# 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.