Operation Directions Governing Management of Infectious Biological Materials, Ministry of Health and Welfare

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1 These Directions are set forth pursuant to Paragraph 2 of Article 4, Article 8, Paragraph 1 of Article 19 and Paragraph 2 of Article 21 of the Regulations Governing Management of Infectious Biological Materials to ensure effective management of infectious biological materials and the biosafety and biosecurity of laboratories and storage facilities.

2 Infectious biological materials can be classified into the following three categories:

(1) Infectious pathogens: refer to pathogenic microorganisms (such as bacteria, viruses, fungi, parasites, etc.) and their cultures (media) that may cause infections or diseases in humans;

(2) Derivatives of pathogens: refer to the purified or isolated components of pathogens (such as nucleic acids, plasmids, proteins, etc.) or their secreted products (such as biotoxins); and

(3) Materials confirmed to contain pathogens or their derivatives: refer to positive specimens of patients with communicable diseases (such as blood, sputum, urine, etc.)

3 When the infectious biological materials are pathogens, the lists of Risk Group 1 (RG1) to Risk Group 4 (RG4) are provided in Appendix 1 through Appendix 4.

Vaccine strains and Lentiviral vector that pass related tests and are identified as lentivirus shall be managed as RG2 pathogens.

4 Entities shall have appropriate management mechanism in place for positive specimens of communicable diseases. Laboratories or storage facilities that possess, store, use, dispose, export or import positive specimens (except when deactivated) listed in Appendix 3 and Appendix 4 and packed in compliance with Packing Instruction P620 shall manage such specimens as RG3 or RG4 pathogens.

5 The infectious biological materials listed in Appendix 5 are biotoxins.

6 The infectious biological materials listed in Appendix 6 are select pathogens and biotoxins (referred to as “select agents and toxins” hereunder).

7 The transport and packing of pathogens, biotoxins, specimens and positive specimens of communicable diseases shall comply with the instructions outlined in Appendix 1 through Appendix 5.

Infectious biological materials in the preceding paragraph that have been deactivated are exempted from the transport and packing instructions.

Infectious biological materials to be transported shall be adequately packed and labeled in compliance with the instructions outlined in Appendix 7 to avoid leakage in transit.

8 The provisions of biosafety levels for biosafety laboratories are outlined in Appendix 8.

9 The provisions of biosafety levels for animal biosafety laboratories are outlined in Appendix 9.

10 Experiments that involve biotoxins shall be conducted in laboratory settings that conform to BSL-2 or above. Experiments that involve a large amount or high concentration of biotoxins that have been confirmed to pose high hazards following risk assessment shall be conducted in laboratory settings that conform to BSL-3 or above.

11 Laboratories or storage facilities that handle select agents and toxins must develop and implement the biosafety, biosecurity and incident response plans and shall be maintained in coordination with the following activities:

(1) The plans shall be designed according to a site specific risk assessment.

(2) The plans shall be submitted for initial registration, renewal of registration, or when requested.

(3) The plans should be reviewed and revised after drills or exercises or biosafety or biosecurity incident as necessary. Drills or exercises must evaluate the effectiveness of the plans and be documented completely.

12 The biosafety plan of a laboratory or storage facility that handles select agents and toxins shall contain the following particulars:

(1) Safeguard procedures to protect personnel and laboratory animals against the risk of exposure to or infection with select agents or toxins.

(2) The hazardous characteristics of each select agent and toxin listed on entity's registration.

(3) Safeguard measures to prevent the personnel of the entity, the public and the environment from exposure to or infection with select agents or toxins.

(4) Validated method for disinfection, decontamination or destruction of contaminated materials.

(5) Procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.

(6) The occupational health program for designated personnel who may work with highly dangerous select agents and toxins.

13 The biosecurity plan of a laboratory or storage facility that handles select agents and toxins shall contain the following particulars:

(1) Physical containment, inventory control and information system control procedures.

(2) Provisions for the management of designated personnel who may work with select agents and toxins.

(3) Provisions for routine cleaning, maintenance and repairs.

(4) Procedures for removing unauthorized or suspicious persons into the laboratory or storage facility.

(5) Procedures for handling the loss and unintentional revelation of pass key or password and change of access authority.

(6) Procedures for reporting unauthorized or suspicious persons or activities, and for reporting loss, theft, or release of select agents or toxins, or unauthorized alteration of their inventory records.

(7) Provisions requiring designated personnel to observe the security protocols.

(8) Procedures for reporting suspicious activities to select agents and toxins supervisor and the competent authority.

(9) Provisions for information security.

(10) Provisions and policies for the shipping, receiving, intra-entity transferring and storage of select agents and toxins.

The biosecurity plan of a laboratory or storage facility that handles highly dangerous select agents and toxins shall contain the following particulars in addition to items under the subparagraphs of the preceding paragraph:

(1) Procedures for conducting a pre-access suitability assessment and ongoing suitability assessment of personnel.

(2) Procedures to be performed by the entity’s Responsible Official and institutional biosafety committee.

(3) Procedures regarding entry into highly dangerous select agents and toxins controlled area during the time other than normal business hours.

(4) Procedures regarding visitors, their property and vehicles entering/exiting into/from a registered area or building.

(5) Entry controls for highly dangerous select agents and toxins controlled area:

I. A minimum of three layers security barrier.

II. One of the security barriers must be monitored under all weather, 24-hour video surveillance and recording.

III. The last layer of security barrier should be effectively controlled and only designated personnel can access highly dangerous select agents and toxins.

(6) Response measure for power supply interruption of access control system.

(7) All registered space or areas must be protected by an intrusion detection system (IDS).

(8) The evaluation, judgment and alert capabilities of personnel responsible for monitoring the intrusion detection system.

(9) In the event of an intrusion alert or a security incident report, make sure the security personnel or the local police will arrive at the first security barrier in 15 minutes, or security barriers in place are able to stall unauthorized access until the response personnel have arrived at the first security barrier.

14 The incident response plan drawn up by a laboratory or storage facility that handles select agents or toxins shall contain the following particulars:

(1) Notification and response procedures for the following incidents involving select agents or toxins:

I. Theft, loss or release.

II. Inventory discrepancy.

III. Security breach (including information system).

IV. Severe weather conditions and other natural disasters (e.g., flooding, windstorm, earthquake).

V. Workplace violence.

VI. Bomb threat and suspicious package.

VII. Emergencies such as fire, gas leakage, explosion, power outage and other accidents, etc.

(2) Response procedures when people are exposed to or infected with a select agent or toxin.

(3) The incident response plan shall contain the following information:

I. Names and contact information (e.g., home and work) of responsible officer, responsible official and alternate responsible official.

II. Personnel roles and process for communication with authority.

III. Planning and coordination with local emergency responders.

IV. Procedures to be followed by personnel performing rescue or medical duties.

V. A list of personal protective and emergency equipment and their locations.

VI. Site security and control.

VII. Procedures for emergency evacuation

VIII. Decontamination procedures.

The incident response plan of a laboratory or storage facility that handles highly dangerous select agents and toxins shall contain the following particulars in addition to items under the subparagraphs of the preceding paragraph:

(1) Response procedures for failure of intrusion detection or alarm system.

(2) Procedures for reporting suspicious criminal activity related to the entity, its personnel, or highly dangerous select agents and toxins.

15 The research projects of an entity that may use highly dangerous select agents and toxins as permitted by law shall be reviewed, approved and put

under control by its institutional biosafety committee. The project shall be reported to the central competent authority for record within one month after it is approved by the institutional biosafety committee.

16 The levels, explanations, notification, templates and management of biosafety accidents of laboratories and storage facilities are provided in Appendix 10.

Appendix 1. List of Pathogens in Risk Group 1 (RG1)

No.	Item[1]	Transport and Packing Instructions[2]	Remark
		P650	
1	*Acinetobacter* spp.	v	
2	*Actinoalloteichus* spp.	v	
3	*Actinosynnema mirum*	v	
4	Adeno-associated virus (all serotypes)	v	
5	*Aeromicrobium* spp.	v	
6	*Aeromonas* spp.	v	
7	*Alicyclobacillus* spp.	v	
8	*Alishewanella* spp.	v	
9	*Alistipes onderdonkii*	v	
10	*Anaerococcus hydrogendis*	v	
11	*Anaerococcus tetradius*	v	
12	*Ancylostoma braziliense*	v	
13	*Ancylostoma caninum*	v	
14	*Aneurinibacillus* spp.	v	
15	*Aquabacterium commune*	v	
16	*Aquabacterium citratiphilum*	v	
17	*Aquabacterium parvum*	v	
18	*Aquaspirillum itersonii*	v	
19	*Aquifex aeolicus*	v	
20	*Aquifex pyrophilus*	v	
21	*Arthrobacter globiformis*	v	
22	*Aspergillus niger*	v	
23	*Azomonas macrocytogenes*	v	
24	*Bacillus choshinensis*	v	
25	*Bacillus coagulans*	v	
26	*Bacillus cohnii*	v	
27	*Bacillus formosus*	v	
28	*Bacillus parabrevis*	v	

No.	Item[1]	Transport and Packing Instructions[2]	Remark
		P650	
29	*Bacillus pumilus*	v	
30	*Bacillus reuszeri*	v	
31	*Bacillus thermocloacae*	v	
32	*Bacteroides* spp.	v	
33	*Blastomonas* spp.	v	
34	*Brachybacterium* spp.	v	
35	*Brochothrix* spp.	v	
36	*Brevibacillus* spp.	v	
37	*Brevibacterium* spp.	v	
38	*Brevundimonas vesicularis*	v	
39	*Burkholderia thailandensis*	v	
40	*Buttiauxella agrestis*	v	
41	*Butyrivibrio crossotus*	v	
42	*Candida* spp.	v	
43	*Candida spencermartinsiae*	v	
44	*Candida taylori*	v	
45	*Candida tenuis*	v	
46	*Carnobacterium pisciola*	v	
47	*Carnobacterium divergens*	v	
48	*Caulobacter* spp.	v	
49	*Cellulomonas cellulans*	v	
50	*Clostridium* spp.	v	
51	*Clostridium asparagiforme*	v	
52	*Clostridium butyricum*	v	
53	*Clostridium tetanomorphum*	v	
54	*Clostridium tyrobutyricum*	v	
55	*Collinsella intestinalis*	v	
56	*Collinsella* spp.	v	
57	*Collinsella stercoris*	v	
58	*Comomonas acidovorans*	v	

No.	Item[1]	Transport and Packing Instructions[2]	Remark
		P650	
59	*Corynebacterium accolens*	v	
60	*Corynebacterium afermentans*	v	
61	*Corynebacterium argentoratense*	v	
62	*Corynebacterium genitalium*	v	
63	*Corynebacterium glutamicum*	v	
64	*Corynebacterium macginleyi*	v	
65	*Corynebacterium tuberculostearicum*	v	
66	*Deinococcus* spp.	v	
67	*Delftia* spp.	v	
68	*Dermacoccus nishinomiyaensis*	v	
69	*Desemzia* spp.	v	
70	*Dietzia* spp.	v	
71	*Dysgonomonas* spp.	v	
72	*Escherichia blattae*	v	
73	*Escherichia coli (non-pathogenic strains)*	v	Such us *Escherichia coli* K-12
74	*Exiguobacterium* spp.	v	
75	*Fibrobacter* spp.	v	
76	*Filifactor* spp.	v	
77	*Finegoldia* spp.	v	
78	*Flavobacterium capsulatum*	v	
79	*Flavobacterium psychrophilum*	v	
80	*Fusobacterium prausnitzii*	v	
81	*Glycomyces tenuis*	v	
82	*Gracilibacillus* spp.	v	
83	*Granulicatella* spp.	v	
84	*Halobacterium salinarium*	v	
85	*Helicobacter hepaticus*	v	
86	*Helicobacter muridarum*	v	
87	*Holdemania* spp.	v	

No.	Item[1]	Transport and Packing Instructions[2]	Remark
		P650	
88	*Hungatella hathewayi*	v	
89	*Intrasporangium calvum*	v	
90	*Klebsiella terrigena*	v	
91	*Kocuria* spp.	v	
92	*Kocuria rosea*	v	
93	*Kurthia gibsonii*	v	
94	*Kytococcus* spp.	v	
95	*Lactobacillus leichmannii*	v	
96	*Lactobacillus oris*	v	
97	*Lactobacillus vaginalis*	v	
98	*Lactococcus garvieae*	v	
99	*Lactococcus lactis*	v	
100	*Lautropia* spp.	v	
101	*Lechevaliera* spp.	v	
102	*Lentzia* spp.	v	
103	*Leuconostoc* spp.	v	
104	*Listeria innocua*	v	
105	*Listeria welshimeri*	v	
106	*Luteococcus* spp.	v	
107	*Macrococcus* spp.	v	
108	*Maricaulis* spp.	v	
109	*Megamonas* spp.	v	
110	*Methylobacterium amnivorans*	v	
111	*Methylobacterium mesophilicum*	v	
112	*Micrococcus diversus*	v	
113	*Micrococcus luteus*	v	
114	*Micrococcus roseus*	v	
115	*Micromonas* spp.	v	
116	*Micromonospora coerulea*	v	
117	*Mycoplasma orale*	v	

No.	Item[1]	Transport and Packing Instructions[2]	Remark
		P650	
118	*Nesterenkonia* spp.	v	
119	*Obesumbacterium proteus*	v	
120	*Oerskovia* spp.	v	
121	*Oligella ureolytica*	v	
122	*Paracoccus* spp.	v	
123	*Planobispora rosea*	v	
124	*Pichia haplophila*	v	
125	*Porphyromonas endodontalis*	v	
126	*Porphyromonas gulae*	v	
127	*Pragia fontium*	v	
128	*Propioniferax* spp.	v	
129	*Proteus myxofaciens*	v	
130	*Pseudomonas putida*	v	
131	*Pseudomonas* spp.	v	
132	*Rhizopus microsporus*	v	
133	*Rhodospirillum rubrum*	v	
134	*Rickenella* spp.	v	
135	*Ruminococcus* spp.	v	
136	*Ruminococcus productus*	v	
137	*Saccharomyces carlsbergensis*	v	
138	*Saccharomyces pastorianus*	v	
139	*Saccharothrix longispora*	v	
140	*Saccharothrix mutabilis*	v	
141	*Sanguibacter* spp.	v	
142	*Schineria* spp.	v	
143	*Schizosaccharomyces*	v	
144	*Sebaldella* spp.	v	
145	*Shewanella putrefaciens*	v	
146	*Slackia* spp.	v	
147	*Solobacterium* spp.	v	

No.	Item[1]	Transport and Packing Instructions[2]	Remark
		P650	
148	*Spirometra mansoni*	v	
149	*Sporosarcina ureae*	v	
150	*Staphylococcus carnosus*	v	
151	*Staphylococcus lentus*	v	
152	*Staphylococcus pulvereri*	v	
153	*Stomatococcus* spp.	v	
154	*Streptococcus salivarius* subsp. *thermophilus*	v	
155	*Streptomyces albus*	v	
156	*Streptomyces corchorusii*	v	
157	*Streptomyces olivaceoviridis*	v	
158	*Streptosporangium roseum*	v	
159	*Tetragenococcus halophilus*	v	
160	*Terracoccus* spp.	v	
161	*Thermoanaerobacterium thermosaccharolyticum*	v	
162	*Thermotoga maritima*	v	
163	*Thermus* spp.	v	
164	*Tissaracoccus* spp.	v	
165	*Turicella otitidis*	v	
166	*Vagococcus fluvialis*	v	
167	*Vagococcus salmoninarum*	v	
168	*Xenorhabdus nematophilus*	v	
169	*Yersinia ruckeri*	v	
170	*Zoogloea ramigera*	v	
171	*Zygosaccharomyces bailii*	v	
172	*Zygosaccharomyces rouxii*	v	

Notes:

1. If the listed items correspond to the items in the “Quarantine Requirements for the Importation of Animals and Animal Products” of the Council of Agriculture, relevant regulations stipulated by the Council of Agriculture also apply.
2. The packing and relevant requirements set out in P650 Packing Instruction are outlined in Appendix 7.

Appendix 2. List of Pathogens in Risk Group 2 (RG2)

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
1	*Acanthamoeba* spp.		v	
2	*Acidovorax* spp.		v	
3	*Acinetobacter baumannii*		v	Previously called *Acinetobacter calcoaceticus*
4	*Acinetobacter johnsonii*		v	
5	*Acinetobacter lwoffii*		v	
6	*Acinetobacter lwoffii/haemolyticus*		v	
7	*Acremonium falciforme*		v	
8	*Acremonium kiliense*		v	
9	*Acremonium recifei*		v	
10	*Actinobacillus* spp.		v	
11	*Actinomyces pyogenes*		v	Previously called *Corynebacterium pyogenes*
12	Adenovirus		v	
13	*Aerococcus urinae*		v	
14	*Aerococcus viridans*		v	
15	*Aeromonas caviae*		v	
16	*Aeromonas hydrophila*		v	
17	*Aeromonas salmonicida*		v	
18	*Aeromonas sobria*		v	
19	*Aeromonas veronii*		v	
20	*Aggregatibacter actinomycetemcomitans*		v	Previously called *Actinobacillus actinomycetemcomitans*, *Haemophilus actinomycetemcomitans*

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
21	*Aggregatibacter aphrophilus*		v	Previously called *Haemophilus aphrophilus*
22	*Aggregatibacter segnis*		v	Previously called *Haemophilus segnis*
23	*Akabanevirus*		v	
24	*Alcaligenes faecalis*		v	
25	*Amycolata autotrophica*		v	
26	*Anaerococcus vaginalis*		v	Previously called *Peptostreptococcus vaginalis*
27	*Ancylostoma ceylanicum*		v	
28	*Ancylostoma duodenale*		v	
29	*Arcanobacterium haemolyticum*		v	Previously called *Corynebacterium haemolyticum*
30	*Arizona hinshawii*		v	
31	*Ascaris* spp.		v	
32	*Ascaris lumbricoides*		v	
33	*Ascaris suum*		v	
34	*Aspergillus flavus*		v	Except *Aspergillus flavus var. columnaris*
35	*Aspergillus fumigatus*		v	
36	*Aspergillus hongkongensis*		v	
37	*Babesia divergens*		v	
38	*Babesia microti*		v	
39	*Bacillus cereus*		v	
40	*Bacteroides capillosus*		v	
41	*Bacteroides eggerthii*		v	
42	*Bacteroides fragilis*		v	
43	*Bacteroides ovatus*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
44	*Bacteroides thetaiotaomicron*		v	
45	*Bacteroides ureolyticus*		v	
46	*Bacteroides vulgatus*		v	
47	*Balantidium coli*		v	
48	*Bartonella* spp.		v	
49	*Bartonella bigemina*		v	
50	*Bartonella bovis*		v	
51	*Bartonella henselae*		v	
52	*Bartonella quintana*		v	
53	*Bartonella vinsonii*		v	
54	Bebaru virus		v	
55	*Bergeyella zoohelcum*		v	
56	*Blastocystis hominis*		v	
57	*Blastomyces dermatitidis*		v	
58	Bocavirus		v	
59	*Bordetella* spp.		v	
60	*Bordetella bronchiseptica*		v	
61	*Bordetella parapertussis*		v	
62	*Bordetella pertussis*		v	
63	*Borrelia* spp.		v	
64	*Borrelia burgdorferi*		v	
65	*Borrelia recurrentis*		v	
66	*Brevundimonas diminuta*		v	
67	*Brugia* spp.		v	
68	*Brugia malayi*		v	
69	*Brugia timori*		v	
70	Buffalopox virus		v	
71	Bunyamwera virus		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
72	*Burkholderia* spp.		v	*Burkholderia mallei* and *Burkholderia pseudomallei* is listed in RG3.
73	*Burkholderia cepacia*		v	
74	*Burkholderia gladioli*		v	
75	Cache Valley virus		v	
76	Calicivirus		v	
77	California encephalitis virus		v	
78	*Campylobacter* spp.		v	
79	*Campylobacter coli*		v	
80	*Campylobacter fetus*		v	
81	*Campylobacter jejuni*		v	
82	*Candida albicans*		v	
83	*Candida glabrata*		v	
84	*Candida intermedia*		v	
85	*Candida krusei*		v	
86	*Candida lusitaniae*		v	
87	*Candida parapsilosis*		v	
88	*Candida sake*		v	
89	*Candida tropicalis*		v	
90	*Capillaria philippinensis*		v	
91	*Cedecea davisae*		v	
92	*Cedecea lapagei*		v	
93	*Cedecea neteri*		v	
94	*Cellulomonas hominis*		v	
95	*Chlamydophila pneumoniae*		v	
96	*Chlamydophila psittaci*		v	Avian strains is listed in RG3.
97	*Chlamydophila trachomatis*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
98	*Chromobacterium violaceum*		v	
99	*Chryseobacterium gleum*		v	
100	*Chryseobacterium indologenes*		v	
101	*Citrobacter* spp.		v	
102	*Citrobacter amalonaticus*		v	
103	*Citrobacter braakii*		v	
104	*Citrobacter diversus*		v	
105	*Citrobacter farmeri*		v	
106	*Citrobacter freundii*		v	
107	*Citrobacter koseri*		v	
108	*Citrobacter werkmanii*		v	
109	*Citrobacter youngae*		v	
110	*Cladosporium bantianum*		v	
111	*Cladosporium carrionii*		v	
112	*Cladosporium trichoides*		v	
113	*Clostridium argentinense*		v	**Virulent strains shall comply with select agent regulations.**
114	*Clostridium baratii*		v	**Virulent strains shall comply with select agent regulations.**
115	*Clostridium botulinum*	v (cultures only)	v	**Virulent strains shall comply with select agent regulations.**
116	***Clostridium butyricum* (virulent strains)**		v	**Comply with select agent regulations.**
117	*Clostridium cadaveris*		v	
118	*Clostridium chauvoei*		v	
119	*Clostridium clostridioforme*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
120	*Clostridium difficile*		v	
121	*Clostridium haemolyticum*		v	
122	*Clostridium histolyticum*		v	
123	*Clostridium novyi*		v	
124	*Clostridium perfringens*		v	
125	*Clostridium ramosum*		v	
126	*Clostridium septicum*		v	
127	*Clostridium sporogenes*		v	
128	*Clostridium tetani*		v	
129	*Clostridium tertium*		v	
130	*Coccidia* spp.		v	
131	Colorado tick fever virus		v	
132	Coltivirus		v	
133	Coronavirus		v	SARS Coronavirus and MERS Coronavirus is listed in RG3.
134	*Corynebacterium* spp.		v	
135	*Corynebacterium amycolatum*		v	
136	*Corynebacterium auris*		v	
137	*Corynebacterium bovis*		v	
138	*Corynebacterium diphtheriae*		v	
139	*Corynebacterium jeikeium*		v	
140	*Corynebacterium matruchotii*		v	
141	*Corynebacterium propinquum*		v	
142	*Corynebacterium pseudotuberculosis*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
143	*Corynebacterium pseudodiphtheriticum*		v	
144	*Corynebacterium renale*		v	
145	*Corynebacterium striatum*		v	
146	*Corynebacterium urealyticum*		v	
147	*Corynebacterium xerosis*		v	
148	Cowpox virus		v	
149	Coxsackie virus		v	
150	*Curtobacterium flaccumfaciens*		v	
151	*Cryptococcus neoformans*		v	
152	*Cryptococcus grubii*		v	
153	*Cryptococcus gatti*		v	
154	*Cryptosporidium* spp.		v	
155	*Cryptosporidium parvum*		v	
156	*Cysticercus cellulosae*		v	
157	Cytomegalovirus		v	Abbreviated as CMV.
158	Dengue virus (serotypes 1, 2, 3, 4)	v (cultures only)	v	
159	*Dermatophilus congolensis*		v	
160	*Dientamoeba fragilis*		v	
161	*Dipylidium caninum*		v	
162	*Echinococcus granulosis*		v	
163	*Echinococcus multilocularis*		v	
164	*Echinococcus vogeli*		v	
165	Echo virus		v	
166	*Edwardsiella tarda*		v	
167	*Eikenella corrodens*		v	
168	Elephantpox virus		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
169	*Elizabethkingia meningoseptica*		v	Used to be regarded as *Chryseobacterium meningosepticum*
170	*Empedobacter brevis*		v	
171	*Encephalitozoon cuniculi*		v	
172	*Encephalitozoon hellem*		v	
173	*Encephalitozoon intestinalis*		v	
174	*Entamoeba histolytica*		v	
175	*Enterobacter* spp.		v	
176	*Enterobacter aerogenes*		v	
177	*Enterobacter asburiae*		v	
178	*Enterobacter cancerogenus*		v	
179	*Enterobacter cloacae*		v	
180	*Enterobacter gergoviae*		v	
181	*Enterobacter hormaechei*		v	
182	*Enterobacter sakazakii*		v	
183	*Enterobius* spp.		v	
184	*Enterococcus* spp.		v	
185	*Enterococcus avium*		v	
186	*Enterococcus casseliflavus*		v	Previously called *Streptococcus casseliflavus*
187	*Enterococcus dispar*		v	
188	*Enterococcus durans*		v	
189	*Enterococcus faecalis*		v	
190	*Enterococcus faecium*		v	
191	*Enterococcus flavescens*		v	
192	*Enterococcus gallinarum*		v	Previously called *Streptococcus gallinarum*
193	*Enterococcus hirae*		v	
194	*Enterococcus raffinosus*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
195	Enterovirus		v	
196	*Epidermophyton* spp.		v	
197	*Epidermophyton floccosum*		v	
198	Epstein-Barr virus		v	Abbreviated as EBV.
199	*Erysipelothrix rhusiopathiae*		v	
200	*Escherichia coli*	v (only cultures of enterotoxigenic E.coli)	v	Includes all enteropathogenic, enterotoxic, intestinal invasive and strains carrying the K1 antigen.
201	*Escherichia fergusonii*		v	
202	*Escherichia hermannii*		v	
203	*Escherichia vulneris*		v	
204	*Exophiala castellanii*		v	
205	*Exophiala dermatitidis*		v	
206	*Exophiala mansonii*		v	
207	*Exophiala spinifera*		v	
208	*Fasciola* spp.		v	
209	*Fasciola gigantica*		v	
210	*Fasciola hepatica*		v	
211	*Fonsecaea pedrosoi*		v	
212	*Fusobacterium* spp.		v	
213	*Fusobacterium necrogenes*		v	
214	*Fusobacterium nucleatum*		v	
215	*Gardnerella vaginalis*		v	
216	*Gemella morbillorum*		v	
217	*Giardia* spp.		v	
218	*Giardia lamblia*		v	
219	*Haemophilus* spp.		v	
220	*Haemophilus aegyptius*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
221	*Haemophilus ducreyi*		v	
222	*Haemophilus influenzae*		v	
223	*Haemophilus parainfluenzae*		v	
224	*Hafnia alvei*		v	
225	Hazara virus		v	
226	*Helicobacter pylori*		v	
227	Hepatitis A virus		v	
228	Hepatitis B virus	v (cultures only)	v	
229	Hepatitis C virus		v	
230	Hepatitis D virus		v	
231	Hepatitis E virus		v	
232	Herpes simplex viruses (Type 1, 2)		v	
233	Herpesvirus		v	Herpesvirus simiae is listed in RG4.
234	Herpesvirus zoster		v	
235	*Heterophyes* spp.		v	
236	Human B lymphotropic virus		v	
237	Human herpesvirus (Type 6, 7,8)		v	
238	Human metapneumovirus		v	
239	Human rhinovirus		v	
240	*Hymenolepis* spp.		v	
241	*Hymenolepis diminuta*		v	
242	*Hymenolepis nana*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
243	Influenza virus (Type A, B, C)		v	H1N1, H5N2 and H6N1 is listed in RG2; H5N1 and H7N9 is listed in RG3.
244	Influenza virus type A (subtype H5N1 vaccine strain)		v	
245	Influenza virus type A (subtype H7N9 vaccine strain)		v	
246	*Isospora* spp.		v	
247	Japanese encephalitis virus	v (cultures only)	v	
248	*Kingella* spp.		v	
249	*Kingella denitrificans*		v	
250	*Klebsiella* spp.		v	*Klebsiella terrigena* is listed in RG1.
251	*Klebsiella oxytoca*		v	
252	*Klebsiella ozaenae*		v	
253	*Klebsiella pneumoniae*		v	
254	*Kluyvera ascorbata*		v	
255	*Kluyvera cryocrescens*		v	
256	*Kluyvera intermedia*		v	Also called *Enterobacter intermedius*
257	*Leclercia adecarboxylata*		v	
258	*Legionella* spp.		v	
259	*Legionella pneumophila*		v	
260	*Legionella anisa*		v	
261	*Legionella birminghamensis*		v	
262	*Legionella bozemanii*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
263	*Legionella cincinnatiensis*		v	
264	*Legionella feeleii*		v	
265	*Legionella hackeliae*		v	
266	*Legionella jordanis*		v	
267	*Legionella lansingensis*		v	
268	*Legionella longbeachae*		v	
269	*Legionella parisiensis*		v	
270	*Legionella sainthelensi*		v	
271	*Legionella tucsonensis*		v	
272	*Legionella wadsworthii*		v	
273	*Leishmania* spp.		v	
274	*Leishmania braziliensis*		v	
275	*Leishmania donovani*		v	
276	*Leishmania ethiopia*		v	
277	*Leishmania major*		v	
278	*Leishmania mexicana*		v	
279	*Leishmania peruvania*		v	
280	*Leishmania tropica*		v	
281	*Leptospira interrogans* (all serotypes)		v	
282	*Listeria ivanovii*		v	
283	*Listeria monocytogenes*		v	
284	*Loa Loa*		v	
285	Lymphocytic choriomeningitis virus (non-neurotropic strains)		v	
286	*Mannheimia* spp.		v	
287	*Mannheimia glucosidal*		v	
288	*Mannheimia granulomatis*		v	
289	*Mannheimia haemolytica*		v	
290	*Mannheimia ruminalis*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
291	*Mannheimia varigena*		v	
292	Measles virus		v	
293	*Microsporum* spp.		v	
294	Milker's node virus		v	
295	*Moellerella wisconsensis*		v	
296	*Moraxella* spp.		v	
297	*Moraxella catarrhalis*		v	Also called *Branhamalla catarrhalis*
298	*Morganella morganii*		v	
299	Mumps virus		v	
300	Murine leukemia virus (Include amphotropic strain and xenotropic strain)		v	
301	*Mycobacterium* spp.		v	*M. tuberculosis* complex (included *M. tuberculosis*, *M. bovis*) is listed in RG3.
302	*Mycobacterium avium* complex		v	
303	*Mycobacterium asiaticum*		v	
304	*Mycobacterium bovis* BCG vaccine strain		v	
305	*Mycobacterium chelonae*		v	
306	*Mycobacterium fortuitum*		v	
307	*Mycobacterium kansasii*		v	
308	*Mycobacterium leprae*		v	
309	*Mycobacterium malmoense*		v	
310	*Mycobacterium marinum*		v	
311	*Mycobacterium avium* subsp. *Paratuberculosis*		v	Previously called *Mycobacterium paratuberculosis*

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
312	*Mycobacterium scrofulaceum*		v	
313	*Mycobacterium simiae*		v	
314	*Mycobacterium szulgai*		v	
315	*Mycobacterium ulcerans*		v	
316	*Mycobacterium xenopi*		v	
317	*Mycoplasma caviae*		v	
318	*Mycoplasma fermentans*		v	
319	*Mycoplasma genitalium*		v	
320	*Mycoplasma hominis*		v	
321	*Mycoplasma penetrans*		v	
322	*Mycoplasma pneumoniae*		v	
323	*Mycoplasma primatum*		v	
324	*Mycoplasma salivarium*		v	
325	*Myroides odoratus*		v	
326	*Naegleria fowleri*		v	
327	*Necator* spp.		v	
328	*Necator americanus*		v	
329	*Neisseria* spp.		v	
330	*Neisseria gonorrhoeae*		v	
331	*Neisseria lactamica*		v	
332	*Neisseria meningitidis*		v	
333	Newcastle disease virus		v	
334	*Nocardia* spp.		v	
335	*Nocardia asteroides*		v	
336	*Nocardia brasiliensis*		v	
337	*Nocardia otitidiscaviarum*		v	
338	*Nocardia transvalensis*		v	
339	Norovirus		v	
340	*Ochrobactrum anthropi*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
341	*Ochroconis gallopava*		v	Previously called *Dactylaria galopava*
342	*Olsenella uli*		v	Previously called *Lactobacillus uli*
343	*Onchocerca* spp.		v	
344	*Onchocerca volvulus*		v	
345	O'Nyong-Nyong virus		v	
346	Orbivirus		v	
347	Orf virus		v	
348	*Paenibacillus popilliae*		v	
349	*Pantoea agglomerans*		v	
350	Papillomaviruses		v	Also called Human papillomavirus (HPV)
351	*Paracoccidioides brasiliensis*		v	
352	Parainfluenza virus (Type 1, 2, 3, 4)		v	
353	Human Parvovirus (B19)		v	
354	*Paragonimus spp.*		v	
355	*Pasteurella* spp.		v	
356	*Pasteurella multocida*		v	Type B ‘buffalo’ and other virulent strains is listed in RG3.
357	*Penicillium marneffei*		v	
358	*Peptostreptococcus* spp.		v	
359	*Peptostreptococcus anaerobius*		v	
360	*Phialophora verrucosa*		v	
361	*Photobacterium damsela*		v	
362	*Plasmodium cynomologi*		v	
363	*Plasmodium falciparum*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
364	*Plasmodium knowlesi*		v	
365	*Plasmodium malariae*		v	
366	*Plasmodium ovale*		v	
367	*Plasmodium vivax*		v	
368	*Plesiomonas shigelloides*		v	
369	Poliovirus (attenuated strain)		v	
370	Poliovirus (vaccine like strain)		v	
371	*Porphyromonas asaccharolytica*		v	
372	*Porphyromonas gingivalis*		v	
373	*Prevotella* spp.		v	
374	*Prevotella bivia*		v	
375	*Prevotella buccae*		v	
376	*Prevotella melaninogenica*		v	
377	*Prevotella oralis*		v	
378	*Propionibacterium acnes*		v	
379	Prospect Hill virus		v	
380	*Proteus* spp.		v	
381	*Proteus mirabilis*		v	
382	*Proteus penneri*		v	
383	*Proteus vulgaris*		v	
384	*Providencia* spp.		v	
385	*Providencia alcalifaciens*		v	
386	*Providencia rettgeri*		v	
387	*Providencia stuartii*		v	
388	*Pseudallescheria boydii*		v	
389	*Pseudomonas aeruginosa*		v	
390	*Pseudomonas alcaligenes*		v	
391	*Pseudomonas fluorescens*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
392	*Pseudomonas luteola*		v	
393	*Pseudomonas oryzihabitans*		v	
394	Rabbitpox virus		v	
395	Rabies virus (all strain)	v (cultures only)	v	
396	Respiratory syncytial virus		v	Abbreviated as RSV
397	Rhinovirus		v	
398	*Rhodococcus equi*		v	
399	Rift Valley Fever/ Zinga virus vaccine strain MP-12		v	
400	Ross river virus		v	
401	Rotavirus		v	
402	Rubella virus		v	
403	Rubivirus		v	
404	*Salmonella* spp.		v	
405	*Salmonella arizonae*		v	
406	*Salmonella cholerasuis*		v	
407	*Salmonella enteritidis*		v	
408	*Salmonella gallinarum-pullorum*		v	
409	*Salmonella meleagridis*		v	
410	*Salmonella paratyphi* (Type A, B, C)		v	
411	*Salmonella typhi*		v	
412	*Salmonella typhimurium*		v	
413	Sandfly fever virus		v	
414	*Sarcocystis* spp.		v	
415	*Sarcocystis suihominis*		v	
416	*Scedosporium apiospermum*		v	
417	*Scedosporium prolificans*		v	
418	*Schistosoma* spp.		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
419	*Schistosoma haematobium*		v	
420	*Schistosoma intercalatum*		v	
421	*Schistosoma japonicum*		v	
422	*Schistosoma mansoni*		v	
423	*Schistosoma mekongi*		v	
424	*Serratia liquefaciens*		v	
425	*Serratia marcescens*		v	
426	*Serratia rubidaea*		v	
427	*Shewanella algae*		v	
428	*Shigella* spp.		v	
429	*Shigella boydii*		v	
430	*Shigella dysenteriae*	v (type 1 cultures only)	v	
431	*Shigella flexneri*		v	
432	*Shigella sonnei*		v	
433	*Sindbis virus*		v	
434	*Sphaerophorus necrophorus*		v	
435	*Sphingobacterium multivorum*		v	
436	*Sphingobacterium spiritivorum*		v	
437	*Sphingobacterium thalpophilum*		v	Previously called *Flavobacterium thalpophilum*
438	*Sphingomonas paucimobilis*		v	
439	*Sphingomonas yanoikuyae*		v	
440	*Sporothrix schenckii*		v	
441	*Staphylococcus aureus*		v	
442	*Staphylococcus caprae*		v	
443	*Staphylococcus epidermidis*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
444	*Staphylococcus haemolyticus*		v	
445	*Staphylococcus hyicus*		v	
446	*Staphylococcus intermedius*		v	
447	*Staphylococcus lugdunensis*		v	
448	*Staphylococcus saprophyticus*		v	
449	*Stenotrophomonas maltophilia*		v	
450	*Streptobacillus moniliformis*		v	
451	*Streptococcus* spp.		v	
452	*Streptococcus acidominimus*		v	
453	*Streptococcus agalactiae*		v	
454	*Streptococcus anginosus*		v	
455	*Streptococcus bovis*		v	
456	*Streptococcus canis*		v	
457	*Streptococcus constellatus*		v	
458	*Streptococcus difficilis*		v	
459	*Streptococcus dysgalactiae*		v	
460	*Streptococcus equinus*		v	
461	*Streptococcus equi*		v	
462	*Streptococcus gallolyticus*		v	
463	*Streptococcus iniae*		v	
464	*Streptococcus intermedius*		v	
465	*Streptococcus mitis*		v	
466	*Streptococcus mutans*		v	
467	*Streptococcus oralis*		v	
468	*Streptococcus parasanguinis*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
469	*Streptococcus phocae*		v	
470	*Streptococcus pneumoniae*		v	
471	*Streptococcus porcinus*		v	
472	*Streptococcus pyogenes*		v	
473	*Streptococcus salivarius*		v	*Streptococcus salivarius* subsp. thermophilus (previously called *Streptococcus thermophiles*) is not included.
474	*Streptococcus sanguinis*		v	
475	*Streptococcus sobrinus*		v	
476	*Streptococcus somaliensis*		v	
477	*Streptococcus suis*		v	
478	*Streptococcus uberis*		v	
479	*Strongyloides* spp.		v	
480	*Strongyloides stercoralis*		v	
481	Swine vesicular disease virus		v	
482	Tacaribe virus complex		v	
483	*Taenia saginata*		v	
484	*Taenia solium*		v	
485	*Tannerella forsythia*		v	Previously called *Bacteroides forsythus*
486	*Tatlockia maceachernii*		v	
487	*Tatlockia micdadei*		v	
488	Tick-borne orthomyxovirus		v	
489	Toscana virus		v	
490	*Toxocara* spp.		v	
491	*Toxocara canis*		v	
492	*Toxoplasma* spp.		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
493	*Toxoplasma gondii*		v	
494	*Treponema carateum*		v	
495	*Treponema denticola*		v	
496	*Treponema pallidum*		v	
497	*Trichinella* spp.		v	
498	*Trichinella spiralis*		v	
499	*Trichophyton* spp.		v	
500	*Trichuris trichiura*		v	
501	*Trypanosoma* spp.		v	
502	*Trypanosoma brucei brucei*		v	
503	*Trypanosoma brucei gambiense*		v	
504	*Trypanosoma brucei rhodesiense*		v	
505	*Trypanosoma cruzi*		v	
506	Vaccinia virus		v	
507	Varicella zoster virus		v	
508	Venezuelan equine encephalomyelitis virus vaccine strain TC-83 and V3526		v	
509	Vesicular stomatitis virus (laboratory adapted strains, include VSV-Indiana, San Juan, Glasgow)		v	
510	*Vibrio* spp.		v	
511	*Vibrio alginolyticus*		v	
512	*Vibrio cholera*		v	
513	*Vibrio cincinnatiensis*		v	
514	*Vibrio fluvialis*		v	
515	*Vibrio furnissii*		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
516	*Vibrio hollisae*		v	
517	*Vibrio mimicus*		v	
518	*Vibrio parahaemolyticus*		v	
519	*Vibrio vulnificus*		v	
520	*Vittaforma cornea*		v	
521	*Wuchereria bancrofti filaria worms*		v	
522	Yatapox viruses (Tana & Yaba)		v	
523	Yellow fever virus vaccine strain 17D		v	
524	*Yersinia* spp.		v	
525	*Yersinia enterocolitica*		v	
526	*Yersinia intermedia*		v	
527	*Yersinia pseudotuberculosis*		v	
528	*Yokenella regensburgei*		v	Previously called *koserella trabulsii*
529	Zika virus		v	

Notes:

1. If the listed items correspond to the items in the “Quarantine Requirements for the Importation of Animals and Animal Products” of the Council of Agriculture, relevant regulations stipulated by the Council of Agriculture also apply.
2. The packing and relevant requirements set out in P620 and P650 Packing Instruction are outlined in Appendix 7.

Appendix 3. List of Pathogens in Risk Group 3 (RG3)

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
1	***Bacillus anthracis***	v (cultures only)	v	**Comply with select agent regulations.**
2	Bovine spongiform encephalopathy (prion)		v	Abbreviated as BSE
3	*Brucella spp.*	v (B. melitensis cultures only)	v	
4	***Brucella abortus***	v (cultures only)	v	**Comply with select agent regulations.**
5	*Brucella canis*		v	
6	***Brucella melitensis***	v (cultures only)	v	**Comply with select agent regulations.**
7	***Brucella suis***	v (cultures only)	v	**Comply with select agent regulations.**
8	***Burkholderia mallei***	v (cultures only)	v	1. Previously called *Pseudomonas mallei* 2. **Comply with select agent regulations.**
9	***Burkholderia pseudomallei***	v (cultures only)	v	1. Previously called *Pseudomonas pseudomallei*; 2. **Comply with select agent regulations.**
10	*Chlamydophia psittaci* (avian strains)	v (cultures only)	v	
11	Chikungunya virus		v	
12	*Coccidioides immitis*	v (cultures only)	v	
13	***Coxiella burnetii***	v (cultures only)	v	**Comply with select agent regulations.**

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
14	Creutzfeldt-Jacob disease (prion)		v	Abbreviated as CJD.
15	**Eastern equine encephalomyelitis virus**	v (cultures only)	v	1. Abbreviated as EEEV; 2. **Comply with select agent regulations.**
16	Everglade virus		v	
17	Fatal Familial Insomnia (prion)		v	Abbreviated as FFI.
18	Flexal virus	v[3]		
19	***Francisella tularensis***	v (cultures only)	v	**Comply with select agent regulations.**
20	Gerstmann-Straussler-Scheinker syndrome (prion)		v	
21	Hanta virus	v (cause Hemorrhagic Fever with Renal Syndrome only)	v	
22	Hantaan virus	v[3]		The causataive agent of Korean haemorrhagic fever.
23	*Histoplasma capsulatum*		v	
24	*Histoplasma duboisii*		v	
25	*Histoplasma farciminosum*		v	
26	Human Immunodeficiency virus (Type 1, 2)	v (cultures only)	v	Abbreviated as HIV.
27	Human T-cell lymphotropic viruses (Type 1, 2)		v	Abbreviated as HTLV.
28	Influenza A virus subtype H5N1	v (cultures only)	v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
29	Influenza A virus subtype H7N9	v (cultures only)	v	
30	Influenza A virus subtype H7N9 candidate vaccine virus	v (cultures only)	v	
31	Influenza A virus subtype H2N2 (1957-1968)	v (cultures only)	v	
32	**1918 pandemic influenza virus (1918 H1N1)**	v (cultures only)	v	**Reconstructed virus; Comply with select agent regulations.**
33	Kuru (Prion)		v	
34	Louping ill virus		v	
35	Lymphocytic choriomeningitis virus (neurotropic strains)		v	Abbreviated as LCMV.
36	Mayaro virus		v	
37	**Middle East Respiratory Syndrome Coronavirus (MERS-CoV)**		v	**Comply with select agent regulations.**
38	**Monkeypox virus**	v[3]		**Comply with select agent regulations.**
39	Mopeia virus		v	
40	Mucambo virus		v	
41	Murray Valley encephalitis		v	
42	*Mycobacterium bovis*		v	BCG vaccine strain is listed in RG2.
43	*Mycobacterium canetti*		v	
44	*Mycobacterium tuberculosis*	V (cultures only)	v	
45	*Mycobacterium tuberculosis complex*	v (cultures only)	v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
46	Nairobi Sheep Disease		v	
47	Ndumu virus		v	
48	Oropouche virus		v	
49	Pasteurella multocida (Type B 'buffalo' and other virulent strains)		v	
50	Poliovirus (wild strain)	v (cultures only)	v	
51	Poliovirus (vaccine derived strain, VDPV)	v (cultures only)	v	
52	Powassan virus		v	
53	Puumala virus		v	
54	Rickettsia spp.		v	
55	Rickettsia akari		v	
56	Rickettsia australis		v	
57	Rickettsia canada		v	
58	Rickettsia conorii		v	
59	**Rickettsia prowazakii**	v (cultures only)	v	**Comply with select agent regulations.**
60	Rickettsia rickettsii	v (cultures only)	v	
61	Rickettsia siberica		v	
62	Rickettsia tsutsugamushi		v	Scientific name is *Orientia sutsugamushi*
63	Rickettsia typhi (R. mooseri)		v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
64	**Rift Valley fever virus**	v (cultures only)	v	1. Zinga virus is one of the strains. 2. Vaccine strain is listed in RG2。 3. **Comply with select agent regulations.**
65	Rocio virus		v	
66	**SARS-associated coronavirus (SARS-CoV)**		v	**Comply with select agent regulations.**
67	Semliki forest virus		v	
68	Seoul virus		v	
69	Simian immunodeficiency virus		v	Abbreviated as SIV.
70	St. Louis encephalitis virus		v	
71	Tonate virus		v	
72	Variant Creutzfeldt-Jacob disease (Prion)		v	Abbreviated as vCJD.
73	**Venezuelan equine encephalitis virus**	v (cultures only)	v	**Comply with select agent regulations.**
74	Vesicular stomatitis virus		v	Laboratory adapted strains including VSV Indiana, San Juan, Glasgow are listed as RG2.
75	Wesselsbron virus		v	
76	West Nile virus	v (cultures only)	v	
77	Western equine encephalomyelitis virus		v	
78	Yellow fever virus (wild strain)	v (cultures only)	v	

No.	Item[1]	Transport and packing Instructions[2]		Remark
		P620	P650	
79	***Yersinia pestis***	v (cultures only)	v	**Comply with select agent regulations.**

Notes:

1. If the listed items correspond to the items in the "Quarantine Requirements for the Importation of Animals and Animal Products" of the Council of Agriculture, relevant regulations stipulated by the Council of Agriculture also apply.
2. The packing and relevant requirements set out in P620 and P650 Packing Instruction are outlined in Appendix 7.
3. The packing for the transport of communicable disease specimens and positive specimens under the item shall comply with P620 Packing Instruction; the use, disposal, export or import of positive specimens under the item shall be managed as RG3 pathogens.

Appendix 4. List of Pathogens in Risk Group 4 (RG4)

No.	Item[1]	Transport and packing instruction[2]		Remark
		P620	P650	
1	Absettarov[3]	v (cultures only)	v	
2	Central European encephalitis[3]	v (cultures only)	v	
3	**Chapare virus[4]**	v[5]		**Comply with select agent regulations.**
4	**Crimean-Congo hemorrhagic fever virus**	v[5]		**Comply with select agent regulations.**
5	**Ebola virus**	v[5]		**Comply with select agent regulations.**
6	**Guanarito virus[4]**	v[5]		**Comply with select agent regulations.**
7	Hanzalova[3]	v (cultures only)	v	
8	**Hendra virus**	v[5]		1. Previously called Equine morbillivirus. 2. **Comply with select agent regulations.**
9	Herpesvirus simiae (Herpes B or Monkey B virus)	v (cultures only)	v	
10	Hypr virus[3]	v (cultures only)	v	
11	**Junin virus[4]**	v[5]		**Comply with select agent regulations.**
12	Kumlinge virus[3]	v[5]		
13	**Kyasanur forest disease virus[3]**	v[5]		**Comply with select agent regulations.**

No.	Item[1]	Transport and packing instruction[2]		Remark
		P620	P650	
14	**Lassa virus**	v[5]		**Comply with select agent regulations.**
15	**Lujo virus**	v [5]		**Comply with select agent regulations.**
16	**Machupo virus[4]**	v[5]		**Comply with select agent regulations.**
17	**Marburg virus**	v[5]		**Comply with select agent regulations.**
18	**Nipah virus**	v[5]		**Comply with select agent regulations.**
19	**Omsk hemorrhagic fever virus[3]**	v[5]		**Comply with select agent regulations.**
20	**Russian spring-summer encephalitis virus[3]**	v (cultures only)	v	1. Tick-borne encephalitis complex (flavi) viruses：Far Eastern subtype 2. **Comply with select agent regulations.**
21	**Sabia virus[4]**	v[5]		**Comply with select agent regulations.**
22	**Tick-borne encephalitis virus[3]**	v (cultures only)		**For Siberian subtype, Comply with select agent regulations.**
23	**Variola major virus (Smallpox virus)**	v[5]		**Comply with select agent regulations.**
24	**Variola minor virus (Alastrim)**	v[5]		**Comply with select agent regulations.**
25	Whitepox (Variola)	v[5]		

Notes:

1. If the listed items correspond to the items in the “Quarantine Requirements for the Importation of Animals and Animal Products” of the Council of Agriculture, relevant regulations stipulated by the Council of Agriculture also apply.
2. The packing instruction and relevant requirements set out in P620 and P650 Packing Instruction are outlined in Appendix 7.
3. This is tick-borne encephalitis virus complex.
4. This is South American Haemorrhagic Fever viruses.
5. The packing for the transport of communicable disease specimens and positive specimens under the item shall comply with P620 Packing Instruction; the use, disposal, export or import of positive specimens under the item shall be managed as RG4 pathogens.

Appendix 5. List of Biotoxins

No.	Item	Transport and packing instruction[1,2]		Remark
		P620	P650	
1	**Botulinum neurotoxins**	v		**Comply with select agent regulations.**
2	Cholera toxin		v	
3	Clostridium perfringens toxins		v	
4	Corynebacterium diphtheriae toxin		v	
5	**Diacetoxyscirpenol**	v		**Comply with select agent regulations.**
6	Pertussis toxin		v	
7	Shiga toxin；shiga-like toxins		v	
8	*Staphylococcus aureus* toxins		v	
9	**Staphylococcal enterotoxins (Subtypes：A、B、C、D and E)**	v		**Comply with select agent regulations.**
10	**T-2 toxin**	v		**Comply with select agent regulations.**
11	Tetanus toxin		v	
12	Verotoxin		v	
13	Verruculogen		v	

Notes:

1. The packing instruction and relevant requirements set out in P620 and P650 Packing Instruction are outlined in Appendix 7.
2. The transport and packing requirements for commercialized biotoxins shall follow the manufacturer's instructions.

Appendix 6. List of Select Pathogens and Biotoxins

No.	Item	Control type			Control limit	Highly dangerous select pathogens and biotoxins
		Pathogen	specimen containing select pathogens or biotoxins	Biotoxin		
1	*Bacillus anthracis*	v			-	v
2	Botulinum neurotoxins			v	≧1mg	v
3	Botulinum neurotoxin producing species of *Clostridium* (such as *C. botulinum*, *C. baratii*, *C. butyricum*, part of *C. argentinense*)	v			-	v
4	*Burkholderia mallei*	v			-	v
5	*Burkholderia pseudomallei*	v			-	v
6	*Brucella abortus*	v			-	
7	*Brucella melitensis*	v			-	
8	*Brucella suis*	v			-	
9	*Coxiella burnetii*	v			-	
10	Crimean-Congo haemorrhagic fever virus	v	v		-	
11	Diacetoxyscirpenol			v	≧ 10,000 mg	
12	Eastern Equine Encephalitis virus	v			-	
13	Ebola virus	v	v		-	v
14	*Francisella tularensis*	v			-	v
15	Hendra virus	v	v		-	

No.	Item	Control type			Control limit	Highly dangerous select pathogens and biotoxins
		Pathogen	specimen containing select pathogens or biotoxins	Biotoxin		
16	Kyasanur Forest disease virus	v	v		-	
17	Lassa virus	v	v		-	
18	Lujo virus	v	v		-	
19	Marburg virus	v	v		-	v
20	Middle East Respiratory Syndrome coronavirus (MERS-CoV)	v			-	v
21	Monkeypox virus	v			-	
22	Nipah virus	v	v		-	
23	Omsk hemorrhagic fever virus	v			-	
24	Reconstructed 1918 Influenza virus	v			-	v
25	*Rickettsia prowazekii*	v			-	
26	Rift Valley fever virus	v			-	
27	SARS-associated coronavirus (SARS-CoV)	v			-	v
28	South American Haemorrhagic Fever viruses：Chapare	v	v		-	
29	South American Haemorrhagic Fever viruses：Guanarito	v	v		-	
30	South American Haemorrhagic Fever viruses：Junin	v	v		-	

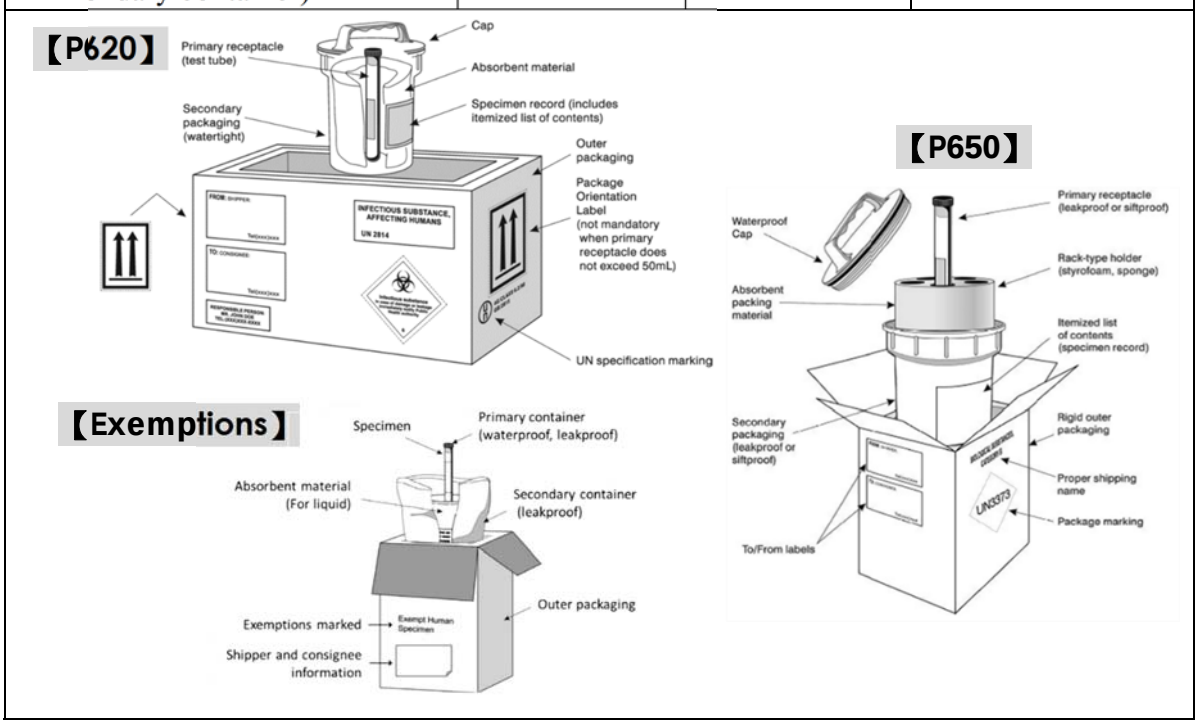
No.	Item	Control type			Control limit	Highly dangerous select pathogens and biotoxins
		Pathogen	specimen containing select pathogens or biotoxins	Biotoxin		
31	South American Haemorrhagic Fever viruses：Machupo	v	v		-	
32	South American Haemorrhagic Fever viruses：Sabia	v	v		-	
33	Staphylococcal enterotoxins A,B,C,D,E subtypes			v	≧ 100mg	
34	T-2 toxin			v	≧ 10,000 mg	
35	Tick-borne encephalitis complex (flavi) viruses：Far Eastern subtype	v			-	
36	Tick-borne encephalitis complex (flavi) viruses：Siberian subtype	v			-	
37	Variola major virus (Smallpox virus)	v	v		-	v
38	Variola minor virus (Alastrim)	v	v		-	v
39	Venezuelan equine encephalitis virus	v			-	
40	*Yersinia pestis*	v			-	v

Notes:

1. The packing instruction and relevant requirements are outlined in Appendix 2 to Appendix 5 and Appendix 7.
2. The transport and packing requirements for commercialized biotoxins shall follow the manufacturer's instructions.
3. Specimens containing select pathogens or biotoxins under control shall be managed as pathogens.

Appendix 7. Transport and packing instruction of Infectious Biological Materials

Transport and packing instruction / Item	P620	P650	Exemptions
Primary (major) container	Yes (leakproof)	Yes (leakproof)	Yes (leakproof)
Secondary container	Yes (leakproof)	Yes (leakproof)	Yes (leakproof)
Outer packaging	Yes	Yes	Yes (Human specimens shall marked with the words “Exempt human specimen”)
An absorbent material between the primary container(s) and the secondary one(s)	Yes	Yes	Yes
Drop test from 1.2 m (completed package)	—	Pass	—
Drop test from 9 m (secondary container)	Pass	—	—
Puncture test at 7 Kg (secondary container)	Pass	—	—
Pressure test at 95 KPa (primary or secondary container)	Pass	Pass	—



Appendix 8. Requirement of Biosafety Levels for Biosafety Laboratory

Item / Level	Practices	Primary Barrier and Safety Equipment	Facilities (Secondary Barriers)
Biosafety Level 1 (BSL-1) Laboratory	Standard microbiological practices	1. No primary barriers required. 2. Personal Protective Equipment (PPE): laboratory coats, gloves, eye and face protection, as needed.	Laboratory bench and sink required.
Biosafety Level 2 (BSL-2) Laboratory	BSL-1 practices plus: 1. Limited access; 2. Biohazard warning signs; 3. “Sharps” precautions; 4. Biosafety manual defining any needed waste decontamination or medical surveillance policies.	1. Primary barriers: BSCs or other physical containment devices used for manipulations of agents that cause splashes or aerosols of infectious materials; 2. PPE: Laboratory coats, gloves, eye and face protection, as needed.	BSL-1 plus: Autoclave available.
Biosafety Level 3 (BSL-3) Laboratory	BSL-2 practices plus: 1. Controlled access; 2. Decontamination of all waste; 3. Decontamination of laboratory clothing before laundering.	Primary barriers: 1. BSCs or other physical containment devices used for all open manipulations of agents; 2. PPE: Protective laboratory clothing, gloves, face, eye and respiratory protection, as needed.	BSL-2 plus: 1. Physical separation from access corridors; 2. Self-closing, double-door access; 3. Exhausted air not recirculated; 4. Autoclave shall available in

Item / Level	Practices	Primary Barrier and Safety Equipment	Facilities (Secondary Barriers)
			facility; 5. Negative airflow into laboratory; 6. Entry through airlock or anteroom; 7. Hand washing sink near laboratory exit.
Biosafety Level 4 (BSL-4) Laboratory	BSL-3 practices plus: 1. Clothing change before entering; 2. Shower on exit; 3. All material decontaminated on exit from facility.	Primary barriers: All procedures conducted in Class Ⅲ BSCs or Class Ⅱ BSCs in combination with full-body, air-supplied, positive pressure suit.	BSL-3 plus: 1. Separate building or isolated zone; 2. Dedicated supply and exhaust, vacuum, and decontamination systems.

Appendix 9. Requirement of Biosafety Levels for Animal Biosafety Laboratory

Item / Level	Practices	Primary Barrier and Safety Equipment	Facilities (Secondary Barriers)
Animal Biosafety Level 1 (ABSL-1) Laboratory	Standard animal care and management practices, including appropriate medical surveillance programs.	1. As required for normal care of each species; 2. PPE: laboratory coats and gloves; eye, face protection, as needed.	Standard animal facility: 1. No recirculation of exhaust air; 2. Directional air flow recommended; 3. Hand washing sink available.
Animal Biosafety Level 2 (ABSL-2) Laboratory	ABSL-1 practices plus: 1. Limited access; 2. Biohazard warning signs; 3. "Sharps" precautions; 4. Biosafety manual; 5. Decontamination of all infectious wastes and animal cages prior to washing.	ABSL-1 equipment plus primary barriers: 1. Containment equipment appropriate for animal special; 2. PPE: Laboratory coats, gloves, face, eye and respiratory protection, as needed.	ABSL-1 plus: 1. Autoclave available; 2. Hand washing sink available; 3. Mechanical cage washer recommended; 4. Negative airflow into animal and procedure rooms recommended.
Animal Biosafety Level 3 (ABSL-3) Laboratory	ABSL-2 practices plus: 1. Controlled access; 2. Decontamination of clothing before laundering; 3. Cages decontaminated after bedding is removed; 4. Disinfectant foot bath as needed.	ABSL-2 equipment plus: 1. Containment equipment for housing animals and cage dumping activities; 2. Class Ⅱ or Ⅲ BSCs available for manipulative procedures (inoculation, necropsy) that may	ABSL-2 facility plus: 1. Physical separation from access corridors; 2. Self-closing, double-door access; 3. Sealed penetrations; 4. Sealed windows; 5. Autoclave shall available in facility; 6. Entry through anteroom or airlock;

Item / Level	Practices	Primary Barrier and Safety Equipment	Facilities (Secondary Barriers)
		create infectious aerosols; 3. PPE: Appropriate respiratory protection.	7. Negative airflow into animal and procedure rooms; 8. Hand washing sink near exit of animal or procedure room.
Animal Biosafety Level 4 (ABSL-4) Laboratory	ABSL-3 practices plus: 1. Entrance through change room where personal clothing is removed and laboratory clothing is put on; shower on exit; 2. All wastes decontaminated before removal from the facility.	ABSL-3 equipment plus: Maximum containment equipment (i.e., Class III BSC or partial containment equipment in combination with full body, air-supplied positive-pressure suit) used for all procedures and activities.	ABSL-3 facility plus: 1. Separate building or isolated zone; 2. Dedicated supply and exhaust, vacuum, and decontamination systems.

Appendix 10. Levels, Explanations, Reporting and Management of Biosafety Accidents

Risk Level	Explanation	Reporting	Examples	Procedures
High	Suspected leakage of infectious biological materials to areas outside of the laboratory or storage facility, and poses fear of infection or harm to laboratory workers, other department personnel, or people in the surrounding community.	1. The person concerned or the discoverer must report to the director of the laboratory or storage facility immediately, and must keep a written record for reference. 2. The director of the laboratory or storage facility must report to the biosafety committee (or the biosafety staff) of the entities immediately. 3. The entities shall report to the local competent authority and the central competent authority	1. Leakage of infectious biological materials to areas outside the laboratory or storage facility caused by earthquake, flood or other natural disaster. 2. Workers, being infected due to inadequate handling or insufficient protection, and left laboratory.	1. Manage the incident according to the laboratory or storage facility biosafety emergency response plan of the entities. 2. Perform necessary management on suspected infected persons; provide medical treatment if they are confirmed by laboratory testing or observation of symptoms to have been infected. 3. The central competent authority shall overall command organizations

Risk Level	Explanation	Reporting	Examples	Procedures
		within 24 hours.		concerned for collaboration. 4. The entities shall report to the central competent authority the management of the accident and improvement measures.
Moderate	Leakage of infectious biological materials limited within the area of the laboratory or storage facility; there may be fear of infecting or injuring personnel or workers.	1. The person concerned must report to the director of the laboratory or storage facility, and must keep a written record for reference. 2. The director of the laboratory or storage facility must report to the biosafety committee (or the biosafety staff) of the entities. 3. When a laboratory personnel is	1. The infectious biological materials spread to the laboratory area while handling in the biosafety cabinet due to the positive pressure produced by abnormality of exhaust fans. 2. The infectious biological materials spatter on personnel due to careless handling. 3. Drop on ground and	1. Manage the incident according to the laboratory or storage facility biosafety emergency response plan of the entities. 2. Perform necessary management on suspected infected persons; provide medical treatment if they are confirmed by laboratory testing or observation of

Risk Level	Explanation	Reporting	Examples	Procedures
		suspected to have been infected, the entities must report to the local competent authority, and send a copy to the central competent authority.	spatter by accident when handling the infectious biological materials.	symptoms to have been infected. 3. The competent authority may request the entities to report the management of infection and improvement measures in the laboratory or storage facility.
Low	Leakage of infectious biological materials limited within the containment equipment of the laboratory and poses less fear of infection or injuries to laboratory personnel.	The person concerned must report to the director of the laboratory, and must keep a written record for reference.	1. The infectious biological materials leak or drop out while handling in biosafety cabinet. 2. The centrifuge tubes breaks while centrifuging.	Manage the incident according to the laboratory biosafety emergency response plan of the entities.