**Subcommittee on**
**Human Organ Transplant (Amendment) Regulation 2010**
**and Human Organ Transplant (Appeal Board) Regulation**

**The Administration's Response**

***Definition of "regulated product" and "organ" in the HOTO***

At the meeting of the Subcommittee on 16 November 2010, Members enquired about the definitions of "regulated product" and "organ" in the Human Organ Transplant Ordinance (Cap.465) (HOTO)[1], specifically what products might potentially be captured and whether human sperm, egg or gamete fell within the definitions. The Administration undertook to examine the issue and revert.

2. "Regulated product" is defined in section 7A(1) of the HOTO[2] as "*a product containing any structured arrangement of tissues that (i) falls within paragraph (a)(iii) of the definition of "organ" in section 2; and (ii) has been subjected to processing"*.

3. Under the definition above, the first test in determining what constitutes a "regulated product" is whether there is a "structured arrangement of tissues". It is commonly accepted within the medical field that "tissues" are a collection of cells specialised to perform a particular function. A single cell is not regarded as tissues.

4. We have consulted medical experts including those from the University of Hong Kong and Chinese University of Hong Kong. According to the experts, human egg, sperm and gamete are individual cells; they are not tissues and are not considered "structured arrangement of tissues". As such, they, and any product containing them, do not fall within the definition of "regulated products" under the HOTO.

5. As regards Members' concerns whether exemption for "regulated products" would create a loophole for commercial dealings in human organs, it should be noted that one of the conditions for granting exemption under section 7A(3)(c) is that "no payment has been made or is intended to be made to the donor for his supplying the tissues from his body". Thus an exemption for regulated product made from human tissues would not be granted if the human tissues were supplied for payment.

6. As regards Members' enquiry as to the products that might potentially be captured by the definition of "regulated products", a list of possible "regulated products" is set out in ***Annex***. The list is compiled based on information available and their actual status under HOTO and consideration of exemption will only be made upon application to be made under the relevant provisions of the HOTO after they come into force.

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[1] As added by the Human Organ Transplant (Amendment) Ordinance 2004, but has yet to commence operation.
[2] As added by the Human Organ Transplant (Amendment) Ordinance 2004, but has yet to commence operation.

7. Members also enquired about the definition of "organ" in the HOTO. Under the HOTO, unless otherwise specified in the Schedule[3], a first test in determining what constitutes an "organ" is also whether there is a "structured arrangement of tissues". As human sperm, egg and gamete are individual cells and not tissues, they are not considered as "organs" under the HOTO.

8. Incidentally, Members may wish to note that the use of sperm, egg and gamete for any purpose in reproductive technology procedures, including their commercial dealings, is regulated under the Human Reproductive Technology Ordinance (Cap. 561) (HRTO).

***Prohibition of commercial dealings in human organs under the HOTO***

9. Members asked about the prohibition of commercial dealings in human organs under the HOTO especially its application to activities outside Hong Kong. Section 4 of the HOTO prohibits commercial dealings in human organs. It was included when the HOTO was first passed into the law in 1995, and had not been amended by the Human Organ Transplant (Amendment) Ordinance 2004. Specifically, section 4 prohibits the following activities concerning commercial dealings in supply of or offer to supply an organ intended for transplant –

(a) make or receive any payment for such;

(b) seek to find a person willing to do so for payment;

(c) initiate or negotiate any arrangements involving the making of a payment for such; or

(d) publish or distribute an advertisement for such.

The section also makes it an offence for a person to import, export or remove for transplant or to transplant an organ if the person knew or ought after reasonable inquiry to have known that a payment was made or was to be made for that organ.

10. Section 4 of the HOTO was first proposed as Clause 4 of the Human Organ Transplant Bill ("HOT Bill") introduced in 1992. It is noted that the drafting of the clause was later refined by committee stage amendments intended to reflect more clearly "the policy intention … to make it an offence, as long as there is an element of commercial dealings, for any person to remove or transplant an organ, to make or receive payment for an organ, or to act as an agent in the processes if any of these acts or events takes place in Hong Kong".[4]

[3] The Schedule, which has yet to commence, includes only blood (including cord blood) and bone marrow.
[4] Hong Kong Legislative Council, sitting of 22 February 1995, Official Record of Proceedings, p.2182.

11. Incidentally, Members also referred to similar provisions on prohibition of commercial dealings in gametes or surrogacy, namely sections 16 and 17 of the HRTO. These provisions were proposed as clauses 14 and 15 of the Human Reproductive Technology Bill (HRTB) first introduced in 1998 similar to clause 4 of the HOT Bill, as first introduced, prohibiting commercial dealings in human organs. The then Administration's intention was to catch commercial dealings "if any part of the act is committed in Hong Kong"[5].

12. It should be noted that the HRTO does not in any event relate or affect the two subsidiary legislation currently under scrutiny by the Subcommittee.

Food and Health Bureau
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[5] Administration's reply to paragraph (b) of the letter from Clerk to Bills Committee dated 9 December 1998, Bills Committee on Human Reproductive Technology Bill (CB(2)940/98-99(02)).

***Annex***

# List of Possible "Regulated Products"

At the meeting of the Subcommittee on 16 November 2010, Members enquired as to the products that might potentially be captured by the definition of "regulated products". A list of possible "regulated products" is set out below. Members may wish to note that this is an illustrative list of possible "regulated products" that may fall within the definition under the Human Organ Transplant (Amendment) Ordinance 2004 and may seek exemption by making an application to the Director of Health after the relevant provisions come into force. It is by no means exhaustive, and inclusion in this list does not imply that these products will necessarily be considered for exemption. Whether or not exemption will be granted is subject to the examination of the information submitted by the applicant and the nature of the product in accordance with HOTO, having regard to the requirements under section 7A(3) of the HOTO[6], viz –

*"The Director may, on application, exempt a regulated product from the application of this Ordinance if he is satisfied—*

*(a) that using the product for transplant purposes is safe and has no adverse impact on public health;*

*(b) either that the donor of the tissues concerned has given his consent to the removal of the tissues for the purpose of producing the product without coercion or the offer of inducement, or that the tissues are removed for the therapy of the donor;*

*(c) that no payment has been made, or is intended to be made to that donor for his supplying the tissues from his body;*

*(d ) that all applicable laws of the place where the tissues were obtained or processed have been complied with in obtaining and processing the tissues; and*

*(e) that the circumstances and manner in which the tissues are obtained and processed are not affected by any matter that the Director may consider to be objectionable."*

| No. | Tissue | Product name (company) | Description of product | Use |
|---|---|---|---|---|
| 1 | Skin (dermis) | Dermaplant® (Collagenesis) | It is a tissue matrix composed of collagen fibers, proteoglycans and an elastic network. | Lip augmentation |
| 2 | Skin | Alloderm® Regenerative Tissue Matrix (LifeCELL) | It is a collagen matrix with intact basement membrane. | Hernia repair, abdominal wall ／ breast ／nasal septum and periorbital reconstruction, depressed scar revision, burns |

[6] As added by the Human Organ Transplant (Amendment) Ordinance 2004, but has yet to commence operation.

| No. | Tissue | Product name (company) | Description of product | Use |
|---|---|---|---|---|
| 3 | Skin | Apligraf® (Novartis) | It is a skin substitute with the epidermal layer formed by human keratinocytes and stratum corneum and the dermal layer formed by human fibroblasts in a cow collagen lattice. | Skin repair therapy, diabetic foot ulcer, venous ulcer |
| 4 | Skin | OrCel® (Forticell Bioscience, Inc.) | It is a bilayered cellular matrix which is composed of human keratinocytes and fibroblasts and cow collagen. | Treatment of donor site wounds |
| 5 | Skin | Dermagraft® (Advanced Biohealing, Inc.) | It is a human fibroblast-derived dermal substitute which is composed of fibroblasts, extracellular matrix, and a bioabsorbable scaffold. | Treatment of diabetic foot ulcers |
| 6 | Cartilage | BioSeed®-C (Biotissue Technology) | BioSeed®-C is an autologous 3 dimensional chondrocyte graft. It consists of patient's own chondrocytes (cartilage cells) embedded in a 3 dimensional bioresorbable scaffold. | Treatment of articular cartilage defects in the knee, ankle or hip |
| 7 | Bone | Opteform® and Optefil® (Exactech), Grafton® DBM Gel & Grafton® DBM Flex (Osteotech), etc. | These products are demineralised bone sold in various forms such as gel, paste and particulate. The products are moldable into different shapes for repair. | Bone repair in orthopaedic and dental surgery e.g. bone void filling, fracture repair |
| 8 | Bone | BioCleanse® processed bone products (Regeneration Technologies, Inc. Biologics) | BioCleanse® is a patented tissue processing method. Tissues are subjected to a combination of mechanical and chemical process to remove blood, marrows and lipids, and inactivate or remove pathogenic microorganisms. | A wide range of BioCleanse® processed bone products for use as spine and general orthopaedic implants: for example, cervical interbody spacers for use in procedures that restore height and lordosis in the cervical spine; and cancellous chips to fill bony voids or gaps in a patient's skeletal system as result of surgery or traumatic injury. |

| No. | Tissue | Product name (company) | Description of product | Use |
|---|---|---|---|---|
| 9 | Bone-tendon-bone | Tutoplast® Patella Bone-Tendon-Bone (Regeneration Technologies, Inc. Biologics) | Tutoplast® is a patented tissue processing method. Tissues are treated with mechanical process and chemical agents to remove lipids, red blood cells and white blood cells and to disrupt the cell membranes. The tissue retains the matrix with fiber and mineral components.<br><br>It is a Tutoplast® processed Patella Bone-Tendon-Bone allograft. | Anterior Cruciate Ligament Replacement and Revision |
| 10 | Fascia Lata | Tutoplast® Fascia Lata (Regeneration Technologies, Inc. Biologics) | It is a Tutoplast® processed Fascia Lata allograft. | Eyelid ptosis, facial palsy |
| 11 | Pericardium | Tutoplast® Pericardium (Regeneration Technologies, Inc. Biologics) | It is a Tutoplast® processed pericardium allograft. | Glaucoma drainage, retina repair, eyelid reconstruction |
| 12 | Sclera | Tutoplast® Sclera (Regeneration Technologies, Inc. Biologics) | It is a Tutoplast® processed sclera allograft. | Contour wrapping of orbital implant in enucleation surgery |
| 13 | Heart valve | SynerGraft® aortic heart valve and SynerGraft® pulmonary human heart valve (CryoLife) | They are SynerGraft® processed aortic heart valve and pulmonary heart valve.<br><br>SynerGraft® is a patented tissue processing method. The process involves hypotonic lysis and nuclease digestion of the cellular elements, along with sequential washing of the tissue to remove the cells and cellular debris from the allograft and produces scaffold of collagen and connective tissues. | Heart valve replacement |
| 14 | Artery | SynerGraft® pulmonary artery (CryoLife) | They are SynerGraft® processed pulmonary artery. | Cardiac reconstructions for defects such as Tetralogy of Fallot and pulmonary atresia |