Maybe a bit of legal background helps to identify the scope of application of the Cartagena Protocol (CP)

1. Scope:

   Article 4:

   This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. Obligations:

   Article 2 (2):

   The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

   Article 4 (1)-(3):

   Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

   "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

   Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

   Article 6 (2)

   Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

   Article 8 (2)

   The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. […]

   Annex III (4)

   Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

3. Terms and definitions

   Article 3

(g) “Living modified organism” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
(h) “Living organism” means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;
(i) “Modern biotechnology” means the application of:
a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
b. Fusion of cells beyond the taxonomic family,
that overcome natural physiological reproductive or recombination barriers and
that are not techniques used in traditional breeding and selection;

My suggestion for answering the question posed:

Elements of the legal definition of an LMO	***Kinds and parts of SynBio products not covered by the LMO definition***
The LMO must be an organism	*Synthesized or extracted bioparts*
The LMO must be living	*Synthesized or extracted bioparts, protocell, minimal cell (?)*
The LMO must possess a novel combination of genetic material [i.e. it must have been derived from an organism]	*Entirely synthesized organism [apparently not yet achieved but prognosticated?]*
The genetic material must have been modified	*Modification on the level of aminoacids or proteins (xenobiochemistry)*
The genetic material must have been modified	*Complete replacement of the cell content, be it of conventional or new design*
The novel combination must have been obtained through biotechnology, i.e. through in vitro nucleic acid techniques, direct injection of nucleic acids or fusion of cells	*Products from targeted mutagenesis*
Biotechnology that overcomes natural physiological reproduction or recombination barriers	*Products from cisgenesis, targeted mutagenesis, transgenesis as an intermediate step of breeding processes where the transgene is subsequently removed, and other “new breeding techniques”*

As there is increasing international trade in bioparts, protocells and minimal cells the question arises if this entails risks of misuse and should therefore be subjected to some regulatory oversight.

Risks may also result from products from xenobiochemistry and new breeding techniques.

It should be noted that the CP requirements only apply if LMOs shall be exported. They do not establish an elaborate standard for the regulation of domestic activities (although Article 2 (2) points into that direction, as does the reference to Articles 8 (g) and 17 CBD in the second preambular clause).

It should also be noted that the requirement of prior informed notification does not apply to transboundary movements for contained uses (Article 6 (2)).

It should as well be noted that the risk assessment methodology relies on the comparison or familiarity principle (Annex III 4).