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[…]

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Amending Regulation (EC) No 273/2004 on drug precursors

(Text with EEA relevance)

{SWD(2012) 278 final}
{SWD(2012) 279 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

General Context

Many chemicals are used in a wide variety of important industrial processes (e.g. in the synthesis of plastics, pharmaceuticals, cosmetics, perfumes, detergents and aromas) and they are traded for these licit uses on regional and global markets. Some of these chemicals can, however, be misused for the illicit manufacture of narcotic drugs and psychotropic substances. The chemicals produced for a licit purpose which can be misused in the illegal drug production are called **drug precursors**.

Drug precursors are rarely produced by the criminals that intend to use them in the illicit manufacture of drugs, as their production often requires important industrial infrastructure. Therefore, criminals try to **divert these substances from the licit trade**.

The trade in drug precursors is not in itself prohibited because of their important legitimate uses. 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 (hereafter referred as UN 1988 Convention). The European Union 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. This **industry-authority partnership** is key to the well functioning of the regulatory framework.

Public authorities monitor that companies dealing with drug precursors properly exercise their obligations under the legislation by conducting on-site inspections and via administrative procedures such as granting licences and registrations.

Grounds for and objectives of the proposal

Traffickers purchase the drug precursors they need from different regions of the world and exploit weaknesses of control to their benefit. 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 AA happened in the EU. **Heroin use** has been contributing to public health problems in Europe since the 1970s. It still accounts for the greatest share of morbidity and mortality-related drug use in the European Union.

Even though the quantities of AA seized in the EU have decreased very substantially since 2008, the INCB[1] continues to mention in its annual reports that the European legislative

[1] United Nations' International Narcotics Control Board.

control measures are not sufficiently strict to prevent the diversion of the main heroin precursor from the intra-EU trade.

On 7 January 2010, the European Commission adopted a **Report on the implementation and functioning of the existing EU legislation on drug precursors**[2] which concluded that the legislation is overall functioning well but also identified some weaknesses and made recommendations how to address these[3].

This proposal addresses, by amending Regulation (EC) No 273/2004, the recommendation of the Commission Report **to improve the prevention of the diversion** from the EU-internal trade of **AA, the main drug precursor for heroin,** by **extending the registration requirement**, which so far applies only to operators placing AA on the market, to also include users of the substance and by enhancing the harmonised registration provisions to achieve a more robust level playing field preserving the internal market and avoiding adoption of divergent national measures.

Consistency with other policy and objectives of the Union

This proposal is fully consistent with the objectives of the EU Drugs Strategy 2005-2012[4] and the EU Drugs Action Plan (2009-2012)[5], which set out the objective to reduce the diversion and trafficking in/via the Union of drug precursors used for the production of illicit drugs.

As the drug problem is a complex phenomenon, it requires a multidisciplinary approach of combining *demand* and *supply reduction*[6]. Preventing the diversion and trafficking of drug precursors **aims at reducing the *supply* of illicit drugs** – the ultimate objective being a high level of protection, well-being and social cohesion for EU citizens by preventing and reducing drug use in line with the EU Drug Strategy. The European Commission Services are currently carrying out an evaluation of the 2005-2012 EU Drugs Strategy; in preparation of the EU Drug Strategy from 2013[7]. This evaluation is, however, not questioning the pillar 'supply reduction' (which includes the prevention of diversion of drug precursors) and the Union being a Party to Article 12 of the 1988 UN Convention is in any case bound to work towards the objective of preventing the diversion of drug precursors.

A high level of **human health protection** is a basic principle of the Treaty, which shall be ensured in the definition and implementation of all policies and activities of the EU. The control of drug precursor diversion contributes to the protection of human health, specifically

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2 Report from the Commission to the Council and the European Parliament pursuant to Article 16 of Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 and to Article 32 of Council Regulation (EC) No 111/2005 on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors, COM(2009)709 final, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0709:FIN:en:PDF.

3 For further details, see under Section 4.2.2 "Strength and weaknesses of the legislation" of the above-mentioned Report COM(2009)709 final.

4 EU Drugs Strategy 2005-2012, endorsed by the European Council of November 2004 (15074/04 CORDROGUE 77 SAN 187 ENFOPOL 187 RELEX 564).

5 EU Drugs Action Plan for 2009-2012 (2008/C 326/09).

6 The EU Drug Strategy additionally complements these two key dimensions with three cross-cutting themes: coordination; international cooperation and information; research and evaluation.

7 For further details see http://ec.europa.eu/justice/newsroom/anti-drugs/opinion/111027_en.htm.

in the area of drugs-related health damage where the Treaty invites the Union to complement Member States' actions on prevention of drug-use[8].

In addition, the initiative is also in line with the principle of the Treaty that the Union shall endeavour to ensure a **high level of security** through measures to prevent and combat crime, and through measures for coordination and cooperation between police and other competent authorities[9].

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

Consultations of interested parties, collection and use of expertise

The Commission Services consulted in 2009 and early 2010 all stakeholders on the implementation of Regulation (EC) No 273/2004 and presented its findings in a Report to the European Parliament and the Council, which was adopted on 7 January 2010[10]. In May 2010, the Council adopted conclusions on the Commission's Report, recognising the importance of continuing active co-operation among authorities and industry and of improving the implementation of the European legislation. The Council invited the Commission to set up a work programme to address the identified weaknesses of the legislation in co-operation with Member States and to propose legislative amendments before the end of 2011 after carefully assessing their potential impacts on Member States authorities and economic operators[11].

The Commission subsequently developed six potential policy options (see the next section for details) and discussed them with the Member States and industry representatives in a special meeting of the Drug Precursor Working Group in June 2010.

Member States and industry stakeholders were further consulted on the six options via a written consultation, carried out from 23 July to 18 October 2010. Three main target groups were identified: manufacturers and traders (operators), end-users and competent authorities of Member States. In addition, an SME-consultation was carried out via the Enterprise Europe network from 1 October until 24 November 2010 to ensure that the concerns of a specific target group – end-users of drug precursors most of which are SMEs – were considered.

Finally, the Commission mandated a study to an external consultant to evaluate in detail the administrative costs on companies and authorities that would result from each of the policy options.

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:

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8 Article 168 TFEU (Treaty on the Functioning of the European Union).

9 Article 67 TFEU.

10 See footnote 1.

11 Council conclusions on the functioning and implementation of the EU drug precursor legislation – 3016th Competitiveness Council meeting Brussels, 25 May 2010.

– 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 AA from category 2 to category 1 scheduled substances.

For options 2 to 5, two sub-options were analysed, i.e. to either limit them specifically to AA or to apply them to all scheduled substances in category 2.

The overall conclusion of the impact assessment[12] was that both, option 4 (for only AA) and option 5 (for only AA) would be good choices to address the identified objectives. Both would have effects on SMEs as end-users dealing with AA are primarily SMEs, 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) AA end-users is lacking in the European legislation, and the somewhat lower burden on SMEs tip the balance in the end in favour of option 5.

3. LEGAL ELEMENTS OF THE PROPOSAL

Legal basis

The legal basis of the proposal is Article 114 of the Treaty on the Functioning of the European Union (TFEU). Article 114 has the objective to establish an internal market while ensuring a high level of protection of human health and the environment.

Subsidiarity principle

The subsidiarity principle as set out in Article 5(3) of the Treaty on the European Union applies insofar as the proposal does not fall under the exclusive competence of the Union.

The general objective of Regulation (EC) No 273/2004 is to prevent the diversion of drug precursors from legitimate trade in accordance with the Union's obligations under Article 12 of the 1988 UN Convention. It contributes to the world-wide combat against the illicit production and trafficking of narcotic drugs and psychotropic substances, while ensuring a proper functioning of the internal market for drug precursors by subjecting operators to the same, harmonised rules within the EU whilst avoiding unnecessary obstacles to legitimate trade and administrative burden for enterprises and competent authorities.

[12] The report on the impact assessment is available at: http://ec.europa.eu/governance/impact/ia_carried_out/cia_2012_en.htm.

The objective of this proposal, namely to strengthen control measures on AA in order to prevent it diversion from the EU internal market while avoiding market distortions, cannot be sufficiently achieved by the Member States alone and action by the Union will be more efficiently achieved for the following reasons:

– Some Member States feel legally prevented from adopting national control measures going beyond the EU legislation on the basis of Article 10 of Regulation (EC) No 273/2004, which empowers Member States to adopt national measures which are necessary to enable its authorities to perform their control and monitoring duties. They argue that the EU legislation is subjecting only *operators* to control measures (no obligations are imposed on end-users), which should be understood as a deliberate and binding decision of the EU-legislator that end-users should *not* be subject to the control of the drug precursor legislation

– On the contrary, other Member States are contemplating or have already based substantive national controls on Article 10, leading in first instance to different approaches of control in different Member States which might be detrimental to the functioning of the Union Market and, secondly, isolated actions in individual Member States risks shifting the problem from one Member State to the next, as traffickers will exploit the "weakest link" in the Union market. A combination of different national measures will not be as effective as a harmonised approach at EU-level. This is also confirmed by the fact that both, Member States and concerned industry sectors have called on the Commission to act to preserve the internal market with a level playing field, and not to rely too much on supplementary national measures.

Proportionality principle

The proposal does not go beyond what is necessary in order to achieve the intended objectives, in accordance with the principle of proportionality, as set out in Article 5(4) of the Treaty on European Union. By preventing the diversion of drug precursor from the legal trade to illicit drug production, this proposal is expected to contribute to the fight against illicit trafficking in narcotic drugs and psychotropic substances, and consequently to protect citizens from the health damage related to drug addiction. Furthermore by ensuring that operators and users engaged in the legal trade of those drug precursors are subject to harmonised rules, it should 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.

The proposal only tackles the weaknesses identified in the evaluation on the functioning and on the implementation of the Regulations on Drug Precursors, namely by requiring registration not only for operators placing AA on the market but also for users possessing it for their own uses or processes (i.e. end-users). The proposal does not extend the envisaged provisions for AA to other scheduled substances in category 2.

Choice of the instrument

The chosen legal instrument is a Regulation as it aims to harmonise the rules applicable to economic operators (end-users) dealing with AA for their own uses or processes. It amends the already existing Regulation (EC) No 273/2004.

Main provisions of the proposal

The proposal introduces the requirement that end-users of AA must obtain a registration as already exists for operators placing the substance on the market, and strengthens the rules for registration.

Additionally it 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.

Finally, the draft Regulation adapts the provisions of Regulation (EC) No 273/2004 regarding ex-Comitology to the new rules of the Lisbon Treaty.

4. BUDGETARY IMPLICATION

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. Therefore it does not have a budgetary impact over and above the appropriations already foreseen for the years to come in the official programming of the Commission.

5. ADDITIONAL INFORMATION

– The proposal is subject to a notification to the WTO in the framework of the TBT Agreement.

– The proposed act is relevant for the European Economic Area (EEA).

– The proposed act contains transitional period for the coming into force of the new registration obligations for end-users of AA.

– The proposed act includes a review clause to assess whether the amended Regulation will have been effective to prevent the diversion of AA.

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REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Amending Regulation (EC) No 273/2004 on drug precursors

(Text with EEA relevance)

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 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],

Having regard to the opinion of the European Data Protection Supervisor[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Pursuant to Article 16 of Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors[3], the Commission adopted on 7 January 2010 a report to the Council and the European Parliament on the implementation and functioning of the existing EU legislation on drug precursors[4].

(2) In that report, the Commission recommended further 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.

(3) In its Conclusions on the functioning and implementation of the EU drug precursor's legislation of 25 May 2010, the Council invited the Commission to propose legislative amendments after assessing their potential impacts on competent authorities and economic operators.

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1 OJ C , , p. .

2 OJ C…p….

3 OJ L 47, 18.2.2004, p. 1.

4 Report from the Commission to the Council and the European Parliament pursuant to Article 16 of Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 and to Article 32 of Council Regulation (EC) No 111/2005 on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors, COM(2009)709 final.

(4) The definition of scheduled substances should be clarified: the term 'pharmaceutical preparation' stemming from the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988, (hereinafter referred to as the "United Nations Convention") should be replaced by the relevant terminology of the Union legislation, 'medicinal products', and the term 'other preparations' should be deleted as it duplicates the term 'mixtures' already used in the definition.

(5) A definition of the term 'user' should be introduced for companies possessing substances for purposes other than placing them on the market.

(6) It should be clarified that companies using scheduled substances in category 1 for other purposes than placing them on the market are obliged to obtain a licence.

(7) 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. For substances scheduled in a new subcategory 2A of Annex I, not only operators but also users should be subject to a registration requirement.

(8) In order to safeguard the competitiveness of microenterprises, no fees should be imposed on them for obtaining a registration or a licence.

(9) Explicit provisions should be foreseen to clarify 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.

(10) A European database on drug precursors should be created to simplify the reporting by Member States with regard to seizures and stopped shipments, to create a European register of operators and users holding a license or a registration which will facilitate verification of the legitimacy of commercial transactions involving scheduled substances, and to enable operators to provide the competent authorities with information about their legal transactions involving scheduled substances.

(11) Regulation (EC) No 273/2004 envisages the processing of data. Such processing of data may also cover personal data which should be carried out in accordance with Union Law.

(12) Acetic anhydride, currently scheduled in category 2 of Annex I, should be included in a new subcategory 2A of Annex I to allow increased control of its trade. The remaining substances of category 2 should be listed as subcategory 2B.

(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 of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[5] as amended by Council Decision 2006/512/EC[6].

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5 OJ L 184, 17.7.1999, p. 23.

6 OJ L 200, 22.7.2006, p. 11.

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

(15) In order to achieve the objectives of Regulation (EC) No 273/2004, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission to specify the requirements and conditions for the granting of the licence and registration, for obtaining and using customer declarations, for the documentation and labelling of mixtures, for provision of information by the operators on transactions involving scheduled substances, for listing operators and users having obtained a licence or registration in the European register and in order to amend the Annexes. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(16) The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

(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 of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers[7].

(18) 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; to set up details on how to provide the information about transactions of operators with scheduled substances to a European database.

(19) Since the objectives of this Regulation, namely to strenghen the rules for registration of operators placing on the internal market or possessing scheduled substances of category 2, in particular acetic anhydride, in order to prevent its diversion towards the illicit production of drugs, cannot be sufficiently achieved by Member States because traffickers gain from national differences in registration and move their illicit business where drug precursors are easiest to divert and can therefore be better achieved at the level of the Union, 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 those objectives.

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

[7] OJ L 55, 28.2.2011, p. 13.

HAVE ADOPTED THIS REGULATION:

Article 1

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

(1) Article 2 is amended as follows:

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

"(a) 'scheduled substance' means any substance used for the illicit manufacture of narcotic drugs or psychotropic substances and listed in Annex I including mixtures and natural products containing such substances. This excludes natural products and mixtures 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 and medicinal products within the meaning of Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council[8];"

(b) the following point (h) is inserted:

"(h) 'user' means any natural or legal person 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."

(2) Article 3 is amended as follows:

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

"2. Operators and users shall be required to obtain a licence from the competent authorities before they may possess or place on the market scheduled substances of category 1 of Annex I. Special licences may be granted by the competent authorities to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or armed forces. Such special licences shall only be valid 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 referred to in paragraph 2 shall supply scheduled substances of category 1 of Annex I only to operators or users who hold such a licence and have signed a customer declaration as provided for in Article 4(1)."

(b) paragraph 5 is replaced by the following:

"5. Without prejudice to paragraph 9, the competent authorities may either limit the validity of the licence to a period not exceeding three years or may oblige the operators to demonstrate at intervals not exceeding three years that

[8] OJ L 311, 28.11.2001, p. 67.

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 substances concerned. Special licences within the meaning of paragraph 2 shall be granted in principle for an unlimited duration but may be suspended or revoked by the competent authorities under the conditions of paragraph 4, third sentence."

(c) paragraph 6 is replaced by the following:

"6. From [18 months after the date of publication] operators shall be required to obtain a registration from the competent authorities before placing on the market scheduled substances of category 2 of Annex I. Furthermore, users shall be required to obtain a registration from the competent authorities before possessing scheduled substances of subcategory 2A of Annex I. Special registrations may be granted by competent authorities to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or the armed forces. Such registrations shall be considered valid only for the use of scheduled substances of category 2 of Annex I within the scope of the official duties of the operators or users concerned."

(d) the following paragraphs 6a and 6b are inserted:

"6a. Any operator holding a registration referred to in paragraph 6 shall supply scheduled substances of subcategory 2A of Annex I only to other operators or users who hold such a registration and have signed a customer declaration as provided for in Article 4(1).

6b. When considering whether to grant a registration, the competent authorities shall take into account in particular the competence and integrity of the applicant the registration is to be refused 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. The registration may be suspended or revoked by the competent authorities whenever there are reasonable grounds for believing that the holder is no longer a fit and proper person to hold a registration, or that the conditions under which the registration was granted are no longer fulfilled."

(e) in paragraph 7, the following sentence is added:

"An operator or user who is a microenterprise within the meaning of Article 2(3) of the Annex to the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized companies[9] shall not be required to pay any such fees."

(f) the following paragraphs 8 and 9 are added:

"8. The competent authorities shall enter operators and users having obtained a licence referred to in paragraph 2 or a registration referred to in

[9] OJ L 124, 20.5.2003, p.36.

paragraph 6 in a European Database on drug precursors to be developed by the Commission as provided for in Article 13a.

9. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning:

(a) the requirements and conditions for the granting of the licence referred to in paragraph 2;

(b) the requirements and conditions for the granting of the registration referred to in paragraph 6.

(c) the requirements and conditions for listing operators and users having obtained a licence or registration in a European Database on drug precursors referred to in paragraph 8."

(3) Article 4 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. Without prejudice to paragraph 4, Articles 6 and 14, any operator established within the Community who supplies a customer with a scheduled substance of categories 1 or 2 of Annex I shall obtain a declaration from the customer which shows the specific use or uses of the scheduled substances. A separate declaration shall be required for each scheduled substance. This declaration shall conform to the model set out in point 1 of Annex III. In the case of legal persons, the declaration shall be made on headed notepaper."

(b) the following paragraph 4 is added:

"4. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for obtaining and using customer declarations."

(4) In Article 5, the following paragraph 7 is added:

"7. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for the documentation of mixtures containing substances listed in Annex I."

(5) In Article 7, the following second paragraph is added:

"The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for the labelling of mixtures containing substances listed in Annex I."

(6) Article 8 is replaced by the following:

"1 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 this end,

operators shall provide any available information allowing the competent authorities to verify the legitimacy of the relevant order or transaction.

2. Operators shall provide the competent authorities in summary form with relevant information about their transactions involving scheduled substances.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for operators to provide information as referred to in paragraph 2."

(7) In Article 9, paragraph 1 is replaced by the following:

"In order to facilitate cooperation between the competent authorities, the operators, and the chemical industry, in particular as regards non-scheduled substances, the Commission shall draw up and update guidelines to assist the chemical industry."

(8) In Article 10, paragraph 2 is replaced by the following:

"2. Each Member State may adopt the measures necessary to enable its competent authorities to control and monitor suspicious transactions with non-scheduled substances, in particular:

(a) to obtain information on any orders for non-scheduled substances or operations involving non-scheduled substances;

(b) to enter operators' business premises in order to obtain evidence of suspicious transactions with non-scheduled substances.

3. The competent authorities shall respect confidential business information."

(9) The following Article 13a is inserted:

"*Article 13a*

Database

The Commission shall develop a European Database on drug precursors with the following functions:

(a) facilitating the communication of information pursuant to Article 13(1), its synthesis and analysis on the level of the Union, and the reporting to the International Narcotics Control Board pursuant to Article 13(2);

(b) creating a European register of operators and users, which have been granted a licence pursuant to Article 3(2) or registration pursuant to Article 3(6);

(c) enabling operators to provide the competent authorities with information about their transactions according to Article 8(2) in electronic form, as specified in implementing measures adopted pursuant to Article 14."

(10) The following Article 13b is inserted:

"*Article 13b*

Data protection

1. The processing of personal data by the competent authorities in the Member States shall be carried out in accordance with Directive 95/46/EC[10] and under the supervision of the public independent authority of the Member State referred to in Article 28 of this Directive.

2. The processing of personal data by the Commission, including for the purpose of the European Database provided for in Article 13a, shall be carried out in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council[11] and under the supervision of the European Data Protection Supervisor."

(11) Articles 14 and 15 are replaced by the following:

"*Article 14*

Implementing Acts

1. The Commission may adopt the following implementing acts:

(a) rules on how to provide customer declarations referred to in Article 4 in electronic form, where appropriate;

(b) rules on how to provide the information referred to in Article 8(2) in electronic form to a European database, where appropriate.

2. The acts referred to in paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 14a(2).

Article 14a

Committee Procedure

1. The Commission shall be assisted by the Drug Precursors Committee established by Article 30 of Council Regulation (EC) No 111/2005[12]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. When reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 15

Adaptation of Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 15a in order to adapt Annexes I, II and III to new trends in diversion of drug

[10] OJ L 281, 23.11.1995, p. 31.
[11] OJ L 8, 12.1.2001, p. 1.
[12] OJ L 22, 26.1.2005, p.1.

precurors and to follow an amendment to the tables in the Annex to the United Nations Convention.

Article 15a

Exercise of delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Article 3(9), 4(4), 5(7), 7**,** 8(2), 13a(2), 15 shall be conferred for an indeterminate period of time from [date of entry into force of this amending Regulation].

3. The delegation of powers referred to in Article 3(9), 4(4), 5(7), 7, 8(2), 13a(2), 15 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power spedified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and the Council.

5. A delegated act adopted pursuant to Article 3(9), 4(4), 5(7), 7, 8(2), 13a(2), 15 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliamant and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council."

(12) Article 16 is replaced by the following:

"*Article 16*

Information about measures adopted by Member States

1. Member States shall inform the Commission of the measures it adopts pursuant to this Regulation, and in particular of the measures adopted pursuant to Articles 10 and 12. They shall also notify any subsequent amendments thereof.

2. The Commission shall communicate that information to the other Member States.

3. The Commission shall evaluate the implementation and functioning of this Regulation by [78 months after of the date of entry into force of this amending Regulation]."

(13) Annex I is amended as follows:

(a) the title of Annex I is replaced by the following:

"List of scheduled substances";

(b) the text set out for Category 2 is replaced by the text set out in the Annex to this Regulation;

(14) In Annex III, the term "authorisation/" shall be deleted.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.* This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX

"CATEGORY 2

SUBCATEGORY 2A

Substance	CN designation (if different)	CN code[1]	CAS No[2]
Acetic anhydride		2915 24 00	108-24-7

The salts of the substances listed in this category, whenever the existence of such salts is possible.

---

(1) OJ L290, 28.10.2002, p.1.

(2) The CAS No is the 'chemical abstracts service registry number', which is a unique numeric identifier specific to each substance and its structure. The CAS No is specific to each isomer and to each salt of each isomer. It must be understood that the CAS Nos for the salts of the substances listed above will be different to those given.

SUBCATEGORY 2B

Substance	CN designation (if different)	CN code[1]	CAS No[2]
Phenylacetic acid		2916 34 00	103-82-2
Anthranilic acid		2922 43 00	118-92-3
Piperidine		2933 32 00	110-89-4
Potassium permanganate		2841 61 00	7722-64-7

The salts of the substances listed in this category, whenever the existence of such salts is possible.

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(1) OJ L290, 28.10.2002, p.1.

(2) The CAS No is the 'chemical abstracts service registry number', which is a unique numeric identifier specific to each substance and its structure. The CAS No is specific to each isomer and to each salt of each isomer. It must be understood that the CAS Nos for the salts of the substances listed above will be different to those given.

LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

1.2. Policy area(s) concerned in the ABM/ABB structure

1.3. Nature of the proposal/initiative

1.4. Objective(s)

1.5. Grounds for the proposal/initiative

1.6. Duration and financial impact

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2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

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3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

3.2.2. Estimated impact on operational appropriations

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.4. Compatibility with the current multiannual financial framework

3.2.5. Third-party participation in financing

3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 273/2004 on Drug Precursors

1.2. Policy area(s) concerned in the ABM/ABB structure[25]

Title 2: Enterprise and Industry

Chapter 02.03: Internal market for goods and sectoral policies

1.3. Nature of the proposal/initiative

☐ The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action**[26]

X The proposal/initiative relates to **the extension of an existing action**

☐ The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objectives

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

1a. Competitiveness for growth and employment

Following the continuous review of existing internal market acquis and its implementation, the new legislative proposal aims at improving efficiency of exiting legislation on drug Precursors.

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Specific objective No.

The development of a European Database aims at facilitating exchange of information between the Member States Competent Authorities and the Commission, and the economic operators and the Member States Competent Authorities.

ABM/ABB activity(ies) concerned

Title 2 – Chapter 02.03 Internal market for goods and sectoral policies

25 ABM: Activity-Based Management – ABB: Activity-Based Budgeting.

26 As referred to in Article 49(6)(a) or (b) of the Financial Regulation.

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The proposal, amending Regulation (EC) No 273/2004 aims mainly at improving the prevention of the diversion from the EU-internal trade of **acetic anhydride, the main drug precursor for heroin,** by extending the registration requirement, which so far applies only to operators placing acetic anhydride on the market, to also include users of the substance and by enhancing the harmonised registration provisions to achieve a more robust level playing field preserving the internal market and avoiding adoption of divergent national measures.

Additionally, it proposes to establish and maintain a European Database on Drug Precursors in order to modernize the annual collection of the information provided by Member States on seizures and stopped shipments of drug precursors, in accordance with Article 13 of Regulation (EC) No 273/2004, as well as to maintain a list of EU licensed or registered operators and users legally trading or using drug precursors;

The EU Database on Dugs precursors aims at providing a modern tool for strengthening the control of legitimate trade in drug precursors:

- to Member States' Competent Authorities to comply with their reporting obligations to the Commission in accordance with Article 13 of Regulation (EC) No 273/2004 and Article 29 of Commission Regulation (EC) No1277/2005;

- to Member States' Competent Authorities and to EU industry operators to facilitate checking the legitimacy of potential clients and to reduce the burdens for operators related to the yearly reporting of their transactions involving drug precursors in accordance with Articles 4 and 8.2 of Regulation (EC) No 273/2004 and with Articles17 and 19 of Council Regulation (EC) No 111/2005,

- to the Commission to facilitate completion of its obligations towards the International Narcotics Control Board under Article 13 (1) of Regulation (EC) No 273/2004 and Article 32 (1) of Regulation No 111/2005 as well as towards Member States under Article 29 of Commission Regulation (EC) No 1277/2005.

Finally, the proposal adapts the provisions of Regulation (EC) No 273/2004 regarding ex-Comitology to the new rules of the Lisbon Treaty.

1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

The proposed Regulation aims to improve the prevention of the diversion of drug precursors – in particular acetic anhydride - by traffickers from the legitimate trade towards production of illicit drugs. Annual trends in EU diversion of drug precursors will continue to be collected and reported, to the general public, the Member States and the International Narcotics Control Board. The objective is to achieve a decreasing trend in seizures and stopped shipments.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The main aim of the proposal to amend Regulation (EC) No 273/2004 is to address the weaknesses identified in the functioning of that Regulation in preventing the diversion of certain drug precursors (in particular acetic anhydride) from the legitimate trade to production of illicit drugs, through control and monitoring of this legitimate trade.

The EU Drug Precursors' Database should facilitate the monitoring and control activities by Member States, as well as the reporting tasks for Member States and operators.

1.5.2. Added value of EU involvement

The objective of this proposal, namely to strengthen control measures on acetic anhydride in order to prevent it diversion from the EU internal market while avoiding market distortions, cannot be sufficiently achieved by the Member States alone and action by the Union will be more efficient for the following reasons:

1. Some Member States feel legally prevented from adopting national control measures going beyond the EU legislation on the basis of Article 10 of Regulation (EC) No 273/2004, which empowers Member States to adopt national measures which are necessary to enable its authorities to perform their control and monitoring duties. They argue that the EU legislation is subjecting only *operators* to control measures (no obligations are imposed on end-users), which should be understood as a deliberate and binding decision of the EU-legislator that end-users should *not* be subject to the control of the drug precursor legislation.

2. On the contrary, other Member States are contemplating or have already based substantive national controls on Article 10, leading in first instance to different approaches of control in different Member States which might be detrimental to the functioning of the Union Market and, secondly, isolated actions in individual Member States risks shifting the problem from one Member State to the next, as traffickers will exploit the "weakest link" in the Union market. A combination of different national measures will not be as effective as a harmonised approach at EU-level. This is also confirmed by the fact that both, Member States and concerned industry sectors have called on the Commission to act to preserve the internal market with a level playing field, and not to rely too much on supplementary national measures.

1.5.3. Lessons learned from similar experiences in the past

The Commission has conducted a thorough analysis of the functioning of the existing Regulation (EC) No 273/2004 and on 7 January 2010, the European Commission adopted a **Report on the implementation and functioning of the existing EU legislation on drug precursors**[27]. While the Commission's evaluation concluded that the legislation is overall

[27] Report from the Commission to the Council and the European Parliament pursuant to Article 16 of Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 and to Article 32 of Council Regulation (EC) No 111/2005 on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors, COM(2009)709 final, available at: **http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0709:FIN:en:PDF**.

functioning well[28], it identified some weaknesses and made recommendations how to address these, including in particular a modification of some requirements for category 2 substances – either specifically for acetic anhydride or for all category 2 substances – in order to discourage diversion from the EU internal market.

This proposal aims to address this recommendation of the Commission Report by amending Regulation (EC) No 273/2004, mainly to improve the prevention of the diversion from the EU-internal trade of **acetic anhydride, the main drug precursor for heroin,** by extending the registration requirement, which so far applies only to operators placing acetic anhydride on the market, to also include users of the substance and by enhancing the harmonised registration provisions to achieve a more robust level playing field preserving the internal market and avoiding adoption of divergent national measures.

1.5.4. Coherence and possible synergy with other relevant instruments

This proposal is fully consistent with the objectives of the EU drugs strategy 2005-2012 and the EU drugs Action Plan (2009-2012), setting out the objective to reduce the diversion and trafficking in/via the Union of Drug Precursors used in the production of illicit drugs, ultimately aiming at reducing the supply of illicit drugs to EU citizens while ensuring a high level of human health protection and a high level of security.

[28] For further details, see under Section 4.2.1 "Strength and weaknesses of the legislation" of the above-mentioned Report COM(2009)209 final.

1.6. Duration and financial impact

☐ Proposal/initiative of **limited duration**

– ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY

☒ Proposal/initiative of **unlimited duration**

– Implementation with a start-up period from January 2014 to December 2014,

– followed by full-scale operation from 01 January 2015 (Estimated).

1.7. Management mode(s) envisaged[29]

☒ **Centralised direct management** by the Commission

☐ **Centralised indirect management** with the delegation of implementation tasks to:

– ☐ executive agencies

– ☐ bodies set up by the Communities[30]

– ☐ national public-sector bodies/bodies with public-service mission

– ☐ persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

☐ **Shared management** with the Member States

☐ **Decentralised management** with third countries

☐ **Joint management** with international organisations ***(to be specified)***

If more than one management mode is indicated, please provide details in the "Comments" section.

Comments

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29 Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

30 As referred to in Article 185 of the Financial Regulation.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

(1) Members States will yearly communicate to the Commission the information on the cases where the delivery of drug precursors was suspended or seized.

(2) The Member States will regularly forward to the Commission the information concerning their licensed and registered operators and users trading or possessing drug precursors, their respective transactions.

(3) The Commission in turn will regularly compile a report on the basis of the information collected from Member States and will yearly submit the overall EU information on seizures and stopped shipments of drug precursors in the Union to the Member States and to the International Narcotics Control Board. Furthermore the Commission will prepare for public release its annual report on EU drug precursor's seizures and stopped shipments.

2.2. Management and control system

2.2.1. Risk(s) identified

The main risks are:

- Failure of Members States to comply with their reporting obligations and/or the provision of information on licensed/registered operators and users;

- Non uniform implementation of the legislation in the Member States;

- Insufficient control systems in the Members States in particular on licensed and/or registered operators and users.

2.2.2. Control method(s) envisaged

The Member States have already designated authorities responsible for overseeing the implementation of the legislation and for granting licenses & registration to legitimate operators & users involved in the trade of drug precursors;

Implementation of the legislation is monitored through regular meetings of the designated national competent authorities responsible for the EU Drug Precursors legislation;

The day to day management of the EU Database on Drug Precursors will fall under the responsibility of the Commission Services in charge of following the EU Drug Precursors legislation, mainly DG ENTR and DG TAXUD.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

No particular risk of fraud or irregularities has been identified.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description……...…….]	Diff./non-diff (31)	from EFTA[32] countries	from candidate countries[33]	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
1a. Competitiveness for growth and employment	Article 02.03.01 Operation and development of the internal market, particularly in the fields of notification, certification and sectoral approximation	Diff./ DA	YES	NO	NO	NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Heading……..]	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation

31 Diff. = Differentiated appropriations / Non-Diff. = Non-differentiated appropriations.

32 EFTA: European Free Trade Association.

33 Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to 3 decimal places)

Heading of multiannual financial framework:	Number 1a	Competitiveness for growth and employment

DG: ENTR			Year 2014[34]	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020[35]	**TOTAL**
• Operational appropriations										
Article 02.03.01 – Operation and development of the internal market, particularly in the fields of notification, certification and sectoral approximation	Commitments	(1)	0.045	0.045	0.045	0.045	0.045	0.045	0.045	**0.315**
	Payments	(2)	0.045	0.045	0.045	0.045	0.045	0.045	0.045	**0.315**
Number of budget line	Commitments	(1a)								
	Payments	(2a)								
Appropriations of an administrative nature financed from the envelope for specific programmes[36]										
Number of budget line		(3)								
TOTAL appropriations for DG ENTR	Commitments	= 1+1a +3	0.045	0.045	0.045	0.045	0.045	0.045	0.045	**0.315**
	Payments	= 2+2a +3	0.045	0.045	0.045	0.045	0.045	0.045	0.045	**0.315**

34 Year N is the year in which implementation of the proposal/initiative starts.

35 Costs also foreseen after 2020 because of the nature of the project (database maintenance).

36 Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
TOTAL appropriations under HEADING <….> of the multiannual financial framework	Commitments	= 4+ 6								
	Payments	= 5+ 6								

If more than one heading is affected by the proposal / initiative:

• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework (Reference amount)	Commitments	= 4+ 6								
	Payments	= 5+ 6								

Heading of multiannual financial framework:	**5**	" Administrative expenditure "

EUR million (to 3 decimal places)

DG: ENTR		Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	**TOTAL**
• Human resources		0.108	0.108	0.108	0.108	0.108	0.108	0.108	**0.756**
• Other administrative expenditure									
TOTAL DG ENTR	Appropriations	0.108	0.108	0.108	0.108	0.108	0.108	0.108	**0.756**

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)	0.108	0.108	0.108	0.108	0.108	0.108	0.108	**0.756**

EUR million (to 3 decimal places)

		Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	**TOTAL**
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	0.153	0.153	0.153	0.153	0.153	0.153	0.153	**1.071**
	Payments	0.153	0.153	0.153	0.153	0.153	0.153	0.153	**1.071**

3.2.2. Estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations.

– ☒ The proposal/initiative requires the use of operational appropriations, as explained below[37]:

Commitment appropriations in EUR million (to 3 decimal places)

Indicate objectives and outputs ⇩			Year **2014**		Year **2015**		Year **2016**		Year **2017**		Year **2018**		Year **2019**		Year **2020**		**TOTAL**	
			OUTPUTS															
	Type of output[38]	Average cost of the output	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	**Total number of outputs**	**Total cost**
SPECIFIC OBJECTIVE No 1[39]…																		
- Output			1	0.045	1	0.045	1	0.045	1	0.045	1	0.045	1	0.045	1	0.045	**7**	**0.315**
- Output																		
- Output																		
Sub-total for specific objective N°1																		
SPECIFIC OBJECTIVE No 2…																		
- Output																		
Sub-total for specific objective No 2																		
TOTAL COST			1	0.045	1	0.045	1	0.045	1	0.045	1	0.045	1	0.045	1	0.045	**7**	**0.315**

37 No information on the outputs is yet available as the pilot project of the European Database is not yet developed.

38 Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

39 As described in Section 1.4.2. "Specific objective(s)…"

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

– ☐ The proposal/initiative does not require the use of administrative appropriations

– ☒ The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to 3 decimal places)

	Year **2014**	Year **2015**	Year **2016**	Year **2017**	Year **2018**	Year **2019**	Year **2020**	**TOTAL**
HEADING 5 of the multiannual financial framework								
Human resources	0.108	0.108	0.108	0.108	0.108	0.108	0.108	**0.756**
Other administrative expenditure								
Subtotal HEADING 5 of the multiannual financial framework								
Outside HEADING 5[40] of the multiannual financial framework								
Human resources								
Other expenditure of an administrative nature								
Subtotal outside HEADING 5 of the multiannual financial framework								
TOTAL	0.108	0.108	0.108	0.108	0.108	0.108	0.108	**0.756**

[40] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

3.2.3.2. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources

– ☒ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full amounts (or at most to one decimal place)

	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020
• Establishment plan posts (officials and temporary agents)							
02 01 01 01 (Headquarters and Commission's Representation Offices)	0.108	0.108	0.108	0.108	0.108	0.108	0.108
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
• External personnel (in Full Time Equivalent unit: FTE)[41]							
XX 01 02 01 (CA, INT, SNE from the "global envelope")							
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)							
XX 01 04 ***yy*** [42] - at Headquarters[43]							
XX 01 04 ***yy*** [42] - in delegations							
XX 01 05 02 (CA, INT, SNE - Indirect research)							
10 01 05 02 (CA, INT, SNE - Direct research)							
Other budget lines (specify)							
TOTAL	0.108	0.108	0.108	0.108	0.108	0.108	0.108

02 is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary agents	Management and development of EU legislation ensuring a Single Market for chemicals – in particular for drug precursors. Prepare, chair and write reports of meetings of working groups and regulatory committees to ensure uniform implementation of the legislation. Assist Member States and industry. Prepare relevant guidance documents, as well as agreed 'questions and answers' in close co-

41 CA= Contract Agent; INT= agency staff ("*Intérimaire")*; JED= "*Jeune Expert en Délégation"* (Young Experts in Delegations); LA= Local Agent; SNE= Seconded National Expert.

42 Under the ceiling for external personnel from operational appropriations (former "BA" lines).

43 Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).

	operation with Member States authorities and other stakeholders. Publish annual reports on seizures and stopped shipments. Oversee maintenance and further development of European Database on Drug Precursors. Answer parliamentary questions. Prepare adaptations to technical progress and conduct interservices consultations. Ensure close co-operation with DG TAXUD, who is responsible for monitoring external trade in drug precursors.
External personnel	

3.2.4. Compatibility with the current multiannual financial framework

– ☒ Proposal/initiative is compatible with the multiannual financial framework 2014-2020.

– ☐ Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

– ☐ Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework[44].

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. Third-party contributions

– ☒ The proposal/initiative does not provide for co-financing by third parties

– ☐ The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to 3 decimal places)

	Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	… enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations cofinanced								

[44] See points 19 and 24 of the Interinstitutional Agreement.

3.3. Estimated impact on revenue

– ☒ Proposal/initiative has no financial impact on revenue.

– ☐ Proposal/initiative has the following financial impact:

– – ☐ on own resources

– – ☐ on miscellaneous revenue

EUR million (to 3 decimal places)

Budget revenue line:	Appropriations available for the ongoing budget year	Impact of the proposal/initiative[45]						
		Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	… insert as many columns as necessary in order to reflect the duration of the impact (see point 1.6)		
Article …….								

For miscellaneous assigned revenue, specify the budget expenditure line(s) affected.

…

Specify the method for calculating the impact on revenue.

…

[45] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25% for collection costs.