Changes to legislation: *Commission Implementing Regulation (EU) 2015/1013 is up to date with all changes known to be in force on or before 24 December 2020. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Commission Implementing Regulation (EU) 2015/1013 of 25 June 2015 laying down rules in respect of Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and of Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1013

of 25 June 2015

laying down rules in respect of Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and of Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors[(1)], and in particular Article 14 thereof,

Having regard to Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Union and third countries in drug precursors[(2)], and in particular Article 6(3), the third subparagraph of Article 9(2) and Article 28 thereof,

Whereas:

(1) Commission Regulation (EC) No 1277/2005[(3)] lays down provisions for the implementation of Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 in the field of drug precursors. Both Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 have been amended after the adoption of Regulation (EC) No 1277/2005 so as to include empowerments to adopt delegated and implementing acts pursuant to Articles 290 and 291 of the Treaty. Therefore, new rules should be adopted in accordance with the new empowerments.

(2) Although Regulation (EC) No 273/2004 deals with domestic trade and Regulation (EC) No 111/2005 deals with international trade, many of the provisions are common to both Regulations. In order to ensure coherence, it is justified to adopt a single implementing act covering both Regulations.

(3) In order to ensure legal certainty and a coherent enforcement of the provisions of this Regulation, it is necessary to give a definition of ‘business premises’.

(4) The existing provisions regarding the procedural rules for granting licences, the procedure and format for providing information required to monitor trade, and the format and handling of import and export authorisations have proven to be effective and should therefore, in essence on substance, continue to apply by virtue of this Regulation.

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(5) The procedural rules for granting registration to operators and users, as defined in Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005, should reflect those for granting licences.

(6) In order to ensure data quality and coherence, and avoid duplication, in the information fed into the European database on drug precursors, each Member State should establish one single contact point transmitting the information to the database. Information should be transmitted without undue delay. Information on a licence or a registration should include the elements necessary for identifying the operator or user holding the licence or registration, as well as the substance(s) covered. Access to the information should be restricted to the minimum necessary for the public authorities' performance of their duties.

(7) Transitional rules should allow the use of paper forms issued before the entry into force of this Regulation in compliance with previous rules until the stocks of such paper forms have been exhausted.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Drug Precursors Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down uniform procedural rules for the implementation of Regulation (EC) No 273/2004 and of Regulation (EC) No 111/2005 as regards the licensing and registration of operators and users and their listing in the European database on drug precursors, the provision by operators of information required to monitor trade and authorisation of exports and imports in the field of drug precursors.

Article 2

Definitions

For the purposes of this Regulation, ‘business premises’ shall mean building(s) together with the land occupied by an operator at each single location.

Article 3

Licence granting procedure

1 An operator or user shall submit to the competent authority an application to obtain a licence referred to in Article 3(2) of Regulation (EC) No 273/2004 or Article 6(1) of Regulation (EC) No 111/2005, electronically or in writing as prescribed by the Member State concerned.

An application shall be deemed to be complete when it contains all the information listed in Article 3(2)(b) of Commission Delegated Regulation (EU) 2015/1011[(4)].

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2 When assessing an application to obtain a licence, the competent authority may also take into consideration the results of any previous assessments or audits carried out on the applying operator holding the status of Authorised Economic Operator (AEO) as defined in Article 5a of Council Regulation (EEC) No 2913/92[(5)], to the extent they are relevant for the examination of the conditions for granting a licence.

By derogation from Article 3(1) of this Regulation, the competent authority may authorise operators holding the status of AEO not to submit all the information listed in Article 3(2)(b) of Delegated Regulation (EU) 2015/1011 when they are submitting an application.

3 The competent authority shall first assess the completeness of an application.

Where an application is not deemed to be complete, the competent authority shall indicate so to the applicant and invite that applicant to provide any missing or relevant additional information.

Where an application is deemed to be complete, the competent authority shall confirm the receipt of a complete application to the applicant.

4 The competent authority shall take a decision to grant or not to grant a licence within 60 working days from the date of receipt of a complete application in the case of a new licence, and within 30 working days in the case of a renewal of a licence.

5 Any decision not to grant a licence shall be reasoned and notified to the applicant electronically or in writing.

6 The licence may cover the operations referred to in Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005.

Article 4

Scope of the licence

The competent authority may grant a licence:

(a) to cover all scheduled substances and all operations per business premises; or

(b) to cover all scheduled substances and all operations per Member State.

Article 5

Format of the licence

A licence referred to in Article 3(2) of Regulation (EC) No 273/2004 or Article 6(1) of Regulation (EC) No 111/2005 shall be issued in the format set out in Annex I to this Regulation.

Article 6

Subsequent changes

Where, after a licence has been granted, information provided in the application for that licence, other than information referred to in Article 3(9) of Delegated Regulation

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(EU) 2015/1011, has changed, the licence holder shall inform the competent authority electronically or in writing within 10 working days following the change.

Where, after the change, the conditions referred to in Article 3 of Delegated Regulation (EU) 2015/1011 continue to be fulfilled, and the information to be changed is contained in the licence, the competent authority shall amend the licence accordingly.

Article 7

Validity, suspension and revocation of licences

1 Where the validity of a licence has expired, or where a license has been revoked, the licence holder shall return a licence which is no longer valid to the competent authority within 10 working days following the date of expiry of validity or the date of revocation.

2 Where a competent authority decides to suspend or revoke a licence, the decision shall be submitted to the licence holder electronically or in writing and shall specify the grounds that justify the suspension or revocation.

Article 8

Special licences

Articles 3 to 7 of this Regulation shall not apply to special licences referred to in Article 3(2) of Regulation (EC) No 273/2004.

Article 9

Registration procedure

1 Articles 3, 4, 6 and 7 shall apply to the procedure for registration pursuant to Article 3(6) of Regulation (EC) No 273/2004 or Article 7(1) of Regulation (EC) No 111/2005.

2 Registration pursuant to Article 3(6) of Regulation (EC) No 273/2004 or Article 7(1) of Regulation (EC) No 111/2005 shall be granted in the format set out in Annex II.

3 By way of derogation from paragraph 2, the competent authority may grant registration on a form printed before the date of entry into force of this Regulation and complying with national rules in place before the date of entry into force of this Regulation until the stocks are exhausted.

4 Paragraphs 1, 2 and 3 shall not apply to special registrations referred to in Article 3(6) of Regulation (EC) No 273/2004.

Article 10

Information required to monitor trade

1 Operators shall provide the information referred to in Article 8(2) of Regulation (EC) No 273/2004 electronically or in writing, as prescribed by the Member State concerned, before 15 February of each calendar year for scheduled substances of Categories 1 and 2 of Annex I to that Regulation.

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2 Operators shall provide the information referred to in Article 9(2) of Regulation (EC) No 111/2005 electronically or in writing, as prescribed by the Member State concerned, before 15 February of each calendar year.

3 An operator shall submit the annual reports referred to in paragraphs 1 and 2 even where no transactions have taken place in a given year.

Article 11

Export and import authorisations

1 The export and import authorisations referred to in Article 28 of Regulation (EC) No 111/2005 shall have the format set out in Annex III or IV to this Regulation, respectively.

By way of derogation from the first subparagraph, the box relating to the authorisation number may have a different format in cases where the export or import authorisation is granted by electronic means.

2 An export authorisation shall be established in four copies numbered 1 to 4. Copy No 1 shall be kept by the authority issuing the authorisation. Copies No 2 and No 3 shall accompany the scheduled substance and be presented to the customs office where the customs export declaration is made, and subsequently to the competent authority at the point of exit from the customs territory of the Union. The competent authority at the point of exit shall return Copy No 2 to the issuing authority. Copy No 3 shall accompany the scheduled substances to the competent authority of the importing country. Copy No 4 shall be kept by the exporter.

3 An import authorisation shall be established in four copies numbered 1 to 4. Copy No 1 shall be kept by the authority issuing the authorisation. Copy No 2 shall be sent to the competent authority of the exporting country by the issuing authority. Copy No 3 shall accompany the scheduled substance from the point of entry into the customs territory of the Union to the business premises of the importer, who shall send this copy to the issuing authority. Copy No 4 shall be kept by the importer.

4 One single export or import authorisation shall not cover more than two scheduled substances.

5 An authorisation shall be issued in one or more of the official languages of the Union. Unless it is granted by electronic means, it shall have A4 format and a printed guilloche pattern background making any falsification by mechanical or chemical means apparent to the eye.

6 A Member State may print the authorisation forms itself or have them printed by printers approved by it. In the latter case, each authorisation form must include a reference of such approval and bear the name and address of the printer or a mark by which the printer can be identified.

7 By way of derogation from paragraphs 1-6, a Member State may issue an export or import authorisation on a form printed before the date of entry into force of this Regulation and complying with Commission Regulation (EC) No 1277/2005 until the stocks are exhausted.

8 Export authorisations granted by simplified procedure shall be established using copies No 1, 2 and 4 of the form set out in Annex III. Copy No 1 shall be kept by the authority issuing the authorisation. Copy No 2 and Copy No 4 shall remain with the exporter. The exporter shall indicate details of each export operation on the back side of Copy No 2, in particular the quantity of the scheduled substance of each export operation and the remaining quantity.