Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2012/0250(COD)
Monitoring EU/third country trade in drug precursors Subject 4.20.04 Pharmaceutical products and industry 6.20.02 Export/import control, trade defence, trade barriers 7.30.02 Customs cooperation 7.30.05 Police cooperation 7.30.30.04 Action to combat drugs and drug-trafficking	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	INTA International Trade		06/11/2012
		PPE PROUST Franck	
		Shadow rapporteur	
		S&D ANDRÉS BAREA Josefa	
		ALDE RINALDI Niccolò	
		Verts/ALE KELLER Ska	
		ECR ZAHRADIL Jan	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
	JURI Legal Affairs	The committee decided not to give an opinion.	
	LIBE Civil Liberties, Justice and Home Affairs	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Economic and Financial Affairs ECOFIN	3271	15/11/2013
European Commission	Commission DG	Commissioner	
	Taxation and Customs Union	ŠEMETA Algirdas	

Key events

27/09/2012	Legislative proposal published	COM(2012)0521	Summary
22/10/2012	Committee referral announced in Parliament, 1st reading		
25/04/2013	Vote in committee, 1st reading		

06/05/2013	Committee report tabled for plenary, 1st reading	A7-0167/2013	Summary
21/10/2013	Debate in Parliament		
23/10/2013	Results of vote in Parliament		
23/10/2013	Decision by Parliament, 1st reading	T7-0440/2013	Summary
15/11/2013	Act adopted by Council after Parliament's 1st reading		
20/11/2013	Final act signed		
20/11/2013	End of procedure in Parliament		
10/12/2013	Final act published in Official Journal		

Technical information

Procedure reference	2012/0250(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Treaty on the Functioning of the EU TFEU 207
Other legal basis	Rules of Procedure EP 159
Stage reached in procedure	Procedure completed
Committee dossier	INTA/7/10782

Documentation gateway

Legislative proposal		COM(2012)0521	27/09/2012	EC	Summary
Document attached to the procedure		SWD(2012)0267	27/09/2012	EC	
Document attached to the procedure		SWD(2012)0268	27/09/2012	EC	
Document attached to the procedure		N7-0047/2014 OJ C 357 06.12.2013, p. 0009	18/01/2013	EDPS	Summary
Committee draft report		PE504.126	01/02/2013	EP	
Amendments tabled in committee		PE506.180	01/03/2013	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0167/2013	06/05/2013	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0440/2013	23/10/2013	EP	Summary
Draft final act		00071/2013/LEX	20/11/2013	CSL	
Commission response to text adopted in plenary		SP(2013)872	27/11/2013	EC	
Follow-up document		COM(2020)0768	30/11/2020	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2013/1259
OJ L 330 10.12.2013, p. 0030 Summary

Final legislative act with provisions for delegated acts

Delegated acts

2015/2669(DEA)	Examination of delegated act

Monitoring EU/third country trade in drug precursors

PURPOSE: to regulate the external trade in medicinal products containing ephedrine and pseudo-ephedrine and amending Council Regulation (EC) No 111/2005.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

BACKGROUND: drug precursors are chemical substances having a wide variety of licit uses, such as in the synthesis of plastics, pharmaceuticals, cosmetics, perfumes, detergents, or aromas. They are traded for legitimate purposes on global markets, but some of them can also be diverted from the licit distribution channels for the illicit manufacture of narcotic drugs. Taking into account the wide legitimate uses of drug precursors, their trade cannot be prohibited.

Ephedrine and pseudoephedrine are chemical substances used for the manufacture of cold or allergy medicines. These two substances are also the main precursors for the manufacture of methamphetamine. While ephedrine and pseudoephedrine are controlled at international and EU level, the medicinal products containing them are not controlled when they are exported from or transiting through the Union customs territory. They are targeted by drug traffickers as a source of precursors for the illicit manufacture of methamphetamine because the ephedrine or pseudoephedrine contained in these products can be easily extracted.

Extent of the problem: in 2009, almost 7 400 seizures of methamphetamine, amounting to about 600 kg of the drug, were reported in Europe. Both the number of seizures and quantities increased over 2004-2009. In 2009, illicit methamphetamine laboratories were seized for the first time in several European countries. This is an indication that methamphetamine markets may be expanding in Europe.

Seizures of methamphetamine precursors contained in medicinal products have fluctuated considerably from 2007 until 2010. At European level, while in 2007 hardly any preparations were recorded out of the overall quantities seized, in 2008 and 2009 the amount of preparations out of the total quantities seized increased sharply and decreased considerably again in 2010. After the continued increase of seizures of medicinal products from 2007 to 2009, as a result of strengthened controls of medicinal products containing ephedrine and pseudoephedrine in several countries, particularly in Mexico and countries in Central America, the total amount of medicinal products seized worldwide decreased in 2010.

However, the increasing or decreasing level of seizures is only one indicator to illustrate that illicit manufacture is taking place in a given part of the world. The absence of a control mechanism for medicinal products containing ephedrine and pseudoephedrine remains a concern both at European and at global level.

Medicinal products for human use containing ephedrine or pseudoephedrine are excluded from the provisions of Regulation (EC) 111/2005, which applies to trade in drug precursors between the EU and third countries. This has led to a situation where these products could not be stopped or seized by Member States' competent authorities when these products were exported from or transiting through the Union customs territory, even though it was very likely that they would be misused for the illicit manufacture of methamphetamine in their country of destination.

Directive 2011/62/EU which relates to the prevention of the entry into the legal supply chain of falsified medicinal products addresses the distribution chain for medicines within the EU, importation of active substances, and 'introduction' of medicines, i.e. medicines brought into the customs territory without the intention of placing them on the market. These provisions are focused on preventing products that fall within the definition of falsified medicinal products from entering the legal supply chain. Given that the principal issue with drug precursors is one of legitimately produced products leaving the legal supply chain, it is unlikely that these provisions will make a significant contribution to tackling the issue of controlling medicinal products containing ephedrine or pseudoephedrine being exported or transiting through the EU.

The EU is criticised internationally for not taking adequate control measures across Member States to tackle this weakness.

By imposing EU control over these medicinal products, this proposal is aiming to make it more difficult, expensive and risky for criminals to source the chemicals they need to manufacture drugs. The proposal should work as a deterrent: it focuses on preventing the diversion of precursors. It concentrates on the supply reduction of the chemicals to make drugs and not on the supply of the drugs for the consumers.

IMPACT ASSESSMENT: the impact assessment report identified and assessed five policy options:

- Option 1: "baseline scenario": the status quo would be maintained.
- Option 2: voluntary measures by Member States to improve the situation.
- Option 3: giving authorities power to stop suspicious shipments.
- Option 4: giving authorities power to stop suspicious shipments and pre-export notification of legal shipments.
- Option 5: full control of trade in medicinal products containing ephedrine and pseudoephedrine.

The impact assessment concluded that Option 4 would be the most suitable one to address the problem, as it would: (i) provide for a legal basis, (ii) impose only one extra control requirement and (iii) generate hardly any additional administrative burden. The proposal notes that

even though Option 5 could be considered the most effective by applying the strictest controls, the requirements would be disproportionate to the objective pursued by the present initiative. The added value provided by Option 4 compared to Option 3 is that, under the former Option, the synergy of two combined measures increases the effectiveness of each individual measure.

LEGAL BASIS: Article 207 of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the proposal provides that any export of medicinal products containing ephedrine or pseudoephedrine should be preceded by a pre-export notification sent by the competent authorities in the Union to the competent authorities of the country of destination. The pre-export notification system is up and running and measures are already compulsory for scheduled substances of Category 1. The proposal contains compulsory measures for the products containing Category 1 substances, such as medicinal products containing ephedrine or pseudoephedrine.

Member States' competent authorities will be given the powers to stop or seize those products when there are reasonable grounds for suspecting that they are intended for the illicit drug manufacture, when they are exported, imported or in transit. At the moment, most customs authorities can only seize ephedrine or pseudoephedrine as raw substances.

The European Database on drug precursors created by Regulation (EC) No 273/2004 will be used to:

- simplify Member States reporting with regard to seizures and stopped shipments in accordance with Article 12(12) of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988;
- establish a European register of operators holding a licence or a registration, which will facilitate verification of the legitimacy of their transactions involving scheduled substances and enable operators to provide the competent authorities with information about their export, import or intermediary activities involving scheduled substances.

The proposal contains some other amendments aiming at facilitating the implementation of the Regulation and at increasing its effectiveness, the main ones being:

- the possibility of amending the Annex to the Regulation in order to react more quickly to new emerging trends in precursors diversion;
- a review clause to assess whether the amended Regulation will have been effective to prevent the diversion of medicinal products containing ephedrine or pseudoephedrine;
- the adaptation of the provisions of Regulation (EC) No 111/2005 in accordance with the rules on delegated and implementing acts under the Treaty on the Functioning of the European Union (TFEU).

BUDGETARY IMPLICATIONS: the proposal will not have an impact on human resources and on the European Union budget and is therefore not accompanied by a financial statement.

DELEGATED ACTS: in order to achieve the objectives of Regulation (EC) No 111/2005, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union will be delegated to the Commission for specific purposes listed in the text.

Monitoring EU/third country trade in drug precursors

The Committee on International Trade adopted the report by Franck PROUST (EPP, FR) on the proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

The parliamentary committee recommends that Parliaments position adopted at first reading according to the ordinary legislative procedure should be to amend the Commissions proposal as follows:

Inclusion of medicinal products in the definition of scheduled substances: Members considered that medicinal products should also be included within the definition of scheduled substances and that a new category of scheduled substances should therefore be created to take into account the specific characteristics of medicinal products.

Databases: concerning the European database establishing a European register of operators holding a licence or a registration for the legal trade in drug precursors and medicinal products containing ephedrine and pseudoephedrine, Members considered it should be regularly updated and the information provided should be used by the Commission and Member States' competent authorities only for the purpose of preventing the diversion of those products onto the illegal market (and thus not for law enforcement purposes).

Delegated acts: Members call for delegated acts to determine the cases in which a licence is not required and setting other conditions for the granting of licences, and implementing acts establishing a model for licences, that should ensure a systematic and consistent control and monitoring of operators.

Members also amended the duration of the delegation of power so that provision is made for the delegation of power of five years tacitly extended for an identical period of time (instead of for an indeterminate period).

The delegation of power should only apply to the addition of new substances. Accordingly, no scheduled substance may be withdrawn from the Annexes without going through the codecision procedure.

Concerning implementing acts, Members wanted the advisory procedure to apply rather than the examination procedure, given that only minor acts are concerned and that the fight against drug trafficking calls for an ability to react rapidly.

Report:lastly, Members called on the Commission to provide a report evaluating the functioning of the Regulation by 31 December 2017. Where appropriate, that report may be accompanied by a legislative proposal.

Monitoring EU/third country trade in drug precursors

The European Parliament adopted by 583 votes to 58 with 39 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

Parliament adopted its position in first reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise negotiated between Parliament and Council.

Control of medicinal products containing certain scheduled substances: medicinal products and veterinary medicinal products containing ephedrine or pseudo-ephedrine must be included in the definition of scheduled substances. A new category of substances was created (category 4) in the annex of the Regulation in which this type of medicinal product must be included.

Preventing diversions involving non-scheduled substances: with a view to enabling Member States to react more quickly with regard to new trends in drug precursors' diversion, Member States would be able to empower their competent authorities to obtain information on any orders for or operations involving non-scheduled substances, or to enter business premises to obtain evidence of suspicious transactions involving such substances. In addition, competent authorities should prevent the introduction into, or the departure from, the customs territory of the Union of non-scheduled substances, where it can be demonstrated that such substances will be used in the illicit manufacture of narcotic drugs or psychotropic substances.

Labelling of products: Operators must ensure that labels are affixed on any packaging containing scheduled substances, except substances listed in Category 4 of the Annex, indicating their name or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, contained in the mixture or in the natural product.

Licensing and registration procedure: operators established in the Union, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances shall hold a licence or a registration as the case may be, depending on the category of product. The competent authority of the Member State in which the operator is established shall issue the licence.

In considering whether to grant a licence or a registration, the competent authority shall take into account the competence and integrity of the applicant, in particular the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

Database: competent authorities should share between themselves and with the Commission, through the European database on drug precursor), established under Regulation (EC) No 273/2004, information on seizures and stopped shipments in order to improve the overall level of information on trade in drug precursors, including medicinal products. The European database should be used to simplify the reporting by Member States with regard to seizures and stopped shipments. It should also serve as a European register of operators holding a licence or registration which will facilitate verification of the legitimacy of their transactions involving scheduled substances, and should enable operators to provide the competent authorities with information about their export, import or intermediary activities involving scheduled substances. That European register should be regularly updated and the information it contains should be used by the Commission and Member States' competent authorities only for the purpose of preventing the diversion of drug precursors onto the illegal market.

Processing of personal data: Member States and the Commission should process personal data only in a manner compatible with the purposes of Regulation (EC) No 111/2005, as amended by this Regulation, and the delegated and implementing acts adopted pursuant thereto. Those data should be processed in accordance with Union legislation concerning the protection of individuals with regard to the processing of personal data, in particular Directive 95/46/EC of the European Parliament and of the Council and Regulation (EC) No 45/2001 of the European Parliament and of the Council.

Communication with Member States: the competent authorities in each Member State must communicate to the Commission in electronic form via the European database in a timely manner all relevant information on the implementation of the monitoring measures laid down in this Regulation, in particular as regards substances used for the illicit manufacture of narcotic drugs or psychotropic substances and methods of diversion and illicit manufacture, and their licit trade.

Delegated acts: the Commission will be empowered to adopt by delegated acts a series of technical provisions, notably those setting put the conditions for granting registrations and for determining cases where a registration is not required .The duration of the delegation of power is 5 years. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

Implementing acts: implementing powers are conferred on the Commission, namely to establish a model for licences, the procedural rules on the provision of information that is required by the competent authorities to monitor export, import or intermediary activities of operators

Report: the Commission will submit a report to the European Parliament and to the Council on the implementation of the Regulation, and in particular on the possible need for additional action to monitor and control suspicious transactions with non-scheduled substances.

Annex: the list of schedules substances has been amended and a new Category 4 has been inserted for medicinal products containing ephedrine or pseudo-ephedrine.

Monitoring EU/third country trade in drug precursors

PURPOSE: to regulate the external trade in medicinal products containing ephedrine and pseudo-ephedrine and amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

LEGISLATIVE ACT: Regulation (EU) No 1259/2013 of the European Parliament and of the Council amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

CONTENT: this Regulation aims to strengthen the control of international trade in medicinal products containing ephedrine or pseudoephedrine exported from or transiting through the customs territory of the Union in order to prevent their diversion for the illicit manufacture of narcotic drugs or psychotropic substances.

To this end, the following measures are provided:

- control of medicinal products containing certain scheduled substances: medicinal products and veterinary medicinal products containing ephedrine or pseudo-ephedrine must be included in the definition of scheduled substances. A new category of substances was created (category 4) in the annex of the Regulation in which this type of medicinal product must be included;
- preventing diversions involving non-scheduled substances: with a view to enabling Member States to react more quickly with regard to new trends in drug precursors' diversion, Member States would be able to empower their competent authorities to obtain information on any orders for or operations involving non-scheduled substances, or to enter business premises to obtain evidence of suspicious transactions involving such substances. In addition, competent authorities should prevent the introduction into, or the departure from, the customs territory of the Union of non-scheduled substances, where it can be demonstrated that such substances will be used in the illicit manufacture of narcotic drugs or psychotropic substances. Member States competent authorities should be given the powers to stop or seize those medicinal products where there are reasonable grounds for suspecting that they are intended for the illicit manufacture of narcotic drugs or psychotropic substances, when they are exported, imported or in transit.

It should be noted that 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 (the United Nations Convention), 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.

Labelling of products: operators must ensure that labels are affixed on any packaging containing scheduled substances, except substances listed in Category 4 of the Annex (Medicinal products and veterinary medicinal products containing ephedrine or its salts) indicating their name or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, contained in the mixture or in the natural product.

Licensing and registration procedure: operators established in the Union, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances shall hold a licence or a registration as the case may be, depending on the category of product. The competent authority of the Member State in which the operator is established shall issue the licence.

In considering whether to grant a licence or a registration, the competent authority shall take into account the competence and integrity of the applicant, in particular the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

Database: competent authorities should share between themselves and with the Commission, through the European database on drug precursor), established under Regulation (EC) No 273/2004, information on seizures and stopped shipments in order to improve the overall level of information on trade in drug precursors, including medicinal products. The European database should be used to simplify the reporting by Member States with regard to seizures and stopped shipments. It should also serve as a European register of operators holding a licence or registration which will facilitate verification of the legitimacy of their transactions involving scheduled substances, and should enable operators to provide the competent authorities with information about their export, import or intermediary activities involving scheduled substances. That European register should be regularly updated and the information it contains should be used by the Commission and Member States' competent authorities only for the purpose of preventing the diversion of drug precursors onto the illegal market.

Processing of personal data: Member States and the Commission should process personal data only in a manner compatible with the purposes of Regulation (EC) No 111/2005, as amended by this Regulation, and the delegated and implementing acts adopted pursuant thereto. Those data should be processed in accordance with Union legislation concerning the protection of individuals with regard to the processing of personal data, in particular Directive 95/46/EC of the European Parliament and of the Council and Regulation (EC) No 45/2001 of the European Parliament and of the Council.

Communication with Member States: the competent authorities in each Member State must communicate to the Commission in electronic form via the European database in a timely manner all relevant information on the implementation of the monitoring measures laid down in this Regulation, in particular as regards substances used for the illicit manufacture of narcotic drugs or psychotropic substances and methods of diversion and illicit manufacture, and their licit trade.

Report: the Commission shall submit by 31 December 2019 a report to the European Parliament and to the Council on the implementation and functioning of this Regulation, and in particular on the possible need for additional action to monitor and control suspicious transactions with non-scheduled substances.

Annex: the list of scheduled substances has been amended and a new Category 4 has been inserted for medicinal products containing ephedrine or pseudo-ephedrine.

ENTRY INTO FORCE: 30.12.2013.

DELEGATED ACTS: the power to adopt delegated acts shall be conferred on the Commission for a period of five years from 30 December 2013. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension.

The European Parliament or the Council may raise objections to a delegated act within a period of two months from the date of notification (this may be extended by two months.) If the European Parliament or Council express objections, the delegated act will not enter into force.