Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2012/0261(COD)
Monitoring intra-EU trade in drug precursors Amending Regulation (EC) No 273/2004 2002/0217(COD) Subject 2.10.01 Customs union, tax and duty-free, Community transit 2.80 Cooperation between administrations 4.20.04 Pharmaceutical products and industry 6.40.13 Relations with/in the context of international organisations: UN, OSCE, OECD, Council of Europe, EBRD 7.30.30.04 Action to combat drugs and drug-trafficking	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	LIBE Civil Liberties, Justice and Home Affairs		10/12/2012
		S&D HEDH Anna	
		Shadow rapporteur	
		PPE PIRKER Hubert	
		ALDE IN 'T VELD Sophia	
		Verts/ALE KELLER Ska	
		ECR KIRKHOPE Timothy	
	Committee for opinion	Rapporteur for opinion	Appointed
	INTA International Trade	The committee decided not to give an opinion.	
	ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
	IMCO Internal Market and Consumer Protection	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	
	Internal Market, Industry, Entrepreneurship and SMEs	TAJANI Antonio	
European Economic and Social Committee			

Key events

27/09/2012	Legislative proposal published	COM(2012)0548	Summary

22/10/2012	Committee referral announced in Parliament, 1st reading		
24/04/2013	Vote in committee, 1st reading		
15/05/2013	Committee report tabled for plenary, 1st reading	A7-0153/2013	
23/10/2013	Results of vote in Parliament		
23/10/2013	Decision by Parliament, 1st reading	T7-0442/2013	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	2012/0261(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation (EC) No 273/2004 2002/0217(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114-p1
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	LIBE/7/10801

Documentation gateway

Legislative proposal		COM(2012)0548	27/09/2012	EC	Summary
Document attached to the procedure		SWD(2012)0278	27/09/2012	EC	
Document attached to the procedure		SWD(2012)0279	27/09/2012	EC	
Economic and Social Committee: opinion, report		CES2301/2012	16/01/2013	ESC	
Document attached to the procedure		N7-0047/2014 OJ C 357 06.12.2013, p. 0009	18/01/2013	EDPS	Summary
Committee draft report		PE504.107	06/02/2013	EP	
Amendments tabled in committee		PE506.184	04/03/2013	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0153/2013	15/05/2013	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0442/2013	23/10/2013	EP	Summary
Draft final act		00061/2013/LEX	20/11/2013	CSL	

Commission response to text adopted in plenary		SP(2013)872	27/11/2013	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2013/1258
OJ L 330 10.12.2013, p. 0021 Summary

Final legislative act with provisions for delegated acts

Monitoring intra-EU trade in drug precursors

PURPOSE: to prevent the diversion from the EU-internal trade of acetic anhydride, the main drug precursor for heroin, by extending the registration requirement to include users of the substance, and amending Regulation (EC) No 273/2004 on drug precursors

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. However, in order to prevent their diversion to illicit drug production, a specific regulatory framework has been set up on international level through Article 12 of the United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances. The EU is a Party to the Convention and has implemented its obligations through Regulation (EC) No 273/2004 governing the monitoring of the intra-EU trade in drug precursors and Regulation (EC) No 111/2005 governing the external trade. The Union regulatory framework provides for the monitoring and control of the legitimate trade in drug precursors. Operators, i.e. manufacturers, distributors, brokers, importers, exporters and wholesalers of chemicals engaged in the legitimate trade of drug precursors are required to take measures against theft, check their customers, detect suspicious transactions and notify the authorities thereof.

In 2010, the European Commission adopted a Report on the implementation and functioning of the existing EU legislation on drug precursors, and recommended analysing ways to strengthen the control of the trade of acetic anhydride (scheduled substance in Category 2) in order to better prevent the diversion of acetic anhydride for the illicit production of heroin.

Heroin use accounts for the greatest share of morbidity and mortality-related drug use in the EU. Even though the quantities of acetic anhydride seized in the EU have decreased very substantially since 2008, certain reports consider that the European legislative control measures are not sufficiently strict to prevent the diversion of the main heroin precursor from the intra-EU trade.

IMPACT ASSESSMENT: the main problem driver being the insufficient control by competent authorities over all economic players involved in the legitimate trade with drug precursors, all policy options examined seek to improve control via enhanced reporting, notification or registration obligations imposed on the economic players. The impacts of the following six policy options have been analysed:

- Option 1 (baseline option): no action: the current EU legislation will remain unchanged;
- Option 2: strengthened reporting obligations;
- Option 3: strengthened rules and obligations on operators related to customer declarations from end-users;
- Option 4: require operators to systematically notify new end-users to the authorities to allow verification;
- Option 5: require registration for end-users and reinforce requirements regarding registration;
- Option 6: move acetic anhydride from category 2 to category 1 scheduled substances.

Option 5 is the preferred option. The overall conclusion of the impact assessment was that both, Option 4 and Option 5 would be good choices, but Option 5 would be less burdensome than Option 4 in terms of annual costs for enterprises (provided authorities do not pass on all costs to registrants by imposing fees), an argument which is particular relevant for SMEs. All in all the strong political support which Option 5 has from most Member States, combined with views expressed on international level that a more systematic control of (all) acetic anhydride end-users is lacking in the European legislation, and the somewhat lower burden on SMEs tip the balance in favour of Option 5.

LEGAL BASIS: Article 114 of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: this proposal aims to address a specific weakness which has been detected in the European Union, when large quantities of acetic anhydride ("AA"), the main drug precursor for heroin, were diverted from the EU- internal trade: in 2008, 75% of the global seizures of Acetic anhydride happened in the EU. Until now only EU companies producing or trading Acetic anhydride have to register with their national authorities.

The Commission proposes to:

· extend the registration requirement, which so far applies only to operators placing Acetic anhydride on the market, to include users of the substance;

· enhance the harmonised registration provisions to achieve a more robust level playing field preserving the internal market and avoiding adoption of divergent national measures. More detailed rules on registration are introduced to ensure uniform conditions of registration in all Member States for scheduled substances in category 2 of Annex I. For substances scheduled in a new subcategory 2A of Annex I, not only operators but also users will be subject to a registration requirement.

By ensuring that operators and users engaged in the legal trade of drug precursors are subject to harmonised rules, the proposal will ensure a proper functioning of the Union market by avoiding unnecessary barriers to such legitimate trade and by reducing administrative burdens for operators and competent authorities.

Additionally the Commission proposes to establish and maintain a European Database on Drug Precursors in order to modernize the collection of the information provided by Member States on drug precursor seizures and stopped shipments, in accordance with current Article 13 of Regulation (EC) No 273/2004, and to maintain a list of EU licensed or registered operators and users legally trading or using drug precursors, as well as to enable operators to provide competent authorities in summary form with information about their transactions involving scheduled substances in accordance with current Article 8 (2) of Regulation (EC) No 273/2004.

In addition, it should be noted that the proposal is:

- subject to a notification to the WTO in the framework of the TBT Agreement;
- relevant for the European Economic Area (EEA);
- contains a transitional period for the coming into force of the new registration obligations for end-users of Acetic anhydride;
- includes a review clause to assess whether the amended Regulation will have been effective to prevent the diversion of Acetic anhydride.

Annex: the proposal does not extend the provisions for acetic anhydride to other scheduled substances in category 2. Acetic anhydride, currently scheduled in category 2 of Annex I, will be included in a new subcategory 2A of Annex I to allow increased control of its trade. The remaining substances of category 2 will be listed as subcategory 2B.

BUDGETARY IMPLICATIONS: the proposal has no impact on the European Union budget because no additional resources are required to implement the action proposed. The necessary resources to implement the European database are already included in the allocations granted during the budget procedure and within the Internal Market line.

DELEGATED ACTS: the Commission shall have the power, in accordance with Article 290 of the Treaty on the Functioning of the European Union, to adopt certain acts for which provision is made in the proposal.

Monitoring intra-EU trade in drug precursors

Opinion of the European Data Protection Supervisor on the proposal for a regulation amending Regulation (EC) No 273/2004 on drug precursors and the proposal for a regulation amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

On 27 September 2012, the Commission adopted the proposal for a regulation amending Regulation (EC) No 273/2004 on drug precursors and the proposal for a Regulation 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 EDPS was consulted on the same day.

The proposals aim to implement the 1988 UN Convention against illicit drug trafficking and psychotropic substances. The UN Convention and the Regulations aim at recognising and protecting legal trade of drug precursors while, at the same time, discouraging their diversion for illicit purposes.

Currently, measures to control intra-EU trade imply the processing of data of operators since they include the obligation for certain industry operators to appoint a responsible officer and notify his contact details to the competent authorities, obtain a licence or registration, ask customers to declare the uses of the drug precursors provided to them and immediately notify the competent authorities in case they suspect an order or transaction might be aimed at diverting drug precursors for illicit purposes.

As regards the control of external trade, the processing of data of operators is also necessary, as operators are obliged, for example, to apply to competent authorities for authorisation before importing or exporting drug precursors. Obligations for EU competent authorities include notifying certain third countries before an export of drug precursors takes place, and communicating to the Commission the result of their monitoring measures.

Following criticisms by the UN International Narcotics Control Board (INCB) on specific weaknesses of the current measures, the new proposals include, among others, the following amendments to the Regulations:

- the creation of a European Database on Drug Precursors,
- the reinforcement of the harmonised registration provisions,
- the extension of the registration requirement to users of acetic anhydride.

EDPSs position: the EDPS welcomes the general references to the applicability of EU data protection legislation, the fact that many of the categories of data to be processed are specified and the fact that the principle of purpose limitation is mentioned in the external trade proposal.

However, he recommends laying down in the main legislative texts the essential elements of the processing operations such as the exclusion of the processing of sensitive data. All the categories of data to be processed should also be specified preferably in the proposals, and at least by delegated acts.

He also recommends:

- adding to the intra-EU trade proposal that personal data on suspicious transactions may only be used for the purpose of preventing the diversion of scheduled substances,
- laying down maximum retention periods in the proposals for all processing operations and specifying in the proposals that data on suspicious transactions has to be deleted as soon as they are not necessary any more,
- adding a new article to the proposals on how information on the processing operations should be provided to data subjects,
- as regards international transfers of personal data, including data protection safeguards in the text of the external trade regulation and

in an international binding text or in binding agreements with the recipient third countries,

- as regards the European Database, if operators need to have access to it or it is to be used for additional purposes, this should be specified in the substantive part of the proposals, ensuring the supervision of the European database by a system of coordinated supervision between the EDPS and national Data Protection Authorities, similar to what is foreseen for the Internal Market Information System,
- as regards the register of European operators and the processing of summaries of transactions through the European database, specific data protection and security safeguards should be added, preferably to the proposals and at least by delegated or implementing acts,
- if the European Database is to be used for purposes other than those stated in Article 1(9) of the intra- EU trade proposal (e.g., for the processing of customs declarations), this should be specified in the substantive part of the proposals.

As regards the principle of purpose limitation, the EDPS would like to remind that the interconnection and exchange or correlation of data of the European database with other databases managed by the Commission or by other entities for different purposes should in principle not be allowed.

Monitoring intra-EU trade in drug precursors

The European Parliament adopted by 575 votes to 34 with 54 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 273/2004 on 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.

Scope and objectives: the Regulation established 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.

Definitions: several definitions were clarified, including the definition of placing on the market of scheduled substances within the meaning of the Regulation.

The meaning of user has also been clarified so that it cannot be confused with an operator within the meaning of the Regulation.

Registration: 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.

It is also provided that competent authorities may require operators and users to pay a fee for the application for a licence or for registration.

Where a fee is levied, competent authorities must consider adjusting the level of the fee depending on the size of the enterprise. Such a fee must be levied in a non-discriminatory manner and shall not exceed the cost of processing the application.

Database: the proposal provided for the creation of a European database to simplify the reporting by Member States with regard to seizures and stopped shipments. Data should, where possible, be 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 kind of data which can be stored in the European database would be established through delegated acts.

The Commission must make publicly available, in a clear, comprehensive and understandable manner, information concerning the European database.

Exchange and processing of personal data: Regulation (EC) No 273/2004 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. However, the amended text specified that the processing of personal data should be carried out in a manner compatible with EU legislation on data protection and, in particular, with 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.

Operators must not disclose any personal data collected pursuant to this Regulation other than to the competent authorities.

Seizure of certain substances: competent authorities will have the power where necessary, to detain and seize consignments to prevent the use of specific non-scheduled substances for the illicit manufacture of narcotic drugs or psychotropic substances.

Communication from Member States: to permit any necessary adjustments to the arrangements for monitoring trade in scheduled substances and non-scheduled substances, the competent authorities in each Member State shall communicate to the Commission in electronic form via the European database all relevant information on the implementation of the monitoring measures laid down in the 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.

The Commission will be empowered to adopt delegated acts specifying the conditions and requirements concerning the information to be provided in this context. .

Delegated acts regarding the processing of personal data: the scope of the delegation of power has been redefined so that the Commission would also be empowered to adopt delegated acts on:

- 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.

The Commission should seek the opinion of the European Data Protection Supervisor when preparing delegated acts relating to the processing of personal data.

The power to adopt delegated acts will be conferred on the Commission for a period of five years and 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.

Review: the Commission must submit a report to the European Parliament and to the Council on the implementation and functioning 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 scheduled substances has been amended.

Monitoring intra-EU trade in drug precursors

PURPOSE: to prevent the diversion from the EU-internal trade of acetic anhydride, the main drug precursor for heroin, by extending the registration requirement to include users of the substance, and amending Regulation (EC) No 273/2004 on drug precursors.

LEGISLATIVE ACT: Regulation (EU) No 1258/2013 of the European Parliament and of the Council amending Regulation (EC) No 273/2004 on drug precursors.

CONTENT: 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.

Definitions: several definitions have been amended such as:

- user: this term has been clarified so that it concerns persons possessing substances for purposes other than placing them on the market (the aim being that it cannot be confused with an operator within the meaning of the Regulation);
- scheduled substance: this term has been clarified so as to delete 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, 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.

Registration: more detailed rules on registration should be introduced to ensure uniform conditions of registration in all Member States for scheduled substances as laid down in the Regulation (EC) No 273/2004. For acetic anhydride, in addition to operators users should also be subject to a registration requirement.

Licence: provisions as regards holding a licence for the placing on the market of a scheduled substance has been clarified. The competent authorities may either limit the validity of the licence to a period not exceeding three years.

For acetic anhydride, operators shall obtain registration from the competent authorities of the Member State in which they are established before placing the substance on the market. From 1 July 2015, users shall obtain a registration from the competent authorities of the Member State in which they are established before possessing this substance.

When considering whether to grant registration, the competent authorities shall take into account, in particular, the competence and integrity of the applicant. They shall refuse registration if there are reasonable grounds for doubting the suitability and reliability of the applicant or of the officer responsible for the trade in scheduled substances.

Fees: 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. It is also provided that competent authorities may require operators and users to pay a fee for the application for a licence or for registration.

Where a fee is levied, competent authorities must consider adjusting the level of the fee depending on the size of the enterprise. Such a fee must be levied in a non-discriminatory manner and shall not exceed the cost of processing the application.

Database: a European database on drug precursors shall 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.

The kind of data which can be stored in the European database would be established through delegated acts.

Exchange and processing of personal data: Regulation (EC) No 273/2004 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. However, it is specified that the processing of personal data should be carried out in a manner compatible with EU legislation on data protection and, in particular, with 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.

Operators must not disclose any personal data collected pursuant to this Regulation other than to the competent authorities.

Notification of the competent authorities: operators shall notify the competent authorities immediately of any circumstances, such as unusual orders or transactions involving scheduled substances to be placed on the market, which suggest that such substances might be diverted for the illicit manufacture of narcotic drugs or psychotropic substances. To that end, operators shall provide any available information allowing the competent authorities to verify the legitimacy of the relevant order or transaction.

Competent authorities will have the power where necessary, to detain and seize consignments to prevent the use of specific non-scheduled substances for the illicit manufacture of narcotic drugs or psychotropic substances.

Communication from Member States: to permit any necessary adjustments to the arrangements for monitoring trade in scheduled substances and non-scheduled substances, the competent authorities in each Member State shall communicate to the Commission in electronic form via the European database all relevant information on the implementation of the monitoring measures laid down in the 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.

The Commission shall be empowered to adopt delegated acts concerning the requirements and conditions for operators to provide information.

Report: the Commission shall, by 31 December 2019, submit 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: 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.

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.