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Report on the implementation of the decisions adopted by the Conference of the Parties at its sixth meeting

Draft guidance paper on hazard characteristic H6.2 (infectious substances)

I. Introduction - purpose and scope of this document

1. This document provides guidance on the application of hazard characteristic H6.2, "Infectious substances", to wastes covered by the Basel Convention. It is intended to assist in determining whether a given waste displays the characteristic to a degree sufficient to render it hazardous.

2. A classification of an infectious waste as hazardous may be made for several purposes, including: consideration of wastes to be allocated to Annexes VIII or IX of the Basel Convention (lists A and B); determining on a case by case basis whether a particular waste should be treated as hazardous; or assisting the Secretariat to the Basel Convention in providing technical support for individual requests.

3. This guidance is intended for use by all Parties, for reference, but it does not supersede determinations made, using objective criteria, set by Parties by their own domestic legislation, standards or guidelines.

4. This guidance is subject to review and updating as new information is made available.

A. Criterion

5. The criterion for determining whether a waste is considered to be hazardous by virtue of the characteristic H6.2 is considered to be:

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> Any waste known or clinically assessed to be at risk of being contaminated with any of the infectious substances in Category A of Division 6.2 of chapter 2.6 of the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations, 13th Edition, or any waste known to contain cultures of Category B of the substances listed in Division 6.2.

6. The criterion is to be used adaptively according to the individual circumstances of Parties. How it has been derived and should be employed is described in the ensuing text.

II. Background

7. Under the Basel Convention, hazardous wastes are defined according to a list of substances (Annex I - categories of waste to be controlled) and their characteristics. Some of the characteristics have not been well defined.

8. The hazard characteristic H6.2, "Infectious", is described in Annex III to the Convention. It defines this characteristic as:

> "Substances or wastes containing viable micro-organisms or their toxins which are known or suspected to cause disease in animals or humans"

9. This definition has no objective elaboration, and further interpretation is therefore necessary to enable assessments of individual wastes to be made. This is made clear by the footnote to Annex III, headed "Tests" which states that:

> "The potential hazards posed by certain types of wastes are not yet fully documented; tests to define quantitatively these hazards do not exist. Further research is necessary in order to develop means to characterize potential hazards posed to man and/or the environment by these wastes. Standardized tests have been derived with respect to pure substances and materials. Many countries have developed national tests which can be applied to materials listed in Annex I, in order to decide if these materials exhibit any of the characteristics listed in this Annex."

10. The characteristic H6.2 falls into this category. Opinions vary as to what wastes may be deemed hazardous by reason of infectiousness according to national laws, standards and classifications. Many Parties to the Convention have already adopted definitions and classifications to provide a basis for declaring a waste stream to be infectious. This guidance does not supplant those definitions, but provides a reference point for common understanding of the nature of the characteristic.

11. An inspection of Annexes VIII and IX of the Convention shows that it is unlikely that any of the wastes listed in either of the annexes needs to be tested for, or assessed against, the H6.2 characteristic. Either they will be deemed hazardous by virtue of one of the other characteristics or they are unlikely to possess the characteristic in accordance with Article 1.1(a) of the Convention.

12. There are some cases in which the potential for infectiousness has been recognized. For example, Annex IX contains two entries regarded as not normally considered to be infectious but having the potential to be so:

> B3060 "Wastes arising from agro-food industries provided it is not infectious";
>
> B3110 "Fellmongery wastes not containing hexavalent chromium compounds or biocides or infectious substances".

There are also two such entries on Annex VIII:

> A3110 "Fellmongery wastes containing hexavalent chromium compounds or biocides or infectious substances";
>
> A4020 "Clinical and related wastes: that is wastes arising from medical, nursing, dental, veterinary or similar practices, and wastes generated in hospitals or other facilities during the investigation or treatment of patients, or research projects".

13. A3110, referring to wastes normally considered to be infectious, but having the potential not to be, is a "mirror" listing to B3110. Infectiousness is known or suspected to be commonly associated with the wastes described in A4020 and there is no "mirror" entry to Annex IX. A4020 wastes may also possess a number of the other Annex III characteristics.

14. This small number of entries does not preclude the possibility that other wastes not yet listed might need to be assessed for the H6.2 characteristic to enable them to be listed. Also, it would help the Parties to the Convention if they had available to them a commonly agreed interpretation when deciding which waste categories should be considered to be infectious.

15. Deciding whether a waste should be classed as hazardous by reason of infectiousness depends on the criteria and method of analysis adopted. One frequently employed approach is to examine the potential for causing infection by employing a risk-assessment methodology. This approach identifies the type of organism, the likelihood of its presence, the potential for causing disease and the likelihood of its transmission to others. This particular approach has been used to classify wastes as hazardous in many countries. For example, reference is often made to the World Health Organization (WHO) classification of infectious substances to determine whether a waste should be classed as hazardous.

16. A similar risk-based approach was used in a European Community investigation into the health care waste stream under the European Priority Waste Stream project, carried out in the early 1990s. This project identified two main types of waste and their associated risks according to the origin of the waste. General waste from health care activities was classified as "health care waste" and waste likely to contain infectious organisms was classified as "health care risk waste".

17. Model regulations on the transport of dangerous goods published by the United Nations (*United Nations Recommendations on the Transport of Dangerous Goods: Model Regulations*, 12th Edition, Sales No. 01.VIII.4 & Corr.1, 2 & 3 (the "Orange Book")) also used the risk-based approach, but it was considered that it had limitations for safety in transport purposes. The United Nations Committee of Experts on the Transport of Dangerous Goods (UNEDTG), at its nineteenth session, considered the definition of "infectious substances" in the context of transport and reviewed this aspect of the model regulations.

18. Following discussion, the experts examined the 12th edition of the United Nations model regulations. The decision was taken to retain the term "infectious substances", but to modify it slightly to improve clarity.

19. The WHO risk group categories were replaced by two new categories. There are no references to the WHO risk groups. Category A contains a list of high-risk pathogenic substances and cultures with an indicative list. Category B contains other substances of lower risk. These two are subject to the model regulations controls. A third group defined as having negligible impact for health are outside the scope of the regulations.

20. The proposed indicative A list (which comprises a wider range of infectious organisms than the WHO laboratory manual risk group 4 and includes known organisms taken from WHO risk groups 2, 3 and 4 that meet the Category A criteria) has these features: First, the title clarifies that it is an example list (other organisms with similar properties would be treated as Category A-like); and second, it identifies those infectious substances with respect to which only cultures need be included (a definition of culture is given). A decision was taken not to provide a list B.

21. To a great degree, all classifications of infectiousness rely on some form of risk-based decision making, whether or not the result is in the form of a procedure to be applied to specific cases or a classification to be used.

22. How the classifications available might be applied in the context of the Basel Convention and used to provide an interpretation of the characteristic H6.2is described in the following sections of this document.

III. Infectiousness and "intrinsic" properties of Basel Convention hazard characteristics

A. Intrinsic nature of other Basel Convention hazard characteristics

23. The Basel Convention utilizes the hazardous characteristics of wastes in the definition of hazardous wastes set forth in article 1.1(a), which distinguishes between those wastes that "possess" the characteristics set out Annex III and those that do not. The term "intrinsic" is not used in the text of the Convention, although possession of a characteristic is commonly discussed by reference to its "intrinsic characteristic (or property)". This clearly holds true for a large number of substances whose characteristics can be readily and accurately identified by reference to their chemical properties,

exhibited in relation to their concentration, which do not vary when subject to commonly defined test procedures.

24. The ordinary definition of the word "intrinsic" is an essential quality of something. In the case where wastes are to be considered to be infectious, they will have been exposed to and become contaminated with micro-organisms to the degree that they can exhibit such a property. Here the "essential quality" is that exhibited by the micro-organisms themselves, which have the "intrinsic" property and confer it upon the waste with which they are associated.

25. This description assumes that the association of waste and micro-organism enables the infectious micro-organism to continue to be capable of giving rise to infection on subsequent exposure by some route (such as absorption, ingestion or inhalation). This may not always be the case. For example, some substances, chlorine-based bleaches, for example, which may be chemically hazardous may also be sterilants and kill infectious organisms with which they come into contact.

26. Therefore, although the potential exists for any waste to be contaminated in such a way as to render it infectious, only a few specific waste types are so intimately associated with infectious organisms that infectiousness can be regarded as a true "intrinsic" hazard. In general, wastes do not have or exhibit an intrinsic hazard of infectiousness, except in very specific cases. Those most likely to do so are wastes from health care and the practice of medicine (including veterinary medicine) as listed under A4020 in Annex VIII.

B. Infectiousness changes with time

27. Time is a significant factor that influences the likelihood that a potentially infectious waste will display the property of infectiousness. With the passage of time, the property may become more, or less, enhanced. This is in contrast to many of the other Basel Convention hazard characteristics. For example, a flammable solvent remains flammable or an acid remains corrosive because these properties are an intrinsic quality of their chemical composition.

28. The concentration of micro-organisms changes with time in several ways. They may lose their viability, causing a decline in infectiousness. Micro-organisms may multiply, or even become dormant but still retain the ability to be revived under more favourable environmental conditions. This change depends on factors such as:

(a) the type of organism (some form resistant spores);

(b) nutrient availability;

(c) ambient conditions:

(i) moisture;

(ii) temperature;

(iii) exposure to light (or other forms of radiation).

C. Conclusion: Infectiousness is not an intrinsic hazard

29. Infectiousness is an inherently unstable and variable property dependent on biological qualities. Different test results can be obtained at different times under the same test conditions.

30. The characteristic cannot therefore be assessed as an "intrinsic characteristic" in a reliable and consistent manner. A different approach than that taken with other Basel Convention hazard characteristics must be taken when determining whether a waste is infectious.

31. Often, this property is judged to be present without confirmatory analysis using a risk-based approach. Thus, the combination of the type of waste, its source, treatment and handling are considered to be indicators of whether there has been sufficient contact with or contamination by infectious organisms to render it liable to be infectious.

32. The assessment of a waste that may posses the H6.2 property thus depends on a simple, systematic evaluation.

IV. Risk assessment approach

A. Definition of infectious organisms, degree of pathogenicity and route of exposure and infection

33. The common approach to classifying infectiousness is by reference to categories of specific risk groups of organisms according to their potential to cause and spread infection and their potential for clinical treatment.

34. A widely known system is the World Health Organization (WHO) *Laboratory Biosafety Manual*, in which four risk groups are identified. A risk group is characterized by:

(a) The pathogenicity of the organism;

(b) The mode and relative ease of transmission;

(c) The degree of risk both to an individual and the community;

(d) The reversibility of the disease through the availability of known and effective preventative agents and treatment.

35. The criteria for each risk group according to the level of risk are described below:

(a) Risk Group 4 (high individual risk, high community risk,) comprises pathogens that usually cause severe human or animal disease and can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatment and preventative measures are not usually available.;

(b) Risk Group 3 (high individual risk, low community risk,) comprises pathogens that usually cause severe human or animal disease but do not ordinarily spread from one individual to another, and for which effective treatment and preventative measures are available;

(c) Risk Group 2 (moderate individual risk, low community risk,) comprises pathogens that can cause human or animal disease but are unlikely to be a serious hazard. While they are capable of causing serious infection on exposure, effective treatment and preventative measures are available and the risk of spread of infection is limited.

(d) Risk Group 1 (low individual and community risk,) comprises micro-organisms that are unlikely to cause human or animal disease.

36. These groups had been used in the United Nations classification of dangerous goods for the assignment of packing classes to materials for transportation.

37. Similar groupings were used in a study conducted by the European Union: The European Priority Waste Stream Project, which considered the various wastes commonly arising across Europe from clinical treatment and other sources and the health risks they posed. It concluded that a class of waste should be called “health care risk waste”. A subset of this waste was called infectious waste. The definition of health care risk waste (infectious) was given as:

> “any healthcare waste known or clinically assessed to be at risk of being contaminated with any of the biological agents mentioned in Article 2(d) groups 3 and 4 of the Council Directive (90/679/EEC) of 26th November 1990 on the protection of workers from risks related to exposure to biological agents, of Article 16(1) of Directive 89/391/EEC, or with viable biological agents artificially cultivated to significantly elevated numbers.”

38. The United Nations classification of infectious substances set out in Division 6.2 of of chapter 2.6 of the *United Nations Recommendations on the Transport of Dangerous Goods: Model Regulations,* also used this approach. This has now been superseded by two new groups, A and B. The updated version now depends on the prior assessment of those infectious agents reclassified by a group of health and transport experts. There is an indicative list for Group A. Group A is more extensive than the WHO Risk Group 4, containing other organisms and cultures from the other WHO risk groups deemed appropriate for inclusion in Group A.

39. In making such changes, the indicative list still retains the option to include for control organisms similar to those mentioned, where judgment dictates. In this way, the approach retains a risk assessment basis. This allows, without testing, a professional, reasoned, judgment to be made to determine whether or not a waste may be deemed hazardous by virtue of H6.2.

V. Criterion for determination by non-test risk assessment method

40. Non-test methods for assessing infectiousness avoid the hazards to the operator associated with testing. They rely on knowledge of the origin, type and other properties of the waste to establish whether it is likely to have been in contact with infectious micro-organisms. If the waste in question meets with the relevant criteria, it would be deemed to be hazardous by virtue of H6.2. A second stage of testing can be applied where checking of a result from non-test assessment is desired.

41. The criterion for determining whether a waste is considered to be hazardous by virtue of the characteristic H6.2 is:

> Any waste known or clinically assessed to be at risk of being contaminated with any of the infectious substances in Category A of division 6.2 of chapter 2.6 of the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations, 13th Edition, or any waste known to contain cultures of Category B of division 6.2.

VI. Relationship with transport regulations

42. For the purposes of the *United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations* and of related legal instruments governing the international carriage of dangerous goods (which also apply to wastes) (e.g., International Maritime Dangerous Goods Code, International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air, European Agreement concerning the International Carriage of Dangerous Goods by Road, Regulations concerning the International Carriage of Dangerous Goods by Rail, European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways), the provisions relating to infectious substances will apply effectively as from 1 January 2005. The relevant extract from chapter 2.6.3 of the Model Regulations is reproduced in the annex to this guidance paper.

43. Infectious substances (including wastes contaminated with such substances, such as medical or clinical wastes) in category A as well as cultures of infectious substances of category B must be classified, under transport regulations, as

> UN 2814 “infectious substance, affecting humans”
> or UN 2900 “infectious substance, affecting animals only”.

44. Medical or clinical wastes containing infectious substances in category B, other than cultures, and medical and clinical wastes which are reasonably believed to have a low probability of containing infectious substances, must be assigned to UN 3291 “clinical waste, unspecified N.O.S”. or “(bio)medical waste, N.O.S.” or “regulated medical waste, N.O.S.”

45. In practice, the criterion in this guidance document covers all wastes which, for transport purposes, would have to be classified under UN 2814 or UN 2900. It covers as well clinical waste or medical waste which would have to be classified under UN 3291.

VII. Wastes to which hazard characteristic H6.2 might apply

46. Wastes to be controlled under the Basel Convention are listed in Annex I to the Convention. With respect to H6.2, some of these wastes are more likely than others to possess the characteristic. Those most likely to be infectious waste have been mentioned in paragraph [9] above. The majority of waste types would not be expected to be intrinsically infectious. Annex I waste streams Y1, Y2 and Y4 would need to be considered.

47. The wastes included under A4020 are those most commonly associated with infectious micro-organisms. Not all will be contaminated or contain pathogens and may not be hazardous by virtue of H6.2 (but may by reason of some other Annex III hazard characteristic).

[1] Proposal by the UNECE secretariat to delete this text in square brackets.

VIII. Consideration of regional variations

48. Chapter II (Background) recognizes that variations may occur as national legislation, standards and guidelines may impose different interpretations of the hazard characteristic. These may be a result of the consideration of risk to the environment and health and safety, climatic differences and approaches to health care.

49. Such standards will be important factors in determining on a regional or national level the categorization of some wastes.

IX. When analysis is needed

50. There exists a range of procedures that are usually performed in micro-biological and pathology laboratories to identify viable micro-organisms capable of causing diseases. (The United Kingdom Public Health Laboratory Service, for example, has an extensive range of protocols available). These are well documented in medical and scientific literature and many are now available in electronic format and on the Internet. For determination of wastes, a complete procedure would require a protocol for sampling and analysis from the target waste stream.

51. Typically, a protocol to detect whether organisms are present would involve sample collection, preservation, culturing and identification. A number of different methods exist. These include:

(a) Traditional cultivation in defined laboratory nutrient media, with morphological examination of the culture and its biochemical reactions or ability to grow in a defined nutrient medium;

(b) Rapid tests;

(c) Genetic typing.

52. The sensitivity of these tests can be very high. A micro-organism may be recovered from a sample that itself was not able to confer infection on a human being (or animal) because there were insufficient numbers of viable micro-organisms to supply an infective dose.

53. Testing is inherently variable: obtaining a reliable, representative sample can be difficult due to several factors, including:

(a) The inherent instability of the micro-organism,

(b) Random distribution of the micro-organism,

(c) Changes in viability and preservation prior to testing, especially when the organism is unknown.

54. Additionally, sampling poses health and safety risks that might be better avoided.

55. Testing may be used to assist determinations, for example when risk assessment may indicate more precision is required or a waste stream is being examined for the first time or is proposed to be listed.

56. Appendix B list some commonly used test methods.

Appendix A - References

Laboratory Biosafety Manual, World Health Organization, 2nd Edition 1993 ISBN 9241544503

Recommendations on the Transport of Dangerous Goods, Model Regulations, 13th Revised Edition, United Nations ISBN

Technical Guidelines on the Environmentally Sound Management of Biomedical and Healthcare Wastes (Y1; Y3) 2003 ISBN 9211586216, UNEP, Basel Convention.

Appendix B - National and international standards and test methods

The literature on medical microbiology and tests for micro-organisms – bacteria, viruses and fungi – is extensive, both in print and on the Internet. Major publishers have considerable lists of textbooks. Many countries that have centres for disease control and reporting mechanisms also have their own public

health laboratory services. These often have devised protocols for tests and publish them. The health authorities in these countries are also sources of relevant information on test methods and standards.

Standard Operating Procedures- Public Health Laboratory Service, United Kingdom

Special Wastes – A Technical Guidance note on their definition and classification, Section B9, Assessment of Hazard H9 Infectious, pp IB.44-45, Environment Agency (for England and Wales), 1999, ISBN 0 11 310158 9.

Annex

Abstract from the *Recommendations on the Transport of Dangerous Goods, Model Regulations*, thirteenth edition, chapter 2.6.3, infectious substances

2.6.3 Division 6.2 - Infectious substances

2.6.3.1 *Definitions*

For the purposes of these Regulations:

2.6.3.1.1 *Infectious substances* are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

2.6.3.1.2 *Biological products* are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines.

2.6.3.1.3 *Cultures* (laboratory stocks) are the result of a process by which pathogens are amplified or propagated in order to generate high concentrations, thereby increasing the risk of infection when exposure to them occurs. This definition refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for diagnostic and clinical purposes.

2.6.3.1.4 *Genetically modified micro-organisms and organisms* are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

2.6.3.1.5 *Medical or clinical wastes* are wastes derived from the medical treatment of animals or humans or from bio-research.

2.6.3.2 *Classification of infectious substances*

2.6.3.2.1 Infectious substances shall be classified in Division 6.2 and assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

2.6.3.2.2 Infectious substances are divided into the following categories:

2.6.3.2.2.1 Category A: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals. Indicative examples of substances that meet these criteria are given in the table in this paragraph.

***NOTE**: Exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.*

(a) Infectious substances meeting these criteria which cause disease in humans or both in humans and animals shall be assigned to UN 2814. Infectious substances which cause disease only in animals shall be assigned to UN 2900.

(b) Assignment to UN 2814 or UN 2900 shall be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

NOTE 1: *The proper shipping name for UN 2814 is INFECTIOUS SUBSTANCE, AFFECTING HUMANS. The proper shipping name for UN 2900 is INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only*.

***NOTE 2*:** *The following table is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria shall be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it shall be included in Category A.*

NOTE 3: *In the following table, the micro-organisms written in italics are bacteria, mycoplasmas, rickettsia or fungi.*

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (2.6.3.2.2.1 (a))	
UN Number and Proper Shipping Name	**Micro-organism**
UN 2814 Infectious substances affecting humans	*Bacillus anthracis (cultures only)* *Brucella abortus (cultures only)* *Brucella melitensis (cultures only)* *Brucella suis (cultures only)* *Burkholderia mallei - Pseudomonas mallei* – Glanders *(cultures only)* *Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only)* *Chlamydia psittaci* - avian strains (cultures only) ***Clostridium botulinum (cultures only)*** *Coccidioides immitis (cultures only)* *Coxiella burnetii (cultures only)* Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) *Escherichia coli*, verotoxigenic (cultures only) Ebola virus Flexal virus *Francisella tularensis (cultures only)* Guanarito virus Hantaan virus Hantaviruses causing hantavirus pulmonary syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Human immunodeficiency virus (cultures only) Highly pathogenic avian influenza virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus *Mycobacterium tuberculosis (cultures only)* Nipah virus Omsk hemorrhagic fever virus Poliovirus (cultures only) Rabies virus *Rickettsia prowazekii (cultures only)* *Rickettsia rickettsii* (cultures only)

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (2.6.3.2.2.1 (a))	
UN Number and Proper Shipping Name	**Micro-organism**
	Rift Valley fever virus Russian spring-summer encephalitis virus (cultures only) Sabia virus *Shigella dysenteriae type 1 (cultures only)* Tick-borne encephalitis virus (cultures only) Variola virus

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (2.6.3.2.2.1 (a))	
UN Number and Proper Shipping Name	**Micro-organism**
UN 2814 **Infectious substances affecting humans** *(cont'd)*	Venezuelan equine encephalitis virus West Nile virus (cultures only) Yellow fever virus (cultures only) *Yersinia pestis* (cultures only)
UN 2900 Infectious substances affecting animals only	African horse sickness virus African swine fever virus Avian paramyxovirus Type 1 - Newcastle disease virus Bluetongue virus Classical swine fever virus Foot and mouth disease virus Lumpy skin disease virus *Mycoplasma mycoides* - Contagious bovine pleuropneumonia Peste des petits ruminants virus Rinderpest virus Sheep-pox virus Goatpox virus Swine vesicular disease virus Vesicular stomatitis virus

2.6.3.2.2.2 **Category B**: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373 except that cultures, as defined in 2.6.3.1.3, shall be assigned to UN 2814 or UN 2900 as appropriate.

NOTE: *The proper shipping name of UN 3373 is "DIAGNOSTIC SPECIMENS" or "CLINICAL SPECIMENS."*

2.6.3.2.3 Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

2.6.3.2.4 Blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation are not subject to these Regulations.

2.6.3.2.5 Substances for which there is a low probability that infectious substances are present, or where the concentration is at a level naturally encountered, are not subject to these Regulations. Examples are: foodstuffs, water samples, living persons and substances which have been treated so that the pathogens have been neutralized or deactivated.

2.6.3.2.6 A live animal which has been intentionally infected and is known or suspected to contain an infectious substance shall only be transported under terms and conditions approved by the competent authority.

2.6.3.3 ***Biological products***

2.6.3.3.1 For the purposes of these Regulations, biological products are divided into the following groups:

(a) Those which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals. Substances in this group are not subject to these Regulations.

(b) Those which do not fall under paragraph (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. Substances in this group shall be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

NOTE: *Some licensed biological products may present a biohazard only in certain parts of the world. In that case, competent authorities may require these biological products to be in compliance with local requirements for infectious substances or may impose other restrictions.*

2.6.3.4 ***Genetically modified micro-organisms and organisms***

2.6.3.4. Genetically modified micro-organisms not meeting the definition of infectious substance shall be classified according to Chapter 2.9.

2.6.3.5 ***Medical or clinical wastes***

2.6.3.5.1 Medical or clinical wastes containing Category A infectious substances or containing Category B infectious substances in cultures shall be assigned to UN 2814 or UN 2900 as appropriate. Medical or clinical wastes containing infectious substances in Category B, other than cultures, shall be assigned to UN 3291.

2.6.3.5.2 Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances shall be assigned to UN 3291.

NOTE*: The proper shipping name for UN 3291 is "CLINICAL WASTE, UNSPECIFIED, N.O.S." or "(BIO) MEDICAL WASTE, N.O.S" or "REGULATED MEDICAL WASTE, N.O.S.".*

2.6.3.5.3 Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to these Regulations unless they meet the criteria for inclusion in another class.