

## Supplementary list of materials

This list is intended to provide supplementary guidance to the HTA's broader policy framework on tissue and cells above.

The list provides guidance to the human application sector on which types of 'tissues and cells' are regulated under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. It is not intended as exhaustive or exclusive, but is intended to provide information to stakeholders in respect of a number of materials for which advice on their status has previously been sought. The HTA will review and update the list periodically.

Where a material is not included within the following list stakeholders should contact the HTA for further advice.

Material	Tissue and cells for the purposes of the Regulations?
Acellular bone products	Yes
Acellular skin products	Yes
Amniotic membrane	Yes
Antibodies	No
Appendages (severed, for reattachment)	No
Blood (whole blood)*	No
Blood vessels	Yes
Bone marrow	Yes
Bone (e.g. femoral heads, skull flaps)	Yes
Breast milk for nutritional purposes	No
Cartilage cells (chondrocytes)	Yes
Cell lines	Yes
Dendritic cells	Yes
Donor lymphocytes (for the purposes of haematopoietic stem cell transplantation)	Yes
Eggs*	No

Embryonic stem cells	Yes
Embryos (outside the body) *	No
Faecal material <sup>□</sup>	Yes
Fetal tissue	Yes
Fibroblasts	Yes
Gametes*	No
Haematopoietic stem cells	Yes
Heart valves	Yes
Hepatocytes	Yes
Keratinocytes (type of skin cell)	Yes
Ligaments	Yes
Limbal stem cells	Yes
Liver lobe	No
Meniscus	Yes
Musculoskeletal tissue	Yes
Non blood derived stem cells	Yes
Ocular tissue (e.g. cornea, sclera)	Yes
Organs	No
Pancreatic islet cells	Yes
Placenta (for human consumption) <sup>□</sup>	Yes
Plasma <sup>♦</sup>	No
Platelets <sup>♦</sup>	No
Primary cell cultures	Yes
Red blood cells <sup>♦</sup>	No
Skin (allograft, autograft, cultured)	Yes
Sperm*	No
Tendons	Yes
Tumour tissue	Yes
Umbilical cord blood	Yes

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♦ While outside the definition of tissue and cells for the purposes of the Regulations, these materials fall under the Blood Safety and Quality Regulations 2005 and are regulated by the MHRA.

\* While outside the definition of tissue and cells for the purposes of the Regulations, these materials fall under the Human Fertilisation and Embryology Act 1990, and are regulated by the HFEA.

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□ While included in the definition of tissue and cells for the purposes of the Regulations, these materials are currently subject to a policy decision by HTA to take a proportionate approach to enforcement. Please refer to the individual policy document for details.