	SN	"
Avian encephalomyelitis virus	Van Roekel strain	"	"	"	"	ELISA	"
Avian nephritis virus	G-4260 strain	"	"	"	"	FA	"
Infectious laryngotracheitis virus	NS-175 strain	"	"	"	"	ELISA	"
Reticuloendotheliosis virus	T strain	"	"	"	"	FA	"
Marek's disease virus	JM strain	"	"	"	"	FA	"
Infectious bursal disease virus	J1 strain	"	"	"	"	ELISA	"
Avian reovirus	Uchida strain	"	"	"	"	DID	"
Avian adenovirus	Ote strain	"	"	"	"	DID	"
EDS-76 virus	JPA-1 strain	"	"	"	"	HI	"
Avian influenza virus	5331 strain	"	"	"	"	DID	"
Chicken anemia virus	Gifu-1 strain	"	"	"	"	FA	"
Turkey rhinotracheitis virus	MM-1 strain	"	"	"	"	FA	"
Avian paramyxovirus	Yucaipa strain	"	"	"	"	HI	"
<i>Haemophilus paragallinarum</i> type A	221 strain	"	"	"	"	HI	"
<i>Haemophilus paragallinarum</i> type C	S1 strain	"	"	"	"	HI	"
<i>Salmonella pullorum</i>	9-25 strain	"	"	"	"	AGG	"
<i>Mycoplasma gallisepticum</i>	S6 strain	"	"	"	"	AGG	"
<i>Mycoplasma synoviae</i>	WVU-1853 strain	"	"	"	"	AGG	"
<i>Salmonella</i> (except for <i>Salmonella pullorum</i>)		"	"	"	"	Bacterial isolation	"
Chickenpox virus		Everyday	100	Everyday	100	Clinical observation	Positive chickens culling

Note All health conditions and abnormalities of chickens shall be completely recorded. For dead chickens, histopathological examinations and other associated examinations shall be performed.

- 1) The antigen may be substituted with another appropriate strain.
- 2) An equivalent inspection method may be applied, if available. The alternate inspection method to be applied shall be verified and guaranteed to ensure their validity. HI: Hemagglutination test
ELISA: Enzyme-linked immunosorbent assay SN: Serum neutralization test FA: Fluorescence antibody test
DID: Double immunodiffusion test AGG: Agglutination test
- 3) Cohabitant group refers to a group of animals not completely isolated from the positive group.