SCHEDULE 16

Regulation 2

Synthetic biology

Interpretation

1. In this Schedule—

"basic scientific research" means experimental or theoretical work undertaken principally to acquire new knowledge of the fundamental principles of phenomena or observable facts and not primarily directed towards a specific practicable aim or objective;

"medicine" means—

- (i) any substance or combination of substances presented as having properties of preventing or treating disease in human beings or animals;
- (ii) any substance or combination of substances that may be used by or administered to human beings or animals with a view to—
 - (aa) restoring, correcting or modifying a physiological function by asserting a pharmacological, immunological or metabolic action;
 - (bb) making a medical diagnosis;

"services" means routine synthetic biology processes that are outsourced to specialist providers for completion before being re-integrated into the original work stream to assemble into an experiment or goods, including making a specific strand of DNA or running a proprietary algorithm on a dataset.

Activities

- **2.** Subject to the exceptions referred to in paragraphs 5 and 6, a qualifying entity carrying on activities that consist of or include any of the following—
 - (a) carrying on basic scientific research into synthetic biology;
 - (b) the development of synthetic biology;
 - (c) the production of goods using synthetic biology;
 - (d) the formulation of synthetic biology to enable the degradation of materials;
 - (e) the provision of services that enable the activities in paragraphs (a) to (d).

Meaning of synthetic biology

- **3.** In this Schedule, "synthetic biology" means the process of applying engineering principles to biology to design, redesign or make biological components or systems that do not exist in the natural world.
 - **4.** Synthetic biology includes but is not limited to—
 - (a) the design and engineering of biological-based parts of—
 - (i) enzymes;
 - (ii) genetic circuits and cells;
 - (iii) novel devices and systems;
 - (b) redesigning existing natural biological systems;
 - (c) using microbes to template materials;
 - (d) cell-free systems;

- (e) gene editing and gene therapy;
- (f) the use of DNA for data storage, encryption and bio-enabled computing.

Exceptions - general

- **5.** Exceptions to the activities described in paragraph 2 are—
 - (a) general services or servicing not related to core synthetic biology, where "core" means those activities without which experiments cannot be conducted, such as DNA synthesis or cloning;
 - (b) the use of microorganisms to remove harmful contaminants, pollutants or toxins from the environment (known as bioremediation), including bio-based reagents that allow for testing for contaminants;
 - (c) any approach used to gather clinical information for the purpose of making a clinical decision or making a diagnosis (known as diagnostics) but not the storage or ownership of sensitive human genetic information that enables the identification of an individual;
 - (d) industrial biotechnology research, development or production using enzymes or organisms that have not been modified through the application of synthetic biology;
 - (e) the production of substances ordinarily consumed as food or used as feed, including any ingredient or component of such substances;
 - (f) gene therapy, where it is used solely for the purpose of replacing missing or defective genes to restore phenotypes to achieve a therapeutic effect;
 - (g) cell therapy, where cells are modified by genetic engineering and then introduced into a patient to treat disease.

Exceptions – human or veterinary medicines or immunomodulatory approaches

- **6.**—(1) Exceptions to the activities described in paragraph 2 are the ownership, ownership of intellectual property or development of the matters set out in sub-paragraph (2) that employ synthetic biology at any stage of the development or production, unless the circumstances set out in sub-paragraph (3) apply.
 - (2) The matters referred to in sub-paragraph (1) are—
 - (a) human or veterinary medicines;
 - (b) immunomodulatory approaches.
- (3) The circumstances referred to in sub-paragraph (1) are where the matter described in sub-paragraph (2)—
 - (a) has a synthetic biology technology that could be employed or modified to produce, deliver or produce and deliver—
 - (i) toxic chemicals to achieve an incapacitating or lethal effect on humans or animals;
 - (ii) materials restricted under Schedule 5 to the Anti-terrorism, Crime and Security Act 2001(1); or
 - (b) uses substances or pathogens set out in Schedule 5 to the Anti-terrorism, Crime and Security Act 2001.

⁽¹⁾ Schedule 5 was amended by S.I. 2007/929 and 2012/1466.