7. *An approved classification is not exhaustive and a biological agent that does not appear in one does not automatically fall into Group 1. The correct group for an unlisted agent must be determined by the employer, applying the infection criteria in Schedule 9, paragraph 3 and taking into account the relevant factors used in making the risk assessment required by COSHH regulation 6 (see also paragraphs 8 - 13 of this Code). If the agent subsequently appears in a later edition of an approved classification, the classification given to it in that edition takes priority.* (Biological Agents ACOP, COSHH 94).

vii) *The Classification Directive*

4. A second Directive (93/88/EEC), providing a Community classification of biological agents, was adopted in October 1993. This contains the numerous species of bacteria, viruses, fungi and parasites known to be capable of causing infection in people not compromised by pre-existing disease, medication or pregnancy. The new categorisation appearing here, which is based closely on the Classification Directive (recently amended by the European Commission through technical adjustment procedures), has the status of law as it is an 'Approved List' made under Section 15 of the HSWA (see paragraph 30). Infectious agents are categorised in numbered hazard groups according to definitions which are effectively identical to those adopted by the ACDP in 1984.

5. Genetically modified microorganisms ('GMMOs' - bacteria, viruses, fungi and parasites), although included in the definition of a biological agent, have not been categorised in the Approved List as it is not practical to do so, there being so many variants, of so many different species. GMMOs that have any harmful properties for humans are subject to the controls demanded by COSHH, including, for example those concerning laboratory containment. But other regulations also apply and extensive guidance dealing specifically with genetic modification has been published elsewhere.

6. Cell cultures are also biological agents according to the definition but they are not classified as the classification is based solely on disease caused by infection. However, as cell cultures may present other hazards, these must be taken into account in complying with COSHH. Appendix 13 provides guidance on work with cell cultures. Therefore, except where the text is otherwise explicit, reference here to 'biological agents' or simply 'agent' means wild-type microorganisms (which includes bacteria, viruses and fungi) and endoparasites.

BIOLOGICAL AGENTS

18. Of necessity, the new categorisation of biological agents appearing in this publication closely reflects the classification Directive 93/88/EEC. Adoption of European Directives by the Council of Ministers of the European Union means that Member States are obliged to implement the provisions they contain in domestic legislation. Consequently, early in 1994, the HSE acting on behalf of the Health and Safety Commission conducted an extensive public consultation on a proposal to implement the classification by use of an Approved List (made under Section 15 of the HSWA) which is now specifically invoked by COSHH and thereby has legal status. The same consultation proposed raising the minimum standards set by the Directive which is permissible under the Treaty base on which it was devised. In effect, this simply meant reinstating certain agents in the higher Hazard Group to which they had been allocated by the ACDP since at least 1990. At the same time, some agents have been relegated to a lower group in line with the Community classification. Furthermore, some agents now appear in a higher group than before as a result of the Directive although in many cases, the burden that this might impose has been relieved by formal derogation (see paragraph 19 and paragraph 38 onwards). Still other agents have been added, including a number that had not been listed before because they were unknown at the time or because their pathogenicity for healthy persons had not been recognised. Some agents have been deleted altogether from the categorisation published in 1990 in the light of improved knowledge.

19. As indicated, the classification Directive has placed a number of agents in a higher Hazard Group than before. As both the Biological Agents Directive and the classification Directive contain minimum standards, Member States are not at liberty to allocate any agent to a group lower than that in which it appears in the Directive. However, with some agents in Group 3, there is the facility for government authorities to allow use of less stringent levels of containment than is strictly indicated by the hazard grouping. This may be applied only to certain specified agents selected because there is deemed to be a low probability of their transmission by the airborne route. This principle of 'derogation' has been an important feature of the ACDP categorisation in the past where, for example guidance has indicated that use of a safety cabinet is not essential for work with certain parasites and enteric pathogens. Where this allowance is permissible, within the terms of the classification Directive, it has been carried forward selectively in the new categorisation (see paragraph 39 onward and the certificate of exemption in Appendix 23).

The Hazards of Biological Agents

20. As before, biological agents have been categorised into four Hazard Groups using a framework of criteria which includes the following questions.

(a) Is the agent pathogenic for humans?

(b) Is it a hazard to employees?

(c) Is it transmissible to the community?

(d) Is effective prophylaxis or treatment available?

21. Using definitions based on these factors, biological agents known to cause infection have been assigned to one of the three higher Hazard Groups (see paragraph 44) but the lists are not exhaustive. Moreover, it must be emphasised that the categorisation does not allow for any additional risk for those people who

may be more severely affected due to compromising factors. These include, for example:

(a) pre-existing disease;

(b) compromised immunity;

(c) the effects of medication;

(d) pregnancy.

When necessary, the assessment of risk should consider these additional factors as individual protective measures may be required. For example, the Management of Health and Safety at Work Regulations have recently been amended to implement control measures that may be applicable, subject to the assessment of risk in individual cases, to pregnant and breastfeeding women at work (see footnote on page 4). (Categorisation of biological agents according to hazard and categories of containment. Advisory Committee on Dangerous pathogens, 1995, HSE Books, ISBN 0-7176-1038-1.

A4.2 Overseas Legislation and Governmental

viii. *"Invasion and multiplication of micro-organisms in body tissue which may or may not be clinically apparent".* (Health Protection Branch, Canada).

ix. *"The question of how to define infectious waste has been discussed for years without resolution satisfactory to all interested parties. ... Even the terminology that has been used for this type of waste is imprecise - the terms infectious, pathological, biomedical, biohazardous, toxic, and medically hazardous have all been used at various times to describe similar material.*

"Infectious or infective is defined as "capable of producing infection; pertaining to or characterised by the presence of pathogens". A pathogen is "any disease-producing micro-organism or material". Etiologic agent is defined as "a viable micro-organism or its toxin which causes, or may cause, human disease". The related term "biohazard" - which is defined as an "infectious agent, presenting a risk or potential risk to the well-being of man, either directly through his infection or indirectly through disruption of his environment" - is commonly used ...

"From these definitions it would appear to be simple enough to define infectious waste as "waste that contains pathogens." However, infectiousness as a characteristic of some wastes is difficult to define and impossible to quantify". (Draft Manual for Infectious Waste Management, USEPA, 1982 draft).

x. *"... EPA defined infectious waste in the following manner (quoted from 40 CFR 240.101, 1986 edition):*

"Infectious waste means: (1) equipment, instruments, utensils, and fomites of a disposable nature from the rooms of patients who are suspected to have or have been diagnosed as having a communicable disease and must, therefore, be isolated as required by public health agencies; (2) laboratory wastes such as pathological specimens (e.g., all tissues, specimens of blood elements, excreta, and secretions obtained from patients or laboratory animals) and disposable fomites (any substance that may harbour or transmit pathogenic organisms) attendant thereto; (3) surgical operating room pathologic specimens and disposable fomites attendant thereto and similar disposable materials from out-patient areas and emergency rooms.

"For a waste to be infectious, it must contain pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible host could result in an infectious disease." (CC Lee, GL Huffman / Journal of Hazardous Materials 48 (1996) 1-30).

xi. *"The US Environmental Protection Agency first promulgated enforceable definitions of infectious waste in March 1989 in the Medical Waste Tracking Act of 1988. This act listed the following ten categories of regulated medical waste:*

(1) Cultures and stocks of infectious agents
(2) Pathological wastes (tissues, organs, body parts)
(3) Blood and other body fluids
(4) Contaminated sharps
(5) Animal body parts
(6) Surgery wastes
(7) Laboratory wastes
(8) Dialysis wastes
(9) Contaminated medical equipment and biological waste
(10) Materials contaminated by contact with bodily fluids.

These regulations only define which items need to be tracked and do not specify what waste types are actually infectious and should be treated." (Cross FL, Hesketh HE and Rykowski PIL, "Infectious Waste Management", Technomatic Publishing Co., 1990, ISBN 87762.751-7).

xii. *70-1.2 Definitions. (a) "Regulated medical waste" shall mean any waste which is generated in the diagnosis, treatment or immunisation of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals, when listed by the Department of Environmental Conservation (see Section 27 - 1502 of the Environmental Conservation Law), provided, however, that regulated medical waste shall not include any hazardous waste identified or listed by the Department of Environmental Conservation and shall include the following:*

(1) Cultures and stocks of infectious agents and associated biologicals, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures;

(2) Human pathological wastes, including tissues, organs, body parts and body fluids that are removed during surgery or autopsy or other medical procedures and specimens of body fluids and their containers;

(3) Waste human blood and products of blood, including serum, plasma, and other blood components and their containers;

(4) Sharps that have been used in animal or human patient care or in clinical laboratories, including hypodermic needles, syringes, pasteur pipettes, broken glassware and scalpel blades, blood vials, test tubes, needles with attached tubing, and such unused sharps that have been discarded;

(5) Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research, production of biologicals, or testing of pharmaceuticals;

(6) Wastes from surgery or autopsy that were in contact with infectious agents, including soiled dressings, sponges, drapes, lavage tubes, drainage sets, underpads, and surgical gloves;

(7) Laboratory wastes from clinical laboratories that were in contact with infectious agents, including slides and cover slips, disposable gloves, laboratory coats and aprons;

(8) Dialysis wastes that were in contact with the blood of patients undergoing hemodialysis or renal dialysis, including contaminated disposable equipment and supplies such as tubing, filters, disposable sheets, towels, gloves, aprons, and laboratory coats;

(9) Biological waste and discarded materials contaminated with blood, excretion, exudates or secretion from human beings or animals who are isolated to protect others from highly communicable diseases; and

(10) Any other waste material designated by the administrator of the U.S. Environmental Protection Agency as a regulated medical waste (see the provisions of federal Public Law 100-582, known as the Medical Waste Tracking Act of 1988) and the regulations promulgated pursuant thereto. Such regulations are set forth in Part 259 of Title 40 of the Code of Federal Regulations, and were published in Volume 54 of the Federal Register, National Archives and Records Administration and may be purchased from the superintendent of Documents, Government Printing Office, Washington, D.C. 20402. Copies are available for inspection in the office of Donald Macdonald, Records Access Officer, NYS Department of Health, Corning Tower, Room 2230, Empire State Plaza, Albany, NY 12237-0042.

(b) "Infectious Agents" shall mean those organisms that cause disease in humans.

(c) "Storage" shall mean the containment of regulated medical waste in such a manner as not to constitute disposal of such waste.

(d) "Transport" shall mean the movement of regulated medical waste from the generator's facility site to any intermediate points and finally to the point of ultimate disposal.

(e) "Treatment" shall mean any method, technique or process designed to change the character or composition of any regulated medical waste so as to either neutralise such waste or to render such waste not infectious, safer for transport, amenable for recovery, amenable for storage or reduced in volume. (US Public Health Law Section 1389).

xiii. *(b) "Infectious agents" shall mean any organisms that cause disease or an adverse health impact to humans and listed in Section 2.1 of the State Sanitary Code. In addition to the list referenced in Section 2.1 of the State Sanitary code, Human Immunodeficiency Virus (HIV) shall also be included in this definition for the sole purpose of managing regulated medical waste generated in the care and*

treatment of patients known to be infected with HIV. (Draft New York Codes, Rules and Regulations, Title 10 (Health) Chapter 11).

A4.3 Other

xiv. *"The entry and development or multiplication of an infectious agent, i.e. one capable of producing infection or infectious disease in the body of man or animal. Infection is not synonymous with disease and may be inapparent or manifest. The presence of living infectious agents on exterior surfaces of the body or upon articles of clothing is not infectious but contamination."* (Control of Communicable Diseases in Man, 15th Edition).

xv. *"In addition to the problem of differing recommendations, each published guideline states or implies that the final decision about classifying waste as infectious should be made only by someone who has sufficient knowledge to do so. In other words, for many types of waste the decision must be based on assessment of the particular risks involved rather than on specific guidance or scientific evidence. Infection control practitioners can help make this judgement.*

"The best approach is to address the issue from the aspect of the potential infectiousness of the waste. Evaluate each type of waste to determine whether it should be managed as infectious. In the decision making process, ask the following questions:

- *What type of waste is it?*
- *What is the likelihood that the waste contains infectious agents? Is the waste potentially infectious?*
- *What risk is potentially inherent in the waste? What risk do these infectious agents pose to health care workers? To sanitation workers? To operators of waste treatment equipment? To waste haulers? To landfill workers? To the public?*
- *What is the likelihood that someone will be exposed to the waste if it is managed as infectious waste?*

- *Will management of the waste as infectious waste eliminate or reduce this risk?*

"It is best to make the decisions on the basis of the potential risk inherent in the waste. If the waste could be infectious, it is prudent to manage it as infectious". (Reinhardt PA and Gordon JG, "Infectious and Medical Waste Management, Lewis Publishers, 1991, ISBN 0 87371 158 0).

xvi. *"Definition: Infectious waste is waste that is suspected of being capable of producing infectious disease. Such waste must contain pathogens with sufficient virulence and quantity to cause infections in (a) susceptible host(s)."* (ISWA, "Management of Infectious Health Care Waste", date unknown).

xvii. *"In 1983 the WHO/EU invited an international group of experts to report on the state of affairs relating to the subject of "Management of Waste from Hospitals". Several categories of waste from healthcare were identified and described. A definition of (Potentially) Infectious Waste was formulated:*

"All waste holding sufficient virulent pathogens to constitute a risk to people coming into contact with it is considered as infectious waste". (Quotation from the above ISWA document).

xviii. *"Infectious waste ... Testing all potentially infectious waste for the presence of pathogens is neither warranted nor advocated. Therefore, most states define infectious waste as waste that in all probability contains or could contain pathogenic micro-organisms and that, because of the type, concentration, and quantity of these micro-organisms, may cause disease in persons exposed to it.*

"... Infectious waste includes materials considered to be potential health hazards because of possible contamination with pathogenic micro-organisms. Although this definition seems straightforward, regulatory agencies, healthcare facilities, and the waste service industry, for example, all have different perspectives, which influence their interpretation of what types of waste should be classified as

infectious". (Green, AEA, "Medical Waste Incineration and Pollution Prevention, Van Nostrand Reinhold, 1992, ISBN 00442 008198).

"A better definition of the term "hospital specific wastes", including all possible types of waste from the medical sector, is given in a new guideline "For the avoidance and management of wastes from public and private health care establishments"

" ... the new guideline classifies health care waste as follows:

(A) Wastes which can be managed without the use of special measures designed to prevent infective and environmental risks:

(B) Wastes which require special measures to prevent infective risks during their management inside the health care establishment:

(C) Wastes which require special measures to avoid infective risks inside and outside the health care establishment (infectious waste)."

(Drauschke, S, "Clinical Waste Policy in Germany", IWM Proceedings, October 1995).

xix. *"The EU Priority Waste Stream Health Care Waste Project Group recommends that the definitions be adopted as a common European standard in future regulations ...*

(c) Health Care Risk Waste: Biological (recognisable anatomical waste), infectious (see note below), chemical, toxic or pharmaceutical, including cytotoxins, sharps (e.g. needles, scalpels, sharp broken material), radioactive (refer to Radioactive Waste Directive(s)).

"... Note 2: Infectious waste is any health care 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 or identified through the procedure set out in article 3 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 other viable biological agents artificially cultivated to significantly elevated numbers." (Quoted in Drauschke, S, 1995, op.cit).

xx. *"Infectious waste .. that which contains sufficient pathogens to cause disease:*
laboratory cultures and stocks of infectious agents,
surgical and autopsy waste from patients with infectious diseases,
waste from infected patients in isolation wards,
haemodialysis waste, including gowns etc.
waste from animals inoculated with infectious agents or suffering from an infectious disease".

(Collins CH and Kennedy DA, "The Treatment and Disposal of Clinical Waste", HHSC Handbook No. 13, H&H Scientific Consultants, 1993, ISBN, 0-948237-18-X).

xxi. *"Infectious Waste: Wastes, such as those from a hospital or laboratory which may contain concentrated amounts of pathogens. See also Hazardous Waste."* (Compendium of Solid Waste Management Terms and Definitions", Solid Waste Association of North America (SWANA), 1991.

xxii. *"Infectious waste*
(1) Equipment, instruments, utensils and fomites of a disposable nature from the rooms of patients who are suspected to have or have been diagnosed as having a communicable disease and must, therefore, be isolated as required by public health agencies; (2) laboratory wastes, such as pathological specimens (e.g., all tissues, specimens of blood elements, excreta, and secretions obtained from patients or laboratory animals) and disposable fomites (any substance that may harbour or transmit pathogenic organisms) attendant thereto; (3) surgical operating room pathologic specimens and disposable fomites attendant thereto, and similar disposable materials from out-patient areas and emergency rooms."

(Environmental Regulatory Glossary, Ed. Frick GW and Sullivan TFP, Government Ind. Inc., 5th Edition, 1990). (NB - same as definition viii).

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医療廃棄物新処理技術一覧

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