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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 2

On August 2005, the new Community legislation on drug precursors (Regulation (EC) N° 273/2004 on drug precursors, Council Regulation N°111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors and Commission Regulation N°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 and Drug Precursors Working Group. The Committee and the Working Group reached consensus on this document, which gathers the main questions and the answers agreed upon by competent authorities and Commission services.

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 common questions pertaining to the two main pieces of legislation, whereas the second part deals with the Intra Community trade, and the third part relates to questions on trade between the Community and third countries.

This guidance document is regularly updated and published on the website of the European Commission. Latest update is this **Version 2 of June 2008**.

PART I

Questions pertaining to both Regulation (EC) N°273/2004 (Intra-community trade) and Regulation (EC) N°111/2005 (Trade between the EU and Third countries)

1. Natural products

Question: *Are ephedra leaves covered by the Community legislation on drug precursors?*

Answer: According to Article 2 of Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005, natural products containing pure scheduled substances are to be considered themselves scheduled substances and covered by these Regulations, unless they are "compounded in such a way that they cannot be easily used or extracted by readily applicable or economically viable means".

The alkaloids ephedrine and pseudoephedrine are the active constituents of ephedra. It has been shown that these substances can be easily extracted and used for illicit drug manufacturing activities.

As a consequence, ephedra leaves should be regarded as scheduled substances of category 1.

2. Concerns laboratories benefiting from the exemptions provided for in the Community drug precursors legislation

Question: *Which laboratories are covered by the wording "official laboratories of competent authorities" and therefore benefit from the exemptions provided for in Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005?*

Answer: According to Article 12 of Regulation (EC) No 1277/2005, "official laboratories of competent authorities" are subject to special licences/registrations for placing category 1 and 2 substances on the market. According to Article 13, they are exempted from the requirements of licensing and registration for imports, export and intermediary activities.

In the general context of Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005, the wording "competent authorities" designates competent authorities in the field of drug precursors. These "competent authorities" can be law enforcement authorities, customs, inspectorates and authorities entitled to receive registrations and issue licences and import/export authorisations

The "official laboratories" of these competent authorities are those designated in pursuance to national legislation, regulations or administrative provisions, or appointed by public bodies entitled to perform specific work for the benefit of these "competent authorities". In no case can all public laboratories (forensic toxicological laboratories, health care laboratories, scientific research laboratories...) be considered "official laboratories of competent authorities".

PART II

Questions pertaining to the implementation of Regulation (EC) N°273/2004

(Intra-Community Trade)

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

Question: *Operators placing on the market category 2 substances below certain thresholds (set out in Annex II of Regulation (EC) No 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 (EC) No 273/2004 and article 17 of Regulation (EC) No 1277/2005?*

Answer: Article 6 of Regulation (EC) No 273/2004 foresees **no** exemption to the obligations of Article 8.2 for these operators. 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 licence/ registration

Question: *Do operators holding a special licence/registration also have to provide information to the competent authorities pursuant to Article 8.2 of Regulation (EC) No 273/2004 and Article 17 of Regulation (EC) No 1277/2005?*

Answer: As a consequence of the implementation of Article 12 of Regulation (EC) No 1277/2005, the more detailed rules pertaining to the granting of special licences and special registration are established at national level. Therefore, even though **no** specific exemption is provided for under Article 17 of Regulation (EC) No 1277/2005 for holders of special licences and registration, these operators should provide this information according to the national rules concerning special licence/ registration.

3. Concerns the manufacturers and suppliers of medicinal products

Question: *Do manufacturers of medicinal products or other products, which are not scheduled substances, need a licence when they possess category 1 scheduled substances 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 (EC) No 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 scheduled substances, need a registration and will need to report information to the authorities when they use category 2 substances?*

Answer: Pursuant to Article 3 (6) Regulation (EC) No 273/2004, operators engaged in the placing on the market of substances of category 2 are required to register with the authorities. But it appears that 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, as required by operators under Article 17 of Regulation (EC) No 1277/2005.

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

Answer: No, the wholesalers of medicinal products and other products made from scheduled substances, which are not scheduled substances themselves, are not covered as such by Regulation (EC) No 273/2004.

4. Are universities covered within the scope of Regulation (EC) 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 (EC) No 273/2004 requires operators holding a licence 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 (EC) No 273/2004 and (EC) No 1277/2005 (i.e. 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) of Regulation (EC) No 273/2004, operators engaged in the placing on the market of scheduled substances 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 scheduled 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 category 2 substances. Neither do they have to provide information to the authorities about their transactions in pursuance to Article 17 of Regulation (EC) No 1277/2005.

Question: *Are other entities in the same situation as universities?*

Answer: The same conclusions apply to all natural or legal persons that buy, possess and use category 1 (respectively category 2) substances, without placing them on the market as such. They apply in particular to laboratories (forensic toxicological laboratories, health care laboratories, scientific research laboratories...) and the industrial activities that comply with the abovementioned criterion (e.g. pharmaceutical or chemical industrial companies that only use scheduled substances as feedstock). Users of category 1 substances may be granted a special licence if they comply with the criteria set down in Article 3(2) of Regulation (EC) No 273/2004.

5. Reporting obligations on users of substances of category 1 or 2

Question: *Are users of substances of category 1 or 2 subject to the reporting obligations laid down in Article 17 of Regulation (EC) No 1277/2005?*

Answer: Article 17 of Regulation (EC) No 1277/2005 requires operators to inform the competent authorities in a summary form of the quantities of scheduled substances used or supplied to third parties.

A natural or legal person that would only use such substances without placing them on the market would not fall under the definition of "operators" and consequently, neither under the scope of Article 17 of Regulation (EC) No 1277/2005.

However, a natural or legal person should be considered an operator as long as it is engaged in the placing on the market of scheduled substances. If it has registered premises or obtained a licence, it must report annually quantities used or supplied, even if these quantities happen to equal to zero. This reporting must be done for all substances mentioned in the application for licence or registration.

PART III
Questions pertaining to the implementation of Regulation (EC) N° 111/2005
(Trade between the EU and Third countries)

1. Concerns the period of time within which a decision on the application for an export authorisation is taken

Question: *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 be extended if a pre-export notification precedes 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 Regulation (EC) No 111/2005 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 third country of destination before issuing the export authorisation (pursuant to second paragraph of Article 17 of Regulation (EC) No 111/2005) , and not in cases where a pre-export notification is required, pursuant to first paragraph of Article 11 of Regulation (EC) No 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 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

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 15th February each year) about the quantities of scheduled substances involved in transactions also if they do not exceed the amounts specified in Annex II of Regulation N° 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 where 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 licencing and registration requirement for pharmacies, dispensaries of veterinary medicine, customs, police, official laboratories of competent authorities, and armed forces.

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. Concerns the manufacturers and wholesalers of medicinal products.

Question: *What types of operators/type of operations are covered by the Community drug precursor legislation? Do wholesalers buying the "pure" substance need a licence? Do manufacturers + wholesalers of medicinal products need a licence?*

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). On the other hand, import/export of the medicinal products as such is principally not covered by the Drug precursor legislation (cf. definition of scheduled substances).

6. 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 1 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. 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. 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 authorisation is required, but the demonstration of the licit purposes may be required pursuant to Article 8 of Regulation (EC) No 111/2005 and Article 16 of Regulation (EC) No 1277/2005.

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. 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 but the authorities may require the operator to demonstrate the licit purposes of the transaction pursuant to Article 8 of Regulation (EC) No 111/2005 and Article 16 of Regulation (EC) No 1277/2005.

Question: *Can the import authorisation requirement be avoided by transshipment/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. 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.

Case C) Re-export requires an export authorisation (when re-export does not take place within 10 days, which is the time limit set out by Article 12 of Regulation (EC) No 111/2005).

11. 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. 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. Concerns the import/export authorisations granted by electronic means

Question: *Are there any difficulties related to authorisations granted via electronic means?*

Answer: The legislation allows granting 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.