

93.2: Genetically modified microorganisms, such as a cell and a virus (e.g., transformed, fused, hybrid, and the like): This subclass is indented under subclass 93.1. Subject matter involving a microorganism, cell, or virus, which (i) is a product of recombination, transformation, or transfection with a vector or a foreign or exogenous gene or (ii) is a product of homologous recombination if it is directed rather than spontaneous or (iii) is a product of fused or hybrid cell formation. (1) Note. Examples of subject matter included in this and the indented subclass are compositions containing microorganisms, cells, or viruses resulting from (i) a process in which the cellular matter of two or more fusing partners is combined, producing a cell, which initially contains the genes of both the fusing partners or (ii) a process in which a cell is treated with an immortalizing agent, which results in a cell that proliferates in long-term culture or (iii) a process involving recombinant DNA methodology. (2) Note. Excluded from this subclass are the products of unidentified or noninduced mutations; products of microbial conjugation, wherein specific genetic material is not identified and controlled; and products of natural, spontaneous, or arbitrary conjugation or recombination events. These products are not considered genetically modified for this subclass and therefore will be classified as unmodified microorganisms, cells, or viruses.

93.21: Eukaryotic cell: This subclass is indented under subclass 93.2. Subject matter involving a eukaryotic cell, such as an animal cell, plant cell, fungus, protozoa, and higher algae, which has been genetically modified. (1) Note. A eukaryotic cell has a nucleus defined by a nuclear membrane wherein the nucleus contains chromosomes that comprise the genome of the cell.

93.3: Intentional mixture of two or more microorganisms, cells, or viruses of different genera: This subclass is indented under subclass 93.1. Subject matter involving a mixture consisting of two or more different microbial, cellular, or viral genera. (1) Note. A mixture of *Escherichia coli* and *Pseudomonas* or a mixture of *Aspergillus* and *Bacillus* would be considered proper for this subclass, while a mixture of *Bacillus cereus* and *Bacillus brevis* would be classified under *Bacillus* rather than in this subclass, as they are both in the genus *Bacillus*. (2) Note. Rumen, intestinal, vaginal, and other microflora mixtures are mixtures appropriate for this subclass unless mixture constituents are disclosed and are found to be contrary to the subclass definition.

133.1: Structurally modified antibody, immunoglobulin, or fragment thereof (e.g., chimeric, humanized, complementarity determining region-grafted, mutated, and the like): This subclass is indented under subclass 130.1. Subject matter involving an antibody, immunoglobulin, or fragment thereof that is purposely altered with respect to its amino acid sequence or glycosylation or with respect to its composition of heavy and light chains or immunoglobulin regions or domains, as compared with that found in nature, or wherein the antibody, immunoglobulin, or fragment thereof is part of a larger, synthetic protein. (1) Note. Structurally modified antibodies may be made by chemical alteration or recombination of existing antibodies or by various cloning techniques involving recombinant DNA or hybridoma technology. (2) Note. Structurally modified antibodies may be chimeric (i.e., comprising amino acid sequences derived from two or more nonidentical immunoglobulin molecules, such as interspecies combinations, and so on). (3) Note. Structurally modified antibodies may have domain deletions or substitutions (e.g., deletions of particular constant-region domains or substitutions of constant-region domains from other classes of immunoglobulins). (4) Note. Structurally modified antibodies may have deletions of particular glycosylated amino acids or may have their glycosylation otherwise altered,