

**Biological Agents Controlled
under the Import and Export Ordinance
(from 17 September 2021)**

1C351 Human and animal pathogens and "toxins", as follows:

- (a) Viruses, whether natural, enhanced or modified, either in the form of "isolated live cultures" or as material including living material which has been deliberately inoculated or contaminated with such cultures, as follows:
 - (1) African horse sickness virus;
 - (2) African swine fever virus;
 - (3) Andes virus;
 - (4) Avian influenza virus that meets any of the following descriptions:
 - (a) Uncharacterized;
 - (b) Defined in Annex I(2) EC Directive 2005/94/EC (O.J. L. 10, 14.1.2006, p.16) as having high pathogenicity, as follows:
 - (1) Type A viruses with an IVPI (intravenous pathogenicity index) in 6-week old chickens of greater than 1.2; or
 - (2) Type A viruses of the subtypes H5 or H7 with genome sequences codified for multiple basic amino acids at the cleavage site of the haemagglutinin molecule similar to that observed for other HPAI viruses, indicating that the haemagglutinin molecule can be cleaved by a host ubiquitous protease;
 - (5) Bluetongue virus;
 - (6) Chapare virus;
 - (7) Chikungunya virus;
 - (8) Choclo virus;
 - (9) Crimean-Congo hemorrhagic fever virus;
 - (10) (*Repealed*);
 - (11) Dobrava-Belgrade virus;
 - (12) Eastern equine encephalitis virus;
 - (13) Ebolavirus: all members of the Ebolavirus genus;
 - (14) Foot-and-mouth disease virus;
 - (15) Goat pox virus;
 - (16) Guanarito virus;
 - (17) Hantaan virus;
 - (18) Hendra virus (Equine morbillivirus);
 - (19) Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);
 - (20) Classical swine fever virus (Hog cholera virus);
 - (21) Japanese encephalitis virus;
 - (22) Junin virus;
 - (23) Kyasanur Forest disease virus;
 - (24) Laguna Negra virus;

- (25) Lassa virus;
- (26) Louping ill virus;
- (27) Lujo virus;
- (28) Lumpy skin disease virus;
- (29) Lymphocytic choriomeningitis virus;
- (30) Machupo virus;
- (31) Marburgvirus: all members of the Marburgvirus genus;
- (32) Monkeypox virus;
- (33) Murray Valley encephalitis virus;
- (34) Newcastle disease virus;
- (35) Nipah virus;
- (36) Omsk haemorrhagic fever virus;
- (37) Oropouche virus;
- (38) Peste des petits ruminants virus;
- (39) Swine vesicular disease virus;
- (40) Powassan virus;
- (41) Rabies virus and all other members of the Lyssavirus genus;
- (42) Rift Valley fever virus;
- (43) Rinderpest virus;
- (44) Rocio virus;
- (45) Sabia virus;
- (46) Seoul virus;
- (47) Sheep pox virus;
- (48) Sin nombre virus;
- (49) St Louis encephalitis virus;
- (50) Porcine Teschovirus;
- (51) Tick-borne encephalitis virus (Far Eastern subtype);
- (52) Variola virus;
- (53) Venezuelan equine encephalitis virus;
- (54) Vesicular stomatitis virus;
- (55) Western equine encephalitis virus;
- (56) Yellow fever virus;
- (57) Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);
- (58) Reconstructed 1918 influenza virus;

(b) *(Repealed)*

- (c) Bacteria, whether natural, enhanced or modified, either in the form of "isolated live cultures" or as material including living material which has been deliberately inoculated or contaminated with such cultures, as follows:

- (1) Bacillus anthracis;
- (2) Brucella abortus;

- (3) *Brucella melitensis*;
 - (4) *Brucella suis*;
 - (5) *Burkholderia mallei* (*Pseudomonas mallei*);
 - (6) *Burkholderia pseudomallei* (*Pseudomonas pseudomallei*);
 - (7) *Chlamydomphila psittaci* (formally known as *chlamydia psittaci*);
 - (8) *Clostridium argentinense* (formerly known as *clostridium botulinum* Type G), botulinum neurotoxin producing strains;
 - (9) *Clostridium baratii*, botulinum neurotoxin producing strains;
 - (10) *Clostridium botulinum*;
 - (11) *Clostridium butyricum*, botulinum neurotoxin producing strains;
 - (12) *Clostridium perfringens*, epsilon toxin producing types;
 - (13) *Coxiella burnetii*;
 - (14) *Francisella tularensis*;
 - (15) *Mycoplasma capricolum* subspecies *capripneumoniae* (strain F38);
 - (16) *Mycoplasma mycoides* subspecies *mycoides* SC (small colony);
 - (17) *Rickettsia prowazekii*;
 - (18) *Salmonella enterica* subspecies *enterica* serovar Typhi (*Salmonella typhi*);
 - (19) Shiga toxin producing *Escherichia coli* (STEC) of serogroups O26, O45, O103, O104, O111, O121, O145 and O157, and other shiga toxin producing serogroups;
- Note:
- Shiga toxin producing *Escherichia coli* (STEC) includes inter alia enterohaemorrhagic *E. coli* (EHEC), verotoxin producing *E. coli* (VTEC) or verocytotoxin producing *E. coli* (VTEC).
- (20) *Shigella dysenteriae*;
 - (21) *Vibrio cholerae*;
 - (22) *Yersinia pestis*;

(d) "Toxins", as follows, and "sub-units of toxins" thereof:

- (1) Botulinum toxins;
- (2) *Clostridium perfringens* alpha, beta 1, beta 2, epsilon and iota toxins;
- (3) Conotoxin;
- (4) Ricin;
- (5) Saxitoxin;
- (6) Shiga toxin (shiga-like toxins, verotoxins and verocytotoxins);
- (7) *Staphylococcus aureus* enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as *staphylococcus enterotoxin F*);
- (8) Tetrodotoxin;
- (9) (*Repealed*);
- (10) Microcystin (Cyanginosin);
- (11) Aflatoxin;
- (12) Abrin;

- (13) Cholera toxin;
- (14) Diacetoxyscirpenol;
- (15) T-2 toxin;
- (16) HT-2 toxin;
- (17) Modeccin;
- (18) Volkensin;
- (19) Viscum Album Lectin 1 (Viscumin);

Note:

1C351(d) does not control botulinum toxins or conotoxins in product form meeting all of the following criteria:

- (a) Are pharmaceutical formulations designed for human administration in the treatment of medical conditions;
 - (b) Are pre-packaged for distribution as medical products;
 - (c) Are authorized by a state authority to be marketed as medical products.
- (e) Fungi, whether natural, enhanced or modified, either in the form of "isolated live cultures" or as material including living material which has been deliberately inoculated or contaminated with such cultures, as follows:
- (1) *Coccidioides immitis*; *and*
 - (2) *Coccidioides posadasii*;

Note : 1C351 does not control "vaccines" or "immunotoxins".

1C352 (*Repealed*)

1C353 'Genetic elements' and 'genetically modified organisms', as follows:

- (a) Any 'genetically-modified organism' that contains, or 'genetic element' that codes for, any of the following:
 - (1) Any gene or genes specific to any virus specified in 1C351(a) or 1C354(a);
 - (2) Any gene or genes specific to bacterium specified in 1C351(c) or 1C354(b) or fungus specified in 1C351(e) or 1C354(c), and which is any of the following:
 - (a) In itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health;
 - (b) Could 'endow or enhance pathogenicity';
 - (3) Any "toxins" specified in 1C351(d) or "sub-units of toxins" for such "toxins";

Technical Notes:

- 1. 'Genetically-modified organisms' include organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation.
- 2. 'Genetic elements' include inter alia chromosomes, genomes, plasmids, transposons, vectors and inactivated organisms containing recoverable

nucleic acid fragments, whether genetically modified or unmodified, or chemically synthesized in whole or in part. For the purposes of the genetic elements control, nucleic acids from an inactivated organism, virus, or sample are considered recoverable if the inactivation and preparation of the material is intended or known to facilitate isolation, purification, amplification, detection, or identification of nucleic acids.

3. 'Endow or enhance pathogenicity' is defined as when the insertion or integration of the nucleic acid sequence or sequences is/are likely to enable or increase a recipient organism's ability to be used to deliberately cause disease or death. This might include alterations to, among other things: virulence, transmissibility, stability, route of infection, host range, reproducibility, ability to evade or suppress host immunity, resistance to medical countermeasures, or detectability.

Note:

1C353 does not include nucleic acid sequences of shiga toxin producing *Escherichia coli* of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups, other than those genetic elements coding for shiga toxin, or for its sub-units.

1C354 Plant pathogens, as follows:

- (a) Viruses, whether natural, enhanced or modified, either in the form of "isolated live cultures" or as material (including living material) which has been deliberately inoculated or contaminated with such cultures, as follows:
 - (1) Andean potato latent virus (Potato Andean latent tymovirus);
 - (2) Potato spindle tuber viroid;
- (b) Bacteria, whether natural, enhanced or modified, either in the form of "isolated live cultures" or as material which has been deliberately inoculated or contaminated with such cultures, as follows:
 - (1) *Xanthomonas albilineans*;
 - (2) *Xanthomonas axonopodis* pv. *citri* (*Xanthomonas campestris* pv. *citri* A) [*Xanthomonas campestris* pv. *citri*];
 - (3) *Xanthomonas oryzae* pv. *oryzae* (*Pseudomonas campestris* pv. *oryzae*);
 - (4) *Clavibacter michiganensis* subsp. *sepedonicus* (*Corynebacterium michiganensis* subsp. *sepedonicum* or *Corynebacterium sepedonicum*);
 - (5) *Ralstonia solanacearum*, Race 3, Biovar 2
- (c) Fungi, whether natural, enhanced or modified, either in the form of "isolated live cultures" or as material which has been deliberately inoculated or contaminated with such cultures, as follows:
 - (1) *Colletotrichum kahawae* (*Colletotrichum coffeanum* var. *virulans*);
 - (2) *Cochliobolus miyabeanus* (*Helminthosporium oryzae*);
 - (3) *Microcyclus ulei* (syn. *Dothidella ulei*);

- (4) *Puccinia graminis* ssp. *graminis* var. *graminis*/ *Puccinia graminis* ssp. *graminis* var. *stakmanii* (*Puccinia graminis* [syn. *Puccinia graminis* f. sp. *tritici*]);
- (5) *Puccinia striiformis* (syn. *Puccinia glumarum*);
- (6) *Magnaporthe oryzae* (*Pyricularia oryzae*);
- (7) *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*);
- (8) *Sclerophthora rayssiae* var. *zeae*;
- (9) *Synchytrium endobioticum*;
- (10) *Tilletia indica*;
- (11) *Thecaphora solani*;

Remarks: The products list is for reference only and may be subject to change from time to time. Traders are advised to refer to the schedules promulgated in the Import and Export (Strategic Commodities) Regulations (Cap. 60G) for up-to-date information in relation to scope of products subject to licensing requirements.