Council of the
European Union

Brussels, 30 November 2020
(OR. en)

13542/20

UD 374
CORDROGUE 73
COMER 190
ENT 143

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	30 November 2020
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2020) 768 final
Subject:	REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Evaluation of the EU drug precursors regulations

Delegations will find attached document COM(2020) 768 final.

Encl.: COM(2020) 768 final

EUROPEAN
COMMISSION

Brussels, 30.11.2020
COM(2020) 768 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

Evaluation of the EU drug precursors regulations

1. CONTEXT

The production of illicit drugs such as heroin, cocaine and amphetamines requires the use of chemicals. However, these chemicals have primarily large and varied legitimate uses, for example in the production of pharmaceuticals, cosmetics, plastics and perfumes. These chemicals are referred to as 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. This pattern (which had informed international and EU legislation regarding drug precursors until now) is suffering changes with the advent of the so-called designer-precursors (see p.4 *et seq*).

The trade in drug precursors is not in itself prohibited because of their important legitimate uses. Effective monitoring and control of the legitimate trade of these chemicals is the best way of fighting against their diversion for illicit drug manufacture. To this end, a specific regulatory framework has been set up both at international and at EU level.

At international level, the 1988 UN Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances (hereafter, "the 1988 UN Convention") was adopted in Vienna on 19 December 1988 and contains provisions aiming at preventing the diversion of substances frequently used in the illicit manufacture of drugs.

At EU level, *Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Union and third countries in drug precursors*[1] (further 'the external trade regulation') and *Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors*[2] (further 'the intra-EU trade regulation') and their joint delegated and implementing regulations have been enacted to this end. These will be hereafter referred to as "the Regulations".

Measures countering diversion and trafficking of drug precursors are an essential part of the EU Action Plan on Drugs 2017-2020, established under the overall EU Drugs Strategy set up

[1] Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors, OJ L 22, 26.1.2005, p. 1.

[2] Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors, OJ L 47, 18.2.2004, p. 1.

for the period 2013-2020[3]. Drug precursor control is one of the priorities identified under the chapter dealing with drug supply reduction. Tackling the diversion and trafficking of drug precursors are also among the aims of the EU Agenda and Action Plan on Drugs 2021-2025[4]. The concerned measures are included under the overall strategic priority of enhancing security through the disruption of drugs markets.

This report presents the results of the evaluation of the Regulations which was conducted between 2017 and 2019. It was supported by a study commissioned by the Commission from an external contractor. Also stakeholder and public consultations, interviews and a stakeholder workshop have been carried out.

The evaluation addresses the requirement of both Regulations to submit by 31 December 2019 "a report to the European Parliament and to the Council on the implementation and functioning of these two Regulations, and in particular on the possible need for additional action to monitor and control suspicious transactions with non-scheduled substances"[5].

2. FINDINGS OF THE EVALUATION

The evaluation assesses the implementation, effectiveness, efficiency, relevance, coherence and EU added value of the Regulations.

2.1. Implementation

The Regulations on drug precursors are directly applicable in the Member States. There is therefore no need for the Member States to transpose them into national legislation.

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 the bona fides of their customers, detect suspicious transactions and alert the authorities. An effective industry-authority partnership is therefore the keystone of the implementation of the regulatory framework.

---

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012XG1229(01)&from=EN

[4] European Commission, *Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, EU Agenda and Action Plan on Drugs 2021-2025*, COM(2020) 606 final.

[5] See Article 16(3) of Regulation 273/2004 and Article 32(4) of Regulation 111/2005.

The Regulations apply to drug precursors that are defined as "scheduled substances" and which are included in the annexes to the Regulations. However, they also contain some provisions that are applicable to "non-scheduled substances", in particular the need to report suspicious transactions to the authorities. Non-scheduled drug precursors are substances which, although not listed in the EU drug precursors legislation, can be used for illegal drug production. The most commonly used non-scheduled substances are included in the EU Voluntary Monitoring List of Non-scheduled Substances. This list is confidential and distributed to trusted economic operators only; they are requested to report suspicious transactions concerning the substances on the list to the authorities.

The chemicals are "scheduled" – i.e. formally included in the Regulations – when the cost of scheduling for operators and competent authorities would not outweigh the benefits of stricter control or because the substance can be easily substituted for illegal drug manufacture.

The requirements of the Regulations are modulated according to the aptness and importance of the substances for illegal drug manufacture, which are grouped into several categories (3 categories for intra-EU trade and 4 categories for external trade).

The evaluation has shown that the implementation of the Regulations varies substantially between Member States. This is a result of, *inter alia*, the different amounts of human resources devoted to these tasks by different Member States, the significant differences in the frequency of on-site verifications checks to licence or registration holders, the different interpretations of the definition of mixtures containing drug precursors, the level of penalties applicable to infringements of the Regulations, as well as of the large differences in the number of notifications of suspicious transactions in various Member States. A significant degree of variability can be accounted for by the existence of specific circumstances at Member State level though. For instance there are huge differences in scale and development of the chemicals industries among Member States. Additionally, the scale of illicit drug production varies greatly between Member States and this has an impact on the importance which is given to drug precursor policy. Moreover, also huge differences as to which illicit drugs cause the most health or social problems explain why Member States give different attention to monitoring certain drug precursors. For instance, a Member State where illicit methamphetamine production or consumption is non-existent or marginal may not give high priority to monitoring the drug precursors needed for illicit methamphetamine production. Nevertheless, some of these differences, for instance the considerable variation of penalties for infringements against the EU drug precursor legislation may require further attention in particular to assess whether they are dissuasive, effective and proportionate.

2.2. Effectiveness

Analyses starting from the suspected illegal drug manufacture

To assess the overall effectiveness of the Regulations a distinction is made between the main types of drug precursors which are relevant for EU policy and the regions in which they are typically used for illegal drug manufacture.

a) Synthetic drug manufacture in the EU (mostly MDMA and amphetamines[6])

Key drug precursors[7]

Generally speaking the key drug precursors - that in the manufacturing process become incorporated in full or in part into the molecule of the drug (i.e. the final product) and thus which are fully or partly responsible for the psychotropic effects which the drug user seeks - are not produced in the EU and are thus legally or illegally imported into the EU.

The evaluation indicates that these drug precursors are not 'diverted' in a traditional way. Key drug precursors for amphetamines and MDMA production in the EU are now almost exclusively designer-precursors. Designer-precursors are close chemical relatives of a scheduled drug precursor that are purpose-made to circumvent controls by the authorities and usually do not have any known legitimate use. Additionally, methamphetamine is also often produced in the EU on the basis of the key precursors ephedrine and pseudoephedrine. In many cases these are extracted from medicines containing these substances which have been legally purchased over the counter in pharmacies in certain Member States. In other words, these precursors are also not 'diverted' in the traditional sense. Therefore, as far as the supply of key chemicals for the illicit synthetic drug production in the EU is concerned, we can conclude that, generally speaking, the prevention of diversion of drug precursors has been effective. However, the successful prevention of diversion combined with the emergence of new production techniques which do not require scheduled substances have most likely prompted traffickers to use increasingly designer-precursors (see Relevance).

Auxiliary drug precursors[8]

On top of the key drug precursors, synthetic drug production in the EU also requires large amounts and different types of auxiliary drug precursors like reagents, solvents, separation or dispersing agents that are used in the course of a chemical synthesis but are not incorporated into the drug.

[6] Amphetamines include amphetamine and methamphetamine.

[7] Usually Category 1 and 2 in the Regulations

[8] Usually Category 3 substances in the Regulations

The evaluation shows that many of these auxiliary drug precursors are traditionally diverted from legal to illegal channels within the EU. This is supported by the fact that the EU customs authorities hardly ever seize auxiliary drug precursors at the EU's external borders which suggests they originate from within the EU.

These chemicals, many of which are 'bulk chemicals', are typically produced and traded in very large volumes which makes prevention of diversion particularly challenging. Only a minor percentage of the total produced and traded volume is needed to supply the illicit synthetic drug producers. This means that even though the overwhelming majority of operators may fully comply with the Regulations it takes only a very limited number of careless or corrupt operators to provide the illegal drug manufactures with the required auxiliary drug precursors. Nevertheless, this suggests that in relation to the synthetic drug manufacture in the EU and for the auxiliary chemicals the prevention of diversion of drug precursors has not been effective in the EU.

b) Heroin manufacture typically in Central and South East Asia

Acetic anhydride (AA) is used as an acetylation agent to process morphine into heroin and is subject to international drug precursor control because of this critical role in the manufacture of heroin[9]. It is one of the drug precursors which receives the most attention by the authorities around the world because heroin is one of the most addictive drugs, being responsible for a disproportionately large share of the health problems and mortality associated with drug use, and also because the production of heroin in Afghanistan is suspected to be linked to terrorism financing.

The global legitimate manufacture and trade in AA is large and expanding, and this, combined with the fact that comparatively small amounts are required in illegal heroin manufacture (about 0.01%), makes preventing diversion for illicit purposes a very challenging task. In December 2013, the EU strengthened its precursor legislation by introducing a requirement for the registration of end-users of AA with the aim to reduce diversion in the EU. However, despite the stringent controls, diversion of AA still occurs in the EU. Turkey in particular regularly seizes AA which is allegedly coming from the EU and is on its way to Afghanistan. Also, the latest reports of the International Narcotics Control Board[10] have drawn attention to this problem and called upon the authorities in the EU to take appropriate measures.

[9] The main steps in the production process of heroin are: Poppy(cultivation)→opium→morphine→heroin

[10] Annual Reports on Precursors (2018 and 2019) - Precursors and chemicals frequently used in the illicit manufacture of narcotic drugs and psychotropic substances, INCB.

Additionally, in certain EU Member States, illegal laboratories producing heroin from morphine have been discovered. The reason for this atypical production location – usually heroin is synthesised closer to the regions where the plants from which it is made, namely poppies, grow – is according to experts the cheaper and easier availability of AA in the EU than in Afghanistan or other traditional heroin producing regions. This suggests that the prevention of diversion of (AA) in the EU has not been effective.

Analysis starting from the number of seizures and stopped shipments

An analysis of the seizures and stopped shipments over time can also give an insight into the evolution of diversion and the effectiveness of the EU drug precursor policy[11]. Seizures are shipments detained on the basis of an instruction issued by a court or a competent authority. Stopped shipments are shipments permanently withheld at the initiative of an operator or of the competent authorities because reasonable grounds exist to believe that the transaction may constitute an attempted diversion of drug precursors.

Such an analysis has been carried out in the context of this evaluation. However, practically the only general conclusion which can be drawn is that the continued, although erratic, seizures of almost all scheduled precursor substances indicate that diversion from licit trade is continuing to occur. Moreover, and that whilst strengthening some of the Regulations (e.g. the reclassification in 2013 of AA as Category 2A with obligations for end-users to register as well as operators) has resulted in strengthened monitoring controls, there have still been significant levels of seizures after the implementation of these changes.

Another way to look into this is via the seizures of key chemicals, usually scheduled in Category 1, together with the non-scheduled substances which can be used as their substitute. This has been done in a recent report of the Dutch customs authorities[12]. According to this report, at least 189 tonnes of key chemicals were seized in 2017 and 2018 in the EU. About 170 million MDMA tablets and 103 tonnes of amphetamine paste could be produced on the basis of the 189 tonnes of key chemicals.

However, the real scale of the diversion or smuggling is probably much bigger. This can be deduced from the many empty packages which are found at the illegal labs and the many dumping sites of used chemicals. According to the European Reporting Instrument on Sites related to Synthetic Production (ERISSP) 311 dumping sites have been reported in 2018.

[11] It should be remarked that interpreting this indicator should be done with care. An increase in the number of seizures and/or the seized quantities may at first sight be viewed as positive since it means that the authorities have been more effective in preventing that chemicals will be used for illegal drug manufacture. However, it could equally simply mean that the diversion has increased and that 'the problem' has become in fact worse. Conversely, a decrease in the number seizures or the quantities seized does not necessarily mean that the authorities have been less effective in addressing diversion. This may mean that diversion is decreasing, which would obviously be a positive development

[12] The smuggling of (pre-)precursors for the production of synthetic drugs – Situation Report 2017-2018, Douane Belastingdienst, 2019

An additional consequence of this large synthetic drug production in the EU which can be deduced from the significant quantities of key chemicals that have been discovered is that even more auxiliary substances (solvents, reagents, etc.) must somehow have reached the illegal labs – and hence must have been diverted[13]. According to intelligence from law enforcement authorities, most of the auxiliary substances in the illegal laboratories are sourced intra-EU as they are almost never seized by customs authorities at the EU's external borders. In conclusion, it is very likely that the number of cases of intra-EU diversion of auxiliary substances is very high in the EU. This confirms the above-mentioned conclusion that the prevention of diversion of auxiliary substances in the EU has not been effective.

2.3. Efficiency

Efficiency generally considers the relationship between the resources used by an intervention and the changes generated by it. In the context of this particular evaluation, establishing a clear relationship was not possible. There is no method with any reasonable degree of rigour that allows for the monetary quantification of the effects in terms of reduced drugs supply further to the prevention of precursors needed for their production from being diverted into this use.

Although the key benefit (prevention of diversion) cannot be monetised, the evaluation offered sufficient indications to the effect that the efficiency of the Regulations is not in doubt. The costs they engender for both authorities and operators cannot be regarded as excessive and their contribution to obtaining significant benefits (though not amenable to quantification) was widely recognised.

Nevertheless, the evaluation has also shown that there may be room for improving efficiency, in particular in the field of external trade, by shortening the deadlines for pre-export notifications and introducing thresholds for a number of obligations and an electronic system for import and export authorisations (eLicensing) and to automate the validation of those authorisations by national customs authorities in context of the EU Single Window environment for customs initiative[14].

[13] For instance, acetone is used in the manufacture of cocaine, heroin, lysergic acid diethylamide (LSD), amphetamine and methamphetamine derivatives. Several tens of litres of this substance are necessary to obtain 1 kg of these drugs (Source: Drug Precursors Brochure by DG TAXUD, 2012)

[14] https://ec.europa.eu/taxation_customs/general-information-customs/electronic-customs/eu-single-window-environment-for-customs_en

2.4. Relevance

Since the illicit drug market is very dynamic, with constant changes in available illicit drugs and the precursors used to produce them, the relevance of drug precursor legislation is determined by the extent to which it continues to limit the supply of precursors for the illicit production of drugs thereby contributing to limiting the amount of illegal drug which are produced and subsequently supplied to our society.

Speed with which new drug precursors can be included in the Regulations

Since the revision of the legislation in 2013 substances can be added to the Regulations (also called "scheduling") via a Commission Delegated Regulation. This has reduced the time needed to adapt the Regulations to 12 to 15 months. Although the situation has significantly improved compared to the period before 2013 when additions were only possible via the ordinary legislative procedure (which often took several years), 12 to 15 months is still considered too long. This offers drug criminals a substantial period during which they can continue to relatively easily use the substance for illegal drug manufacture and furthermore can develop alternatives while the process for scheduling new substances is being completed.

It can thus be concluded that the Regulations are to an extent able to address the emergence of new substances used in illegal drug manufacture but that there is also a need to continue to explore ways to accelerate the scheduling process considering the speed and ease with which illegal drug manufactures are able to develop new ones which are outside the scope of the Regulations.

Are the Regulations able to cope with the increased use of non-scheduled substances, in particular 'designer-precursors'?

As mentioned before, illegal synthetic drug producers in the EU currently use almost exclusively designer-precursors.

Law enforcement authorities and specialists in chemistry explain that there are hardly any limitations to the innovations of the producers of designer-precursors. In other words, each time a new substance is scheduled the criminals will be able to 'tweak some molecules' and come up with a new designer-precursor. The time needed for this can be short and in any case is often shorter than the period needed to schedule a new substance. So authorities will never be able to react quickly enough to address this problem within the existing legislative framework.

To illustrate this mechanism, we can look at the evolution of the main precursor used in the EU for the production of amphetamine in the last ten years. Before 2010, illegal manufacture of this drug in the EU was based mainly on the scheduled precursor substance BMK. However, presumably because of the effective control and monitoring measures by the authorities illicit drug producers looked for alternatives. This led to the subsequent development of APAAN, then APAA and finally MAPA; these are all designer-precursors used to replace BMK in the manufacture of amphetamine. In the meantime there are indications that the amount of amphetamine illegally produced in the EU continues to increase. This process clearly shows the limits and the challenges of a drug precursor control approach which is mainly based upon substance-by-substance scheduling.

It should also be noted that traditional techniques of "prevention of diversion of substances" that have a legal use have thus become outdated and are much less effective in this context. In particular cooperation with the chemical industry via the obligation to notify suspicious transactions, which is a key feature in the EU's drug precursors approach, is problematic. The economic operators involved in the production of these designer-precursors are most likely knowingly operating illegally and will thus never cooperate with the authorities or notify suspicious transactions.

During the revision of the legislation in 2013 the legislators were already aware of this problem (the emergence of APAAN having occurred before 2013) and therefore they enacted the so-called 'catch-all'-provisions in the Regulations. The aim of these provisions was to allow the competent authorities to intervene in cases where non-scheduled substances, including designer-precursors, were traded or smuggled with a view to use in illegal drug manufacture.

The catch-all provision in the external trade regulation obliges the competent authorities of the EU Member States to prohibit the introduction of consignments of non-scheduled substances into the customs territory of the EU or their departure from it where there is sufficient evidence that those substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances. In the intra-EU trade regulation each EU Member State may adopt the measures necessary to enable its competent authorities to control and monitor suspicious transactions involving non-scheduled substances, and in particular, where necessary, to detain and seize consignments to prevent the use of specific non-scheduled substances for the illicit manufacture of narcotic drugs or psychotropic substances.

However, experience since the entry into force of these provisions has shown that most Member States do not or cannot apply these catch-all provisions mainly because of lack of clarity as to what constitutes "sufficient evidence".

The problems with the catch-all provisions and possible ways to overcome them have been the subject of many discussions by the EU Group of Experts on Drug Precursors in recent years. All experts and law enforcement authorities agree that there is an absolute and urgent need for a method which can effectively address the issue of non-scheduled substances, in particular designer-precursors, without the need to schedule the substances in question.

It should however also be remarked that although alternative ways need to be developed to address the challenge posed by designer-precursors, the 'prevention of diversion' of traditional key chemicals such as safrole, BMK and PMK remain relevant because traffickers will always use the path of least resistance. Any loosening by the authorities will be exploited immediately by the criminals and thus illegal drug producers will go back to using safrole, BMK, PMK etc.

It can thus be concluded that the current drug precursor control and monitoring regime is not able anymore to successfully address the overall needs in society which it was intended to cater for.

In this context it should be remarked that drug precursor diversion and trafficking is a global phenomenon which also requires international cooperation. At multilateral level the legal basis for this is provided for by the UN 1988 Convention and it is the Commission on Narcotic Drugs (CND) of the UN and the Precursor Task Force of the International Narcotics Control Board (INCB) that give shape to this cooperation. As to the problem of designer-precursors all parties agree that no ready-available solution is at hand and that novel approaches will be required, including via international cooperation.

Additionally, the EU has concluded agreements on drug precursors with 11 third countries such as China, the US, Mexico, Colombia and Turkey. At this moment the cooperation with China is the most important because, as far as is known, all designer-precursors used in illicit drug manufacture in the EU originate in China.

Assessing international cooperation is outside the scope of this evaluation however. It should be noted that the ongoing evaluation of the EU-China Cooperation and Mutual Assistance Agreement in Customs Matters does look into the need to strengthen EU-China customs cooperation on drug precursors.

Are the Regulations able to cope with the misuse of online-trading platforms

A concern highlighted by stakeholders from industry during the evaluation was the lack of control over online-trading platforms. Such trading platforms can take various forms: some

only provide buyer and supplier information, for a fee or free of charge, and are not involved in transactions; others act as trading platforms and are directly engaged in sales; and manufacturers often sell their products via their corporate websites.

However, at the moment there is very little reliable information available on this topic. Whether or not these online-trading platforms need to be regulated with special provisions in the Regulations is a difficult matter and depends also on the precise form they take or services they provide. This will need to be further analysed. In this context it will be important to ensure coherence with the European Digital Strategy.

2.5. Coherence

The evaluation of coherence as concerns the Regulations on drug precursors has examined several dimensions.

How well the Regulations work internally and in relation to each other

The public and targeted consultations carried out allowed to identify a number of concrete elements of criticism with the internal coherence of the legislation being evaluated. These referred to: the definition of mixtures; the fact that Category 4 substances[15] (listed in the Annex to the external trade regulation) are not covered also by the intra-EU trade regulation; and the desirability of merging the existing two distinct Regulations.

The analysis of these criticisms (which have been formulated only by a minority of respondents) led to the conclusion that they do not in themselves call into question the internal coherence of the Regulations *per se*. The difficulties related to the definition of mixtures is not attributable to contradictions or ambiguities in the legal texts, but rather to its non-uniform implementation. The absence of Category 4 substances from the intra-EU trade Regulation does not hamper in any way the effectiveness of the relevant provisions of the external trade regulation, as the latter sets obligations related to these substances only in respect of exports, i.e. whose effects are felt outside the EU. As concerns the possible merging of the two Regulations, all reasons cited for such decision were informed by considerations of convenience, no specific provisions having been identified that are

[15] Medicinal products and veterinary medicinal products containing ephedrine and/or pseudo-ephedrine or its salts

engendering uncertainty about the required course of action, let alone contradicting each other.

How do the Regulations relate to other EU-level interventions

By taking measures to avoid the diversion of key chemicals into drug production, the Regulations contribute to fulfilling one of the five objectives of the EU Drugs Strategy 2013-2020, namely "to contribute to a disruption of the illicit drugs market and a measurable reduction of the availability of illicit drugs". The number of seizures and stopped shipments of drug precursors indicates that the existing drug precursor legislation leads to a reduction of the supply of illicit channels with drug precursors and, consequently, to reducing the supply of illicit drugs. However, it is not possible to quantify the exact impact of this legislation on the overall reduction of drug precursors diverted into illicit channels.

Nevertheless, it will continue to be important that the EU drug precursor policy remains fully aligned with the EU Drugs Agenda and Action Plan. One particularly important aspect in this context relates to the support that the European Monitoring Centre for Drugs and Drug Addition (EMCDDA) could give in terms of collection, consolidation and analysis of drug precursors-related data.

Can the Regulations co-exist without tensions with related national interventions which are allowed by the EU Treaties

A potential problem of coherence originates in the fact that one particular substance, gamma-butyrolactone (GBL), is both a drug precursor and a drug on its own. The ambiguous status of the substance has led to a situation whereby it is regulated in very different ways across the Member States. Also, a number of substances have been identified which are scheduled as a drug in the narcotics legislation at Member State level and as a drug precursor in the Regulations. By themselves, these issues are not affecting the effectiveness of the Regulations, but in specific cases they may pose problems for the integrity of the EU internal market. This, however, is not due to the provisions of the Regulations themselves, nor is it possible to remove this threat by amending the Regulations. Indeed, the substances included in the Tables of the UN 1988 Convention have to remain scheduled in the drug precursors Regulations irrespective of whether some of them are considered (and treated) as drugs by some Member States. From the standpoint of the Regulations, it is important to ensure that the scheduling of substances is done according to criteria that are applied consistently, though this cannot be ensured with full certainty given the binding obligations deriving from the text of the UN 1988 Convention.

Compatibility of the Regulations with international obligations

The Regulations incorporate the obligations that the UN 1988 Convention imposes on its signatories, such as in particular the obligation to take measures to prevent the diversion of specifically-designated substances for the purpose of illicit manufacture of drugs (Article 12:1 of the Convention) and the obligation to establish and maintain a system to monitor international trade in specifically-designated substances (Art.12:9:a).

With respect to the substances in relation with which these obligations apply, there are some differences between the substances listed in Tables I and II of the UN 1988 Convention and the substances scheduled under the Regulations. However, these differences exist because the EU legislation, while scheduling all substances listed in the UN 1988 Convention, includes additional substances that were scheduled in order to tackle specific problems identified in the EU. As such, there appear to be no coherence issues with the 1988 UN Convention. Apart from the obligations stemming from the UN 1988 Convention, the CND regularly adopts resolutions on drug precursor control and monitoring. These resolutions are not binding and, moreover, in many cases the EU is implementing the recommendations of the resolutions already before their adoption as the EU is often an early adopter of 'good practices' or innovative approaches on drug precursor policy.

As a general conclusion, the evaluation did not lead to the identification of serious coherence problems related to the drug precursors Regulations. In particular, no elements of incoherence appear to exist internally and from the standpoint of the international obligations binding the EU in this area.

2.6. EU added value

The examination of the added value brought by the Regulations on drug precursors has two important specificities:

- because of the existence of the 1988 UN Convention, which counts all the EU Member States as signatories, legislating in this area would have been required anyway, irrespective of whether at national or EU level;

- the counterfactual to an intervention at EU level (i.e., Member States implementing measures at national level) is either impossible from a legal standpoint or feasible only in narrowly defined circumstances.

It should also be pointed out that the regulation at EU level of the external trade in drug precursors is the direct consequence of EU's exclusive competence in the matter and coherence considerations render desirable the symmetrical regulation of intra-EU trade.

Notwithstanding the fact that the room for national-level interventions is limited anyway, there are compelling reasons why EU-level intervention is intrinsically preferable. In particular, the Regulations on drug precursors make reference to mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission. This is an extremely valuable (and almost indispensable) tool for a regulatory intervention whose purpose is to avoid that specific goods are diverted into illicit channels and used for criminal activities because such activities are by definition not publicly known and information related to them can only be obtained by competent authorities and is often confidential.

The targeted questionnaires provided additional insights into what concrete benefits are deriving from controlling drug precursors at EU level, such as the existence of common definitions, criteria and approaches, which ensure greater consistency in implementing controls and also provide clear and predictable rules for economic operators.

The negative effects attributed to the EU intervention relate to the slowness of the amendments of the Regulations in order to have additional substances scheduled (see Relevance) and to the problems that arise when individual Member States have different priorities in terms of substances they wish to place under control.

On balance, however, the responses received from both Member State authorities and from economic operators have highlighted significantly more benefits than negatives.

The evaluation has also convincingly shown that legislative interventions at national level, besides being inherently limited by the provisions of the Treaties, tend to be inferior not only from the standpoint of legal certainty, but also from that of efficacy, to the intervention at EU level.

3. CONCLUSIONS

The evaluation has shown that additional action with regard to non-scheduled substances, in particular designer-precursors, is necessary.

Therefore the Commission will consider a revision of the EU drug precursor Regulations and related legal instruments such as Council Framework Decision 2004/757/JHA of 25 October

2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, taking into account this finding and without prejudging the outcomes of the better regulation process.

This opportunity could also be used to consider strengthening a number of other aspects of the Regulations such as those concerning the diversion of auxiliary drug precursors and AA from intra-EU trade, reducing the administrative burden for economic operators and competent authorities and stricter control of online-trading platforms.

To this end a holistic approach will be required so as to ensure consistency with other initiatives and policies at EU level, and in particular with: the EU Drugs Agenda and Action Plan; the revision of the mandate of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA); the European Digital Strategy; the new Customs Action Plan, in particular in relation to customs risk management (and the possibilities for strengthening the contribution of customs risk analysis and controls to precursors detection); the new initiative on customs sanctions; the EU Single Window environment for customs initiative; and the evaluation of the customs cooperation between the EU and China.