Regulation (EU) No 1258/2013 of the European Parliament and of the Council of 20 November 2013 amending Regulation (EC) No 273/2004 on drug precursors (Text with EEA relevance)

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) On 7 January 2010, the Commission adopted a report pursuant to Article 16 of Regulation (EC) No 273/2004 of the European Parliament and of the Council[(3)] on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors.

(2) In that report, the Commission recommended further analysing ways to strengthen the control of the trade of acetic anhydride, a scheduled substance in category 2 of Annex I to Regulation (EC) No 273/2004, pursuant to Article 2(a) of that Regulation, in order to better prevent the diversion of acetic anhydride for the illicit production of heroin.

(3) In its Conclusions of 25 May 2010 on the functioning and implementation of the EU drug precursors legislation, the Council invited the Commission to propose legislative amendments after carefully assessing their potential impact on Member States' authorities and economic operators.

(4) This Regulation clarifies the definition of a scheduled substance: in this regard, the term 'pharmaceutical preparation', which stems from the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988, is deleted as it is already covered by the relevant terminology of Union legal acts, namely 'medicinal products'. Moreover, the term 'other preparations' is deleted as it duplicates the term 'mixtures' already used in that definition.

(5) A definition of the term 'user' should be introduced for persons possessing substances for purposes other than placing them on the market and it should be clarified that persons using scheduled substances in category 1 of Annex I to Regulation (EC) No 273/2004 for other purposes than placing them on the market are obliged to obtain a licence.

(6) More detailed rules on registration should be introduced to ensure uniform conditions of registration in all Member States for scheduled substances in category 2 of Annex I to Regulation (EC) No 273/2004. For substances scheduled in a new subcategory 2A of Annex I to that Regulation, in addition to operators users should also be subject to a registration requirement.

(7) Where fees are levied for obtaining a licence or registration, Member States should consider adjusting such fees in order to safeguard the competitiveness of microenterprises.

(8) It should be made clear that Member States have the possibility to act with regard to suspicious transactions involving non-scheduled substances in order to enable them to react more quickly with regard to new trends in the illicit production of drugs.

(9) A European database on drug precursors ('the European database') should be created to simplify the reporting by Member States with regard to seizures and stopped shipments, where possible in an aggregated and anonymised manner and in the least intrusive manner as regards the processing of personal data, taking into account the state of the art of privacy-enhancing technologies and the principle of data limitation. The European database should also serve as a European register of operators and users holding a licence or registration which will facilitate verification of the legitimacy of commercial transactions involving scheduled substances, and should enable operators to provide the competent authorities with information about their transactions involving scheduled substances.

(10) Regulation (EC) No 273/2004, as amended by this Regulation, envisages the processing of information, including the processing of personal data, for the purposes of enabling the competent authorities to monitor the placing on the market of drug precursors and to prevent the diversion of scheduled substances. The processing of personal data should be carried out in a manner compatible with the purpose of that Regulation and in accordance with Directive 95/46/EC of the European Parliament and of the Council[(4)] and Regulation (EC) No 45/2001 of the European Parliament and of the Council[(5)] and, in particular, with Union requirements relating to data quality, proportionality, purpose limitation, and rights to information, access, rectification of data, erasure and blocking, organisational and technical measures and international transfers of personal data.

(11) The processing of personal data for the purposes of Regulation (EC) No 273/2004, as amended by this Regulation, and any delegated and implementing acts adopted pursuant thereto should respect the fundamental right to respect for private and family life recognised by Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms as well as the rights to respect for private and family life, and the right to the protection of personal data recognised, respectively, by Articles 7 and 8 of the Charter of Fundamental Rights of the European Union. The delegated and

implementing acts should also ensure that any processing of personal data takes place in accordance with Directive 95/46/EC and Regulation (EC) No 45/2001.

(12) Acetic anhydride, currently scheduled in category 2 of Annex I to Regulation (EC) No 273/2004, should be included in a new subcategory 2A of Annex I thereto to allow increased control of its trade. The remaining substances of category 2 of Annex I to Regulation (EC) No 273/2004 should be listed as subcategory 2B of Annex I thereto.

(13) Regulation (EC) No 273/2004 confers powers on the Commission in order to implement some of its provisions, to be exercised in accordance with the procedures laid down in Council Decision 1999/468/EC[(6)].

(14) As a consequence of the entry into force of the Treaty of Lisbon, those powers should be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).

(15) In order to achieve the objectives of Regulation (EC) No 273/2004, as amended by this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to specify the requirements and conditions for the granting of the licence and registration, for listing operators and users having obtained a licence or registration in the European database, for obtaining and using customer declarations, for the documentation and labelling of mixtures containing scheduled substances, for the provision of information by the operators on transactions involving scheduled substances, and for information to be provided by Member States on the implementation of the monitoring measures laid down in Regulation (EC) No 273/2004, and in order to amend the Annexes thereto. Such delegated acts should also determine the categories of personal data which can be processed by Member States and operators pursuant to Regulation (EC) No 273/2004, the categories of personal data which can be stored in the European database and the safeguards for the processing of personal data. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure the simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(16) It is also important that the Commission seek the opinion of the European Data Protection Supervisor when preparing delegated acts relating to the processing of personal data.

(17) In order to ensure uniform conditions for the implementation of Regulation (EC) No 273/2004, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[(7)]. The examination procedure should be used for the adoption of the implementing acts in order to set up details on how customer declarations should be provided in electronic form and on how to provide the information about transactions of operators with scheduled substances to a European database.

(18) Since the objective of this Regulation, namely to strengthen the rules for registration of operators placing on the market or possessing scheduled substances of category 2

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) No 1258/2013 of the European Parliament and of the Council. (See end of Document for details)*

of Annex I to Regulation (EC) No 273/2004, in particular acetic anhydride, in order to prevent its diversion towards the illicit production of drugs, cannot be sufficiently achieved by the Member States because traffickers gain from national differences in registration and move their illicit business where drug precursors are easiest to divert, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(19) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 18 January 2013[8].

(20) Regulation (EC) No 273/2004 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 273/2004 is amended as follows:

(1) Article 1 is replaced by the following:

Article 1

Scope and objectives

This Regulation establishes harmonised measures for the intra-Union control and monitoring of certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances with a view to preventing the diversion of such substances.;

(2) in Article 2:

(a) point (a) is replaced by the following:

(a) "scheduled substance" means any substance listed in Annex I that can be used for the illicit manufacture of narcotic drugs or psychotropic substances, including mixtures and natural products containing such substances but excluding mixtures and natural products which contain scheduled substances and which are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means, medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council[9] and veterinary medicinal products as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council[10];;

(b) point (c) is replaced by the following:

(c) "placing on the market" means any supply, whether in return for payment or free of charge, of scheduled substances in the Union; or the storage, manufacture, production, processing, trade,

distribution or brokering of these substances for the purpose of supply in the Union;;

(c) the following points are added:

(h) "user" means a natural or legal person other than an operator who possesses a scheduled substance and is engaged in the processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, transformation or any other utilisation of scheduled substances;

(i) "natural product" means an organism or a part thereof, in any form, or any substances which occur in nature as defined in point 39 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(11)].;

(3) in Article 3:

(a) paragraphs 2 and 3 are replaced by the following:

2. Operators and users shall obtain a licence from the competent authorities of the Member State in which they are established before they may possess or place on the market scheduled substances of category 1 of Annex I. The competent authorities may grant special licences to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or armed forces. Such special licences shall be valid only for the use of scheduled substances of category 1 of Annex I within the scope of the official duties of the operators concerned.

3 Any operator holding a licence shall supply scheduled substances of category 1 of Annex I only to operators or users who also hold a licence and have signed a customer declaration as provided for in Article 4(1).;

(b) paragraphs 5, 6 and 7 are replaced by the following:

5. Without prejudice to paragraph 8, the competent authorities may either limit the validity of the licence to a period not exceeding three years or may oblige the operators and users to demonstrate at intervals not exceeding three years that the conditions under which the licence was granted are still fulfilled. The licence shall mention the operation or operations for which it is valid, as well as the scheduled substances concerned. The competent authorities shall, in principle, grant special licences for an unlimited duration but may suspend or revoke them where there are reasonable grounds for believing that the holder is no longer a fit and proper person to hold a licence, or that the conditions under which the licence was granted are no longer fulfilled.

6 Operators shall obtain registration from the competent authorities of the Member State in which they are established before placing on the market scheduled substances of category 2 of Annex I. From 1 July 2015 users shall obtain a registration from the competent authorities of the Member State in which they are established before possessing scheduled substances of subcategory 2A of Annex I. The competent authorities may grant special registrations to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or the armed forces. Such special registrations shall be considered valid only for the use of scheduled