EUROPEAN
COMMISSION

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COMMISSION DECISION

of 3.7.2015

establishing a model for agreements between the Commission and relevant organisations on the provision of product codes for use in the Single European Code

(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells[1], and in particular Article 10c (3) thereof,

Whereas:

(1) Directive 2004/23/EC[2] lays down the legal framework for the traceability of human tissues and cells including an obligation for the Member States to establish systems for the identification of human tissues and cells.

(2) Directive 2004/23/EC also requires the Commission, in cooperation with the Member States, to design a single European coding system to provide information about the main characteristics and properties of human tissues and cells.

(3) The requirements relating to the format, application, accessibility and maintenance of the single European coding system are laid down in Commission Directive 2006/86/EC as amended by Commission Directive (EU) 2015/565.

(4) The single European coding system has been developed in a form of a Single European Code, supported by an online database called the EU Coding Platform.

(5) The product codes used in certain already existing product coding systems are permitted to be used as part of the Single European Code as laid down in Article 10(1) of Directive 2006/86/EC in conjunction with Article 2(k), (o) and (p) of the Directive. Their use is subject to the condition that the relevant product code is published in the EU Tissue and Cell Product Compendium.

(6) In line with Article 10c (3) of Directive 2006/86/EC, agreements should be concluded between the organisations which manage such product codes and the Commission which hosts and maintains the EU Coding Platform. Those agreements should ensure that updated product codes are regularly made available to the Commission for inclusion in the EU Tissue and Cell Product Compendium by establishing the terms

[1] OJ L 294, 25.10.2006, p. 32, as amended by Commission Directive (EU) 2015/565 (OJ L 93, 9.4.2015, p. 43).

[2] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48)

for the provision of information on those product codes and for their publication on the EU Coding Platform.

(7) Therefore, a model agreement should be established to ensure that all organisations whose product codes are permitted to be used as part of the Single European Code provide the relevant information under the same terms and conditions. The Director-General for Health and Food Safety should be empowered to sign the agreement for the Commission taking into account that the EU Coding Platform is managed by the services of this Directorate General. The adoption of a model should not preclude the Director-General for Health and Food Safety from introducing non-substantial changes to the model before concluding an agreement,

HAS DECIDED AS FOLLOWS:

Article 1

The model for agreements on the provision of product codes for use within the Single European Code set out in the Annex is hereby adopted.

This model shall be used for all agreements to be concluded between the Commission and relevant organisations managing product codes for human tissues and cells in order to set out the terms and conditions for the provision of those products codes to the Commission to be used within the Single European Code, for their updates, for their publication and for other exchanges of information between the parties relating to the Product Compendium.

Article 2

The Director-General of the Directorate-General for Health and Food Safety is authorised to sign, on behalf of the Commission, agreements with the relevant organisations administering product codes based on the model referred to in Article 1.

The Director-General of the Directorate-General for Health and Food Safety shall be entitled to introduce, where appropriate, non-substantial changes to the model.

Done at Brussels, 3.7.2015

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION