EUROPEAN COMMISSION

DIRECTORATE GENERAL
TAXATION AND CUSTOMS UNION
Customs Policy
Risk management, Security and Specific Controls

DIRECTORATE GENERAL
ENTERPRISE & INDUSTRY
Chemicals and construction
Chemicals

Brussels, 9th October 2006

Drug Precursors Committee

Subject: Questions of interpretation pertaining to the EU drug precursors legislation (Agenda item 3.10)

Delegations will find attached:

- An explanatory note
- A text proposal for a document to be published on the website of the European Commission

These documents will be discussed during the next meeting of the Drug Precursors Committee, on 16-17 October 2006.

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"QUESTIONS/ANSWERS" DOCUMENT – EXPLANATORY NOTE

The Commission services gathered in one single document a number of questions of interpretation of Regulations 273/2004, 111/2005 and 1277/2005 and the replies agreed by the Drug Precursors Committee. This document was circulated to all delegations on 30 May 2006 (working document TAXUD/1447/ENTR/G2/D(2006)). Since no modification was required, this document was deemed adopted by the Committee.

Furthermore, during the 65th meeting of the Drug Precursors Committee on 3-4 April 2006, the Commission announced that it would examine whether it was possible to put this document on the COM website. As a matter of fact, COM publishes a number of such non legally binding implementation documents ("guidance document") on its website on a wide range of legislations, with a view to inform economic operators and authorities about the common approaches adopted by the competent authorities and COM with regard to the interpretation of the legislation concerned. The publication on the Commission's website can be regarded as the most efficient way to inform operators and to ensure a consistent and transparent implementation of the legislation in all EU Member States. With regard to the principle according to which cooperation between operators and authorities is the cornerstone of drug precursors' control in the EU, COM believes that the interpretations agreed by the Committee should be published on its website.

However, it should be noted that document TAXUD/1447/ENTR/G2/D(2006) cannot be published as such on the Internet and requires some slight amendments. COM has therefore drafted an amended version of this document aimed at publication on the Internet. In comparison with the version previously agreed by the Committee,

- This version for publication contains an introductory part addressing the status of the document, explaining in particular that this document does not oblige Member States to adopt the same attitude and is not legally binding since only the European Court of Justice can give an authoritative interpretation of existing Community law. This introductory part makes use of a wording classically used by the Commission services for such "guidance documents".

- All the mentions emphasizing the imperfections of the legislation were deleted (e.g. "a clarification could be provided in that respect in a future revision of the legislation."). Certain questions were deleted because they are only relevant for authorities and not for operators. Furthermore, some parts were reworded in a more readable and less administrative style.

The substance of document TAXUD/1447/ENTR/G2/D(2006) has not been modified. Delegations will find attached the draft version for publication, the double-underlined parts corresponding to the additions in comparison with the previous version of working document TAXUD/1447/ENTR/G2/D(2006), and the deleted parts being struck out.

Whilst delegations have already agreed on the substance of the issues raised in the document, delegations are invited to give their approval on this guidance document. COM will then publish it on its website. Subsequent questions of interpretation (including those addressed during the 66th meeting of the Committee) and their

corresponding replies will be included in updated versions, which will be published once agreed by the Committee during future meetings.

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Brussels, 16 October 2006

TAXUD/1447/ENTR/G2/D (2006)

DRAFT

Guidance document agreed between the Commission services and the competent authorities of Member States on the implementation of the Community legislation on drug precursors – Version 1

On 18 August 2005, the new Community legislation on drug precursors (Regulation 273/2004 on drug precursors, Regulation 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors and Commission Regulation 1277/2005 laying down implementing rules for these two Regulations) entered into force. Since that date, several questions of interpretation have been raised by competent authorities of Member States. With a view to endorsing a Community approach, these questions were discussed by the Drug Precursors Committee. The Committee reached consensus on this document, which gathers the main questions and the answers agreed upon by competent authorities and Commission services, during its 66th meeting of 16 October 2006.

It attempts to provide guidance to all Member States and economic operators.

This document represents the opinion of the Commission services involved, but it is not legally binding upon the competent authorities of Member States. Only the European Court of Justice can give an authoritative interpretation of Community legislation. Furthermore, these answers represent the opinion of the Commission services concerned, but may not necessarily represent the opinion of the Commission. This guidance document does not constitute any formal commitment on behalf of the Commission.

The first part of the document relates to questions pertaining to the intra Community trade, whereas the second part relates to questions on trade between the Community and third countries.

This guidance document will be regularly updated and published on the website of the European Commission.

PART I:

Questions pertaining to the implementation of Regulation 273/2004

(Intra community trade)

1. Concerns the provision of information by operators ~~who trade~~ placing category 2 substances on the market

Question: *Operators ~~who trade~~ placing on the market category 2 substances below certain ~~amounts~~ thresholds (set out in Annex 2 of Regulation 273/2004) are exempted from registration obligation. Do they have nevertheless to report annually the quantities of scheduled substances used or supplied in compliance with article 8.2 of Regulation 273/2004 and article 17 of Regulation 1277/2005?*

Answer: Article 6 of Regulation 273/2004 foresees no exemption to the obligations of Article 8.2 for these operators in. ~~Nevertheless this seems to have been overlooked and this could be the object of a future revision of the legislation. This question will need to be discussed again when there is more experience in the implementation of these provisions.~~ As a consequence, these operators have to report annually the quantities of scheduled substances used or supplied to the competent authorities, which are then in a position to be aware that these companies are engaged in the placing on the market of scheduled substances and check that they benefit from the exemptions provided for in the legislation.

2. Concerns the provision of information in relation with special licenses

Question: *Do operators holding a special license/registration also have to provide information to competent authorities pursuant to Article 8.2 of Regulation 273/2004 and Article 17 of Regulation 1277/2005?*

Answer: As a consequence of the implementation of Article 12 of Regulation 1277/2005, the more detailed rules pertaining to the granting of special licences and special registration are established at national level. Therefore, even though ~~despite the fact that~~ no specific exemption is provided for under Article 17 of Regulation 1277/2005 for holders of special licences and registration, ~~it seems logical that~~ these operators should provide this information according to the national rules concerning special licences and registration. ~~A clarification could be provided in that respect in a future revision of the legislation.~~

3. Concerns the manufacturers and suppliers of medicinal products:

Question: *Do manufacturers of medicinal products or other products, which are not drug precursors, need a licence when they possess category 1 drug precursors which are solely used for the manufacture of medicinal products or other products, and not placed on the market ?*

Answer: Yes, according to Article 3 (3) of Regulation 273/2004, companies wishing to possess category 1 substances in order to manufacture other products have to obtain a licence.

Question: *Do manufacturers of medicinal products or other products, which are not drug precursors, need a registration and will need to report when they use category 2 drug precursors.*

Answer: Pursuant to Article 3 (6) Regulation 273/2004, operators engaged in the placing on the market of drug precursors of category 2 are required to register with the authorities. But it appears that companies only using category 2 substances and manufacturing and placing on the market other products will not need to register, as they do not fall within the definition of "operators". They will not have to report either to the authorities information about their transactions.

Question: *Do wholesalers of medicinal products or other products manufactured with drug precursors need to register or obtain a licence?*

Answer: No, the wholesalers of medicinal products and other products made from drug precursors are not covered by ~~the~~ Regulation 273/2004~~on drug precursors~~.

4. Are universities covered within the scope of EC Regulation No. 273/2004?

Question: *Do universities need a Licence when dealing with category 1 drug precursors?*

Answer:

- Article 3 (2) requires operators to obtain a licence from competent authorities before they possess or place on the market category 1 substances.
- Article 3 (3) of Regulation 273/2004 requires operators holding a license to only sell to natural or legal persons who hold a licence.

These two provisions combined should be interpreted as requiring universities which buy, possess and use category 1 substances to apply for a licence and comply with the relevant provisions of Regulations No 273/2004 and No 1277/2005 (appointing a Responsible officer, having secure facilities).

Question: *Do universities need a registration when dealing with category 2 drug precursors?*

Answer:

- Pursuant to Article 3 (6) Regulation 273/2004 operators engaged in the placing on the market of drug precursors of category 2 are required to register with the authorities. But it appears that natural or legal persons buying and using category 2 drug precursors, but not engaged in the placing on the market of such substances, do not fall within the definition of "operators" pursuant to Article 2.

- As a consequence universities do not need to register when only buying, using, and/or possessing ~~dealing with~~ category 2 substances. Neither do they have to report to the authorities and to provide information about their transactions pursuant to Article 17 of Regulation 1277/2005.

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PART II:

Questions pertaining to the implementation of Regulation (EC) No 111/2005

(Trade between the EU and third countries)

1. Concerns ~~Article 13 (2) of Reg. 111/2005~~ the period of time within which a decision on the application for an export authorisation is taken

Question: *~~We'd like to have your opinion whether~~ Shall the period of 15 working days within which a decision on the application for an export authorisation shall be taken, pursuant to Article 13 (2) of Regulation (EC) No 111/2005, ~~shall~~ be extended if a pre-export notification proceeds the authorisation and the sending of pre-export notification does not serve the verification of authenticity of the import authorisation? This question arises, because Article 13 (2) of 111/2005 ~~refers~~ only foresees an extension of the time limit in cases where the competent authorities of Member States are obliged to satisfy themselves as to the authenticity of the import authorisation issued by the competent authorities of the third county of destination before issuing the export authorisation (pursuant to second paragraph of Article 17 of 111/2005), and not in cases where a pre-export notification is required, pursuant ~~to not referring~~ to 1st paragraph of Article 11 of 111/2005.*

Answer: Yes, Article 13 (2) of Regulation (EC) No 111/2005 only refers to cases where the third country import authorisation is checked in the context of the bilateral drug precursor agreement. On the other hand, the competent authority has ~~all the~~ flexibility with regard to the start of the period for granting the authorisation, which begins when the competent authorities considers the file to be complete.

2. Concerns those bilateral drug precursor agreements which stipulate that exports may not be authorised unless an import authorisation has been issued by the third country of destination ~~Article 17 (1) of Reg. 111/2005~~

Question: *What is the up-dated list of countries mentioned in 1st paragraph of Article 17 of Regulation (EC) No 111/2005?*

Answer: Currently, two bilateral drug precursor agreements provide for the verification of the import authorisation. These are the EC/Turkey agreement OJ L 64 p. 28 of 7.3.2003, and the EC/Mexico agreement OJ L 77 p. 22 of 1997.

3. Concerns the provision of information

Question: *Do the operators need to inform competent authorities (before 15~~.2~~.February each year) about the quantities of scheduled substances involved in transactions also if they don't exceed the amounts specified in Annex II of Regulation 1277/2005?*

The operators shall also inform the competent authorities, where no operations have taken place (second paragraph of Article 19). Does this mean also information about transactions of small quantities regardless to the exemptions mentioned above?

Answer: Annex II of Regulation (EC) No 1277/2005 applies to the "registration" requirement for category 3 substances and sets out thresholds, where no registration is required. Only operators holding a registration need to inform competent authorities and only in cases where an export authorisation is required. Article 19 2nd subparagraph of Regulation (EC) No 1277/2005 sets out that the operator must also inform the competent authorities were no operations have taken place. In principle, this provision can only apply in the case of operations covered by Article 18. Category 3 exports falling under the threshold would hence not be covered by this provision, because the operator is not registered in this case.

4. Concerns the exemption of licensing and registration requirement for pharmacies, dispensaries of veterinary medicine, customs, police, official laboratories of competent authorities, and armed forces~~ Article 13 of Reg. 1277/2005~~

Question: *Does the exemption provided by Article 13 of Regulation (EC) No 1277/2005 also cover the obligation of Import/export authorisation?*

Answer: No, the exemption does not cover the obligation of import/export authorisation.

5~~6~~. Concerns the manufacturers and wholesalers of medicinal products ~~pharmaceutical preparations~~

Question: *What type of operators/type of operations are covered by the Community drug precursor legislation? Do wholesalers buying the 'pure' substance need a license? Do manufacturers + wholesalers of medicinal products ~~pharmaceutical preparations~~ need a license?*

Answer: From an external trade point of view, an operator acquiring a pure category 1 substance through import must have a licence and import authorisation. This applies to any natural or legal person engaged in the import operations. Consequently, this obligation applies also to operators importing the pure substance for wholesale or operators importing the substance for manufacturing (including manufacturing into products not covered by the Drug precursor legislation like medicinal products ~~pharmaceutical preparations~~). On the other hand, import/export of the medicinal products ~~pharmaceutical preparations~~ as such is principally not covered by the Drug precursor legislation (cf. definition of scheduled substances).

6~~7~~. . Concerns the "intermediaries"

Question: *Operator A in EC-MS 1 directly exports to Operator B in "Third Country X", while the Operator C in EC-MS 2 is the official contractor of Operator B. In the import authorisation of the "Third Country X", the name of Operator C appears. However, Operator C is just an 'accommodation address'. Who is the "Exporter"?*

Answer: The Legislation cannot cover all the different and complex scenarios. It seems necessary to find practical solutions which take account of the "economic realities" and satisfy the criteria to minimise the risk of diversion.

The spirit of the new Legislation is to make sure that the operator chiefly responsible for the export operations has to comply with the export authorisation obligations.

Operator C is the official contractor, but just an accommodation address, not registered and therefore, strictly speaking, not authorised. Therefore, Operator A would have to obtain the export authorisation. Operator C should be mentioned in the export authorisation as "other operator involved" in Box 7 of the authorisation form.

7~~8~~. Concerns the import through Community Free Zone with intermediaries

"Import Scenario": *Operator A intends to introduce drug precursors in a Community Free Zone for warehousing and subsequent distribution to different operators in the Community.*

Operator A does not intend to enter the goods into a customs procedure involving the payment of import duties. Therefore, operator A will not become "importer" and will not have to obtain the import authorisation.

However, depending on the third country of export, the export might not take place, unless the competent authority in the Member State of Operator A has issued an import authorisation/"letter of no objection".

Import duties will have to be paid by the operators buying the goods and who enter the goods into a customs procedure for release for free circulation. Those operators will become 'importers' and will have to obtain an import authorisation. The importers will not know the third country exporter.

8~~9~~. Concerns the import via Temporary Storage areas and subsequent re-export

"Import/export Scenario": Operator A introduces drug precursors into the Community Customs territory into temporary storage and subsequent re-export to "Third Country X". The Community Customs Code allows non Community goods to remain under temporary storage 20 days/45 days depending whether transport was made by sea or other means.

Under this scenario no import or export authorisations is required, (but the general proof of legitimacy).

Depending on the third country of export, the export might not take place, unless the competent authority of EC Member State of Operator A has issued an import authorisation/"letter of no objection".

9~~10~~. Concerns the scope of the import authorisation requirement

Question: *Does the import authorisation requirement cover the Community transit procedure?*

Answer: No pursuant to Article 20 paragraph 2 of Regulation (EC) No 111/2005, the import authorisation is not required where category 1 substances are placed into the Community transit procedure,.

Question: *Can the import authorisation requirement be avoided by transhipment/temporary storage?*

Answer: Theoretically yes. However the operator must always be in the position to demonstrate the licit purposes of the transaction which the competent authorities may always request. The licit purposes may be demonstrated through the document provided for in Annex III of Regulation No (EC) 1277/2005. This document constitutes a fall-back control mechanism.

10~~12~~. Concerns the control of drug precursors entered into a Customs Warehouse.

Question: *How can control be ensured when drug precursors leave a customs warehouse?*

Answer: The entry into a customs warehouse is subject to import authorisation. The requirement upon discharge depends on the subsequent activity. Case A) Entry into a new suspensive regime (except for transit) requires an import authorisation. Case B) Entry into the transit-regime or customs approved treatment or use entails the requirement to be able to demonstrate the licit purposes of the transaction, C) Re-export requires an export authorisation (unless export takes place within a certain time limit).

11~~13~~. Concerns the compliance with the drug precursors legislation and the ECS (Export Control System)

Question: *Is it possible to use the Export control system for drug precursor purposes?*

Answer: The ECS aims to provide a paperless environment for movements of declared export goods between the customs "office of export" and the customs "office of exit". However, according to specific modalities provided by the transit procedure provisions, the office of exit is not always located at the "point" of exit from the Community customs territory. Therefore, the drug precursor legislation is focusing on the point of exit to certify physical departure. Consequently, it would seem difficult to achieve compatibility with the ECS.

12~~14~~. Concerns authorities responsible for certifying the physical departure of the Community Customs territory (Export control of drug precursors).

Question: *Which is the responsible authority for certifying the physical departure?*

Answer: Copies 2 + 3 of the export authorisation must accompany the goods and must be presented to the customs office where the export declaration is made and then to the "competent authorities at the point of exit". The “competent authorities at the point of

exit" means those authorities designated by the Member States as being responsible. This can be Customs or other authorities competent for border control.

13~~16~~. Concerns the import/export authorisations granted by electronic means:

Question: ~~*One Member State wished to know whether other delegations see*~~ *Are their any difficulties related to* ~~*when receiving an*~~ *authorisations granted via electronic means?*

Answer: The legislation allows to grant authorisations via electronic means. The authorisation forms are binding with regard to the layout. Only when authorisations are granted via electronic means, the box relating to the authorisation number may be adapted. *No difficulties have been reported*.