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IMPACT ASSESSMENT

Accompanying the document

Draft Proposal for a Regulation

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

{COM(2012) 548 final}
{SWD(2012) 278 final}

Disclaimer: This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

1. INTRODUCTION

A large number of chemicals are used in a wide variety of legitimate and important industrial processes (e.g. in the synthesis of plastics, pharmaceuticals, cosmetics, perfumes, detergents and aromas). Those chemicals are traded for these licit uses on regional and global markets, but some of them can also 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 substantial 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. In order to prevent their diversion to illicit drug production, a specific regulatory framework has been set up (both on international level and in the EU). The main aim of the regulatory framework is to monitor the trade in drug precursors and to identify suspicious transactions. The most important actors in the prevention of diversion are the operators engaged in the licit trade (the manufacturers, distributors, brokers, importers, exporters and wholesalers): the legislation requires them to take measures against theft, check their customers, detect suspicious transactions and alert the authorities. An effective **industry-authority partnership** is key to the implementation 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.

Traffickers purchase the drug precursors they need from different regions in the world and exploit weaknesses of control to their benefit. This impact assessment aims to addresses 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, the EU alone seized 75% of the global seizures of AA. Even though the quantities have decreased very substantially since that year[1], the EU has been and continues to be under international criticism that the European legislative control measures are not sufficiently strong to prevent the diversion of the main heroin precursor from the intra-EU trade.

The present impact assessment concerns the *intra-EU trade* in drug precursors, which is governed by Regulation (EC) No 273/2004 under the responsibility of DG ENTR, *and more specifically the diversion of acetic anhydride, the main precursor for the production of heroin.* A second impact assessment has been conducted concerning the control of extra-EU trade of drug precursors, which is governed by Regulation (EC) No 111/2005 under the responsibility of *DG TAXUD*), and more specifically a possible control of *export/transit of medicinal products containing ephedrine or pseudoephedrine, precursors for methamphetamines*. **Even though both initiatives concern the drug precursor legislation, they tackle different**

[1] Seizures and stopped shipments of AA in the EU dropped from 241 tons (in 2008) to 33 tons (in 2009) and 21 tons (in 2010).

substances and different issues which are not interlinked, and are therefore best dealt with separately. Nevertheless, the two DGs have ensured close coordination throughout the preparation of the respective impact assessments.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

2.1. Identification

Lead DG: DG Enterprise and Industry (DG ENTR)

Other involved DGs: TAXUD, JUST, SANCO, HOME, RTD, SG, SJ and OLAF.

Agenda Planning Reference: 2011/ENTR/021

2.2. Organisation and timing

The work on the present impact assessment started in mid-2010 when six policy options were developed by the Commission Services and a written consultation of Member States and industry stakeholders was carried out. An impact assessment steering group (IASG) was created on 28 January 2011 together with DG TAXUD to oversee the preparation of the respective impact assessments and to ensure consistency between them.

The IASG met four times (on 7 February, 23 June, 27 October and 14 December 2011).

2.3. Consultation and expertise

On 7 January 2010, the European Commission adopted a **Report on the implementation and functioning of the existing EU legislation on drug precursors**[2]. The underlying evaluation had been carried out by the Commission Services, with the assistance of a *group of experts* from national competent authorities, which had been established for the evaluation purposes. In addition, the Commission had mandated an *external contractor*, the consultancy RPA, which gathered information from all relevant stakeholders (competent authorities and industry operators) including quantitative data where available, analysed the impacts of the current legislative requirements on the trade in drug precursors, and collected proposals for improving the system in place.[3]

While the Commission's evaluation concluded that the legislation is overall functioning well[4], it identified some weaknesses and made five recommendations how to address these:

1) Improving harmonised implementation of the current legislation;

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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] Stakeholders have been consulted by RPA during the years 2006 and 2007 via questionnaires on the functioning of (and possible problems with) the current EU legislation. These data were subsequently analysed by RPA, which provided its Final Report to the Commission at the beginning of 2009.

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

2) Enhancing operator reporting on legal transactions in order to provide authorities with a better basis for carrying out their control and monitoring duties;

3) Modifying some requirements for category 2 substances (either specifically for AA or for all category 2 substances) in order to discourage diversion from the internal market;

4) Ensuring appropriate control of pharmaceutical preparations containing ephedrine or pseudo-ephedrine in order to enable customs authorities to stop exports of pharmaceutical preparations to be used for illicit drug production; and

5) Improving and adjusting procedural requirements for pre-export notifications depending on the risk of diversion.

The legislation on intra-EU trade is affected by the first three recommendations of the Commission Report (while recommendations 4 and 5 concern the legislation on external trade). The first recommendation has been implemented by organising workshops and seminars to facilitate an exchange of best practices among competent authorities. Recommendations 2 and 3 are addressed in the present impact assessment.

In reaction to the Commission's Report, the **Council adopted conclusions** in May 2010, which recognise the importance of continuing active co-operation among authorities and industry and of improving the implementation of the European legislation. Furthermore, 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[5].

The Commission Services (DG ENTR) consulted in 2009 and early 2010 industry stakeholders through their EU associations[6] on the weaknesses identified in the Commission's Report (notably the difficulties in preventing diversion of AA) and how to best address them. The Commission subsequently developed six possible options. In June 2010, these options were discussed with the Member States and industry representatives in a special meeting of the Drug Precursor Working Group.

Subsequently, Member States and industry stakeholders were 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 has been carried out via the Enterprise Europe network from 1 October until 24 November 2010. This specific consultation was chosen to ensure that the concerns of a specific target group – end-users of drug precursors most of which are SMEs – could be considered[7]. Table 1 contains an overview of the responses received.

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

[6] Cefic (the European Chemicals Industry Council)/Acetyls Sector Group and FECC (the European Association of Chemical Distributors).

[7] See statistical summary of SME consultation contained in Annex 1. It should also be noted that from the group of consulted end-users, at least 42 companies of the 106 respondents have been identified as SMEs (this number of SMEs could even be much higher as many respondents did not provide the required turnover data to conduct the SME test).

Table 1 Responses to questionnaires on drug precursors

Target group	*Total number of responses (n)*
Operators	54
End-users	106
SME end-users	60
Competent Authorities of Member States	17

The targeted consultation included a range of questions on the elements required to carry out a calculation of administrative costs of the possible options. The addressees were also asked to identify the option that they would consider most efficient to prevent the diversion of AA from legal trade. The results of this consultation are summarized in Table 2 below.

Table 2 **:** Best option according to different stakeholders (in %)

	Operators *(n=54)*	***End-users*** *(n=106[8])*	***SME end-users*** *(n=60)*	***Member States*** *(n=17)*
Option 1	15%	27%	48%	6%
Option 2	2%	3%	7%	19%
Option 3	4%	5%	8%	6%
Option 4	2%	10%	7%	13%
Option 5	7%	3%	15%	56%
Option 6	2%	4%	2%	13%
No opinion	69%	48%	13%	13%

A very large proportion of enterprises did not have any opinion whether the European legislation should be changed (69% of operators, 48% of end-users and 13% of SME end-users). The baseline scenario was favoured by 15% of operators, 27% of end-users and 48% of SMEs. These differences between the three enterprise groups level out, however, if one looks only at those enterprise which *did* express an opinion on the preferred option, within these groups, 48% of operators, 52% of end-users and 55% of SMEs prefer not to modify the existing legislation. In that context, however, it is worth noting that the two major European industry associations have consistently supported the view that a (reasonable) strengthening of *European* legislation is to be preferred over diverging national obligations.

For Member States, only a minority prefers keeping the EU legislation unchanged (6% [7% if "no opinion" is disregarded]), whereas a large majority (56% [64% of “no opinion is

[8] Including at least 42 SMEs.

disregarded"]) preferred option 5, the registration of end-users, as the most suitable option to prevent diversion[9].

The data collected in the consultation was analysed and complemented in a further study by the external consultant EIM, who carried out additional interviews with competent authorities and industry stakeholders. Based on the consultation, EIM provided the Commission with a study on administrative costs ("EIM Report")[10].

The Commission Services opted for the above-described targeted consultations, rather than for a general public consultation, for several reasons: firstly, in view of the sensitive nature of the subject (preventing traffickers from obtaining the key chemical substance for the illegal production of heroin), the potential problems and possible solutions should not be publicised among traffickers/criminals. Secondly, the proposed policy options concern business-to-business trade of a limited group of companies producing, trading or using a specific group of chemical substances. Citizens and civil society groups are actually not affected by the choice of policy options, and it would have been unlikely that they could have provided information on the costs and benefits of the options. Lastly, the options developed under the present impact assessment have to be distinguished from the **overall drug problem** and how to address it as part of the general **European Drug Policy**, on which the Commission has recently carried out a public consultation[11].

2.4. Scrutiny by the Commission Impact Assessment Board

The Impact Assessment Board of the European Commission assessed a draft version of the present impact assessment and issued its opinion on 17/02/2012. The Impact Assessment Board made several recommendations and, in the light of the latter, the final impact assessment report:

- provides a more detailed overview of the market players and of the individual measures taken by Member States to prevent the diversion of drug precursors and on that basis provides a more detailed presentation of the baseline scenario;

- strengthens the subsidiarity analysis to better justify the need for EU action;

- provides more information with regard to the assessment of the costs and effectiveness of the policy options examined;

- reports the views of stakeholders in more details.

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[9] See also statistical summary of consultations contained in Annex 1.

[10] EIM: Administrative costs and administrative burdens imposed by amendments of the EU drug precursor legislation. EIM had provided the Commission with a "Final Report" in October 2011. A corrected "Final Report" dated March 2012 eliminated a number of errors discovered subsequently. A copy of the March 2012 Final Report is accompanying this report as separate document. It has not been published due to the sensitivity of the information concerned.

[11] See **HTTP://EC.EUROPA.EU/JUSTICE/NEWSROOM/ANTI-DRUGS/OPINION/111027_EN.HTM** for details on this consultation.

3. CONTEXT

3.1. Illicit drugs

Drug precursors are involved in the illicit production of both plant-based drugs (such as heroin and cocaine) and synthetic drugs, which are produced entirely from chemicals (such as amphetamine, methamphetamine, and ecstasy). Annex 2 contains an overview of the major drug precursors and the illicit drugs produced. In other words: there are no illicit drugs without drug precursors. The term “drug precursor” (or just “precursor” in the international context) refers to different types of substances: chemicals that are "precursors in the strict sense", i.e. substances which become incorporated into the molecule of the drug, or other chemicals which are reagents[12] or solvents[13,14].

3.2. International legislation and developments

The United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances (“1988 UN Convention”)[15] contains in its Article 12 specific reference to measures to prevent diversion of drug precursor chemicals for use in the illicit manufacture of narcotic drugs and psychotropic substances. Tables I and II of the 1998 UN Convention set out a list of 23 drug precursors (so-called "**scheduled substances**"), which are controlled by the Convention because they are most frequently used in the production of illicit drugs.

The EU is a Contracting Party to the 1988 UN Convention, which has 185 Parties including all major chemical producing countries. The EU has implemented its obligations through legislation and voluntary measures applied by the public and private sectors.

The United Nations’ International Narcotics Control Board (“INCB”) is an independent control body which closely monitors the implementation of the United Nations drug conventions. It publishes annual reports containing diversion statistics and their analysis as well as recommendations to the Parties concerned.

In its 2009 annual report, the INCB considered that the measures applied to monitor the internal trade of AA in the EU could be improved[16]. In the 2010 annual report, the INCB noted that progress has been made in the EU, but upheld its call on the EU to take further measures to prevent diversion in the EU[17] (see section 4.1.2 for further details).

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[12] A reagent is a chemical substance that reacts with, or takes part in a reaction with, another substance (usually a precursor in the strict sense) during the processing or manufacturing of a narcotic drug or psychotropic substance. It does not become part of, or contributes to only a small portion of, the molecular structure of the end product.

[13] A solvent is a liquid chemical substance that is used to dissolve or disperse one or more substances. It does not itself react with other substances, nor is it incorporated into the molecular structure of the end products. A solvent may also be used to purify the end product.

[14] For further information see: Commentary on the United Nations Convention against illicit traffic in narcotic drugs and psychotropic substances 1998, on Article 12, page 251 – available at: HTTP://WWW.UNODC.ORG/DOCUMENTS/TREATIES/ORGANIZED_CRIME/DRUG%20CONVENTION/COMMENTARY_ON_THE_UNITED_NATIONS_CONVENTION_1988_E.PDF

[15] The 1988 UN Convention is available at: HTTP://WWW.INCB.ORG/PDF/E/CONV/1988_CONVENTION_EN.PDF

[16] INCB Annual Report 2009 – Precursors, point 110, available at: HTTP://WWW.INCB.ORG/PDF/PRECURSORS-REPORT/2009/ENGLISH/PRECURSORS_REPORT_09_ENGLISH.PDF .

[17] INCB Annual Report 2010 – Precursors, points 74-76 and 89, available at:

3.3. EU legislation and institutional context

Since the early nineties, the EU has put in place legislation to ensure that diversion of drug precursors is prevented through control and monitoring of their legitimate trade. The legislation aims at striking a balance between necessary actions to prevent diversion of drug precursors and allowing their legitimate trade without creating unnecessary administrative burdens.

Based on the 1988 UN Convention, the European legislation contains a list of **23 scheduled substances**, which are divided into three categories[18]:

- Category 1 covers the most sensitive substances;
- Category 2 covers less sensitive substances and so-called "pre-precursors" (substances which are used to produce other precursors);
- Category 3 covers bulk chemicals that can have different types of uses in the manufacturing process (feedstock, but also solvents, impurities remover, etc).

The severity of control imposed on companies dealing with the drug precursors in question depends on the category concerned: the strictest control applies to category 1 substances, while the least control is imposed on substances in category 3. A summary of the obligations under the legislation is attached in Annex 3. The legal obligations for scheduled substances are complemented by a voluntary monitoring scheme for additional substances (so-called non-scheduled substances[19]), which provides the flexibility required to respond to rapidly changing diversion patterns.

The legislation builds on the key principle of **partnership between authorities and operators** in identifying diversion attempts. Companies having received suspicious orders have to inform the authorities. They may decide not to ship the ordered substances (so-called *'stopped shipments'*) either temporarily until the doubts regarding the transactions can be resolved, or – if the doubts remain – definitely refrain from executing the order. Another possibility is that there is an agreement between the operator and the authorities that delivery should proceed under monitoring of the authorities to track down trafficker networks (so-called *'controlled delivery'*). Authorities may also seize shipments that have been dispatched by a company that did not identify an order as suspicious, if they have sufficient indications from other sources (e.g. police, customs etc.) that a shipment is being diverted for drug production (so-called *'seized shipments'*).

HTTP://WWW.INCB.ORG/PDF/PRECURSORS-REPORT/2010/EN/PRECURSORSREPORT2010_REV_E_V10579291.PDF

[18] Annex 2 contains a list of the 23 scheduled substances.

[19] The list of non-scheduled substances is, due to its sensitivity, not published but is provided by the competent authorities directly to trusted operators.

4. PROBLEM DEFINITION

4.1. The problem that requires action

4.1.1. Diversion of the main drug precursor for heroin within the EU internal market

Preventing the diversion of drug precursors from legitimate trade is one of the main goals of the 1998 UN Convention and is the objective of the European legislation on drug precursors.

Ineffective prevention of the diversion of Acetic Anhydride (AA), the key drug precursor for the production of heroin, has been the **main problem** over the last years under the applicable legislation for drug precursors circulating in the internal market.

AA **is licitly used** as an acetylating agent[20] for producing plastics, textiles, dyes, photochemical agents, perfumes, explosives and aspirin. AA is **used illegally** mainly for the **production of heroin**[21] but it can also be illegally used for manufacturing amphetamine, methaqualone and in some areas it is used as a reagent to produce coca paste and cocaine[22]. According to industry[23], it would be *difficult to find a substitute* for the licit uses of AA, which would present as favourable characteristics in terms of environmental impact on occupational health. In addition, it is precisely the acetylating function which is also used during the illicit drug production, so that replacing AA with another acetylating agent would mean that the replacement chemical could also be misused.

Heroin consumed in Europe **originates predominantly in Afghanistan**, which accounts for most of the global illicit opium output. Other producing countries include: Burma/Myanmar, which mainly supplies markets in east and south-east Asia, Pakistan and Laos, followed by Mexico and Columbia, which are considered to be the larges suppliers of heroin to the United States[24].

Heroin use has been a contributing factor 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.

AA diverted from legal trade in Europe **is trafficked** via the so-called "**Balkan Route**" to Afghanistan, thus following the "reverse route" of heroin trafficked from Afghanistan to Europe. The Balkan Route is the largest opiate conduit in the world with long established criminal networks smuggling significant amounts of heroin from Afghanistan through Iran and Turkey towards the European market and – in a reverse course – trafficking acetic anhydride towards Afghanistan[25]. The second major route is the "Southern Route" via Pakistan towards Asia by sea, including some road transportation through China and also

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[20] i.e. to introduce the Acetyl Group (-(C=O)-CH_2-CH_3) into chemical substances.

[21] The size of the illicit acetic anhydride market is primarily driven by the demand for heroin,cf. UNODC, the Global Afghan opium Trade, under 2, page 92 – available at HTTP://WWW.UNODC.ORG/DOCUMENTS/DATA-AND-ANALYSIS/STUDIES/GLOBAL_AFGHAN_OPIUM_TRADE_2011-WEB.PDF

[22] The size of the illicit acetic anhydride market is primarily driven by the demand for heroin, cf. UNODC, the Global Afghan opium Trade, under 2, page 92 – available at HTTP://WWW.UNODC.ORG/DOCUMENTS/DATA-AND-ANALYSIS/STUDIES/GLOBAL_AFGHAN_OPIUM_TRADE_2011-WEB.PDF

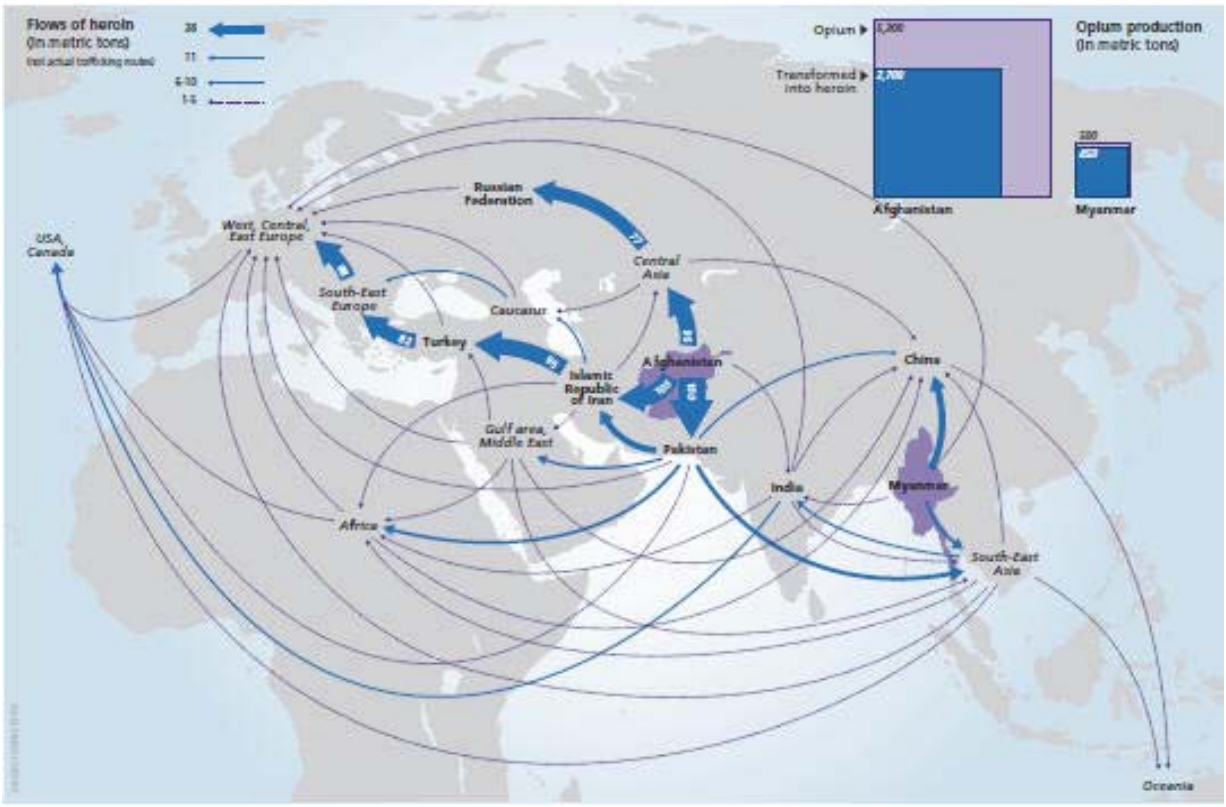
[23] Consultation before the 2010 Commission Report: feedback from the Cefic Drug Precursor Issue Team.

[24] EMCDDA Annual Report 2011, Chapter 6, page 72 with reference to UNODC, the World Drug Report 2011.

[25] UNODC, The Global Afghan Opium Trade, under 2.2, The Balkan Route, page 114.

through India (to a lesser extent). The third, more secondary, route is the "Northern Route" via former GUS States which developed following the opening of borders after the dissolution of the Soviet Union[26]. Figure 1 contains a graphic illustration of the main transport routes.

Figure 1: Global heroin flows from Asian points of origin[27]



4.1.2. The scale of the problem

Seizure data are a commonly used indicator of trends in illicit markets. However, interpreting acetic anhydride seizure data is challenging since, in any given year, seizures constitute a very small percentage of what is estimated to be traded[28]. Globally, over 2 million tons of acetic anhydride is produced annually. Estimating that **illicit acetic anhydride demand in Afghanistan is 380-570 tons per annum**, only a tiny percentage (0.02%) of the global production would need to be diverted and trafficked to Afghan heroin laboratories. These figures can be further narrowed for more accurate risk analysis, since as much as two thirds of global acetic anhydride production is utilized for intra-company industrial use (i.e. use by so-called "end-users" for the production of other products – the AA involved is thus not sold or traded). It is the remainder (329,000 tons in 2009) which is traded internationally and presents a potential target for diversion by traffickers. Traffickers therefore have flexibility to seek the

[26] UNODC, the Global Afghan opium Trade, under 2.2, Acetic Anhydride trafficking to Afghanistan, pages 103 et seq.

[27] Source: UNODC World Drug Report 2010

[28] UNODC, the Global Afghan opium Trade, under section 2.1 The current state of the acetic anhydride market, page 99.

fraction of AA which they require from the legal trade from the least-protected areas of the markets[29].

In **2008**, competent authorities in the **EU seized about 151,000 litres (163 tons)**[30] of AA which represented approximately 75% of world-wide seizures. In addition, about 72,000 litres (78 tons) of AA were stopped in the EU (before delivery) because the orders had been suspected to be intended for illicit drug production. Added together, the total quantities of AA seized or stopped in 2008 amounted to 223,000 litres (241 tons)[31]. With this quantity, it would have been *possible to produce approximately 150,000 -223,000 kg of heroin,* as it is assumed that producers use 1-1.5 litres of acetic anhydride for every kilogram of Afghan heroin[32].

It is necessary to put these figures in perspective of the total Afghan heroin production: in 2009, **Afghanistan produced** 6,900 tons of opium, of which an (estimated) 2,700 tons were transformed into **about 380 tons of heroin**. This production requires between 380 and 570 tons of acetic anhydride smuggled into the country[33]. Therefore, it can be assumed that the quantities of AA seized and stopped in Europe in 2008 would have satisfied about 50% of the yearly Afghan demand for AA to be used in heroin production. Drug users in Western and Central Europe, for whom Afghanistan is the main source for heroin, consume about 70 tons of heroin, which amounts to about 18 % of the total yearly Afghan heroin production of 380 tons.

Seizure statistics of the **subsequent years 2009-2010** have shown a clear and sharp **decline of AA stopped and seized in the EU**: 33 tons / 31,000 litres in 2009 and 21 tons / 19,000 litres in 2010. With these amounts, it would have been *possible to produce approximately 20.4 – 31 tons of heroin in 2009 and 13 - 19 tons of heroin in 2010.*

4.1.3. Underlying drivers of the problem

Despite the recent more promising trend of AA seizures and stopped shipments in the EU, a large number of Member States' competent authorities have consistently voiced their concern that the control mechanisms provided under the European legislation for the control of AA - which is a scheduled substance under category 2 - do not provide the authorities with sufficient tools to prevent AA diversion. Notably, these authorities have pointed to the following difficulties:

- Lack of registration requirement for *end-users* of AA – and hence lack of knowledge of the competent authorities about companies claiming to be only end-users of AA, in contrast to the registration requirement for *operators* placing scheduled substances in category 2 on the market.
- No licence required for operators trading AA, but only a (less stringent) registration requirement. A licence is only required for operators of scheduled substances in category 1.

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29 UNODC, the Global Afghan opium Trade, under section 2.1, pages 98, 99.
30 1 kg of AA equals 0.926 litres of AA (international conversion rate used by the INCB).
31 EU Annual Reports on Drug Precursor Seizures and Stopped Shipments, available at HTTP://EC.EUROPA.EU/ENTERPRISE/SECTORS/CHEMICALS/DOCUMENTS/SPECIFIC-CHEMICALS/PRECURSORS/INDEX_EN.HTM
32 UNODC, the Global Afghan opium Trade, under section 2.1, page 94.
33 UNODC the Global Afghan opium Trade, under section 2.1, page 96.

- Lack of control if substances are traded below the minimum threshold (for AA: 100 litres per year). Below this threshold, operators are exempted from a number of obligations under the Regulation.
- Difficulties for operators to verify information contained in the customer declaration, mainly:
    - whether the customer is legitimate when claiming to be only an end-user (cf. above: lack of registration number to be indicated on customer declarations);
    - when the customer is established in another Member State, the information in the customer declaration cannot be checked as easily as for customers in the operator's own Member States.

While some Member States have addressed these difficulties with additional controls on national level[34] acting under Art. 10 of Regulation (EC) No 273/2004, which requires Member States to adopt national measures necessary to enable the competent authorities to perform their control and monitoring duties, other Member States have considered that the required additional controls would go beyond the scope of Art. 10 and that the necessary additional measures would have to be adopted at the European level.

It should be noted that AA is subject to the same control standards as applicable to all scheduled substances in category 2[35]. Considering that the above-described characteristics (no registration of end-users, difficulties to verify information contained in customer declarations, etc) apply to *all* scheduled substances in category 2, the question arises **whether the driver** for the problem ´diversion of AA´ is an inadequate control mechanism for **AA only *or*** for **all scheduled substances in category 2**. Looking at the European seizure statistics for category 2 substances, there is evidence that **only for the substance AA** diversion has not been adequately prevented[36]. In the 2010 stakeholder consultation, both, Member States and enterprises have reported more than double the *amount of suspicious transactions for AA alone* than for the four other category 2 substances combined[37]. It is the main principle of the European legislation that different levels of control apply to different substances – depending of the *particular diversion risk of each substance* concerned, so that an increased diversion risk for one particular substance does not automatically point to ineffective control mechanisms for other substances within the same category.

A lack of *operators' compliance* with the legislation has *not* been identified as a problem in the consultation process (even though it cannot be excluded as a contributing factor in specific cases). However, some diversion cases have shown that the authority-operator cooperation in the Member State concerned could still be improved.

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[34] For instance: Belgium, Hungary and Italy require their operators to notify each AA transaction to the authorities prior to the delivery of orders. Hungary has increased reporting obligations for legal transactions with the substances AA and potassium permanganate to every 2 months (instead of yearly as foreseen under EU law). Belgium, Denmark and Spain require end-users to register with the authorities.

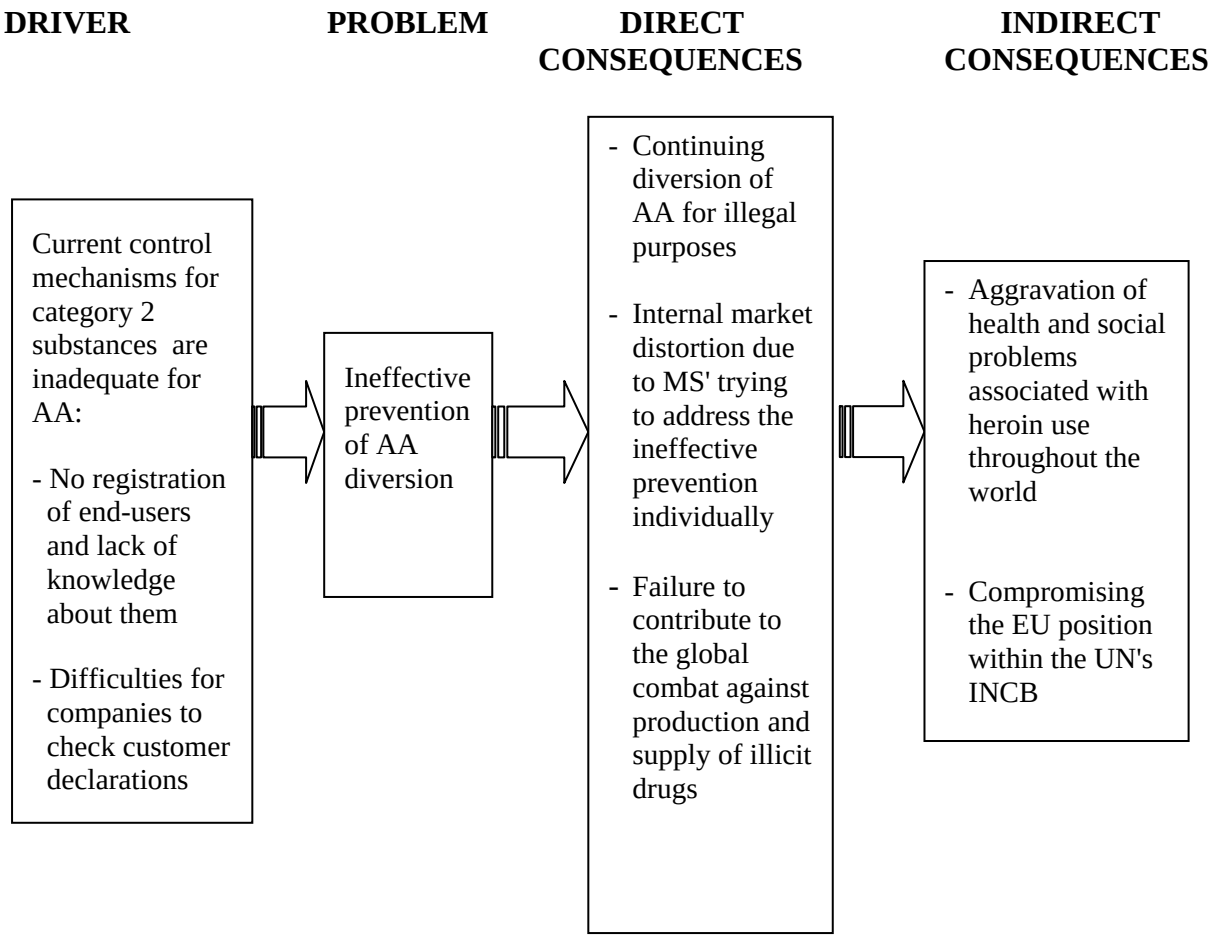
[35] Additional obligations apply to AA for export to third countries, which is, however, not relevant for the present analysis (Art. 11(1) of Regulation (EC) No 111/2005, Commission Regulation (EC) No 1277/2005).

[36] See Annex 4 (Statistics of seizures and stopped shipments for all scheduled substances in category 2) for further details.

[37] See Annex 1 (stakeholder consultation) sections a) and b) under question 3.

The underlying drivers of the problem and the direct and indirect consequences are visualised in Figure 2.

Figure 2: Drivers, problem and consequences of the diversion of AA



4.1.4. Who is affected, in what ways and to what extent?

The following groups are affected by inadequate prevention of the diversion of AA from the intra-EU trade:

4.1.4.1. Member States

Member States are affected by diversion when **conducting enforcement actions** on diverted substances, for instance detecting and monitoring traffickers' storage sites, destroying seized substances etc. These activities may be very labour-intensive and costly for the authorities. To give an example: UNODC has been informed by a national enforcement authority that it costs

almost € 1,000 per day to observe an AA storage site; another authority reported to UNODC to have spent € 250,000 for storage of 93 tons of seized AA[38].

Member States have experienced diversion attempts for AA **to different degrees**. At the peak of European AA seizures in 2008 (151,000 litres), Central European Member States were particularly targeted (86,100 litres in Slovenia and 63,600 litres in Hungary). This geographical trend could already be observed in 2007, where total EU seizures amounting to 7,700 litres took place also in central EU Member States (Slovenia seized 6,500 litres and Romanian 1,200 litres)[39]. These Member States are, due to their geographical location, particularly attractive to traffickers using the "Balkan Route"[40].

Furthermore, the argument has been made that traffickers are exploiting the benefits of the internal market, diverting from internal trade from the weakest-controlled distributor in the EU to the least-controlled exit point, in order to smuggle the substances outside the EU[41].

More indirectly, Member States are affected by the **effect of drugs being produced with diverted substances**. Via their social security systems, they bear the *health costs* resulting from the use of heroin and other drugs. In addition, there are significant costs to the public from *drug-related crime*[42].

4.1.4.2. Citizens

EU citizens are affected through **the supply of drugs** which have been illicitly produced with the diverted drug precursors and also through **drug-related crime**.

AA being available to criminals/traffickers from diversion in Europe can be an important contributing factor to heroin production, mainly in Afghanistan. A substantial part of this heroin (almost 20%) is then sold on the European market. The ultimate consequence of diversion of AA in Europe is an **aggravation of the health and social problems** associated with heroin use in regions throughout the world, including a substantial part in Europe.

The above analysis is, however, to be taken with caution. As set out in section 4.1.2, diverted AA is only a small fraction of worldwide AA production. While it is true that there is no production of illicit drugs without (diversion of) chemical precursors, a better prevention of diversion *in Europe* may lead traffickers to source the substance in other regions of the world and, in consequence **may have little effect on the total heroin production** and, consequentially, very little effect **on the supply of heroin** to EU citizens. Furthermore, drug users can, in case of reduced heroin supply, switch to **other drugs** so that the effect of

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38 UNODC, The Global afghan opium trade, under 2.2, The cost of interdiction, page 116.

39 INCB Annual Reports on Precursors 2000-2010, available at: HTTP://WWW.INCB.ORG/INCB/EN/PRECURSORS_REPORTS.HTML.

40 For a description of the "Balkan Route" see above under Section 0.

41 UNODC: The Global afghan opium trade, a threat assessment 2011, under 2.2, The Balkan Route, p. 116.

42 It is very difficult to estimate drug-related public expenditure in Europe. Even though public expenditure on all aspects of the drug phenomenon has been under scrutiny during the last decade, comprehensive estimates are still a challenge; the amount and quality of information available varies greatly between countries. In the last decade, at least 12 Member States have attempted to arrive at comprehensive estimates of drug-related expenditure. These countries reported public expenditure on the drug problem ranging from 0.04% to 0.48% of GDP. For further information see: EMCDDA Annual Report 2011, Chapter 1, page 21 et seq. and table 2 at page 22 with GDP-related estimates for 12 Member States.

reduced diversion of AA in the EU on the overall health situation in Europe may be very limited.

Despite these possibilities of substitution, the EU is committed to continue its efforts to prevent diversion within its territory, in order not to contribute to the production of illicit drugs. In addition, joined efforts on a world-wide level in the framework of the 1988 UN Convention are aimed at curbing the global production and supply of illicit drugs, including also prevention of diversion of precursors from legal trade in all countries.

4.1.4.3. Companies

In the EU, over 5,000 companies are currently registered or licensed to dealing with the legitimate production and distribution of drug precursors (all scheduled substances combined)[43]. More specifically for the substance AA, approximately 1,600 companies are registered as "operators", i.e. being either manufacturers or traders of AA. AA production in the EU is concentrated in only four Member States Greece, Italy, UK and Spain[44] and in less than 10 companies[45]. This means that over 99% of operators are traders. Based on the consultation carried out by the Commission services in 2010, the majority of traders are SMEs[46].

About 2,500 companies in Europe are estimated to be AA end-users[47], not selling AA themselves, but only using it for production in sectors such as perfume production, food flavouring, metal cleaning, colouring, bleaching, water cleaning, etc. According to the consultation in 2010, the number of AA end-users is particularly high in some of the larger Member States (France, Germany) and in some central European countries (Czech Republic, Hungary).[48] The consultation also confirmed that the majority of AA end-users are SMEs.[49]

Companies dealing with AA may **experience diversion (attempts)** at any stage of handling of the chemical substance. Diversion may occur in the production facilities, during transportation, sale, processing, recycling and even destruction.

Apart from securing premises and processes against theft / unintentional disappearance of the substance, companies producing and trading AA have to be vigilant with regard to the customers who order the substance and have to critically asses whether these customers use the substance only for the claimed licit purpose[50]. Under current European legislation it is an obligation for all operators involved in the production and sale of AA, to notify any

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[43] EIM calculation, based on the 'Ad Hoc Study to be used in the Evaluation of the Community Legislation on Drug Precursors. Final Report prepared for the European Commission'. RPA, February 2009, as detailed in Annex III to the EIM Report.

[44] Eurostat PRODCOM database (data from 2010), available at: HTTP://EPP.EUROSTAT.EC.EUROPA.EU/PORTAL/PAGE/PORTAL/PRODCOM/DATA/TABLES_EXCEL

[45] Acetic Anhydride Supply Chain Analysis conducted by the United States.

[46] Out of 54 respondents in the category "operators of category 2 substances", at least 27 fell under the SME definition (many other respondents did not provide the required information), which amounts to at least 50%.

[47] 2,473 companies are estimated to be end-users of AA in the EU (EIM Report, page 10).

[48] See Annex 1, Summary of stakeholder consultation and SME consultation.

[49] Out of 106 respondents in the category "end-users of category 2 substances", at least 42 could be identified as SMEs (many other respondents did not provide the requested turnover and employee data), in addition the SME-specific consultation for which 60 responses were received, comprised exclusively end-users.

[50] AA is licitly used as an acetylating agent in chemical, photographic and pharmaceutical industry. It is used for producing plastic, textile, dyes, photochemical agents, perfumes, explosives and aspirin.

suspicious circumstances to the authorities. End-users so far have only limited obligations, in particular providing a customer declaration when placing orders for substances of category 2.

Changes of the drug precursor legislation would affect many companies active in the production, trade and further processing of the chemical substances concerned. Changes imposed on **operators dealing with AA** would affect approximately 1,600 companies in the EU. If, on the other hand, the current problem was addressed on a more horizontal level, with changes imposed **operators dealing with all scheduled substances in category 2**, approximately 4,000 companies would be affected in the EU; most of them are based in the larger Member States (Spain, United Kingdom, Germany and France).[51]

A strengthening of the obligations imposed on **end-users of AA** would particularly affect about 2,500 companies in the EU who are only users (not manufacturers or traders) in sectors such as perfume production, food flavouring, metal cleaning, colouring, bleaching, water cleaning, etc. If obligations would be strengthened for **end-users of all scheduled substances in category 2**, about 8,500 companies would be affected in the EU[52].

4.1.5. Foreseen evolution of the problem

It is difficult to foresee the evolution of future diversion trends, as traffickers' behaviour changes over time, and depends on many factors, including insufficient implementation of existing legislation, insufficient international cooperation, or an inadequate legal framework.

The statistics on diversion of acetic anhydride in the EU **do *not show a clear trend*** over the last decade. There have been **two brief spikes in seizures**, **in 2001** (100,000 litres: 65,000 in the UK, 16,000 in Italy, 9,000 in Slovenia and 9,000 in Belgium) **amounting to 55% of global seizures** and **in 2008** (151,000 litres: 86,000 in Slovenia and 64,000 in Hungary) **amounting to 75% of global seizures**[53].

However, as explained in section 4.1.2, according to the statistics for 2009-2010, there has been a clear and sharp decline of AA stopped and seized in the EU: the quantities of AA seizures dropped **in 2009 to 900 litres only, amounting to less than 5% of global seizures**. Seizures and stopped shipments combined dropped to 31,000 litres in 2009 and 19,000 litres in 2010.

From these statistics, two different assumptions can be made in order to forecast the future diversion of AA in Europe:

4.1.5.1. Better implementation by itself will solve the problem

One assumption would be that the activities by Member States over the last years have shown their success. Notably, Member States reported in a workshop organised by the European

[51] 4,056 enterprises are registered in the EU to deal with scheduled substances in category 2 (EIM Report, page 10 and Annex III to EIM Report with reference to RPA.

[52] 8,548 companies are estimated to be end-users of scheduled substances in the EU, (EIM Report, page 10) with reference to the stakeholder consultation.

[53] INCB Annual Reports on Precursors 2000-2010, available at HTTP://WWW.INCB.ORG/INCB/EN/PRECURSORS_REPORTS.HTML.

Commission in June 2011[54] about activities they have been carrying out since 2008 in order to better prevent the diversion of AA:

- Reinforcing cooperation between the industry and the authorities: Member States authorities have participated in annual industry conferences or have organised training of and visits to key economic players;
- Promoting the EU e-learning tool to economic operators;
- Inspecting operators on a risk-based approach;
- Improving cooperation activities a) between different authorities within the same Member State (inter-agency approach) and b) between authorities of different Member States (cross-border cooperation);
- Making use of the EU alert systems (AM[55], RIF[56]) to facilitate the rapid exchange of information on diversion (attempts) among authorities across the EU.

The success already achieved with these measures is evidenced by the dramatic decline of AA seizures over the last two years. It could, therefore, be concluded that traffickers have shifted their attention from the EU to other areas, so that AA diversion from EU-internal trade will not be an issue anymore in the future.

4.1.5.2. Traffickers continue to target the EU – Member States will react by increased national control

Another assumption, however, would be that the decrease in seizures shows that traffickers have learned from the enforcement successes in 2008 and have become more sophisticated. They continue to target the EU-internal market for diversion of AA by exploiting the weaknesses of the current legislation. This view is in line with informal reports received from national enforcement bodies, which report continued activities aiming at diverting AA in the EU.

Indeed, a significant number of Member States have criticised that without adequate legislative tools on European level their control possibilities remain inadequate, especially regarding their means to control end-users. Not acting on European level would mean that the weaknesses of the current legislation would persist and that Member States who feel a need for acting not only by better implementation, but also by "more legislation" would (within the limits of Art. 10 of Regulation (EC) No 273/2004) **adopt more stringent measures on national level** to deal with the risk of diversion. In fact, several Member States have put in

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[54] Workshop on countering heroin precursor diversion, Brussels, 9 June 2011. This workshop was organised as a special meeting of the Drug Precursor Working Group and within the framework of the European Pact to Combat Heroin and Cocaine Trafficking (where Germany and Italy had taken the lead on activities relating to heroin).

[55] The alert messaging system (AM) connects all competent authorities (regulatory, customs, police) and enables them to rapidly disseminate information about diversion (attempts). This ensures a coordinated approach by authorities across the EU and prevents traffickers from "shopping around" for substances in the EU.

[56] The Risk Information Forum (RIF) is a tool under the EU Customs Risk Management System which links Member States' customs authorities in all major ports/airports/frontiers. It allows for exchange of risk-related information directly among operational officials and risk analysis centres.

place extensive additional measures[57]. This would, on the one hand, lead to a **fragmentation of the Internal Market** affecting the wide variety of legitimate industrial uses of AA. On the other hand, the combination of different control standards risks by itself **creating loopholes**: for instance Member States requesting *registration of end-users* in their own territory cannot avoid fraudulent companies placing orders in that territory, when operating as end-users in another Member State and thereby avoiding registration. Assuming that a Member State obliges its operators to *notify all new end-users* to the authorities, a fraudulent company will avoid this obligation by placing orders in another Member State which does not ask for such notification.

4.2. EU right to act

Regulation (EC) No 273/2004 on drug precursors is based on Article 114 TFEU (formerly Article 95 TEC). The Regulation has set common requirements for monitoring and control of the trade in drug precursors, in order to ensure the free licit trade of these chemicals within the EU. Nevertheless, the legislation requires Member States to adopt national measures which are necessary to enable the competent authorities to perform their control and monitoring duties (Art. 10 of Regulation (EC) No 273/2004). Many Member States have used this basis for procedural rules only. In fact, **some Member States feel legally prevented from adopting national control measures** going beyond the EU legislation (e.g. Germany and the Slovak Republic). In particular, the argument has been made by these Member States that the EU legislation subjects 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.

However, others have also based substantive national controls on Art. 10. As set out in the previous section, different approaches of control in different Member States are, firstly, **detrimental to the functioning of the Internal Market** and, secondly, risk creating loopholes, which **weaken the effectiveness** of controls. If the EU-wide structural deficits of the legislation remain unaddressed, 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 Internal Market. Also, historically, the Member States targeted have been different: in 2001 mainly the United Kingdom, Italy and Belgium, then in 2008 mainly Slovenia and Hungary. These examples show that a combination of different national measures is not **as effective as a harmonised approach** at EU-level. This is also confirmed by that fact that both, Member States and industry 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.

While efforts to *implement* the control mechanism to a *similar standard throughout the EU* and for an improved cooperation among competent authorities need to continue, these **efforts for better implementation will not be sufficient** to address the structural weaknesses of the legislative system. There would be a need for *stricter EU legislation* to ensure a uniform standard to adhere to by the competent authorities in the different Member States. The latter view has, for years, been expressed by **INCB who has criticised the EU for non-action** and it is very likely that this criticism will continue in the future, if the European legislation remains unchanged.

[57] See footnote 34 for further details.

In conclusion, an effective strengthening of the control and monitoring mechanism, which would neither create loopholes nor unduly hinder the licit trade of drug precursors in the EU would have to be adopted at the European level.

5. OBJECTIVES

5.1. General policy objectives

There are two general objectives pursued with the present imitative:

(1) **To contribute to the world-wide combat against the illicit traffic in narcotic drugs and psychotropic substances.** Preventing the diversion of drug precursors is an important element by which the EU fulfils its obligations under Art. 12 of the 1988 UN Convention.

(2) **To ensure a proper functioning of the internal market for drug precursors**, by ensuring that operators are subject to the same, harmonised rules within the EU whilst avoiding unnecessary obstacles to legitimate trade and administrative burden for enterprises and competent authorities.

5.2. Specific and operational policy objectives

(1) Linked to the first general objective, the present initiative aims at **preventing diversion from the EU internal market**, **thus achieving a downward trend of diversion attempts and seizures** of AA, and thereby **limiting the input of diverted AA** originating from the EU to the production of illicit drugs, namely heroin.

(2) Linked to the second general objective, the initiative aims at **avoiding market distortions** by introducing **a uniform, effective and efficient standard of controls** for drug precursors within the EU and thereby limiting the costs for operators involved in the licit drug precursor value chain.

5.3. Consistency with other policies and objectives

The control of drug precursors is part of the **EU Drugs Strategy 2005-2012**[58] and the EU Drugs Action Plan (2009-2012)[59], which sets out the objective to reduce the diversion and trafficking in/via the EU of drug precursors used for the illicit manufacture of drugs.

As the drug problem is a complex phenomenon, it requires a multidisciplinary approach of combining *demand* and *supply reduction*[60]. Preventing the diversion and trafficking of drug precursors **aims at reducing the *supply* of illegal drugs** – the ultimate objective being a high level of protection, well-being and social cohesion of EU citizens by preventing and reducing drug use, in line with the EU Drug Strategy. The European Commission Services are

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

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

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

currently carrying out an evaluation of the 2005-2012 EU Drugs Strategy; in preparation of the EU Drug Strategy from 2013[61]. 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 Art. 12 of the 1998 UN Convention[62] 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 in the area of drugs-related health damage where the Treaty invites the Union to complement Member States' action on prevention of drug-use[63].

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[64].

6. POLICY OPTIONS

Based on the weaknesses identified during the evaluation of the existing legislation, the Commission Services (DG ENTR) developed six possible policy options which would address the identified problem drivers. The options were discussed with stakeholders in the Drug Precursor Working Group. The main problem driver being the insufficient control by competent authorities over all economic players involved in the (legal) trade with drug precursors, **all identified options** seek to improve that control via enhanced reporting, notification or registration obligations imposed on the economic players. The following policy options have been analysed:

6.1. Option 1: no action: the current EU legislation will remain unchanged (baseline option)

In this option, the existing EU legislation will not be modified. This means that, notably the following provisions already aimed at controlling the trade of AA (and other drug precursors) will remain unchanged:

- **Category 1 substances are subject to a more stringent control regime than category 2 substances.** The Regulation requires a licence for any dealing with the substance, including possession, end-use and sale. The EU legislation contains detailed requirements for granting a licensing number and imposes obligations on the applicant to provide the authorities with documentation on a number of obligations, such as measures taken to secure premises, a description of all places of storage, manufacturing and processing, a description of the envisaged operation with the substance. Furthermore, a copy of the customer declaration has to accompany any transport of category 1 substances within the EU.

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[61] For further details see http://ec.europa.eu/justice/newsroom/anti-drugs/opinion/111027_en.htm.
[62] See also under Section 0 above.
[63] Article 168 TFEU (Treaty on the Functioning of the European Union)
[64] Article 67 TFEU

- Only **operators for category 2 substances need to be registered** if they place substances on the market. **End-user customers** of category 2 substances are **not registered** with the competent authorities.

- The EU Regulation **does not lay down requirements with regard to the granting of a registration number**, so that some Member States give a registration number to any applicant for registration without particular verifications. Some even consider that registrations cannot be refused.

- **Customer declarations:** operators supplying category 1 or 2 substances have to obtain a declaration from each customer, which contains the name, address, registration details (if applicable) and the intended use of the substance[65]. **New customers** of category 2 substances are treated in the same way as long-standing customers, i.e. solely the obligation to obtain the customer declaration applies.

- **Reporting:** operators are currently under the obligation to inform the competent authorities once a year about scheduled substances used or supplied[66].

The Commission and Member States will continue efforts to improve the implementation of current rules, following-up on the results of the 'Best Practice' workshops which the Commission organised on how AA diversion can be prevented. As detailed above under section 4.1.5.2, Member States could adopt further national legislation in accordance with Art. 10 of Regulation (EC) No 273/2004 if they consider this necessary. Draft national measures would have to be notified in accordance with Directive 98/34/EC, to allow other Member States and the Commission to verify that they are in compliance with the requirements of the EU Treaty.

6.2. Option 2: strengthened reporting obligations

The existing reporting obligations could be strengthened to allow Member States to use the (more comprehensive) reporting by operators to increase their knowledge, target inspections and other enforcement activities, and exchange this information among competent authorities. To avoid unnecessary burdens, the reporting obligations could be reduced or abolished for holders of a special licence or a special registration[67].

Two sub-options could be distinguished (which could be applied either separately or in combination):

a) increasing the frequency of reporting (for example from once to four times per year)

b) extending the scope of reporting (including substances received and produced and requiring explicit reporting when no transactions are made over a given time).

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[65] Art. 4 of Regulation (EC) No 273/2004

[66] Art. 8(2) of Regulation (EC) No 273/2004 in combination with Article 17, 19 or Regulation (EC) No 1277/2005.

[67] Special licences and special registrations are foreseen in Article 3(2) and (6) of Regulation (EC) No 273/2004. Special licences or registrations 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 precursors within the scope of the official duties of the operators concerned.

6.3. Option 3: strengthened rules and obligations on operators related to customer declarations from end-users

The Regulation could be modified to establish that operators placing scheduled substances in category 2 on the market are not allowed to send a consignment following an order unless the customer declaration is completely filled in and they have conducted themselves a verification that the end-user has genuine motives for placing the order (e.g. verification that the end-user is a registered company active in the area of business mentioned under the 'intended use' of the customer declaration). When unable to conduct such verifications themselves, operators would have to involve their authorities.

The completeness of the customer declaration and the verification of the information would have to be documented in the records to be kept in accordance with Article 5 of the Regulation. Furthermore, a requirement could be introduced that a copy of the customer declaration should accompany scheduled substances in category 2 similar to what is already foreseen for substances in category 1. The option could be reinforced by reducing or abolishing the threshold of minimum quantities foreseen in Article 6 of the Regulation.

Two sub-options could be differentiated:

a) new obligations will apply only to AA

b) new obligations will apply to all or some category 2 substances

6.4. Option 4: require operators to systematically notify new end-users to the authorities to allow verification

In this option, operators placing scheduled substances in category 2 on the market would be obliged to systematically notify all orders from end-users who are first time customers to the competent authorities, and would only be allowed to ship the consignment, after having received the agreement of the authorities.

The authorities would verify the legitimate motives of the end-users, if necessary by co-operating with the authorities of another Member State, if the new customer is established in that other Member State.

The option could be reinforced by reducing or abolishing the threshold of minimum quantities foreseen in Article 6 of the Regulation.

Two sub-options could be differentiated:

a) new obligations will apply only to AA

b) new obligations will apply to all or some category 2 substances

6.5. Option 5: require registration for end-users and reinforce requirements regarding registration

In this option, end-users for scheduled substances in category 2 would be required to register[68] and obtain a registration number to be used when submitting a customer declaration in the context of an order for substances. This could give reassurance to operators placing the substances on the market that orders are legitimate, provided, of course, that they can easily verify that registration numbers are genuine (and not fake).

Further consideration has to be given to the verification that competent authorities conduct before granting a registration number to end-users (or operators in general): in its current form, the legislation does not lay down particular requirements with regard to the granting of registration numbers[69]. In order to ensure that registration of end-users will be an effective tool in combating diversion of scheduled substances, authorities will have to verify that end-users who register have genuine business activities – otherwise the registration number, which will appear on customer declarations of end-users, could give a false impression of proven legitimacy to operators receiving orders from registered end-users. European legislation could specify more detailed requirements and conditions for the granting, refusal and withdrawal of registration of end-users (and of operators in general).

The option could be reinforced by reducing or abolishing the threshold of minimum quantities foreseen in Article 6 of the Regulation, and/or foresee exemptions for certain categories of end-users, such as universities or research institutions**.**

Two sub-options could be differentiated:

a) new obligations will apply only to AA

b) new obligations will apply to all or some category 2 substances

6.6. Option 6: move AA from category 2 to category 1

In this option, AA would be moved from category 2 to category 1, which would mean that all those involved in the trade and use of AA would need to obtain a licence before they possess or place AA on the market, and would have to comply with all other requirements of licensed operators (see Annex 3 for an overview of these requirements).

7. ANALYSIS OF IMPACTS

In this chapter the impacts of the six identified options and their sub-options to introduce new requirements for AA only or for all substances in Category 2, respectively, are analysed. However, the possibility foreseen to reinforce options 3, 4, and 5 by reducing or *abolishing the threshold* of minimum quantities[70] has not been further examined for the following reasons: in the consultation, only a minority of Member States commented on this issue. For

[68] A registration requirement of end-users can be achieved with different means, for instance: adaptation of the definition of operators, adaptation of the definition of placing on the market, or introducing a separate provision for end-user registration.

[69] Article 3, paragraph 6, of Regulation (EC) No 273/2004.

[70] This threshold is currently foreseen in Article 6 of Regulation (EC) No 273/2004.

those who did, half wanted to keep the threshold, about one third wanted to reduce it and only one sixth wanted to abolish the threshold. Those providing reasons for their choice argued in favour of keeping the threshold by pointing out that there were a very large number of users of small quantities and abolishing the threshold would amount to a disproportionate burden. Furthermore, all known diversion attempts for AA have targeted larger shipments well above the current threshold of 100 litres. The possibility considered under options 2 and 5 to foresee *exemptions for certain categories of users* (such as holders of special licences/registrations or of universities/research institutions) has not been analysed due to very limited information received during the consultation[71].

The most relevant *economic impacts* include the administrative costs/burdens on businesses and public authorities; they have been quantified in the present report. For the preferred option(s), the IA will also assess impacts on SMEs and competitiveness.

Social impacts, including those on public health and safety as well as crime and security, are of less direct character than economic impacts, as they are related to the total amount of heroin supplied to the EU. While they therefore correlate with the *effectiveness of each option to prevent diversion* of the heroin precursor AA, it has to be noted that heroin would even be supplied to the EU if all of the diversion of European AA was effectively stopped, because traffickers may switch to other AA sources in the world[72]. Another factor of uncertainty in this respect are the actions of third countries[73], which may, either in response to a strengthening of controls in the EU or independently thereof, also improve control of diversion. Social impacts have, therefore, not been analysed for the individual policy option as it would not have been possible to quantify them or describe differences in a qualitative way other than the assessment of the effectiveness of the policy options in preventing diversion. There are *no environmental impacts* associated with the problem identified and any of the options to address the problem. The only environmental aspect concerns the destruction of diverted drug precursors that have been seized. This is regulated by the applicable waste legislation and the rules foreseen for the destruction of seized goods in the Community Customs Code. Nevertheless, reducing the quantities of drug precursors seized will also reduce the amounts that have to be destroyed.

While administrative cost/burdens have been fully monetized in the present report, this was not possible for benefits (i.e. the effectiveness of the options); these have therefore been assessed qualitatively.

7.1. Analysis of costs

7.1.1. Methodology

As the main problem to be addressed by the present initiative is the insufficient control by competent authorities over the economic players involved in the (legal) trade with drug precursors, **all identified options** seek to improve that control via enhanced reporting,

[71] Only three Member States expressed their views, two were favouring an exemption for holders of special licences and one was against such an exemption. This limited information was not considered a sufficient basis to change the status quo.

[72] See also Section 0 above.

[73] For instance the United States have recently conducted a large scale supply chain analysis of AA production and trade, in order to identify most vulnerable points for potential diversion, where enforcement actions should be concentrated on.

notification or registration obligations imposed on the economic players – hence **increasing administrative burdens** on them, with variations as to the degree of that burden and to the group of economic players and authorities concerned.

The administrative costs and administrative burdens stemming from the six policy options for enterprises and the competent authorities of the Member States are quantified, based on calculations carried out by an external contractor (EIM) using the Standard Cost Model (for detailed calculation tables please see Annex I of the final report of the study[74]). EIM based its calculations on a dataset created from the responses received by the Commission during the written consultation carried out in 2010 and further validated them through a series of targeted interviews.

It should be noted that an increase in administrative burden, would, to a certain degree, even be expected under the baseline scenario where existing tendencies of Member States to develop supplementing national legislation would be expected to continue, and hence lead to a risk of fragmentation of the internal market, which would also have detrimental effects on operators.

Therefore, the key question for the analysis of impacts is not whether there will be an increase of burden for industry but rather which kind of increase would be most proportionate in view of the expected benefits.

7.1.2. Assumptions

The administrative cost study has been based on the following main assumptions:

- *Clustering of Member States according to blocks for extrapolation*

As there is data from only 17 Member States, Member States have been dived into 3 blocks on the basis of the total number of licensed and registered operators. In each block, Member States have a similar number of licensed and registered operators. It is assumed that Member States within the same block need equal amounts of time to comply with their monitoring obligations, and this assumption is used to extrapolate data from one Member State for which data is available to another Member State in the same block for which there is no information available[75] – and eventually to the entire EU. For the calculation of administrative burdens in the present impact assessment, only the aggregated data for the entire EU have been used.

- *Hourly tariffs*

For enterprises, a tariff of approximately € 26 per hour[76] has been used for quantifying the administrative costs, which is the (rounded) average of the tariffs for the target group 'professionals' in all 27 Member States[77] - under the assumption that the enterprise staff performing the activities required to comply with information obligations fall into the target group 'professionals'.

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[74] A copy of the EIM Report is accompanying this report as separate document.
[75] For further information see EIM Report, page 9.
[76] As a basis for the calculations, the non-rounded hourly tariff of € 25.63 has been used.
[77] Tariff used in the Action Programme for reducing administrative burdens in 2008-2009.

For Member States, the average (rounded) tariff has been calculated for each of the above-mentioned blocks, based on the Member State tariffs contained in each block[78].

- *Number of enterprises*

The number of enterprises affected varies under the different options and sub-options. Options 2, 3b, 4b have an impact on operators dealing with all scheduled substances of category 2. For these options the total number of registered operators is used: 4,056[79].

Options 3a and 4a have impacts only on registered operators dealing with AA. Based on the answers provided by Member States during the consultation carried out in 2010, 40% of the total number of registered operators are assumed to be affected[80], corresponding to 1,622 enterprises.

Option 5a affects end-users of AA. According to the consultation carried out in 2010, this figure is estimated at 2,473 enterprises. Option 5b affects end-users of all category 2 substances. According to the 2010 consultation, this figure is estimated at 8,548 enterprises.

Option 6 affects (1) all currently registered operators dealing with AA (1,622) and, all end-users of AA, which are currently under no registration requirement (2,473). In total 4,095 enterprises would be affected.

- *Calculated costs are maximum costs*

It should be noted that a number of Member States have, over the last years, adopted national measures (in order to prevent diversion of acetic anhydride) which partly implement elements of the options analysed in this impact assessment. Therefore, the costs calculated are expected to be maximum costs, as in those Member States where presently already some / part of the options are applied, the costs for both operators and Member States for enacting the option in question would be lower than calculated here – specific examples will be mentioned as appropriate for the individual options.

7.2. Benefits

The benefits of the identified options essentially relate to the expected likelihood that the option will be effective in meeting the operational objectives, namely to decrease diversion and diversion attempts of AA and avoiding distortions in the internal market. They will be described qualitatively.

7.3. Option 1: no action

7.3.1. Costs

No additional administrative burden would be imposed on *European level* on either enterprises or competent authorities. However, a possible increase of administrative burdens at *national level* could be expected should Member States introduce complementing national

[78] Block A: €19 per hour, Block B: €21 per hour, Block C: €39 per hour.

[79] 4,056 enterprises are registered in the EU to deal with scheduled substances in category 2 (EIM Report, page 10) with reference to RPA.

[80] See Member State survey, questions 7 and 8.

measures. Drug precursors are used widely for a large variety of legitimate industrial uses. A system which would subject operators to different control standards depending on the Member State they are selling to/from would arguably be more difficult to handle for economic operators than a moderate increase of control applicable uniformly throughout the EU. In fact, a number of Member States have introduced national measures that lead to additional costs for the companies concerned.

For example, in **Denmark, Belgium and Spain**, end-users of all category 2 substances above a threshold of 100 l/year purchase are obliged to be registered with the authorities (following from an interpretation of the Regulation that the term 'operators' includes end-users). Additionally, in Denmark, operators with transaction volumes below the threshold are encouraged to register voluntarily with the authorities.

In the **Czech Republic**, all operators have been requested (without legally binding basis) to provide the authorities with information about their new customers, including also cases where orders have not been executed. The same request has been made in **Germany** by the competent authorities.

Hungary has increased national reporting rules for the category 2 substances AA and Potassium permanganate to every two months. Furthermore, operators have been requested to notify the authorities three days before all delivery of AA either a) above 20 litres or b) to a new customer.

Italy requires its companies to notify every single transaction to a national database before delivery takes place. The requested information also involves providing the authorities with information on end-users, so that authorities claim to have full knowledge on end-users and that, effectively, all end-users are registered via the national database.

The above shows that there is quite a large disparity in the EU on how operators (and in case of Belgium, Denmark, and Spain: also end-users) are controlled. Control standards vary between registration requirements (BE, ES, DK) notification requirements before delivery (IT, HU) or additional reporting obligations (CZ, DE, HU), all of which lead to additional costs. For operators selling in more than one Member State, these different obligations are a substantial burden, plus a competitive disadvantage for operators located in these Member States compared to those in others.

7.3.2. Benefits

On the one hand, no action at European level could be justified by the fact that diversion attempts concerning AA have **targeted** only a rather **limited number of Member States**, mainly in central Europe (see section 4.1.4). Therefore, it could at first sight be assumed that the problem is not 'EU-wide' and thus does not need to be addressed at European level.

Also, in terms of effectiveness of the option in preventing diversion, the recent statistics of seizures and stopped shipments have shown a clear downward trend, which suggests that the efforts of achieving a better implementation (notably to strengthen the authority-industry cooperation, to conduct specific industry-training activities and to increase vigilance of operators and enforcement authorities – see above under Section 4.1.5.1 on measures already taken by Member States) have already brought about a tangible improvement of the effectiveness of the current legislation in preventing diversion. It can be reasonably expected that the **enforcement activities will continue** to contribute to **better prevention of diversion** in the future, if Member States, the Commission and operators maintain their vigilance.

Further improvements might be expected from the implementation of the **European database** that the Commission is currently preparing, which will facilitate reporting of and access to information relating to seizures and stopped shipments by Member States, and allow easier verification of the status of potential clients through a list of registered operators (and possibly also trusted end-users). The database is expected to start being operational from the beginning of 2013.

On the other hand, it is to be expected that the **identified structural weaknesses** of the current legislation with regard to the diversion of the main heroin precursor AA (and possibly other drug precursors of scheduled substances in category 2) **would persist** – even though these may be reduced by efforts of better implementation of the current provisions as can be seen from the latest trends with regard to stopped and seized shipments (see Section 4.1.5).

If considered necessary, Member States could adopt **further national measures** under Article 10 of the current Regulation to reinforce control of trade in drug precursors. However, while this would be effective with regard to the objective of preventing the diversion of AA, it would be counterproductive with regard to the objective of avoiding **fragmentation of the internal market**. Indeed, a number of Member States have already introduced national control measures which have led to disruptions of the Internal Market (see previous section for details). This is why, during the consultations carried out by the Commission Services during 2010, several stakeholders and Member States held the view that diverging national rules should be avoided as there would be no longer a level playing field for all operators in the EU.

Finally, the **international criticism** of the EU as remaining "inactive" despite continued calls for stepping up the control of its internal market legislation would persist. In all of its recent annual reports, the INCB has called on the Commission to propose amendments to the existing legislation in order to eliminate the detected weaknesses[81] – failure to do so might reinforce the criticism voiced by the INCB, which will probably also be shared by several Member States.

7.4. Option 2: strengthened reporting obligations

7.4.1. Costs

7.4.1.1. Enterprises

Operators would become subject to increased administrative costs by additional reporting obligations. The results of the EIM Report are summarised in Table 3. Under sub-option 2a the frequency of reporting would be increased from once to four times a year, which would cause additional annual costs of ca. € 5.6 million. Under sub-option 2b the scope of reporting would be increased, leading to annual cost of ca. € 1.45 million. If both sub-options were implemented the total annual costs would amount to € 11.4 million (€ 5.6 million plus 4 x € 1.45 million).

[81] See section 0.

Table 3 Administrative burdens for registered operators under Option 2

		Total costs per year				
Policy option	*Sub-option*	*Time spent/ action*	*Average price / action*	*Total number of actions/year*	*Number of firms*	*Administrative costs* (AC)
2 Strengthened reporting obligations	2a) Increasing frequency of reporting by operators (quarterly)	18h	€ 461.34	3	4,056	€ 5,613,585
	2b) Extending the scope of reporting (including substances received, produced)	14h	€ 358.82	1	4,056	€ 1,455,374
	2a) + 2b): extending the scope and increasing the frequency	18h 14h	€ 461.34 € 358.82	3 4	4,056 4,056	€ 5,613,585 + € 5,821,496 **= € 11,435,081**

7.4.1.2. Competent authorities

The administrative costs for Member States' competent authorities as calculated in the EIM Report are set out in Table 4. Under sub-option 2a (quarterly reporting) the additional annual costs are € 1 million/year. Under sub-option 2b (increased scope) the annual costs for the authorities would be more limited (€ 0.27 million/year). If both sub-options were implemented the total annual costs would amount to € 2.1 million (€ 1 million + 4 x € 0.27 million, as the information under the extended scope will have to be reported 4 times/year).

It should be noted, though, that according to the results of the consultations, Hungary has already increased its national reporting rules for two of the category 2 substances (AA and potassium permanganate): the frequency has been increased from 1 to 6 times/year. An even further-reaching system has been enacted in Italy, where all transactions have to be registered in a national database before delivery takes place. For operators and competent authorities in these two Member States, the introduction of more frequent reporting rules would thus be less costly than calculated in this section.

Table 4 Administrative burdens for authorities under Option 2

			Total costs per year		
Policy option	*Sub-option*	*Time spent/ action*	*Average price/ action*	*Total number of actions/year*	*Administrative costs* (AC)
2 Strengthened reporting obligations	2a) Increasing frequency of reporting by operators (quarterly)	11,722h	€ 342,306	3	€ 1,026,918
	2b) Extending the scope of reporting (including substances received, produced)	9,377h	€ 273,845	1	€ 273,829
	2a) + 2b): extending the scope and increasing the frequency	11,722h 9,377h	€ 342,306 + € 273,829	3 4	€ 1,026,918 + € 1,095,316 **= € 2,122,234**

7.4.2. Benefits

In terms of effectiveness of the option in preventing diversion, competent authorities could expect to have **a better knowledge of the legal trade flows** – this could allow them to detect more easily unusual trade patterns which could indicate diversion to illicit channels. By having a more complete picture of the trade flows (by including not only substances supplied and used, but also substances produced and received, by making explicit notifications to the authorities also if no transactions have been made in the reporting period) authorities could compare data received from different operators and thereby find conflicting information which could point at diversion to illicit drug production. By getting the reported information more regularly (quarterly instead of yearly) the data would be of more relevance to detect recent diversions than if that data is already one year old.

However, a majority Member States' competent authorities has been sceptical about the real benefits of this option. In order to be able to match trade data from all operators within the EU, a very large amount of data would need to be collected and would have to be matched across EU-internal borders. Even under the assumption that this collection and cross-matching of data could be done, the assumed benefits for detecting diversion of AA were considered not very high. It has to be born in mind, that only 0.02% of AA production is potentially diverted, so that a general "check all transactions" approach is less promising than more targeted, risk-based actions.

With regard to the objective of preserving the internal market, the situation would probably be similar to Option 1: Member States might still consider that it would be necessary to adopt

further national measures under Article 10 of the current Regulation to reinforce control of trade in drug precursors. While this would also be effective with regard to the objective of preventing the diversion of AA, it would be counterproductive with regard to the objective of avoiding fragmentation of the internal market

7.5. Option 3: strengthened rules and obligations on operators related to customer declarations from end-users

7.5.1. Costs

7.5.1.1. Enterprises

For an assessment of the costs of this option for enterprises it has been assumed that operators' obligations will no longer be limited to obtaining a customer declaration but, in addition, the legislation would require them to conduct the verification that the information filled in is both complete and genuine, i.e. the registered customer is indeed in possession of the declared registration number or (for the end-user customer) he is indeed active in the declared business. This administrative cost (in form of carrying out verifications) is calculated to amount to 6 hours, plus an additional 1 hour of documenting the verification conducted. The (yearly) frequency of this operation depends on the average number of customer declaration, which each operator obtains per year.

Sub-option a): the new obligations will apply only to AA. With 52 customer declarations / year, the yearly administrative costs (*including business as usual* costs) for all operators dealing with AA would amount to € 15.1 million. The requirement that a copy of the customer declaration should accompany the substances when transported in the EU which is currently not the case for schedule 2 substances, would amount to an additional € 0.2 million[82].

Sub-option b): the new obligations will apply to all category 2 substances: with 116 customer declarations / year, the yearly administrative costs (*including business as usual* costs) for all operators dealing with substances of category 2 would amount to over € 84.4 million. The requirement that a copy of the customer declaration should accompany the substances when transported in the EU, would amount to an additional € 1 million.

It is debatable, however, to what extent the administrative costs resulting from this option could be considered *business as usual costs*, as diligent operators do actually conduct the verifications already today. Therefore, two different scenarios will be considered.

SCENARIO 1: 100% business as usual costs for customer verification

The EIM Report suggests that, according to the interviews the consultancy carried out, operators declared that they did *only* conduct business with companies that are known to them and for which they can check the authenticity, their activities and creditworthiness. Under this scenario, the costs linked to the main obligation under option 3, verification of the customer declaration, could be considered 100% business as usual costs and there would be no additional administrative burdens.

[82] EIM Report, section 3.4, p. 16.

The only remaining administrative costs would be the costs involved in sending a copy of the customer declaration. This would amount to € 0.2 million for sub option a) and € 1 million under sub-option b). A summary of the calculations is set out in Table 5.

Table 5 Administrative burdens for registered operators under option 3, SCENARIO 1 (100% business as usual for verification of customer declarations)

		Total costs per year		
Policy option	*Sub-option*	*Administrative costs* (AC)	*Business as usual costs (in % of AC)*	***Additional administrative burdens***
3 Strengthened rules and obligations on operators related to customer declarations from end-users (completely filled in customer declaration, verification - if necessary by authorities, copy of customer declaration on substances in category 2)	3a) Verification of the authenticity of the customer declaration data for AA only	€ 15,132,157	100%	**€0**
	3b) Verification of the authenticity of the customer declaration data for all substances of category 2	€ 84,411,687	100%	**€0**
	3a) Send a copy of the customer declaration only for AA	€ 180,145	0%	**€ 180,145**
	3b) Send a copy of the customer declaration for all substances	€ 1,004,901	0%	**€ 1,004,901**

SCENARIO 2: 70% business as usual costs for customer verification

The assumption made in the EIM Report that *all* operators only do business with customers which they have thoroughly checked could be challenged as not realistic, given that there are still cases of diversion which have not been signalled to the authorities (as evidenced by seizures).

In an alternative assumption, 30% of operators do currently not act in an ideal way and would have to increase their efforts under Option 2. This would lead to higher administrative burdens as detailed in Table 6: € 4.7 million (4.5 million + 0.2 million) for sub-option a), and € 26.3 million (25.3 million + 1 million) for sub-option b).

Table 6 Administrative burdens for registered operators under option 3: ***SCENARIO 2*** with 70% business as usual for verification of customer declaration

		Total costs per year		
Policy option	*Sub-option*	*Administrative costs* (AC)	*Business as usual costs (in % of AC)*	***Additional administrative burdens***
3 Strengthened rules and obligations on operators related to customer declarations from end-users (completely filled in customer declaration, verification - if necessary by authorities, copy of customer declaration on substances in category 2)	3a) Verification of the authenticity of the customer declaration data **for AA only**	€ 15,132,157	70%	**€4,539,647**
	3b) Verification of the authenticity of the customer declaration data for **all cat. 2 substances**	€ 84,411,687	70%	**€ 25,323,506**
	3a) Send a copy of the customer declaration **for AA only**	€ 180,145	0%	**€ 180,145**
	3b) Send a copy of the customer declaration **for all cat. 2 substances**	€ 1,004,901	0%	**€ 1,004,901**

7.5.1.2. Competent authorities

The costs for competent authorities under this option would depend on whether / how often operators have to involve their authorities because they cannot check the legitimacy of their customers by themselves.

SCENARIO 1: No involvement of competent authorities

The EIM Report assumes that enterprises are able to verify themselves the data concerning their customers via sources such as Chambers of Commerce, banks, and others and that there is hence *no need* to involve competent authorities in this verification exercise. Consequently, there would be **no additional costs for competent authorities**.

SCENARIO 2: Occasional involvement of competent authorities

An assumption of no involvement of authorities contradicts one of the key findings in the Commission's own evaluation of the functioning of the current legislation, where it was found, and subsequently confirmed by competent authorities on several occasions, that it was very difficult – even for competent authorities themselves – to verify data on customers in other Member States, particularly if those customers claimed to be end-users which are not registered. It is, therefore, assumed that also for operators themselves, it is difficult to verify the accuracy of information provided in a customer declaration, if the customer is based in another Member State, in particular if that customer claims to be an end-user.

Under scenario 2, it is, therefore, considered plausible that competent authorities would need to invest the similar amount of time (per request) for a verification of a customer on request of an operator as they would under option 4 (assessed under Section 7.6.1.2 below) according to which authorities would have to verify all new end-user customers before giving an agreement for delivery. The time per verification (1 hour) amounts – as under option 4 – to an average administrative cost per verification of about € 26 in the EU.

For the *required frequency*, it is assumed that about 10% of all customer declarations would require verification by authorities, because operators cannot conduct full verification themselves. Combined with the relevant number of customer declarations received per operator in the EU (52/year for customer declarations for AA only; and 116/year for customer declarations for all category 2 substances); the administrative costs for the involvement of authorities would amount to € 0.2 million (sub-option a), and € 1.2 million (sub-option b) per year.

Table 7 Administrative costs competent authorities under option 3 – ***SCENARIO 2*** (10% of customer declarations verified by authorities)

		Total costs per year				
Policy option	*Sub-option*	*Time spent/ action*	*Average price/ MS action*	*10% of AA customer declarations / operator*	*Number of operators*	Administrative costs
3	3a) Only for AA	1h	€ 25.63	5.2	1,622	**€ 216,174**
	3b) For all substances cat. 2	1h	€ 25.63	11.6	4,056	**€ 1,205,881**

7.5.2. Benefits

With regard to the objective of preventing diversion of AA, option 3 would increase the responsibility of operators for the choice of their customers. The legislation already requires *customers* to fill-in a customer declaration with details including: the company name and address, its registration details (if applicable), and the intended use of the substance. However, the legislation does not add *expressis verbis* a mirroring responsibility for operators to prevent them from delivering the substance ordered if the customer cannot demonstrate genuine motives for placing an order or if the customer declaration is incomplete. This option would remove this uncertainty.

It should be noted that diligent operators and authorities do already conduct these verifications under the current Regulation – hence, the effectiveness of the option in preventing diversion is probably comparable to that of Option 1 (in particular in the assumption of a 100% *Business as Usual* Scenario). Still, it can be expected that the clarification of the legal text as foreseen in this option would lead to an increased vigilance of operators to verify the genuine motives of clients placing orders with them (in particular also for those who do not act as diligently as they should) and would increase the number of cases where operators would contact their

authorities to signal suspicious transactions, e.g. when customer declarations are incomplete and/or when the indicated uses and quantities of substances ordered do not match the profile of the company having placed the order.

This option would be fully in line with the spirit of the current legislation, which intends to emphasize the responsibility of operators. The co-operation between economic operators and authorities – which is a cornerstone for the success of the drug precursor legislation – might intensify and improve. However, this will only work if operators are prepared to genuinely verify the content of customer declarations (rather than limit themselves to a 'tick-box' check of completeness without verification of the content of the customer declaration). Good and fast responsiveness of authorities to requests for assistance from operators will also be crucial as otherwise the climate of good co-operation might deteriorate quickly – this could become an issue where potential clients are based in other Member States and the 'inquiry chain' would have to involve the authorities of several Member States, which could easily lead to delays.

On the other hand, this option will not prevent traffickers from trying to find a 'weak link' and place orders with many different operators, hoping to find at least one who will not put too many efforts in verification of customer declarations before delivering the order.

With regard to the objective of preserving the internal market, the situation would probably be similar to Option 1: Member States might still consider that it would be necessary to adopt further national measures under Article 10 of the current Regulation to reinforce control of trade in drug precursors. While this would also be effective with regard to the objective of preventing the diversion of AA, it would be counterproductive with regard to the objective of avoiding fragmentation of the internal market.

7.6. Option 4: require operators to systematically notify new end-users to the authorities to allow verification

7.6.1. Costs

7.6.1.1. Enterprises

As detailed in Table 8, option 4 would cause administrative burdens of about € 0.04 million to notify all new **end-user customers for AA** to the authorities (sub-option a). The obligation to notify new **end-user customers for all scheduled substances in category 2** to the authorities (sub-option b) would cost operators about € 0.5 million.

Table 8 Administrative burdens for registered operators under Option 4

		Total costs per year		
Policy option	*Su- option*	*Administrative costs* (AC)	*Business as usual costs (in % of AC)*	*Administrative burdens* (AC – BAU)
4 Require operators to systematically notify new end-users to the authorities to allow verification and request agreement for delivery from CA	4a) Only for AA	€ 41,572	0%	€ 41,572
	4b) For all substances cat. 2	€ 467,799	0%	€ 467,799

7.6.1.2. Competent authorities

It is assumed that competent authorities would need about 1 hour for each new end-user verification. As detailed in Table 9, this would involve an annual cost of € 0.005 million in the EU for the verification of notified new **AA end-user customers** and authorisation of delivery (sub-option a). If the verification and authorisation were required for new end-users of all category 2 substances (sub-option b), the annual costs would amount to € 0.03 million.

Table 9 Administrative costs competent authorities under Option 4

			Total costs per year
Policy option	*Sub-option*	*Member States*	*Administrative costs* (AC)
	4a) Only for AA	All MS (27)	€ 4,939
	4b) For all substances cat. 2	All MS (27)	€ 26,725

It should be noted that Hungary has already requested its operators to make a notification to the authorities three days before any delivery to a new customer. In the Czech Republic and in Germany, operators have recently been requested to provide the authorities with information about their new customers. A notification of all (not only new) customers to the authorities is part of the national legislations of Italy and happens voluntarily in Austria. Consequently, in all of these Member States, the costs incurred by the proposed option 4 are expected to be lower than calculated above, depending on the details of the current notification to the authorities.

7.6.2. Benefits

This option has the potential to be very effective in preventing diversion while keeping the administrative burden both for operators and authorities directly proportionate to the risk. It is reasonable to assume that long-standing customer relations between a supplier and distributor

or end-user of a substance have a very low risk of diversion. In such situations the 'know your customer' principle is fully complied with. On the other hand, new customers – in particular those claiming to be end-users and hence not having a registration number attributed by an authority – always present a bigger challenge for operators in terms of verification of their genuine motives for placing an order. The risk that operators limit their efforts for verification of a new client is relatively high as delays in their acceptance of an order can lead to the result that the order is lost and placed elsewhere.

The obligation to systematically notify all new clients to the authorities will ensure that the authorities themselves can conduct all appropriate verifications – if necessary also involving their homologues in other Member States – and in case of doubt they can prevent the operator from delivering the order and/or they can monitor delivery. It would also be more difficult for traffickers to try to find 'a weak link' in the EU as they should be subject to the same scrutiny by authorities in all Member States. As set out above, Hungary has already implemented this option by requesting notification of every transaction of AA with a new customer (or above a certain threshold) and has reported to find this measure very effective. Germany, however, which recently also requested its operators to provide them with information on new end-users, considered the systematic registration of *all* end-users to be more effective.

On the other hand, this option would entail the risk of de facto creating different control standards between end-users that have been involved in trade with drug precursors for a long time and new market entrants. Whilst it is true that an end-user who changes supplier will become a new customer for the new supplier (and then be reported to the authorities) this will not happen if the end-user does not switch his long-standing supplier(s). On the other hand, new market entrants (i.e. companies starting to buy for the very first time), will always be reported to the authorities, possibly even multiple times if they start ordering from several suppliers. This might even become a barrier for new market entrants.

Furthermore, during the consultations, some stakeholders held the opinion that option 4 could also lead to some counter-productive effects. The drug precursor legislation relies on the sensitisation of the industry to the risks of diversion to illicit uses of the substances and a (mainly voluntary) cooperation of the industry. A systematic notification of new customers to the authorities could weaken this effect of self-responsibility of the industry for detecting suspicious orders indicative of a diversion attempt. In fact, operators already now voluntarily involve the authorities, if they are uncertain about a particular order. This happens in particular for orders from new customers[83].

This option would instead shift the responsibility to authorities who would ultimately decide on the fate of potential new business relationships. If authorities were slow in replying to operators with the results of their verifications, operators might lose potentially genuine business which could create incentives to not comply with the notification obligation and the option could thus become ineffective. Also, some comments in the consultation added that it was only possible for the authorities to respond quickly, if the end-users had previously been registered with the authorities, so that authorities would have the information available.

[83] For instance, Germany reported in the written consultation that requests from operators to the authorities to verify new customers were an important element within the industry-authority partnership to prevent diversion.

According to these views, a notification of new end-user customers would only be effective if combined with an end-user registration[84].

There could be further negative effects for the monitoring of the non-scheduled substances (loss of effectiveness of industry cooperation), which is entirely voluntary and necessary to be able to react to new diversion trends.

With regard to the objective of preserving the internal market, Option 4 would increase the knowledge of authorities related to a part of the end-users (i.e. those placing orders for the first time with operators). This would probably reduce somewhat the likelihood that Member States consider that it would be necessary to adopt further national measures under Article 10 of the current Regulation to reinforce control of trade in drug precursors. However, given that Member States would still not know all end-users (i.e. not those having long-standing business relations with operators), some could still consider it necessary to adopt additional national control measures, which would be detrimental for the Internal Market.

7.7. Option 5: require registration for end-users and reinforce requirements regarding registration

7.7.1. Costs

7.7.1.1. For enterprises

As detailed in Table 10, option 5 would create considerable *one-off costs* for the registration of all existing end-users: € 0.16 million under sub-option 5a (for AA end-users only) and € 0.5 million under sub-option 5b (for all end-users of category 2 substances).

On the other hand, the option involves low *annual costs* for enterprises, with € 0.01 million/year if the new registration requirements would apply only to AA end-users (sub-option a) and € 0.07 million/year for a registration requirement for end-users of all category 2 substances (sub-option b)).

[84] Contribution of Hungary during the written consultation.

Table 10 Administrative burdens for registered end-users under Option 5

		Total costs (per year for ongoing costs)		
Policy option	*Sub-option*	*Administrative costs* (AC)	*Business as usual costs (in % of AC)*	*Administrative burdens* (AC – BAU)
5 Require registration for end-users and reinforce requirements regarding registration	**5a) One off** costs end-user registration (current end-users only AA)	€ 158,457	0%	€ 158,457
	5b) One off costs end-user registration (current end-users all subst. cat. 2)	€ 547,713	0%	€ 547,713
	5a) Ongoing costs end-user registration (new end-users only AA)	€ 12,559	0%	€ 12,559
	5b) Ongoing costs end-user registration (new end-users all subst. cat. 2)	€ 65,357	0%	€ 65,357

However, it cannot be excluded that Member States' authorities will charge registration fees to pass on the administrative costs which they will have to bear under Option 5 for granting the registration to enterprises (see next section for details). So far, only few Member States have already introduced registration fees, in order to carry over their costs to the companies concerned[85], but it cannot be excluded that the significant costs for authorities from Option 5 would lead others to follow this example. Should Member States decide to levy fees for registration of end-users, the costs for enterprises would increase by the amounts calculated in Section 7.7.1.2. As micro-SMEs might be disproportionately affected by such a 'roll-over' of Member States' costs, it might be necessary to consider mitigation measures if Option 5 was implemented, e.g. the legislative proposal could prevent Member States from imposing registration fees on micro-SMEs.

7.7.1.2. Competent authorities

As detailed in Table 11, registration of all existing AA end-users (sub-option a) would create *one-off costs* of € 0.4 million for authorities for registration of all exiting end-users of AA and *annual costs* of € 0.05 million for registration of new end-users of AA.

In sub-option b, competent authorities would have to bear one-off costs of € 1.8 million for the registration of existing category 2 end-users and, in addition, annual costs of € 0.2 million for registration of new category 2 end-users.

[85] Fore example, the UK currently charges £435 (approximately € 520) for issuing a new registration Article 2 of UK Statutory Instrument 2010 No. 2564 - Dangerous Drugs - The Controlled Drugs (Drug Precursors) (Intra-Community Trade and Community External Trade) Regulations 2010, in force since 15 November 2010, available at: HTTP://WWW.LEGISLATION.GOV.UK/UKSI/2010/2564/PDFS/UKSI_20102564_EN.PDF. Also the Czech Republic and Estonia have informed the Commission during the written consultation that they charge fees for granting licences and registrations.

As mentioned in the previous section, competent authorities could decide to pass on these costs to end-users in the form of registration fees. In that case, they would have no additional costs to bear.

Table 11 Administrative costs for competent authorities under Option 5

			Total costs (per year for ongoing costs)
Policy option	*Sub-option*	*Member States*	*Administrative costs* (AC)
	5a) One off costs only for AA	All MS (27)	€ 392,559
	5b) One off costs for all substances cat. 2	All MS (27)	€ 1,801,674
	5a) Ongoing costs only for AA	All MS (27)	€ 47,934
	5 b) Ongoing costs for all substances cat. 2	All MS (27)	€ 236,190

It should be noted that Belgium, Denmark and Spain register end-users already under the current national legislation. An introduction of a registration requirement at European level would, to the extent that the current national system is comparable in terms of registration requirements, involve considerably fewer costs for the companies and competent authorities concerned in these Member States.

7.7.2. Benefits

This option has been proposed by several Member States who have repeatedly stated during the consultations that the main difficulty which currently precludes Member States' competent authorities from effectively preventing diversion is their lack of control and knowledge over end-users. As end-users are not registered under the present European legislation, they are "unknown" to the authorities who have, hence, difficulties to control them.

Member States who have experience with an end-user registration requirement either from past[86] or current[87] national legislation reported that the end-user registration has proved to be an effective tool. As is already required for operators, it will allow **Member States to verify** the genuine motives of end-users with regard to the use of drug precursors during the registration process and thus *before* they can place any orders to purchase drug precursors. This would also **facilitate the tasks of operators** to verify that their customers have genuine motives as end-users placing an order would have to provide a customer declaration including

[86] This is the case for Germany, who had in its national legislation, prior to entry into force or Regulation (EC) No 273/2004, a requirement for all end-users of category 2 substances to be registered, as well as for the Eastern European Member States (EU 12) which had scheduled AA as a category 1 substance prior to accession.

[87] National legislation in Belgium, Denmark and Spain contains an obligation for end-users to register with the authorities. Italy has a very detailed database system, in which companies are required to notify every transaction before delivery, so that the authorities claim to have effectively an overview of all end-users. Austria and France apply a voluntary registration of end-users.

also an official registration number attributed by an authority. In line with these experiences, option 5 is the most favoured option by Member States according to the consultation carried out in 2010: 58% of MS considered option 5 to be the best option to effectively prevent diversion.

However, the expected improvements in preventing diversion will only materialise if Member States do in fact control applicants for registration before attributing a registration number. Information provided during the consultations has cast some doubt on whether this actually happens: in fact, several Member States have claimed that the current wording of Article 3 (6) in Regulation (EC) No 273/2004 does not allow them to refuse registration – an opinion not shared by others or the Commission Services. In order to eliminate any doubts, it would therefore be necessary to amend Article 3 (6) and, in addition, to agree certain minimum requirements with regard to registration including also a visit to the premises of the applicant.

Secondly, the option will only have the intended effect, if operators maintain their vigilance and verify that registration numbers of their (potential) clients are genuine and do not accept them at face value when they appear on a customer declaration. Otherwise, the fact that presumably official registration numbers appear on customer declarations of end-users could actually lead to decreased vigilance as operators would (wrongly) believe that the indication of the registration number does automatically legitimise the client. Consequently, operators will have to conduct the same efforts as described under option 1 (or even 3), involving, where necessary also the authorities. The Commission's intention to provide a data base with all registered operators (and also end-users in this option) would facilitate such verification.

With regard to the objective of preserving the internal market, Option 5 would greatly increase the knowledge of authorities related to end-users and this would strongly reduce the likelihood that Member States consider it necessary to adopt further national measures under Article 10 of the current Regulation to reinforce control of trade in drug precursors. Option 5 would thus be very effective in preserving the Internal Market.

7.8. Option 6: move AA from category 2 to category 1

7.8.1. Costs

7.8.1.1. Enterprises

As detailed in Table 12, option 6 involves **one-off costs** of € 0.3 million for all existing operators and end-users of AA for obtaining a licence to possess or sell AA within the EU.

In addition, the option involves **yearly costs** for licensing new AA operators and new end-users. The number of *new AA end-users* has been calculated based on the Member States' survey as 196 per year[88]), which (based on the total number of AA end-users of 2,473) amounts to a ratio of 8% fluctuation per year. The answers to the survey did not contain information on the number of *new AA operators* per year. However, applying the same ratio of 8% fluctuation to the total number of AA operators in the EU 1,622, the number of new AA operators can be estimated at 49 per year[89]. Based on these calculations, 245 (196+49) companies per year would need to be considered for the yearly costs of this option. Combined

[88] See EIM Report page 20 "origin of some figures" and Annex 1 to that Study "Detailed calculations".

[89] 49 new operators/year can be considered as a maximum, as the number of AA producers and traders (whose businesses requires a certain infrastructure) should be more stable than the number of end-users.

with the calculated price under this option for obtaining a licence (€ 76.89), the ongoing costs would amount to just under € 20,000.

An additional annual cost of € 180,000 has to be added for the obligation of operators to stamp and date a copy of the customer declaration and have it accompany AA shipments being moved within the EU.

Additional yearly costs would be incurred by companies if the change of category would also be considered under Regulation (EC) No 111/2005 **concerning external trade**. Under Art. 20 of that Regulation, import authorisations are required for each individual import consignment of category 1 substances. According to the consultation carried out in 2010, enterprises spend 55 minutes/year to obtain an import authorisation and they obtain on average 3 individual import assignments for AA. An obligation to obtain import authorisations for AA would amount to additional yearly costs of € 0.3 million.

These costs would be further increased if Member States passed on the administrative costs which they bear for granting licences to enterprises. So far, some Member States have already introduced licensing fees, in order to recover their costs from the companies concerned[90]. In such a scenario, the costs for authorities as calculated in the next section would have to be added to the costs for enterprises calculated above. As micro-SMEs might be disproportionately affected by such a 'roll-over' of Member States' costs, it might be necessary to consider mitigation measures if Option 6 was implemented, e.g. the legislative proposal could prevent Member States from imposing licensing fees on micro-SMEs

[90] Fore example, the UK currently charges £3,655 (approximately € 4,370) for issuing a new licence, Article 2 of UK Statutory Instrument 2010 No. 2564 - Dangerous Drugs - The Controlled Drugs (Drug Precursors) (Intra-Community Trade and Community External Trade) Regulations 2010, in force since 15 November 2010, available at: HTTP://WWW.LEGISLATION.GOV.UK/UKSI/2010/2564/PDFS/UKSI_20102564_EN.PDF. Also the Czech Republic and Estonia have informed the Commission during the written consultation that they charge fees for granting licences and registrations.

Table 12 Administrative burdens for licensed companies under Option 6

		Total costs (per year for ongoing costs)		
Policy option	*Costs per activity*	Labour costs per action	*Number of actions*	Administrative burdens
6 Move AA from category 2 to category 1	**One off** costs obtaining a license for AA	€ 76,89	4,095	€ 314,865
	Ongoing costs obtaining a license for AA	€ 76,89	245	€ 18,838
	Ongoing cost: operators must stamp and date a copy of the customer declaration and accompany it with AA being moved within EU	€ 2,13	84,344	€ 180,145
If move of category is also considered under external trade	**Ongoing** costs for obtaining import authorisations for each consignment of AA	€ 28.83	12,285	€ 292,793

7.8.1.2. Competent authorities

Option 6 involves **one-off costs** of € 1.7 million for competent authorities for licensing all existing companies handling AA, which is almost equivalent to the one-off costs for the authorities under option 5b.

In addition, the option involves **yearly costs** for licensing new AA operators and new end-users. According to the calculation above (section7.8.1.1) 245 companies need to be licensed by the authorities each year (i.e. all new AA end-users and all new AA operators). The average price per action (issuing a licence for AA) in the EU has been calculated at € 414. As a result, the total yearly costs of option 6 amount to about € 0.4 million as detailed in Table 13.

Additional yearly costs would be incurred by competent authorities if the change of category would also be considered under Regulation (EC) No 111/2005 **concerning external trade**. Under Art. 20 of that Regulation, import authorisations are required for each individual import consignment of category 1 substances. According to the consultation carried out in 2010, Member States spend 648 hours /year for granting 679 import authorisations for category 1 substances[91]. Based on the estimates provided by enterprises, 12,285 individual import authorisations would have to be granted for AA each year. A requirement to obtain import authorisations for AA would thus amount to additional yearly costs of € 0.1 million.

[91] This amounts to an average time of 57 minutes per import authorisation.

Table 13 Administrative costs competent authorities under Option 6

		Total costs (per year for ongoing costs)		
Policy option	*Costs per activity*	Authorities' average costs per action	*Number of actions*	Administrative costs
6 Move AA from category 2 to category 1	**One off** costs obtaining a license for AA	€ 414	4,095	€ 1,697,070
	Ongoing costs obtaining a license for AA	€ 414	245	€ 101,534
If move of category is also considered under external trade	**Ongoing** costs for obtaining import authorisations for each consignment of AA	€ 24.38	12,285	€ 299,549

7.8.2. Benefits

The benefits of option 6 in terms of a reduced likelihood of diversion of AA from legal trade are expected to be similar or even higher than those of option 5a. A change of category for AA from category 2 to category 1, would automatically subject all end-users of AA to the direct control of the authorities, as these end-users would now need to be licensed (which involves even stricter requirements than a registration). In addition, also *operators of AA* would be subjected to the stricter regime of a licence, instead of the current registration requirement.

Option 6 would thus enable a better control of competent authorities over both end-users and operators of AA than the baseline scenario or any other option.

However, this improved control is linked to the substance AA only. This can be seen as beneficial in the sense that any increase in administrative burden is limited to that substance for which high volumes of diversions and diversion attempts have been shown in the past. On the other hand, however, limiting the option to AA means that the detected structural weaknesses of the regime for category 2 substances are not addressed. In case the focus of traffickers should shift from AA to another substance in category 2, the legislative changes carried out under option 6 would not be able to address this changed diversion trend[92].

With regard to the objective of preserving the internal market, Option 6 would greatly increase the knowledge of authorities related to end-users and this would strongly reduce the likelihood that Member States consider it necessary to adopt further national measures under Article 10 of the current Regulation to reinforce control of trade in drug precursors. Option 6 would thus be very effective in preserving the Internal Market.

[92] The same reasoning applies to sub-options 3a, 4a, and 5a which are also limited to AA.

8. COMPARING THE OPTIONS

Table 14[93] compiles the information regarding expected benefits (in terms of effectiveness to achieve the operational objectives) and costs for each of the (sub-)options.

8.1. Qualitative assessment of benefits

The effectiveness scores of Option 1 (baseline scenario) have been set at "0", both for the prevention of diversion and the preservation of the internal market.

The analysis for Option 2 (increased reporting) has revealed that it is not an effective tool to *prevent the diversion* of AA (Option 2a) or of all category 2 substances (Option 2b), as competent authorities would not have the means to check very large datasets on legal transactions to find a relatively small percentage of diverted substance (0.02% of totally produced AA is diverted). This leads to a '0' score.

Option 3 (increased obligations on operators relating to checking of customer declarations) would require operators *'expressis verbis'* not to deliver any orders if the customer declaration has not been correctly filled in. Even though diligent operators will already now do these checks, the option will provide legal clarity on the obligation to do so and is therefore considered to bring about some improvement in preventing diversion (score: +). With regard to the preservation of the internal market, Member States are likely to consider it equally necessary under option 2 and option 3 to adopt national measures, so that the score for both options would be "0", as in the baseline scenario.

Options 4 and 5 have both the potential to be very effective in *preventing diversion*, but with conceptually different approaches: Option 4 focuses on *new end-user customers*, which are placed under scrutiny through a notification obligation of operators (to authorities) for their new end-user customers. This has the advantage that the authorities focus their limited resources on the group of "most risky customers", the ones not previously known to the operator. This focussed risk-based approach could be considered more efficient than a general "register all end-users" approach under option 5, where fraudulent customers may be lost in the higher numbers of many licit end-user customers. On the other hand, option 4 entails the risk of creating different control standards for end-users, who are new market entrants or switch suppliers, compared to well-established end-users, who remain with existing suppliers, whilst option 5 has the advantage of providing the authorities with a complete overview of all end-users in their territories. In case of need, this enables them to act quickly and target enforcement actions on some of these end-users following specific market intelligence (i.e. to carry out an individual risk-based measure).

As a result, it is considered that options 4 and options 5 can be considered as having almost an equivalent score of effectiveness in preventing diversion (++), option 4 scoring arguably slightly weaker if one factors in that it does imply different control standards, which has been indicated as (+[+]) in the table. In terms of preserving the internal market, however, due to the overwhelming preference of Member States for option 5, option 4 involves a non negligible risk of national measures being adopted in addition. Therefore Option 5 scores better (+++) than option 4 (++) in this respect.

[93] Total costs in this table are based on the sum of the exact individual components. Therefore they do not fully correspond with the totals of the (rounded) components in this table.

Under option 6, the strongest tools available under the current legislation would be applied to AA. Therefore it has the highest effectiveness score for preventing diversion (+++) and, together with option 5, the highest score for preserving the internal market (+++).

8.2. Assessment of costs

When comparing the costs to the expected effectiveness, **Option 2 can be discarded** as it will trigger significant costs – in particular for companies – without clear benefits in terms of reducing the risk of diversion of drug precursors in category 2 from legal trade.

For options 3, 4, and 5, a choice has to be made whether the options should apply to all scheduled substance in category 2 or to AA only, whereas option 6 is targeted at AA exclusively. At first sight, it may seem more consistent to apply the options to all substances in the same category as the *weaknesses identified* in the prevention of diversion (especially insufficient control of end-users) apply equally to all substances in that category. However, the sub-options affecting all category 2 substances subject a considerably higher number of companies to obligations and create significantly higher additional administrative burdens and costs, whilst only AA has been consistently identified by both the INCB and Member States' competent authorities as problematic during the consultation process. In addition, the main principle of the legislation is that there are different levels of control for different substances – depending on the *particular diversion risk of each substance* concerned. Therefore, the choice should be **limited to options addressing AA only**. Consequently, sub-options 3b, 4b and 5b should be eliminated.

The cost calculation of **Option 3a** distinguishes two alternative scenarios. The EIM Report suggested that all (100% of) enterprises are already verifying the legitimacy of their customers' business before delivery (scenario 1: no additional costs for enterprises), and that enterprises never need to involve their authorities in this verification (scenario 1: no additional costs for authorities). As explained under Section 7.4, under a more realistic assumption only 70% of operators do already act in an ideal way and verify their customers before delivery (scenario 2 for enterprise costs), and for 10% of all customer declarations, enterprises need to involve their authorities (scenario 2 for authority costs). Based on scenario 2, option 3a has the **highest total yearly costs** from the remaining options (€ 4.7 million), **without clear benefits** both for reducing diversion and for preserving the internal market and should therefore be eliminated as well.

Table 14 Comparative table on costs and benefits

Option		Benefits/Effectiveness		Costs for companies	Costs for authorities	Total Costs
		Prevent diversion	***Preserve int. market***			
1		0	0	€ 0 Risk of fragmented market	€ 0	€ 0
2	**2a**	0	0	€ 5.6 mio/year	€ 1 mio/year	€ 6.6 mio/year
	2b	0	0	€ 1.5 mio/year	€ 0.3 mio/year	€ 1.8 mio/year
	2a+2b	0	0	€ 11.4 mio/year	€ 2.1 mio/year	€ 12.5 mio/year
3	**3a (AA only)**	+	0	Scen. 1 (100% business as usual): € 0.2 mio/year Scen. 2: (70% business as usual): € 4.7 mio/year	Scen. 1: (no authority involvement) € 0 Scen. 2: (authorities involved in 10% of cases) € 0.2 mio/year	Scen. 1: € 0.2 mio/year Scen. 2: € 4.9 mio/year
	3b	+	0	Scen. 1: € 1 mio/year Scen. 2: € 26.3 mio/year	Scen. 1: € 0 Scen. 2: € 1.2 mio/year	Scen. 1: € 1 mio/year Scen. 2: € 27.5 mio/year
4	**4a (AA only)**	+[+]	++	€ 0.04 mio/year	€ 0.005 mio/year	€ 0.05 mio/year
	4b	+[+]	++	€ 0.5 mio/year	€ 0.03 mio /year	€ 0.53 mio/year
5	**5a (AA only)**	++	+++	€ 0.16 mio + € 0.01 mio/year *Alt. Scen: (company registration fees)* € 0.55 mio + € 0.06 mio/year	€ 0.39 mio +€ 0.05 mio/year *Alt. Scen: € 0*	€ 0.55 mio + € 0.06 mio/year *Alt. Scen:* € 0.55 mio + € 0.06 mio/year
	5b	++	+++	€ 0.5 mio + €0.07 mio/year *Alt. Scen: (company registration fees)* € 2.3 mio + € 0.3 mio/year	€ 1.8 mio + € 0.2 mio/year *Alt. Scen: € 0*	€ 2.3 mio + € 0.3 mio/year *Alt. Scen:* € 2.3 mio + € 0.3 mio/year
6	**(AA only)**	+++	+++	€ 0.3 mio + € 0.2 mio/year *[or: incl. ext. trade* + 0.5 mio/year] *Alt. Scen:(company licensing fees)* € 2.0 mio + € 0.3 *[or* + 0.9*] mio/year*	€ 1.7 mio + € 0.1 mio/year *[or: incl. ext. trade* + 0.4 mio/year] *Alt. Scen: € 0*	€ 2.0 mio + € 0.3 mio/year *[or incl. ext.tr.* + 0.9 mio/year] *Alt. Scen:* € 2.0 mio + € 0.3 *[or* + 0.9*] mio/year*

Options 4a, 5a and 6 have similar benefits, both in preventing diversion and in preserving the internal market. However, **Option 6** can be singled out for creating **very high additional costs**: it involves one-off costs of € 2.0 million (against € 0.55 million for option 5a and none for option 4a) and yearly costs of at least 0.3 million[94] (against € 0.06 million for option 5a and € 0.05 million for option 4a). Looking at the costs for companies only, the differences between Option 6 and options 4a/5a are even more striking. In terms of cost efficiency, option 6 therefore scores as least favourable and can also be excluded.

Options 4a and 5a remain as most promising. The overall costs for Option 5a compared to its benefits are clearly higher than for Option 4a. However, this is mainly due to the 'one-off' costs for the registration of a high number of existing end-users – the main part of these registration costs will be for the authorities: € 0.39 million compared to € 0.16 million for companies.

Based solely on the overall cost/benefits-ratio for authorities and companies combined (and including the one-off registration costs) **Option 4a would prevail as the preferred option**.

However, leaving the fixed costs aside (they can be disregarded once all existing companies have been registered), cost differences are less pronounced: Option 5a is better from the perspective of companies (Option 5a amounts to only 25 % of the yearly costs expected for Option 4a), whereas Option 4a is advantageous from the perspective of authorities (only 10% of the yearly costs expected for Option 5a).

Considering that Option 5a thus involves lower annual costs for companies and that it has, at the same time, the greatest political support from the majority of Member States would be an **argument for choosing Option 5a** as the preferred option. The argument of lower annual costs for companies would, however, no longer be true if Member States decided to recover their costs from registrants by charging registration fees, as for example the UK has introduced recently. The effects of a potential passing-on of the authorities' costs to companies have therefore been calculated as an "alternative scenario" under Option 5.

However, putting the combined total yearly costs of either option (€ 0.05 million for Option 4a and € 0.06 million for Option 5a into perspective with the **total European market value** of AA (> € 257 million/year[95]), their impact is quite limited. Also the one-off costs of € 0.16 million for companies and of € 0.29 million for authorities are low in comparison.

In conclusion, both Options 4a and 5a are considered good choices to address the identified objectives. The selection of either of them is primarily a political choice. The strong political support which Option 5a 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 may tip the balance in the end in favour of Option 5a. An additional argument for Option 5a would be considering the specific impacts on SMEs (see below).

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[94] If the change of category for AA is also carried out in Regulation (EC) No 111/2005 on external trade, the yearly costs under option 6 would rise by an additional 0.6 million to 0.9 million.

[95] An exact relation with the European turnover of AA is not possible, as there are no published market prices for AA. However, based on market research, the production of AA in the Europe amounts to approximately 330,000 tons/year and the EU import value per ton amounted to 780 Euros on average over the last three years (2007-2009), which corresponds to a market value of the European production of € 257,4 mio/year. See: 2010 CEH Marketing Research Report on Acetic Anhydride © by the Chemical Economics Handbook – SRI Consulting, page 30 (European production) and page 32 (price).

Competitiveness check and SME check

In view of the relatively low costs of either option in relation to the overall market value of the European AA production, a tangible impact of the **competitiveness** of European industry is not expected.

The preferred options would both have effects on **SMEs**. SMEs dealing with AA are primarily end-users. SMEs have been involved in the consultation with a targeted consultation via the Enterprise Europe network[96]. While about 50% of them expressed a preference for not changing the legislation at all, option 5 was the second preferred option (15% or respondents), while options 2, 3 and 4 were chosen by respectively 7-8% of the respondents. This result is in line with the analysis that 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), an argument which is particular relevant for SMEs.

The present initiative would, under none of the options, envisage a general exclusion of **micro-companies**, as this would create an easy possibility of circumventing the controls of the legislation. Traffickers could establish themselves as micro-entities in order to evade controls by the authorities. It should, however, be born in mind that micro-companies are most likely to benefit from the existing thresholds under the current legislation: Art. 6 of Regulation (EC) No 273/2004 foresee that companies with sales/purchases of drug precursors below the maximum yearly quantities[97] are excluded from most of the obligations under the legislation[98].

Finally, as mentioned in Section 7.6.1.1 a specific protection of micro-SMEs would be foreseen in option 5 to prevent Member States to impose registration costs on micro-SMEs.

9. MONITORING AND EVALUATION

9.1. Measuring the fulfilment of objectives

The Commission will continue to collect Member States' annual statistics of seizures and stopped shipment of drug precursors diverted in the EU[99]. These statistics will show whether under the new legislative measures a downward trend of seizures of diverted substances and of stopped shipments (indicating diversion attempts) can be observed. These statistics will have to be compared to the overall quantity of AA produced and traded in the EU.

The extent to which Member States will legislate in addition to the European legislation[100] will provide the Commission with an indication whether the objective of ensuring a proper functioning of the internal market will be achieved.

9.2. Supporting the implementation of the new legislative measures

The Commission will develop, together with Member States experts and interested stakeholders, a number of accompanying activities to facilitate the implementation of the new

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[96] See Section 0.

[97] For AA the yearly maximum quantity amounts to 100 litres.

[98] Notably the obligation to register with the authorities, the obligation to comply with the rules on customer declarations and on documentation of transactions.

[99] As foreseen in Article 13 of Regulation (EC) No 273/2004 and Art. 29 of Regulation (EC) No 1277/2005.

[100] Member States are obliged to inform the Commission of national measures they adopted according to Art. 16 of Regulation (EC) No 273/2004.

measures, such as an update of the existing guidelines, e-learning tool, FAQ document and other awareness-raising activities.

9.3. Monitoring the implementation of the new legislative measures

Member States will have to continue their ongoing monitoring activities with regard to the correct implementation of Regulation (EC) No 273/2004, which will include the amended provisions.

As in previous years, the Commission will analyse the data provided by EU Member States which forward results relating to the licit and illicit trade of drug precursors to the Commission on a quarterly basis and will report yearly on statistics of stopped or seized shipments of AA.

The system will be improved with the implementation of the database, which is currently being developed by the Commission that shall facilitate the collection and analysis of statistics. The database is expected to start being operational in the beginning of 2013.

The Drug Precursors Committee/Working Group, composed of the Member States and the Commission, will continue to analyse any issue related to the implementation of the Regulation, including the new measures it will provide for.

The Commission will ensure that all stakeholders are given the opportunity to express their views and concerns with regards to the application of the Regulation, including the new measures, through the appropriate channels. In particular, if considered appropriate, stakeholders will be invited to participate in a meeting of the Drug Precursors Working Group/Committee together with the Commission and representatives of Member States.

Five years following the implementation of the legislative amendments, the Commission Services intend to carry out an evaluation in consultation with Member States and stakeholders, to assess whether the amended legislation will have been effective to prevent the diversion of AA.

ANNEXES

Annex 1: Summary of stakeholder consultation and SME consultation

Annex 2: Overview of major drug precursors, their legitimate and illicit uses

Annex 3: Summary of obligations for drug precursors

Annex 4: Statistics of seizures and stopped shipments for all scheduled substances in category 2

Annex 1: Summary of stakeholder consultation and SME consultation

a) Member States consultation

Results Member States survey

		Block A (9 MS)								Block B (10 MS)										Block C (8 MS)				
		MT	EE	IE	LT	RO	SE	Average per MS	Total all MS	CZ	GR	AT	FI	SK	HU	NL	PT	Average per MS	Total all MS	DK	DE	FR	Average per MS	Total all MS
Option 1	additional national legislation?	no	yes	yes	yes	yes	yes	-	-	yes	yes	yes	no	yes	yes	no	yes	-	-	yes	no	yes	-	-
	number of suspicious transactions category 1 substances	0	1	0	2	0	0	**1**	**5**	20	0	8	12	1	-		0	**15**	**153**	0	4	26	**10**	**80**
	number of suspicious transactions AA	0	0	1	-	0	0	**0**	**2**	10	0	34	0	1	3		0	**7**	**69**	0	23	4	**9**	**72**
	number of suspicious transactions category 2 except AA	0	0	0	-	0	0	**0**	**0**	3	0	26	1	1	-	66	0	**5**	**52**	0	2	3	**2**	**13**
	follow-up-time suspicious transactions (hours)	0	-	16	480	80	0	**115**	**1037**	48	0	-	0	-	80	-	0	**26**	**256**	-	-	240	**240**	**1920**
	time spent on verification of record of transactions (hours)	-	-	320	130	240	20	**178**	**1598**	560	320	-	-	1800	480	-	80	**648**	**6480**	64	3750	240	**1351**	**10811**
	number of operators to verify	5	4	15	58	27	4	**19**	**170**	41	15	15	5	655	30	200	5	**121**	**1208**	-	75	30	**53**	**420**
	percentage of total number of licenced operators	0	67	30	5	35	20	**26**	**236**	10	28	80	50	100	60	56	10	**49**	**493**	-	-	10	**10**	**80**
	percentage of total number of registered operators	67	20	30	60	57	15	**42**	**374**	8	23	60	5	1	40	-	5	**20**	**203**	-	-	2	**2**	**16**
Option 2	Processing time reported info current EU legislation per year (hours)	-	160	160	528	160	100	**222**	**1994**	800	80	-	120	120	880	-	-	**400**	**4000**	16	1760	320	**699**	**5589**
	Processing time reported info additional from national legislation per year (hours)	-	-	-	-	120	-	**120**	**1080**	120	-	-	80	40	1440	-	-	**420**	**4200**	-	-	35	**35**	**280**
Option 3	Number of end-users purchasing cat. 2 substances	1	-	-	200	8	800	**252**	**2270**	450	90	-	140	107	400	-	-	**237**	**2374**	125	650	689	**488**	**3904**
	Number of registered operators purchasing cat. 2 substances	9	34	26	32	26	22	**25**	**224**	45	49	53	50	56	56	-	78	**55**	**553**	-	550	763	**657**	**5252**
	Exempted number of end-users purchasing cat. 2 substances	0	-	-	180	1010	680	**468**	**4208**	1000	-	-	100	92	300	-	-	**373**	**3730**	-	25000	-	**25000**	**200000**
	Exempted number of operators purchasing cat. 2 substances	2	-	-	9	65	120	**49**	**441**	40	15	-	10	10	3	-	-	**16**	**156**	-	-	-	**-**	**-**
	Number of end-users purchasing AA	1	4	-	15	4	40	**13**	**115**	80	10	-	40	37	70	-	-	**47**	**474**	-	140	331	**236**	**1884**
	Number of registered operators purchasing AA	6	3	12	6	17	6	**8**	**75**	26	10	34	15	33	18	-	26	**23**	**231**	-	260	339	**300**	**2396**
	Exempted number of end-users purchasing AA	0	-	-	15	175	40	**58**	**518**	70	-	-	30	31	65	-	-	**49**	**490**	-	-	-	**-**	**-**
	Exempted number of operators purchasing AA	3	-	-	6	24	0	**8**	**74**	3	5	-	5	6	2	-	-	**4**	**42**	-	-	-	**-**	**-**
Option 4	Number of new end-users all substances cat. 2	0	-	46	-	50	80	**44**	**396**	2	-	-	20	-	65	-	-	**29**	**290**	50	-	35	**43**	**340**
	Number of new end-users AA	-	-	-	-	10	2	**6**	**54**	-	-	-	3	-	15	-	-	**9**	**90**	3	-	10	**7**	**52**
Option 5	Time spent on processing applications for registration (in hours)	-	112	-	400	70	20	**151**	**1355**	104	-	80	80	32	264	-	50	**102**	**1017**	60	27	18	**35**	**280**
	Number of applications for registration per year	10	7	144	10	7	25	**34**	**305**	4	10	5	10	6	11	-	18	**9**	**91**	9	18	35	**21**	**165**
	Time spent on processing per application (in hours)	-	16	9	40	10	1	**15**	**136**	26		16	8	5	24		3	**14**	**137**	7	2	1	**3**	**23**
Option 6	Time spent on verification and granting of an application for a licence (hours)	-	56	32	92	20	40	**48**	**432**	112	200	80	100	32	80	-	40	**92**	**920**	3	2	2	**2**	**19**
	Time spent on a check on requirements of licence (hours)	-	-	20	8	5	-	**11**	**99**	-	-	-	8	2	8	-	-	**6**	**60**	-	-	2	**2**	**16**
	Costs of such a check (euro)	-	-	-	-	-	-	**-**	**-**	-	-	-	2500	232	-	-	-	**1366**	**13660**	-	-	100	**100**	**800**
	Time spent on a check of necessary documentation when moving cat 1 substances (hours)	-	-	16	8	-	-	**12**	**108**	-	-	-	-	-	-	-	-	**-**	**-**	-	-	50	**50**	**400**
	Costs of such a check (euro)	-	-	-	-	-	-	**-**	**-**	-	-	-	-	-	-	-	-	**-**	**-**	-	-	100	**100**	**800**
	Number of movements of cat 1 substances per year	-	1	-	1	-	2	**1**	**12**	200	5	-	1	-	-	-	2	**52**	**520**	-	2500	-	**2500**	**20000**
	Number of import authorisations granted per year	-	0	6	1	9	25	**8**	**74**	11	1	5	0	2	3	21	3	**6**	**58**	8	167	30	**68**	**547**
	Time spent on granting an import authorisation (hours)	-	-	48	30	15	25	**30**	**266**	40	40	6	-	16	104	-	4	**35**	**350**	3	1	8	**4**	**32**
	Number of individual import consignments of AA	-	0	-	0	-	0	**0**	**0**	-	0	-	-	0	2	60	-	**16**	**155**	5	50	-	**28**	**220**
Benefits	Experience of diversion?	no	-	no	no	no	no	-	-	yes	no	yes	no	yes	yes	yes	no	**-**	**-**	no	yes	no	**-**	-
	Best option	2	5	3	5	5	6	-	-	-	4 and 5	5	5	5	2, 3 and 4	1	6	**-**	**-**	-	2 and 5	5	**-**	-

b) stakeholder consultation (operators and end-users)

		End-users		Operators	
	General	**Answer**	***n***	**Answer**	***n***
1	Number of respondents		106		54
	Which countries	Austria	9	Austria	3
		Czech Republic	-	Czech Republic	1
		France	49	France	5
		Germany	2	Germany	4
		Greece	5	Greece	4
		Hungary	3	Hungary	1
		Ireland	1	Ireland	5
		Lithuania	7	Lithuania	-
		Norway	-	Norway	1
		Slovakia	5	Slovakia	2
		Spain	6	Spain	2
		UK	1	UK	1
		Several MS	14	Several MS	10
		No answer	4	No answer	15
	Option 1				
2	Have you ever noticed something suspicious?	Yes	7		
		No	99		
3	How many notifications of suspicious transactions for scheduled substances in category 2 other than AA do you make to the authorities per year?			mean = 0,4	36
				0	32
	How many notifications of suspicious transactions for AA do you make to the authorities per year?			mean = 0,9	37
				0	31
4	How much time do you spend per year on contacts with competent authorities on suspicious transactions?			0	26
	Option 2				
5	How much time do you spend per year for reporting of information to authorities under EU-legislation?			mean = 21 hours	42
	How much time do you spend per year for reporting of information to authorities under national reporting rules (if applicable)?			mean = 9 hours	23

Option 3					
6	How many end-user-clients do you have for scheduled substances in category 2?			mean = 56	37
	How many registered-operators-clients do you have for scheduled substances in category 2?			mean = 7	32
	How many customer declarations do you receive per year from end-users?			mean = 134	29
	How many customer declarations do you receive per year from registered operators?			mean = 21	28
	How many end-user-clients are exempted form the registration obligations because they fall under the threshold?			mean = 22	20
	How many registered-operators-clients are exempted form the registration obligations because they fall under the threshold?			mean = 4	17
7	How many end-user-clients do you have for AA?			mean = 31	35
	How many registered-operators-clients do you have for AA?			mean = 5	33
	How many customer declarations do you receive per year from end-users?			mean = 60	26
	How many customer declarations do you receive per year from registered operators?			mean = 12	26
	How many end-user-clients are exempted from the registration obligations because they fall under the threshold?			mean = 10	25
	How many registered-operators-clients are exempted form the registration obligations because they fall under the threshold?			mean = 2	23
8	How much time do you spend to verify a customer declaration (if registered operator)?			mean = 17 minutes	6
	How much time do you spend to verify a customer declaration (if end-user)?			mean = 41 minutes	11
	How many customer declarations do you verify per year (if registered operator)?			mean = 39	26
	How many customer declarations do you verify per year (if end-user)?			mean = 154	23
9	How much time do you spend to fill in a customer declaration for your purchases of category 2 substances?			mean = 46 minutes	19
	How many customer declarations do you fill in per year?			mean = 10	22

Option 4					
10	Do you have information how many new end-users of substances in category 2 there are?			mean = 11	25
11	Do you have information how many new end-users of AA there are?			mean = 3	28
Option 5					
12	How much time do you spend to register for placing on the market of scheduled substances in category 2?			mean = 136 minutes	18
13	Please provide us with the description of the process of registration			*open answers*	47
Option 6					
14	How much time have you spend to obtain a licence for scheduled substances in category 1?			mean = 82 minutes	21
	How much costs have you spend to obtain a licence for scheduled substances in category 1?			mean = 101 euro	10
	How much fees have you spend to obtain a licence for scheduled substances in category 1?			mean = 445 euro	8
15	Please provide us with the description of the process of obtaining a licence			*open answers*	47
16	How much time and costs do you spend per year to implement all requirements to the licence of a scheduled substance in category 1?			*open answers (no categories)*	17
17	How much time do you spend per year to provide for certefied copies of customer declarations accompanying every move of scheduled substances of category 1?			mean = 668 minutes	10
	How much costs do you spend per year to provide for certefied copies of customer declarations accompanying every move of scheduled substances of category 1?			-	1
	How many movements of scheduled substances in category 1 do you make within the EU each year?			mean = 243	19
18	How many import authorisations do you obtain each year?			mean = 3	24
	How much time do you spend each year to obtain import authorisations?			mean = 175 minutes	28
	How much costs do you spend each year to obtain import authorisations?			-	2
19	How many individual import consignments of AA do you obtain each year?			mean = 3	27

Benefits					
20	Do you have experienced specific cases of diversion or diversion attempts of scheduled substances in category 2?			yes	3
				no	28
Best option					
21	Which of the described options would be most efficient to achieve a better to achieve a better prevention of diversion of AA or other scheduled substances in category 2? (*multiple response*)	option 1	29	option 1	8
		option 2	3	option 2	1
		option 3	5	option 3	2
		option 4	11	option 4	1
		option 5	3	option 5	4
		option 6	4	option 6	1

c) SME consultation

A) Profile of your company				
In which country is your company based? Please indicate:				
	Number of requested records	% Requested records(60)	% of total number records(60)	
Austria	4	6,67%	6,67%	
Belgium	3	5,00%	5,00%	
Bulgaria	0	0,00%	0,00%	
Cyprus	0	0,00%	0,00%	
Czech Republic	0	0,00%	0,00%	
Denmark	0	0,00%	0,00%	
Estonia	1	1,67%	1,67%	
Finland	0	0,00%	0,00%	
France	0	0,00%	0,00%	
Germany	13	21,67%	21,67%	
Greece	0	0,00%	0,00%	
Hungary	1	1,67%	1,67%	
Ireland	2	3,33%	3,33%	
Italy	4	6,67%	6,67%	
Latvia	0	0,00%	0,00%	
Lithuania	9	15,00%	15,00%	
Luxembourg	0	0,00%	0,00%	
Malta	0	0,00%	0,00%	
Netherlands	0	0,00%	0,00%	
Poland	8	13,33%	13,33%	

Portugal	0	0,00%	0,00%	
Romania	0	0,00%	0,00%	
Slovakia	0	0,00%	0,00%	
Slovenia	0	0,00%	0,00%	
Spain	4	6,67%	6,67%	
Sweden	7	11,67%	11,67%	
United Kingdom	0	0,00%	0,00%	
Other	4	6,67%	6,67%	
2. How many employees does your company employ?				
	Number of requested records	% Requested records(60)	% of total number records(60)	
a) 0-9	17	28,33%	28,33%	
b) 10-49	21	35,00%	35,00%	
c) 50-250	22	36,67%	36,67%	
4. For what purposes are drug precursors used in your business?(more than 1 choice possible)				
	Number of requested records	% Requested records(60)	% of total number records(60)	
• plastics	6	10,00%	10,00%	
• rubber	1	1,67%	1,67%	
• textiles	2	3,33%	3,33%	
• dyes	7	11,67%	11,67%	
• photochemical agents	3	5,00%	5,00%	
• perfumes	0	0,00%	0,00%	

• explosives	0	0,00%	0,00%	
• pharmaceuticals	13	21,67%	21,67%	
• biocides and plant protection products	4	6,67%	6,67%	
• cleaning	11	18,33%	18,33%	
• bleaching	6	10,00%	10,00%	
• disinfectant	5	8,33%	8,33%	
• deodorants	1	1,67%	1,67%	
• food	3	5,00%	5,00%	
• flavouring	2	3,33%	3,33%	
• other (please specify):	23	38,33%	38,33%	
B) Questions in relation to option 1: no changes of EU legislation				
5. Have you ever noticed anything suspicious, or have you noticed negligent behaviour, when you were offered scheduled substances for purchase?				
	Number of requested records	% Requested records(60)	% of total number records(60)	% of total number records(59)
a) Yes	3	5,00%	5,00%	5,08%
b) No (go to question 6)	56	93,33%	93,33%	94,92%
N/A	-	-	1,67%	-
5.a) How many times have such situations occurred, on average, per year?				
	Number of requested records	% Requested records(3)	% of total number records(60)	
a) 0 times	0	0,00%	0,00%	

b) 1-2 times	2	66,67%	3,33%	
c) 3-5 times	0	0,00%	0,00%	
d) 6-10 times	0	0,00%	0,00%	
e) more than 10 times	0	0,00%	0,00%	
5.b) For which substances? (more than one choice possible)				
	Number of requested records	% Requested records(3)	% of total number records(60)	
a) acetic anhydride (AA)	0	0,00%	0,00%	
b) phenylacetic acid	0	0,00%	0,00%	
c) anthranilic acid	0	0,00%	0,00%	
d) piperidine	0	0,00%	0,00%	
e) potassium permanganate	2	66,67%	3,33%	
5.c) Have you contacted the authorities regarding suspicious or negligent behaviour?				
	Number of requested records	% Requested records(3)	% of total number records(60)	
a) Yes	1	33,33%	1,67%	
b) No	1	33,33%	1,67%	
i. How many times, on average, per year?				
	Number of requested records	% Requested records(1)	% of total number records(3)	
0 times	0	0,00%	0,00%	

1-2 times	1	100,00%	33,33%	
3-5 times	0	0,00%	0,00%	
6-10 times	0	0,00%	0,00%	
more than 10 times	0	0,00%	0,00%	
ii. How much time have you spent on such contacts, on average, per year?				
	Number of requested records	% Requested records(1)	% of total number records(3)	
• up to 30 min	0	0,00%	0,00%	
• 30 min to 1 hour	1	100,00%	33,33%	
• 1-2 hours	0	0,00%	0,00%	
• 3-5 hours	0	0,00%	0,00%	
• 6-10 hours	0	0,00%	0,00%	
• more than 10 hours	0	0,00%	0,00%	
C) Questions in relation to option 3: Strengthened rules and obligations related to the customer declarations from end users				
6. How much time do you spend, on average, to fill in one customer declaration for purchases of scheduled substances in category 2?				
	Number of requested records	% Requested records(60)	% of total number records(60)	% of total number records(27)
a) up to 15 min	8	13,33%	13,33%	29,63%
b) 15-30 min	14	23,33%	23,33%	51,85%
c) 30 min to 1 hour	3	5,00%	5,00%	11,11%
d) 1-2 hours	2	3,33%	3,33%	7,41%

e) more than 2 hours	0	0,00%	0,00%	0,00%
N/A	-	-	55,00%	-
7. How many customer declarations do you fill in, on average, per year?				
	Number of requested records	% Requested records(60)	% of total number records(60)	% of total number records(53)
a) 0	15	25,00%	25,00%	28,30%
b) 1-2	15	25,00%	25,00%	28,30%
c) 3-5	12	20,00%	20,00%	22,64%
d) 6-10	4	6,67%	6,67%	7,55%
e) more than 10	7	11,67%	11,67%	13,21%
N/A	-	-	11,67%	-
D) Questions on possible benefits of changing the legislation				
8. Did you experience specific cases of diversion or diversion attempts of scheduled substances in category 2?				
	Number of requested records	% Requested records(60)	% of total number records(60)	% of total number records(54)
a) Yes	3	5,00%	5,00%	5,56%
b) No (go to question 9)	51	85,00%	85,00%	94,44%
N/A	-	-	10,00%	-
a) Please specify, whether the diversion or diversion attempts related to:				
	Number of requested records	% Requested records(3)	% of total number records(60)	

• acetic anhydride, and/or:	1	33,33%	1,67%	
• other scheduled substance in category 2	2	66,67%	3,33%	
b) Please describe the specific circumstances of the diversion or diversion attempts, such as:				
i. Which market participants were involved (more than one choice possible):				
	Number of requested records	% Requested records(3)	% of total number records(60)	
• producers of drug precursors	0	0,00%	0,00%	
• traders	1	33,33%	1,67%	
• end-users	2	66,67%	3,33%	
iii. In case diversion was not prevented, what were the reasons?				
	Number of requested records	% Requested records(3)	% of total number records(60)	
Lack of industry collaboration	1	33,33%	1,67%	
Lack of knowledge by market participants	0	0,00%	0,00%	
Lack of information flow (please specify from where to where):	0	0,00%	0,00%	
Lack of supervision (please specify by whom):	0	0,00%	0,00%	
Other reasons?	0	0,00%	0,00%	

9. Which of the described option(s) would in your opinion be most efficient to achieve a better prevention of diversion of acetic anhydride (AA) or other scheduled substances in category 2? (For a short description of all options please refer to the background document)				
	Number of requested records	% Requested records(60)	% of total number records(60)	% of total number records(52)
• Option 1	29	48,33%	48,33%	55,77%
• Option 2	4	6,67%	6,67%	7,69%
• Option 3	5	8,33%	8,33%	9,62%
• Option 4	4	6,67%	6,67%	7,69%
• Option 5	9	15,00%	15,00%	17,31%
• Option 6	1	1,67%	1,67%	1,92%
N/A	-	-	13,33%	-

Annex 2: Overview of major drug precursors ("scheduled substances") and their main legitimate and illicit uses

1. CATEGORY 1	
NAME: Other Names: CAS Numbers: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	**EPHEDRINE** alpha-[1-(methylamino)ethyl]-benzene-methanol, alpha-[1-(methylamino)ethyl]benzyl alcohol, 2-methylmino-1-phenyl-1-propanol, 1-phenyl-1-hydroxy-2-methylaminopropane, 1-phenyl-2-methylaminopropanol, alpha-hydroxy-beta-methylaminopropyl-benzene. 299-42-3 29394100 206-080-5 $C_{10}H_{15}NO$ Production of methamphetamine and N-methylcathinone. Used in manufacturing of bronchodilators, as a nasal decongestant, to test blood pressure.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	**ERGOMETRINE** Ergonovine, dextrolysergic acid, 1-(hydroxymethyl)ethylamid, ergobasine, ergotocine. 60-79-7 29396100 200-485-0 $C_{19}H_{23}N_3O_2$ Production of LSD. Medical use such as the treatment of migraine.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	**ERGOTAMINE** 5’alpha-benzyl-12’-hydroxy-2’-methylergotaman-3’,6’,18-trion 113-15-5 29396200 204-023-9 $C_{33}H_{35}N_5O_5$ Production of LSD. Medical use such as the treatment of migraine.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	**LYSERGIC ACID** 9,10-didehydro-6-methylergoline-8-beta-carboxylic acid. 82-58-6 29396300 201-431-9 $C_{16}H_{16}N_2O_2$ Production of lysergide (LSD). Used in organic synthesis and medical investigations.
NAME: Other Names:	**1-PHENYL-2-PROPANONE** phenyl-2-propanone, phenylacetone, P2P, benzyl methyl ketone, methyl benzyl ketone, BMK.

CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	103-79-7 29143100 203-144-4 $C_9H_{10}O$ Production of amphetamine and methamphetamine. Production of propylhexedrine. Used in organic synthesis.
NAME: Other Names: CAS Numbers: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	**PSEUDOEPHEDRINE** alpha-[1-(methylamino)ethyl]-benzenemethanol, 2-methylamino-1-phenyl-1-propanol, 1-phenyl-1-hydroxy-2-methylamino-propane, alpha-hydroxy-beta-methylaminopropylbenzene, alpha-[1-(methylamino)ethyl] benzyl alcohol, PSE. 90-82-4 29394200 202-018-6 $C_{10}H_{15}NO$ Production of methamphetamine and methcathinone. Manufacturing of bronchodilators and nasal decongestants.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	**N-ACETYLANTHRANILIC ACID** Orto-acetamidobenzoic acid, 2-acetamidobenzoic acid. 89-52-1 29242300 201-914-4 $C_9H_9NO_3$ Production of methaqualone and mecloqualone. Used in the manufacture of pharmaceuticals, plastics and fine chemicals.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	**3,4-METHYLENEDIOXYPHENYLPROPAN-2-ONE** 1-(1,3-benzodioxol-5-yl)propan-2-one, 3,4-methylenedioxybenzyl methyl ketone, 1-(3,4-methylenedioxyphenyl)-2-propanone, 5-acetonyl-1,3-benzodioxole, 1-(acetonyl)-3,4-methylenedioxybenzene, 1,3-benzodioxol-5-yl-propane-2-one, 1-(1,3-benzodioxal-5-yl-)-2-propanone, 3,4-MDP-2P, PMK 4676-39-5 29329200 225-128-6 $C_{10}H_{10}O_3$ Production of MDA, MDMA, MDE and N-hydroxy-MDA Perfume industry.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula:	**ISOSAFROLE** 1,2-(methylenedioxy)-4-propenylbenzene, 5-(1-propenyl)-1,3-benzodioxole. 120-58-1 29329100 204-410-2 $C_{10}H_{10}O_2$

Major Illicit Uses: Legitimate uses:	Ring-substituted derivatives of amphetamine and methamphetamine, production of MDMA. Used in the manufacture of piperonal (heliotropin), fragrances and artificial food flavourings.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	**PIPERONAL** 3,4-(methylenedioxy)benzaldehyde, heliotropin, piperonylaldehyde 120-57-0 29329300 204-409-7 $C_8H_6O_3$ Production of ring-substituted derivatives of amphetamine and methamphetamine, production of MDMA. Used in perfumery, in cherry and vanilla flavours, mosquito repellent.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses: NAME: Other Names: Harmonized Code: Legitimate uses:	**SAFROLE** 5-(2-propenyl)-1,3-benzodioxole, 4-allyl-1,2methylenedioxybenzene, allylcatechol methylene ether. 94-59-7 29329400 202-345-4 $C_{10}H_{10}O_2$ Production of ring-substituted derivatives of amphetamine and methamphetamine, production of MDMA. Used as a flavouring agent, preservative and in the production of other chemicals. **SASSAFRAS OIL** *(contains a large share safrole, can be obtained from several plant varieties)* ocotea cymbarum, ocotea pretiosa, sassafras albidum, sassafras officinale 330129 Perfumes and flavours.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	**NOREPHEDRINE** Phenylpropanolamine, PPA. 14838-15-4 ex 29394900 211-850-9 $C_9H_{13}NO$ Production of amphetamines, methamphetamines and phenmetrazine. Pharmaceutical industry.

2. CATEGORY 2	
NAME: Other Names:	**ACETIC ANHYDRIDE** Acetic oxide, acetyl oxide, ethanoic anhydride.

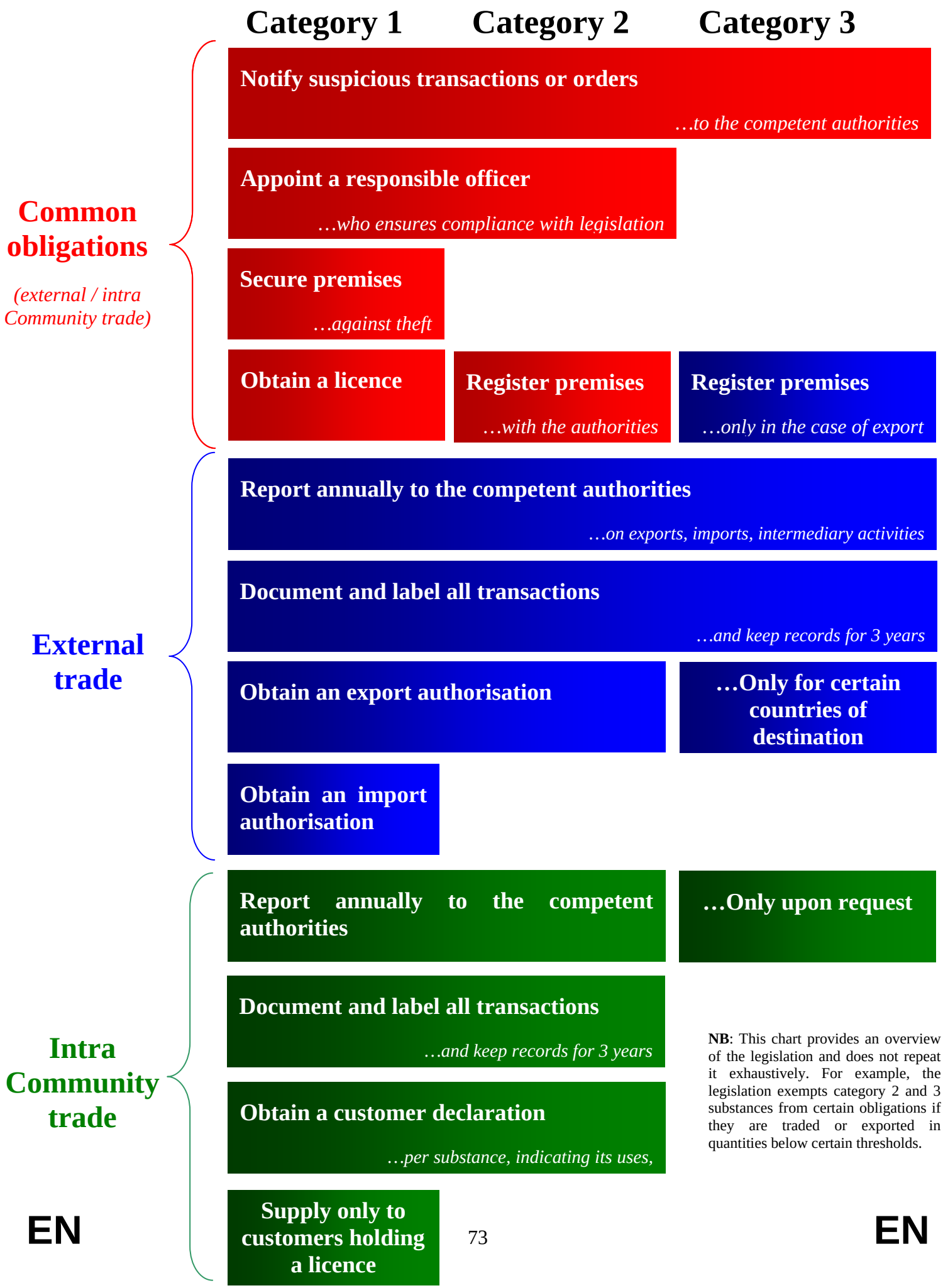
CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	108-24-7 29152400 203-564-8 $C_4H_6O_3$ Acetylating agent in the production of heroin, P2P and N-acetylanthranilic acid, methaqualone and mecloqualone. Precursor for n-acetylanthranilic acid, reagent for heroin. Acetylating agent used in chemical, photographic and pharmaceutical industry. It is used in making plastic, textile, dyes, photochemical agents, perfumes, explosives and aspirin.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	**ANTHRANILIC ACID** Ortho-aminobenzoic acid, 1-amino-2-carboxybenzene, vitamin L1, 2-aminobenzoic acid, ortho-carboxyaniline. 118-92-3 29224300 204-287-5 $C_7H_7NO_2$ Production of methaqualone and mecloqualone. Production of n-acetylanthranilic acid. Manufacturing of dyes, pharmaceutical industry, perfumes and insect repellents.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	**PHENYLACETIC ACID** Benzeneacetic acid, alpha-tolyic acid. 103-82-2 29163400 203-148-6 $C_8H_8O_2$ Production of methamphetamine and P2P. Used in chemical and pharmaceutical industry, perfumes, herbicides, penicillin, cleaning solutions and flavouring agent for foods.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory) Molecular formula: Major Illicit Uses: Legitimate uses:	**PIPERIDINE** Hexahydropyridine, hexazane, pentamethyleneimine. 110-89-4 29333200 203-813-0 $C_5H_{11}N$ Manufacturing of phencyclidine and its analogues. Precursor for thienylcyclohexylpiperidine (TCP). Solvent and reagent in chemical and pharmaceutical industry. Used in rubber products, plastic manufacturing and flavours.
NAME: Other Names: CAS Number: Harmonized Code: EC number (EINECS inventory)	**POTASSIUM PERMANGANATE** Permanganic acid potassium salt, chameleon mineral, PP. 7722-64-7 28416100 231-760-3

Molecular formula:	$KMnO_4$
Major Illicit Uses:	Oxidizing agent to remove impurities in coca paste (cocaine).
Legitimate uses:	Reagent in organic, photographic chemistry, bleaching applications, disinfectants and deodorizer.

3. CATEGORY 3	
NAME:	**ACETONE**
Other Names:	Dimethyl ketone, beta-ketopropane, pyroacetic ether, 2-propanone.
CAS Number:	67-64-1
Harmonized Code:	29141100
EC number (EINECS inventory)	200-662-2
Molecular formula:	C_3H_6O
Major Illicit Uses:	Cocaine, heroin, lysergic acid diethylamide (LSD), methcathinone, ring-substituted derivatives of amphetamines and methamphetamines, used as a solvent in the production of chlordiazepoxide, diazepam, UB329, MDA, phenmetrazine, trimetoxyamphetamine and TMA.
Legitimate uses:	It is used as a solvent in chemical, pharmaceutical and photographic industries, used in manufacturing of plastics, also used as a nail polish remover, etc.
NAME:	**ETHYL ETHER**
Other Names:	1,1'-oxybisethane, ethyl oxide, diethyl oxide, ethoxyethane, sulphuric ether, diethyl ether.
CAS Number:	60-29-7
Harmonized Code:	29091100
EC number (EINECS inventory)	200-467-2
Molecular formula:	$C_4H_{10}O$
Major Illicit Uses:	Heroin, cocaine, amphetamine, methamphetamine, lysergide (LSD), methaqualone, mecloqualone. Used as a solvent in the production of DOB, 4-methoxy-2,5-dimethoxyphenylethylamine, chlordiazepoxide, diazepam, 2,5-dimethoxyamphetamine, dimethyltryptamine, hydromorphone, JB318, JB329, JB336, MDA, mescalin, methadone, PCP, PCE, PHP, phenmetrazine, BMK, psilocin, STP, TCP, TMA.
Legitimate uses:	Widely used as a solvent in the extraction of waxes, fats, oils, perfumes and dyes, and to manufacture other chemicals. It has also been used as an anaesthetic.
NAME:	**METHYL ETHYL KETONE**
Other Names:	2-Butanone, ethyl methyl ketone, 2-oxobutane, methyl acetone, MEK.
CAS Number:	78-93-3
Harmonized Code:	29141200
EC number (EINECS inventory)	201-159-0
Molecular formula:	C_4H_8O
Major Illicit Uses:	Heroin, solvent used in cocaine hydrochloride production.
Legitimate uses:	Manufacturing of coatings, lacquers, resins, etc. Used in the photographic industry. Commonly used as solvent. Secondary uses in perfumes and flavours.

NAME:	**TOLUENE**
Other Names:	Methylbenzene, toluol, phenylmethane, methacide.
CAS Number:	108-88-3
Harmonized Code:	29023000
EC number (EINECS inventory)	203-625-9
Molecular formula:	C_7H_8
Major Illicit Uses:	Solvent used in the production of cocaine hydrochloride and heroin, and other controlled substances like amphetamine, methamphetamine, lysergide (LSD), methaqualone, mecloqualone, methadone, methylphenidate, PCP, PHP, BMK, psilocin, TCP
Legitimate uses:	In manufacturing of explosives, dyes. Gasoline additive. Industrial solvent. Used in the photographic industry.
NAME:	**SULPHURIC ACID**
Other Names:	Oil of vitriol, hydrogen sulphate.
CAS Number:	7664-93-9
Harmonized Code:	28070010
EC number (EINECS inventory)	231-639-5
Molecular formula:	H_2SO_4
Major Illicit Uses:	Heroin, cocaine, amphetamine, methamphetamine. Reagent used in the production of chlordiazepoxide, diazepam, LSD, MDA, mescaline, methylphenidate, phenmetrazine, BMK.
Legitimate uses:	Used in fertilizers, chemicals, dyes, petroleum refining, etching, photographic industry, analytical chemistry, in making iron and steel, and in industrial explosives.
NAME:	**HYDROCHLORIC ACID**
Other Names:	Muriatic acid, hydrogen chloride.
CAS Number:	7647-01-0
Harmonized Code:	28061000
EC number (EINECS inventory)	231-595-7
Molecular formula:	HCl
Major Illicit Uses:	Heroin, cocaine, amphetamine, methamphetamine, lysergide, methaqualone, mecloqualone. Reagent used in the production of Barbiturate, DOB, 4-bromo-2,5-dimethoxyphenylethylamine, chlordiazepoxide, diazepam, diethyltryptamine, dimethyltryptamine, hydromorphone, JB318,JB329, JB336. MDA, methadone, methylamine,methylphenidate, PCE, PCP, PHP, psilocin, STP TCP, TMA, phenimetrazine.
Legitimate uses:	Used in manufacturing of chlorides and hydrochlorides. Used in the photographic industry, in metal products cleaning, etc.

Annex 3: Summary of obligations for drug precursors



NB: This chart provides an overview of the legislation and does not repeat it exhaustively. For example, the legislation exempts category 2 and 3 substances from certain obligations if they are traded or exported in quantities below certain thresholds.

Annex 4: Statistics of seizures and stopped shipments for all scheduled substances in category 2

Scheduled substances in category 2	2008	2009	2010
Acetic anhydride (Liters)	240,963	30,510	21,123
Phenylacetic acid (Kg)	153	277	1
Potassium permanganate (Kg)	2,029	1	3
Anthralinic Acid	0	0	0
Piperidine	0	1	0