European Economic and Social Committee

INT/669
Drug precursors

Brussels, 16 January 2013

OPINION

of the
European Economic and Social Committee
on the
Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 273/2004 on drug precursors
COM(2012) 548 final – 2012/0261 (COD)

_____

Rapporteur: **Mr Sears**

_____

Rue Belliard/Belliardstraat 99 — 1040 Bruxelles/Brussel — BELGIQUE/BELGIË
Tel. +32 25469011 — Fax +32 25134893 — Internet: http://www.eesc.europa.eu

EN

On 15 October 2012, the Council, and, on 22 October 2012, the Parliament decided to consult the European Economic and Social Committee, under Article 114 of the Treaty on the Functioning of the European Union, on the

> *Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 273/2004 on drug precursors*
> COM(2012) 548 final – 2012/0261 (COD).

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 8 January 2013.

At its 486th plenary session, held on 16 and 17 January 2013 (meeting of 16 January), the European Economic and Social Committee adopted the following opinion by 130 votes to 1 with 7 abstentions.

*

* *

1. Summary and recommendations

1.1 This proposal has been developed to remedy specific weaknesses identified in existing EU legislation with respect to the monitoring and control of trade between businesses in the EU in acetic anhydride, a commodity chemical with many legitimate and essential uses but also subject to diversion as a precursor for the illicit production of heroin from morphine, generally in Afghanistan. The EESC recognises the need for this amending regulation and strongly supports the proposal.

1.2 The EESC also supports the proposal to establish a European Database of approved operators and end-users and to improve the collection of reports from the Member States of seizures and stoppages of illicit shipments of all scheduled and unscheduled drug precursors.

1.3 The extension of the existing legislation on registration to "users", as opposed to "operators" requires some new or revised definitions; minor problems are noted and recommendations made. End-users should be fully briefed on the purpose and benefits of registration. Competent authorities should be granted the same rights of access to the business premises of end-users as are currently provided for in the case of operators.

1.4 The EESC recognises that the new proposals will be effective only if communicated properly and without unnecessary additional financial burdens for all those involved. The proposal to exclude micro-enterprises from registration fees is therefore strongly supported.

1.5 Finally the EESC notes that the involved parties in Europe have fully embraced the requirements of the relevant 1988 UN Convention, in particular Article 12, in respect of working together to achieve the desired goals. This has led to successes in working with others, in and outside the EU, to combat crime, to protect the health of citizens, to allow legitimate trade to continue, and to safeguard the reputations of the organisations and businesses concerned. The processes followed, the degree of mutual respect and trust developed, and the style and content of the communications to affected parties, all deserve to be recognised as models for regulatory behaviour and compliance at EU or any other level. It is hoped that planned proposals for controls on psychotropic substances and synthetic "designer drugs" within the framework of strong, well focused and evidence-based public health policies at EU and national level, particularly in the field of prevention, will follow a similar pattern. The EESC looks forward to contributing to these proposals in due course.

2. Introduction

2.1 Drug precursors are substances that are manufactured, traded and used world-wide in a wide variety of legitimate and essential processes, but which can also be diverted to the illicit manufacture of drugs such as cocaine, heroin, ecstasy or methamphetamines. Efforts to control the trade in these substances, required for their physical properties, e.g. as solvents to extract active ingredients from plant sources, or as chemical agents to modify the nature and effect of the resulting drugs, have long been regarded as essential.

2.2 The international framework for action is provided by the 1988 United Nations Convention against illicit traffic in narcotic drugs and psychotropic substances. Article 12 highlights that cooperation between regulating authorities and business is essential to achieve the desired results.

2.3 At European Union (EU) level, the reduction of drug precursor diversion is an important objective of both the EU Drugs Strategy (2005-2012) and Drugs Action Plan (2009-2012). The legal framework for internal trade is currently provided by Regulation (EC) No 273/2004, managed by DG ENTR (Directorate General Enterprise and Industry), and for external trade by Council Regulation (EC) No 111/2005, managed by DG TAXUD (Taxation and Customs Union). Commission Regulation (EC) No 1277/2005 amended by Regulations (EC) No 297/2009 and (EU) No 225/2011 provides the detailed implementing rules for competent authorities and economic operators.

2.4 Under these regulations, Member States collate and report the tonnages of certain scheduled (i.e. specifically monitored and controlled) and unscheduled (voluntarily monitored) substances that have been stopped (before delivery commenced) or seized (during or post-delivery). These quantities can then be related to the total quantities of such substances stopped or seized world-wide. Any unexpected increases in the quantities reported, or changes in the frequency and distribution of stoppages and seizures, can be due to improved

monitoring but may also indicate the increased targeting of a particular market for illicit purposes, possibly due to perceived or actual weaknesses in local controls.

2.5 The consolidated data for 2008 showed a 7-fold increase over 2007 in the quantity reported for one particular precursor, acetic anhydride, used to convert morphine (derived from opium) into heroin. The 241 tonnes seized in the EU represented more than 75% of total world seizures. This led to repeated criticism by the International Narcotics Control Board (INCB) of the UN. A Commission Report COM(2009) 709 on the evaluation and functioning of the relevant legislation concluded that, although generally the performance was satisfactory, there were indeed some weaknesses and made recommendations, in particular with respect to the monitoring and control of acetic anhydride sales within the EU.

2.6 Throughout this process the Commission and all other concerned parties have recognised that acetic anhydride plays an essential role as the alkylating agent in the synthesis of a wide range of coated materials, films, plastics, pharmaceuticals (for instance, aspirin) and other consumer products. The greater part of total global production (currently around 1 million tonnes per year) is said to be used in-house by the producers; a smaller proportion, less than a third of the total, is traded to third-party end-users. The amount required for illicit use, essentially in Afghanistan, is estimated to be between 380 and 570 tonnes per year. This in turn produces around 380 tonnes of Afghan heroin, of which 70 tonnes are supplied to drug users in Europe. At a reported average street value in Europe of EUR 40 per gram, this equates to annual illicit trade worth around EUR 3 billion. The market value of the acetic anhydride required is trivial in comparison to this – and in comparison to the value of legitimate sales or to the cost of lost personal or corporate reputations following such diversions for illicit use. The chemical industry's worldwide Responsible Care programme helps ensure that these points are understood by legitimate operators entering the market for the first time.

2.7 It is also recognised that, even if all the attempted diversions in Europe are successfully prevented, such diversions will take place elsewhere in the world. The financial rewards for drug producers, as above, are just too great. However controls are still fully justified and serve as models for others to follow. Provided they are seen as cost-effective, they are fully supported by the industry sectors affected so that their legitimate trade inside the EU can continue.

2.8 Given the above situation, the Commission considered a number of alternative approaches, as set out in the impact assessment, and consulted the representative bodies of the affected sectors – primarily CEFIC for the producers ("operators") and some large end-users and FECC for the distributors and smaller end-users – and representatives of the Member States who will be required to implement the proposals. There was general agreement that the current proposal was the preferred option.

3. **Summary of the Commission's proposal**

3.1 The Commission's proposal extends the existing registration requirements for acetic anhydride producers, distributors and traders to their industrial end-users, i.e. companies buying acetic anhydride for their own uses or processes within the EU.

3.2 This is intended to further restrict actual or attempted diversions of acetic anhydride within the EU in an effort to reduce illicit usage outside the EU, and to create greater legal security for businesses acting legitimately within the EU.

3.3 The existing Category 2 of substances scheduled under Regulation (EC) No 273/2004 is therefore split into two parts, with Category 2a reserved for acetic anhydride and Category 2b for four other commodity chemicals not affected by this change. The definitions of Category 1, for lower volume specialty chemicals that are subject to even tighter controls as the most sensitive "key" drug precursors, and of Category 3, for multi-purpose bulk chemicals, remain unchanged.

3.4 The proposal also aims to establish a European Database on Drug Precursors to ensure more efficient data collection on seizures and stopped shipments and to maintain a list of EU licensed or registered operators and users legally producing, trading or using drug precursors.

3.5 The proposal also clarifies some existing definitions, provides exemptions for registration fees for micro-enterprises amends existing provisions on Comitology in line with the new rules of the Lisbon Treaty, and eliminates the need for a formal adoption process in the preparation of guidelines. The proposal also clarifies the rights of Member States to adopt additional measures to obtain information and, if necessary, to enter operators' business premises on any suspicious order relating to non-scheduled substances.

3.6 The legal basis for the proposal is Article 114 (Treaty on the Functioning of the EU) and, at least in its current form, meets EU requirements on both subsidiarity and proportionality.

3.7 The regulation would come into force on the twentieth day following that of its publication in the Official Journal of the European Union and would be binding in its entirety and directly applicable in all Member States. The regulation provides for a transition period of up to 18 months for the competent authorities to develop the required processes and for some end-users to register for the first time. The registration processes for all users have been made more rigorous and registration may be now refused if the information supplied to the competent authorities is deemed to be unsatisfactory.

3.8 The proposal is accompanied by an explanatory memorandum and a Commission staff working document (impact assessment). An executive summary of the impact assessment is also available. The relevant web pages of DG ENTR and DG TAXUD summarise the development of Community legislation on the monitoring and control of drug precursors

inside the EU and between the EU and third countries and provide links to all related documents, stakeholders and concerned organisations.

3.9 Commission reports on stoppages and seizures of drug precursors compiled from data supplied by the Member States for the years 2006-2010 provide the motivation for the current proposals and are shown on the websites. A presentation by DG ENTR to the Council Working Group on Customs Union dated 16 October 2012 gave further background. A copy of the "Guidelines for Operators", published jointly by DG ENTR and DG TAXUD for distribution by the national competent authorities only to trusted companies involved in long term licit transactions of scheduled and non-scheduled substances, was supplied under separate cover.

3.10 Other reports, for instance the 2011 "Report on Precursors and chemicals frequently used in the illicit manufacture of narcotic drugs and psychotropic substances" from the INCB and the 2012 "International Narcotics Control Strategy Report Chemical Controls" from the US Department of State, provide external and more global overviews. It is now accepted, for instance, that Afghanistan has no legitimate demand for acetic anhydride and that all imports are therefore illicit. Coalition forces are reported to have seized around 20 tonnes of the much larger total imported in 2011. The primary illicit sources are said to be China, South Korea, Europe, the Central Asian States and India. Clearly this is still work in progress and close international cooperation and hard-earned mutual trust remain essential.

4. General comments

4.1 The EESC gave its opinion on COM(2002) 494 final on 26 February 2003[1], fully endorsing the proposals from the Commission in respect of the proposed controls on drug precursors. This was duly noted in the final version, published as Regulation (EC) 273/2004, in February 2004[2].

4.2 The EESC also strongly supports efforts to reduce drugs usage in and outside the EU, as made clear in its opinion of May 2012 in response to the Commission's Communication "Towards a stronger European response to drugs"[3]. This stressed the need to maintain a balanced approach to both supply and demand. Reductions in supply, which may only be temporary, must be backed by strong, well targeted and effective public health policies, particularly in the field of prevention, at EU and national level (Article 168(1) TFEU). Cooperation and best practice exchange between Member States will be essential. Policies should be based on data and evidence – and not the other way round.

---

1 OJ C 95, 23.4.2003, p. 6.

2 OJ L 47, 18.2.2004, p. 1.

3 COM(2011) 689 final, EESC's opinion: OJ C 229, 31.7.2012, p. 85.

4.3 The EESC therefore strongly supports the current proposal to tighten the monitoring and control of trade in acetic anhydride between businesses inside the EU and to implement further measures to assist the monitoring and control of drug precursors in general, in particular via the establishment of a European Database of licensed or registered operators and end-users and of the information provided by Member States on stoppages or seizures of substances diverted for illicit usage, in particular the manufacture of narcotic and psychotropic drugs, usually outside the EU. The diversion of small quantities of acetic anhydride for the manufacture of heroin is of particular concern.

4.4 The EESC also commends the Commission and all those involved in the implementation of the existing legislation and in the reviews and consultation process that have followed, for the close and continuing cooperation with Member States, regulatory authorities, law enforcement agencies, producers, carriers and end-users, as required under Article 12 of the 1988 UN Convention. This has led to a set of well-focused, well-informed, well-documented and cost-effective proposals, clearly supported, and therefore likely to be fully implemented, by all those directly affected.

4.5 This cooperation has already led to a drastic reduction in the quantities of drug precursors stopped or seized within the EU – hopefully indicating that the EU is no longer regarded as an easy target. The voluntary monitoring of non-scheduled substances is reported to have been particularly effective. Flexibility to deal with such innovative, persistent and highly profitable criminal behaviour is essential. In this area at least, everyone has the same objective. This is fully recognised by all concerned – and could perhaps serve as a model for cost-effective EU legislation in other areas, with wider impacts on businesses, employees and consumers.

4.6 The legislation also works because the producers, distributors and end-users affected are already subject to, and are experienced in implementing, a range of similar controls for radioactive materials, biological agents, dual use chemicals and exports requiring prior informed consent, and so on. New legislation on explosives precursors is about to be introduced. This does however require that the broad patterns of these requirements stay the same and that the list of substances requiring registration or licensing is kept to the minimum necessary. The current proposal is therefore likely to be effective, at least within its rather tightly defined objective to reduce even further any diversions to illicit usage of acetic anhydride during ongoing legal trade within the EU; other less focused or more burdensome alternatives would be more likely to fail.

4.7 The EESC also agrees with the Commission that this proposal does not affect working conditions within the industry or the rights of consumers in general, except to the extent that they as individuals support a reduction in the availability of heroin and related products in or outside Europe. Sadly this will be hard to measure, if indeed any such reduction occurs. This proposal however does not depend on such cost-benefit balancing and therefore should be implemented in this form and as quickly as possible.

4.8 Finally, the EESC looks forward to contributing to further EU initiatives in this area and therefore urges the Commission to bring forward as soon as possible planned new proposals in particular on psychotropic substances and purely synthetic "designer drugs" which are now steadily replacing traditional drugs such as heroin as well as extending the market overall.

5. Specific comments

5.1 The EESC notes that the definitions of "operator" and "user" can be understood to overlap (as all affected "operators" will at some time "possess scheduled substances"). As it is clearly necessary to distinguish between the two, this can be done by inserting the phrase "who is not an operator but" after "legal person" in the first line of the new point (h) of Article 2.

5.2 It is also important to establish that this refers specifically to users incorporated and operating inside the EU. Sales and/or deliveries to users outside the EU are covered under separate legislation. To ensure a smooth functioning of the internal market it should also be made clear between Member States as to where the operator and user registration is required, for instance where the operator or user are established, or where the product (acetic anhydride) is put on the market.

5.3 The requirement for end-users to register for the first time could lead to short term disruptions to legitimate trade. These can be minimised by proactive communications during the 18 months provided for this transition by the operators and distributors, preferably based on clear and appropriately worded guidance notes issued by the competent authorities in the Member States. The existing "Guidelines for Operators" provide an excellent model for such communications. The purpose and benefits of registration should be made clear at the time of registration so that end-users, as well as operators, become aware of the possibility and risks of diversion, and can therefore better contribute to minimising these. Competent authorities should have the same rights of access to the business premises of both end-users and operators.

5.4 The EESC supports the Commission proposal that micro-enterprises should be exempted from any requirement to pay fees for registration as it is crucial that not only does this legitimate trade continue (for the sake of the micro businesses and those employed therein) but that the controls are understood and implemented as widely as possible. Given that the quantities required for illicit use are relatively small, the smaller users are probably most at risk to offers that they feel they cannot afford to miss. Good communication in support of compliance will therefore be essential, in print and electronic form, in all relevant local languages.

5.5 The EESC notes that the reporting and other information requirement for non-scheduled substances reflects its voluntary nature, i.e., Member States "may" rather than "shall" follow the proposed procedures. This is clearly not ideal for the protection of the internal market –

but may be preferable to adding yet more substances to the lists of priority precursors already identified. This situation should therefore be watched carefully by all concerned.

5.6 Finally, in respect of the proposed European Database, the EESC welcomes the proposal and strongly encourages it to go ahead, subject only to the reservation that it should be sufficiently resourced for longer term update and use by all the concerned parties and designed to produce results, not merely accumulate out of date or partial data. The quality and quantity of data collected will be equally important. The continuing support of the law enforcement agencies in the Member States will be critical to this.

5.7 Access to the data must of course be restricted to those firmly and permanently committed to legitimate trade – presumably those recorded within the database. Input requirements for operators, distributors, traders and end-users, as well as for Member States, should, to preserve the internal market and to minimise costs, be harmonised wherever possible. This should not, however, conflict with the primary objective of this proposal, to identify and restrict the illicit diversion of drugs precursors and, hopefully, to apprehend those responsible.

Brussels, 16 January 2013.

The President
of the
European Economic and Social Committee

Staffan Nilsson