Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation 2002/0217(COD)	Procedure completed
Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance Amended by 2012/0261(COD) Subject 7.30.30.04 Action to combat drugs and drug-trafficking	

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	LIBE Citizens' Freedoms and Rights, Justice and Home Affairs	PPE-DE PIRKER Hubert	02/10/2002
	Former committee responsible		
	LIBE Citizens' Freedoms and Rights, Justice and Home Affairs	PPE-DE PIRKER Hubert	02/10/2002
	Former committee for opinion		
	ENVI Environment, Public Health, Consumer Policy	PSE MALLIORI Minerva Melpomeni	02/10/2002
	JURI Legal Affairs and Internal Market	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2528	29/09/2003
	Competitiveness (Internal Market, Industry, Research and Space)	2510	19/05/2003
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs		

Key events

09/09/2002	Legislative proposal published	COM(2002)0494	Summary
09/10/2002	Committee referral announced in Parliament, 1st reading		
18/02/2003	Vote in committee, 1st reading		Summary
17/02/2003	Committee report tabled for plenary, 1st reading	A5-0038/2003	
11/03/2003	Decision by Parliament, 1st reading	T5-0069/2003	Summary
26/05/2003	Modified legislative proposal published	COM(2003)0304	Summary
28/09/2003	Council position published	09732/1/2003	Summary

09/10/2003	Committee referral announced in Parliament, 2nd reading		
25/11/2003	Vote in committee, 2nd reading		Summary
24/11/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0430/2003	
16/12/2003	Decision by Parliament, 2nd reading	T5-0562/2003	Summary
11/02/2004	End of procedure in Parliament		
12/02/2004	Final act signed		
18/02/2004	Final act published in Official Journal		

Technical information

Procedure reference	2002/0217(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amended by 2012/0261(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	LIBE/5/19351

Documentation gateway

Legislative proposal		COM(2002)0494 OJ C 020 28.01.2002, p. 0160 E	10/09/2002	EC	Summary
Committee draft report		PE319.257	13/01/2003	EP	
Committee opinion	ENVI	PE319.389/DEF	28/01/2003	EP	
Committee report tabled for plenary, 1st reading/single reading		A5-0038/2003	18/02/2003	EP	
Economic and Social Committee: opinion, report		CES0277/2003 OJ C 095 23.04.2003, p. 0022-0023	26/02/2003	ESC	
Text adopted by Parliament, 1st reading/single reading		T5-0069/2003 OJ C 061 10.03.2004, p. 0023-0075 E	11/03/2003	EP	Summary
Modified legislative proposal		COM(2003)0304	27/05/2003	EC	Summary
Council statement on its position		11228/1/2003	17/09/2003	CSL	
Council position		09732/1/2003 OJ C 277 18.11.2003, p. 0031-0044 E	29/09/2003	CSL	Summary
Commission communication on Council's position		SEC(2003)1073	07/10/2003	EC	Summary
Committee draft report		PE329.929	18/11/2003	EP	
Committee recommendation tabled for plenary, 2nd reading		A5-0430/2003	25/11/2003	EP	

Text adopted by Parliament, 2nd reading		T5-0562/2003 OJ C 091 15.04.2004, p. 0027-0068 E	16/12/2003	EP	Summary
Implementing legislative act		32005R1277 OJ L 202 03.08.2005, p. 0007-0033	27/07/2005	EU	Summary
Follow-up document		COM(2009)0709	07/01/2010	EC	Summary
Follow-up document		COM(2018)0159	27/03/2018	EC	
Follow-up document		COM(2020)0768	30/11/2020	EC	

Additional information

European Commission	EUR-Lex

Final act

Regulation 2004/273
OJ L 047 18.02.2004, p. 0001-0010 Summary

Final legislative act with provisions for delegated acts

Delegated acts

2018/2596(DEA)	Examination of delegated act
2016/2811(DEA)	Examination of delegated act
2022/2614(DEA)	Examination of delegated act
2020/2728(DEA)	Examination of delegated act

Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance

PURPOSE : to improve the system of drug precursors. CONTENT : the European Commission has presented a proposal for a new EU Parliament and Council Regulation aimed at improving the monitoring and control of EU trade in chemicals known as precursors, in order to prevent them being diverted towards the illegal manufacture of drugs and psychotropic substances The new proposal would strengthen the existing rules on a number of substances used in the production of some illegal drugs, such as heroine and cocaine. In addition it would include rules on licensing, customer declarations, labelling and a monitoring procedure. It would also take account of the changeable nature of the illicit manufacture and traffic of narcotic drugs, and thus align the new Regulation with other legal instruments, both at EU and at international level. By replacing the old Directive, the new Regulation would also simplify the legislation and would make it more user-friendly, both for economic operators and for the Competent Authorities in the Member States. By transforming the current Directive into a Regulation the Commission aims mainly at simplifying the legislation and thus making it more user-friendly. This becomes especially important in the context of the on-going process of enlargement of the European Union where each modification of the Directive and its annexes would have triggered national implementation measures in some twenty-five Member States. The current system, in operation since 1992, is based on a Council and European Parliament Directive, which has been instrumental in establishing good cooperation between EU institutions, Member States' authorities and economic operators, against illegal use. A further improvement to the current situation will be to oblige the Member States to distribute to economic operators information on how to recognise and notify suspect transactions so that economic operators inform the competent authorities of suspect transactions involving substances not currently mentioned in the Directive but which are nevertheless frequently used to manufacture synthetic drugs. The Commission, assisted by the Committee referred to in Article 15 of the new Regulation, will be responsible for drawing up and constantly updating the lists of products which are to be subject to such surveillance. These lists will be distributed to economic operators by the Member States. The Commission also proposes to define "non-scheduled substances" in conformity with Article 12(12)b of the United Nations Convention. As a final point, the Commission considers this a good opportunity to take into account the revision of the classification for Potassium Permanganate as well as for Acetic Anhydride to ensure that internal trade of these products will not be negatively affected.?

Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance

The committee adopted the report by Hubert PIRKER (EPP-ED, A) approving the proposal under the 1st reading of the codecision procedure, subject to just three amendments. In particular, it wanted Member States to be required to inform the Commission annually of the measures they have taken to comply with the regulation. It also proposed that the Commission evaluate the implementation of the regulation three years after its entry into force.?

Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance

The European Parliament adopted a resolution drafted by Hubert PIRKER (EPP-ED, Austria) by 445 votes for, 34 against and 14 abstentions, which makes a few amendments to the Commission's proposal. (Please refer to the document dated 18/02/03). Member States must inform the Commission annually of the measures taken pursuant to the Regulation.?

Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance

The Commission accepted one amendment made by Parliament. This is a new recital, which makes explicit the importance of this new instrument in the context of an enlarged EU. The other amendments were rejected. Since the Regulation will be directly applicable, it is not appropriate to require Member States to send an annual report to the Commission on implementing measures. In addition, the requirement for an evaluation three years after entry into force is not considered to bring added benefit. It should be noted that an evaluation of the current system has already taken place in 2002.?

Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance

The Council's common position, adopted unanimously, follows the general lines of the Commission's amended proposal. It incorporates certain measures deemed necessary to take account of the direct applicability of the Regulation to operators and Competent Authorities. The Council accepted the only amendment accepted by the Commission which proposes the inclusion of a new recital making explicit the importance of the new instrument in the context of an EU that will comprise, from next year, 25 Member States. Of the three amendments adopted by the Parliament, one has been fully accepted, one has been rejected and the third one has been partially accepted. These are as follows: - this amendment proposes the inclusion of a new recital making explicit the importance of the new instrument in the context of an EU that will comprise, from next year, 25 Member States. It has been accepted; - this amendment would require a yearly updating of the list of non-scheduled substances subject to voluntary monitoring measures by operators. This list is currently reviewed and, if necessary, modified at each meeting of the Committee, which meets four times per year. The proposed amendment therefore entails no improvement to the system. It has been therefore rejected; - the third includes in fact two different ones. The first part would oblige Member States to send an annual report to the Commission on implementing measures, although the Regulation will only be implemented once by each Member State. It has been rejected because it did not improve the Commission's proposal. The second part of the amended has been accepted. It requires the Commission to evaluate the functioning of the Regulation 3 years after its entering into force. In addition to the accepted amendments, the new text includes certain modifications to take account of the direct applicability of the new Regulation. These modifications intend to include in the text of the legal instrument some implementation procedures. They harmonise throughout all Member States the way in which the system is being applied by operators and Competent Authorities. New requirements have been adopted by the Council concerning the placing on the market of scheduled substances: - to provide for the appointment by the operator of a particular person to monitor that trade in scheduled substances is in compliance with the Regulation. This provision enables the competent national authorities to assess whether a particular operator should be granted a licence; - to introduce the requirement for operators to hold a licence before they possess scheduled substances, to facilitate more effective control. In addition, the common position allows the competent authorities to exempt certain categories of public authorities and operators from some of the obligations relating to the renewal of licences and the documentation required for transactions. This exemption is provided for through the issue of a special licence and registration. Exemption rules have been included in order to avoid creating an excessive administrative burden for the competent authorities and certain categories of operators. With regard to the introduction of the exemptions, the Council has added a provision stating that competent authorities shouldrefuse to issue a licence if there are reasonable grounds to consider the applicant unsuitable. A new paragraph has been inserted to empower the competent authorities either to limit the duration of validity of the licence or to seek proof that the conditions for granting the licence are still valid. This insertion allows stricter enforcement of the Regulation. The common position also states that competent authorities, in accordance with national practice in some Member States, should be allowed to request a fee for licence or registration, which shall not exceed the administrative costs incurred. Lastly, a series of new measures have been introduced concerning: - documentation provided by operators who hold special licences or are subject to special registration and the possibility for electronic means of storing documentation; - information required from operators on transactions involving scheduled substances; - powers and obligations of competent authorities; - implementation procedure with a view to providing implementing measures in order to determine the requirements and conditions for the granting of licences; - the obligation for Member States to inform the Commission about the measures they take with regard to penalties and to performing their control and monitoring duties. The common position also : - adds a title to Annex I; - corrects the CN code and CAS number for Norephedrine; - adds references to stereoisomeric forms of the substances listed in Category 1, wherever possible; - excludes cathine from the substances included in Category 1; and adds technical explanatory notes.?

Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance

The Commission supports the Common Position because it is in line with the objectives of its proposals.?

Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance

The committee adopted the report by Hubert PIRKER (EPP-ED, A) approving the Council's common position without amendment under the 2nd reading of the codecision procedure.?

Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance

The European Parliament adopted the resolution drafted by Hubert PIRKER (EPP-ED, A) and approved the common position.?

Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance

PURPOSE : To control the sale of drug precursors on the open market.

LEGISLATIVE ACT : Regulation 273/2004/EC of the European Parliament and of the Council on drug precursors.

CONTENT : The stated purpose of this Regulation is to harmonise measures for the intra-Community control and monitoring of certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances. It is an update of existing Directives and has been created in order to simplify the implementation of its provisions following the accession of the new Member States in May 2004.

The Regulation provides a list of definitions including classifications for "scheduled substance", "non-scheduled substance", "placing on the market", "operator" "international Narcotic Control Board", "special license" and "special registration". The substances covered by the provisions of this Regulation are listed in Annex I to the Regulation.

Before substances are allowed onto the market operators must fulfil certain requirements. These include, for example,

- The appointment of special officers;
- Requiring operators to obtain special licenses from competent authorities before scheduled substances can be placed on the market. Special licenses may be granted by the competent authorities to pharmacies, dispensaries of veterinary medicine, certain types of public authorities and the armed forces;
- Prior to granting a license competent authorities must take into account the competence and integrity of the applicant. If there are any grounds for doubting the suitability of the applicant a licence can be refused. Similarly, the licence can be suspended if there are grounds to believe that the holder is no longer fit for holding such a licence;
- In the case of category 2 substances, operators are required to register and update the addresses from which they trade and/or manufacture. Pharmacies, dispensaries of veterinary medicine, certain types of public authorities or the armed forces may be given a special registration.

Other additional measures include:

- A customer declaration stating the use of a substance. A separate declaration is required for each separate substance;
- Proper documentation on the sale of substances;
- Commercial documents must contain information such as the name of the substance, the quantity and weight of the substance and the name/address of the supplier, distributor, consignee etc involved in any transactions;
- Documentation must be kept for at least three years and must be readily available for inspection;
- Operators must ensure that labels are affixed to scheduled substances before they are supplied, and
- Notification to the competent authorities in case of unusual orders or transactions involving scheduled substances.

The Commission will regularly draw up guidelines on how to recognise and notify suspect transactions as well as updated lists of non-scheduled substances. Member States are asked to co-operate closely with each other when applying the Regulation's provisions. They are also responsible for laying down infringement penalties.

Lastly, the competent authorities are obliged to send annual reports to the Commission on theimplementation of the measures outlined above.

ENTRY INTO FORCE: 18/08/2005 (Articles 9, 14 and 15 shall enter into force on 18/02/2004).

Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance

LEGISLATIVE ACT: Commission Regulation 1277/2005/EC laying down implementing rules for Regulation 273/2004/EC of the European Parliament and of the Council on drug precursors and for Council Regulation 111/2005/EC laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

CONTENT: Regulation 273/2004/EC on drug precursors harmonises the provisions concerning the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances within the Community. In order to enhance the

smooth operation of the internal market, for the trade in drug precursors, the provisions for the application for a licence, the granting or refusal of the granting of a licence, its suspension or revocation, are harmonised at Community level. This Regulation lays down rules for the implementation of Regulations 273/2004/EC and 111/2005/EC as regards the responsible officer, the licensing and registration of operators, the provision of information, pre-export notifications and authorisation of exports and imports in the field of drug precursors.

The following points should be noted:

-Since it is important to avoid the unauthorised removal of Category 1 substances, the business premises where these substances are stored or used must be secured against unauthorised removal.

-The competent authority must take a decision on the application for licences within 60 working days from the date of receipt of that application. In the case of a renewal of a licence, the decision shall be taken within 30 working days. There is a model licence set out in Annex I.

-The Regulation contains provisions on the types of operators engaged in intra-Community trade who may benefit from special licences and special registrations. It sets out the cases where operators engaged in trade between the Community and third countries may be exempted from the licensing and registration requirement.

-The provisions governing the licence conditions and the notification obligations of operators engaged in intra- Community trade and trade between the Community and third countries will, to the extent possible, be identical.

-The Regulation contains provisions allowing the verification of the licit purposes of all drug precursor consignments entering the Community customs territory, including, in particular, transit and transhipment consignments and sensitive areas such as Community free zones.

-Specific import authorisation procedures are set out to monitor individual import consignments of Category 1 substances in order to prevent diversion at an early stage and in particular to address the growing problem of amphetamine-type stimulants.

- Detailed rules concerning pre-export notification should allow it to adapt the information transfer and the necessary type of response to the sensitivity of the export consignment. In order to fully exploit the pre-export notification and export authorisation system, efforts should in principle target high risk consignments. Detailed rules on the simplified use of pre-export notifications and the granting of export authorisations by simplified procedure should allow the easing of the administrative burden for mass chemicals with common licit uses.

-In view of an efficient monitoring of trade Member States must enable the competent authorities to exchange information.

-To improve the coordination of the monitoring of drug precursors Member States must provide the Commission regularly with information on the prevention of the diversion of drug precursors.

ENTRY INTO FORCE: 03/08/2005

DATE OF IMPLEMENTATION: from 18/08/2005.

Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance

The Commission presents its report on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors. The current regulatory framework of the Community for drug precursors is made up of Regulation (EC) No 273/2004, which lays down harmonised rules for the intra-Community control and monitoring, and Regulation (EC) No 111/2005, which lays down the rules governing the monitoring of the trade between the Community and third countries in drug precursors. The report examines Community legislation, including guidance documents, mutual administrative assistance, the EU Action Plan on Drugs, actions under the Customs 2013 Programme, bilateral agreements and actions at UN level. It describes Commission actions taken to evaluate the implementation and functioning of the Community legislation.

Findings: overall, the provisions of Regulation (EC) No 273/2004, Regulation (EC) No 111/2005 and the implementing rules contained in Regulation (EC) No 1277/2005 function well and reach the objective pursued, i.e. prevention of diversion without creating unnecessary barriers to the legitimate trade activities for the scheduled drug precursors. Control and monitoring focus on operators rather than on each transaction. The implementation and functioning of the common licensing system introduced for intra- Community trade and for the trade between the Community and third countries for operators handling precursors in Category 1 (the most sensitive substances) proves to work efficiently from both the competent authorities' and industry's perspectives.

However, the registration requirement for operators handling somewhat less sensitive precursors in Category 2 both as regards intra-Community trade and trade between the Community and third countries appears to be insufficient to allow adequate control by competent authorities and prevention of diversion from the important volume of intra-Community trade within these substances. In fact, end-users of Category 2 substances, who do not place on the market the substances, are neither required to register nor to report the quantities they buy for their own end-use. Thus they are hardly known to competent authorities. It is also very difficult for manufacturers or brokers of Category 2 substances to exercise their obligation to check the legitimacy of their customers and of the reported end-use of the substance and consequently to notify as appropriate any suspicious transaction to the competent authorities. The control by competent authorities of the legitimacy of operators is difficult and even more when the manufacturers/brokers and the end-users of the Category 2 substances are based in different Member States, and when the trade chain involves more than two entities based in more than one Member State. These problems have been highlighted particularly for acetic anhydride, a key precursor for illicit heroin manufacture.

The evaluation found differing interpretation of some legislative provisions that would need to be addressed in order to facilitate their correct harmonised implementation within the Community. This includes in particular the application of existing thresholds for exemption of registration for mixtures containing Category 2 substances in accordance with Article 6 of (EC) No 273/2004, when compared to the wording of Article 14 of Regulation (EC) No 1277/2005.

The provisions regarding the frequency of reporting by the operator to the competent authorities does not provide sufficient basis for carrying out the control and monitoring duties. An overview of the legal trade movements constitutes an important instrument to detect suspicious consignments.

Pharmaceutical preparations / medicinal products for human use containing drug precursors are currently excluded from the scope of the drug precursor legislation. The manufacture, import and wholesale distribution of medicinal products, including products for export is subject to an authorisation, specific obligations and regular inspections in line with Community pharmaceutical legislation (Directive 2001/83/EC). Therefore it is considered that these activities should be under sufficient systematic control by Member States' competent authorities. However, such manufacturers, importers and wholesale distributors are not subject to specific pre-notification requirements from drug precursors' legislation when exporting those medicinal products which contain drug precursors. This has led to a situation where in some Member States exports and transit/transhipments of pharmaceutical preparations/medicinal products containing drug precursors - in particular ephedrine or pseudoephedrine - have not been seized even though it was very likely that they would be misused for illicit drug manufacture.

There appear to be further minor weaknesses related to the precursor legislation regarding the external trade. These include in particular the lack of flexibility for competent authorities as regards the period required to wait for the response to pre-export notifications, the lack of simplified authorisation procedures for repetitive consignments between well-known operators in the Community and in the EFTA countries, and the need to further streamline the authorising procedures with the electronic customs environment.

Recommendations: the Commission suggests the following:

- improving harmonised implementation of the current legislation;
- enhancing reporting by increasing the reporting frequency and using modern secured electronic means of exchanging information;
- modifying some requirements for Category 2 substances specifically for acetic anhydride;
- ensuring appropriate control of pharmaceutical preparations/medicinal products containing ephedrine or pseudo-ephedrine;
- improving procedural requirements with regard to the risk of diversion.

The Commission notes that any option pursued would need to be carefully examined in particular towards its impact on economic operators legally trading those substances for legitimate purposes and its effectiveness in preventing their diversion for the illicit drug manufacture.