



Brussels, 3.7.2015
C(2015) 4460 final

ANNEX 1

ANNEX

to the

COMMISSION DECISION

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

ANNEX

Model for agreements on the provision of product codes for use in the Single European Code

Agreement

between

[insert full name of organisation] and

the European Commission

on the terms and conditions for the provision of [insert name of organisation] product codes for use in the Single European Code

The **European Commission**, represented by the Director-General of the Directorate-General for Health and Food Safety, having its seat at 200, Rue de la Loi, 1049 Brussels, Belgium, hereinafter referred to as '**the Commission**',

on the one part,

and

[insert full name of organisation], represented by the Chairperson, having its seat at [insert address of organisation], hereinafter referred to as [insert name of organisation],

on the other part,

hereinafter each individually referred to as '**the Party**' and jointly referred to as '**the Parties**'

Whereas:

- (1) Directive 2004/23/EC of the European Parliament and of the Council¹ lays down the legal framework for traceability of human tissues and cells. In accordance with Article 25(2) of that Directive, the Commission in cooperation with the Member States is to design a single European coding system to provide information about the main characteristics and properties of tissues and cells.
- (2) Commission Directive 2006/86/EC² lays down the structure and characteristics of the Single European Code (hereinafter 'the SEC') to be applied to human tissues and cells distributed in the European Union, as well as the requirements for use of the SEC. In accordance with that Directive, the SEC is comprised of a Donation Identification Sequence and Product Identification Sequence. Furthermore, the Product Identification Sequence contains a product code comprised of a product coding system identifier and a product number. The product codes used in certain existing product coding systems are permitted to be used for this part of the SEC provided the conditions laid down in Article 10c (3) of Directive 2006/86/EC are met.
- (3) The [insert name of product coding system] product coding system administered by [insert name of organisation], is such a product coding system for which its relevant

¹ 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).

² 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 (OJ L 294, 25.10.2006, p. 32) as amended by Commission Directive (EU) 2015/565.

tissue and cell product codes are permitted to be used as part of the Product Identification Sequence of the SEC.

- (4) To support the implementation of the SEC, an online database called the EU Coding Platform has been developed. This platform is hosted and maintained by the Commission. It contains the EU Tissue Establishment Compendium and the EU Tissue and Cell Product Compendium (hereinafter ‘the Product Compendium’).
- (5) In order for the product codes from permitted product coding systems to form part of the SEC, those product codes should be published in the Product Compendium within the EU Coding Platform. No tissues and cells may be distributed within the Union without a SEC containing product codes published in the Product Compendium.
- (6) In order to ensure that updated product codes are regularly made available to the Commission for inclusion in the Product Compendium, it is necessary to establish the terms for the provision of information on those product codes and for their publication on the EU Coding Platform.
- (7) Updates of the [insert name of product codes] product codes and updates of the Product Compendium take place – to the extent possible – simultaneously.
- (8) It falls upon organisations administering permitted product coding systems to provide the Commission with timely updates relating to new or existing product codes so that such information can be published in the Product Compendium,

HAVE AGREED AS FOLLOWS:

Article 1

Subject matter

This agreement lays down the terms and conditions relating to the provision and publication of relevant [insert name of product codes] product codes, and in particular to;

- (a) updates relating to [insert name of product codes] product codes;
- (b) their publication in the Product Compendium;
- (c) the exchange of additional information between the Parties relating to the Product Compendium.

Article 2

Definitions

For the purpose of this agreement, the definitions laid down in Directive 2004/23/EC and Directive 2006/86/EC apply.

In addition, the following definitions apply:

- (a) ‘relevant product codes’ means [insert name of product] tissue and cell product codes for which corresponding EUTC categories of tissues or cells are registered in the Product Compendium;
- (b) ‘update’ means the provision of information from [insert name of organisation] to the Commission relating to a new relevant product code, modification of any existing relevant product code or deletion of a relevant product code;
- (c) ‘working days’ means days on which the Commission's offices in Brussels are open.

Article 3

Procedure for providing updates

1. [insert name of organisation] shall provide the Commission with all updates of relevant product codes with a view to their publication in the Product Compendium.
2. Such updates shall be provided at least five working days in advance of their planned publication by [insert name of organisation] with a view to allowing to the extent possible a simultaneous publication of the updates on the [insert name of organisation] website and in the Product Compendium.
3. If simultaneous publication is not possible [insert name of organisation] may continue with its planned publication of an update on the [insert name of organisation] website prior to the publication of that update in the Product Compendium, without prejudice to Article 10(1) and 10b(1)(d) of Directive 2006/86/EC.
4. The updates shall include the names of the tissues and cell products concerned in English, their product codes, and the indication of corresponding EUTC codes in the Product Compendium ("mapping"). The update documentation shall clearly state whether the updates relate to new relevant product codes, modifications of existing relevant product codes, or deletions of existing relevant product codes. Any other relevant information relating to the updates shall also be communicated. [insert name of organisation] shall make all reasonable efforts to verify the correctness of the updates.
5. The updates shall not include updates of any codes for any products other than tissues and cells intended for human application covered by Directive 2004/23/EC and its implementing Directives. If [insert name of organisation] has any doubts as to whether a planned update contains product codes for products which may fall outside the scope of Directive 2004/23/EC, it shall seek guidance from the Commission prior to submitting the update.
6. All updates shall be communicated via the functional mailboxes indicated by the Parties referred to in Article 11(1) of this Agreement and all correspondence shall be in English.

Article 4

Reception of updates by the Commission

1. Upon receipt of the updates, the Commission shall have the right to verify the information provided, including via consultation of experts, and request, where necessary, clarifications from [insert name of organisation] which may lead to the inclusion or exclusion of specific codes in the Product Compendium.
2. The Commission shall endeavour to include the mapped versions of relevant product codes in the Product Compendium with a view to allowing, to the extent possible, a simultaneous publication of the updates on the [insert name of organisation] website and in the Product Compendium. At the latest, the Commission shall endeavour to include the mapped versions of the relevant product codes in the Product Compendium within 15 working days following receipt of the updates or, if clarifications are requested, within 15 working days following receipt of a satisfactory response to the request for clarification.

3. The final decision on whether to include any given product code in the Product Compendium shall remain at the discretion of the Commission. However, the Commission shall only withhold publication of the code in the Product Compendium in duly justified cases.

Article 5

Non-compliance with the terms of the agreement

1. The Commission may choose to suspend the use partially or in full, of the [insert name of organisation]'s relevant product codes, where there is a failure to comply with the terms of this agreement on the part of [insert name of organisation].
2. Where a suspected case of non-compliance occurs, and before any decision to suspend is taken, [insert name of organisation] shall be given an opportunity to present its views, either in writing or in a meeting.
3. Any suspension shall be lifted when the Parties agree on the resolution of the issue or issues which led to the suspension. The Commission shall only withhold its agreement in duly justified cases.

Article 6

Provision of information relating to the Product Compendium

1. Where the Commission introduces a new category or categories (see explanation above) of tissues or cells in the Product Compendium by establishing a new EUTC code, it shall inform [insert name of organisation] before publication in the Product Compendium.
2. [insert name of organisation] shall provide updates of relevant product codes, including the necessary mapped versions, based on the new category or categories of tissues and cells in the Product Compendium. That information shall be provided within three months following the publication of the new EUTC code or codes in the Product Compendium.
3. Where [insert name of organisation] is of the view that a new category or categories of tissues or cells in the form of an EUTC code should be added to the Product Compendium, it shall inform the Commission as soon as possible. Where possible, [insert name of organisation] shall indicate possible draft relevant product codes including mapping for such new categories.
4. The communication between the European Commission and [insert name of organisation] as regards new categories of tissues and cells in the Product Compendium shall be facilitated, as appropriate, by the participation of one [insert name of organisation] representative in the meetings of the group of experts assisting the Commission with revising the list of tissue and cell categories in the EUTC.
5. [insert name of organisation] shall ensure that its educational and guidance documents relevant to the SEC alert users to the fact that only [insert name of product codes] product codes which have been published in the Product Compendium may be used as part of the SEC.

Article 7

Transfer of rights

The Parties may not assign their rights or obligations under this agreement to a third party without the written consent of the other Party to this agreement.

Article 8

Effective date, term and termination

1. This agreement shall be effective on the date of the final signature by both of the Parties.
2. This agreement shall be valid for an indefinite period of time and may be terminated by either Party.
3. Where either Party wishes to terminate this agreement, it shall give the other Party at least six months' written notice of its decision to terminate the agreement.
4. In the event that this agreement is terminated, the use of the relevant product codes included in the Product Compendium prior to its termination, as laid down in this agreement, shall remain permitted.

Article 9

Liability

1. Responsibility for the information provided in the updates remains with [insert name of organisation].
2. [insert name of organisation] agrees to the publication of the relevant product codes in the Product Compendium as provided and that such publication does not infringe any intellectual property or other rights of [insert name of organisation].
3. The Commission shall not be liable for any indirect, incidental or consequential damage arising out of the use by any third party of the relevant product codes or other information provided by [insert name of organisation] and published in the Product Compendium. A disclaimer regarding [insert name of organisation]'s responsibility for the information provided to the Commission shall be posted on the website hosting the Product Compendium.
4. Liability for the use of the relevant product codes remains with the users of [insert name of product codes] product codes as specified in their licence agreement with [insert name of organisation].

Article 10

Governing law and dispute resolution

1. This agreement shall be governed by the law of the European Union and supplemented where necessary by the national substantive law of Belgium.
2. Any dispute between the Parties which cannot be settled amicably shall be brought before the Court of Justice of the European Union in accordance with Article 272 of the Treaty on the Functioning of the European Union

Article 11

Miscellaneous

1. **Notices:** All notices under this agreement shall be valid if sent to the functional e-mail addresses set forth below:

To the Commission:

To [insert name of organisation]:

[insert functional e-mail address]

[insert functional e-mail address]

If [insert name of organisation] has its main seat outside the EU, it shall nominate a subsidiary in the EU to which all correspondence relating to this agreement can be addressed or if such a subsidiary does not exist it shall nominate another legal or natural person located in the EU, to which such correspondence can be addressed.

Name of subsidiary or other person:

Address:

Functional e-mail address:

2. **Language and copies:** This agreement is done in English in two copies.
3. **Remuneration:** The Parties agree that no remuneration is due in the execution of this agreement.
4. **Modifications:** Any modifications to this agreement shall be made in writing and agreed by each Party.
5. The Parties acknowledge that Directives 2004/23/EC and 2006/86/EC may be amended from time to time, including their repeal or replacement by another Act, and this agreement shall remain unaffected by such changes. However, the Commission shall inform [insert name of organisation] about any changes which may materially affect the terms of this agreement and the Parties shall then decide whether a modification of the agreement is necessary.
6. **Severability:** If a provision of this agreement is or becomes illegal, invalid or unenforceable, the remaining provisions shall remain in force.
7. **Entire agreement:** This agreement constitutes the entire agreement between the Parties.

Signed for and on behalf of:

European Commission

[insert name of organisation]

Signature: _____

Name: _____

Title: Director-General DG SANTE

Place: Brussels

Date: _____
