



Community Controls for Drug Precursors

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Outline of the presentation

- 1. Introduction General features of EC Regulation**
- 2. Specific requirements for Category 1, 2 and 3 substances and customer declarations**
- 3. Other specific features of the legislation**

Part 1 - Introduction

Objectives

1. Prevent illegal use and illegal trade of drug precursors
2. Maintain a competitive internal market for the legitimate trade

**Calls for a Balanced Approach
'Proportionality'**

Reference texts

Intra-community trade:

**Council & Parliament Regulation EC
n°273/2004**

External trade:

Council Regulation EC n°111/2005

Implementing provisions = **Commission Regulation
1277/2005**

in force since 18 August 2005

Scope of Regulation 273/2004

- **What is regulated?**
 - **Cat 1, Cat 2 and Cat 3 substances (listed in Annex 1)**
 - **Mixtures and natural products containing these**
- **What is excluded?**
 - **Medicinal products**
 - **Preparations containing precursors which cannot be extracted by “readily applicable or economically viable means”**

PART 2

**Specific requirements for
Substances category 1, 2 and 3
and customer declaration**

Category 1 substances

	CN code	CAS N°
• 1-phenyl-2-propanone	2914 31 00	103-79-7
• N-acetylanthranilic acid	2924 23 00	89-52-1
• Isosafrol (cis + trans)	2932 91 00	120-58-1
• 3,4-methylenedioxyphenylpropan-2-one	2932 92 00	4676-39-5
• Piperonal	2932 93 00	120-57-0
• Safrole	2932 94 00	94-59-7
• Ephedrine	2939 41 00	299-42-3
• Pseudoephedrine	2939 42 00	90-82-4
• Norephedrine	ex 2939 49 00	14838-15-4
• Ergometrine	2939 61 00	60-79-7
• Ergotamine	2939 62 00	113-15-5
• Lysergic acid	2939 63 00	82-58-6

+ stereoisometric forms and salts

Category 1 substances

Main obligations of operators :

- Appoint a responsible officer
- Obtain a licence from Competent Authority
- Sell only to persons holding a licence and a customer declaration
- In case of unusual orders or transactions => notify to the Competent Authority
- Have secure premises

Category 1 substances : Licensing

The licence (implementing rules)

- Application
- Granting of licences by Competent authorities
 - identical model in the EU
 - within 60 working days
- Maximum duration: 3 years
- Condition for renewal of licences
- Suspension and revocation of licenses
- Distinction between routine changes /major changes

Category 2 substances

Cat 2 Substances:	CN code	CAS N°
– Acetic anhydride	2915 24 00	108-24-7
– Phenylacetic acid	2916 34 00	103-82-2
– Anthranilic acid	2922 43 00	118-92-3
– Piperidine	2933 32 00	110-89-4
– Potassium Permanganate	2841 61 00	7722-64-7
+ Salts		

Category 2 substances :

Registration

Obligations of operators:

- **Register with the Competent Authorities of address of the premises**
 - Exemptions for small annual quantities**
- **Appoint a Responsible officer**
- **Sell only to persons holding a customer declaration**
- **Notify Competent Authorities in case of unusual orders or transactions**

Category 3 substances

	CN number	CAS code
➤ Hydrochloric acid	2806 10 00	7647-01-0
➤ Sulphuric acid	2807 00 10	7664-93-9
➤ Toluene	2902 30 00	108-88-3
➤ Ethyl ether	2909 11 00	60-29-7
➤ Acetone	2914 11 00	67-64-1
➤ Methyleneethylketone / Butanone	2914 12 00	78-93-3

Category 3 substances

Obligations of operators concerning Cat 3 substances

In case of unusual orders or transactions

=> suspicion of diversion for illicit manufacture

=> notification to the competent authorities

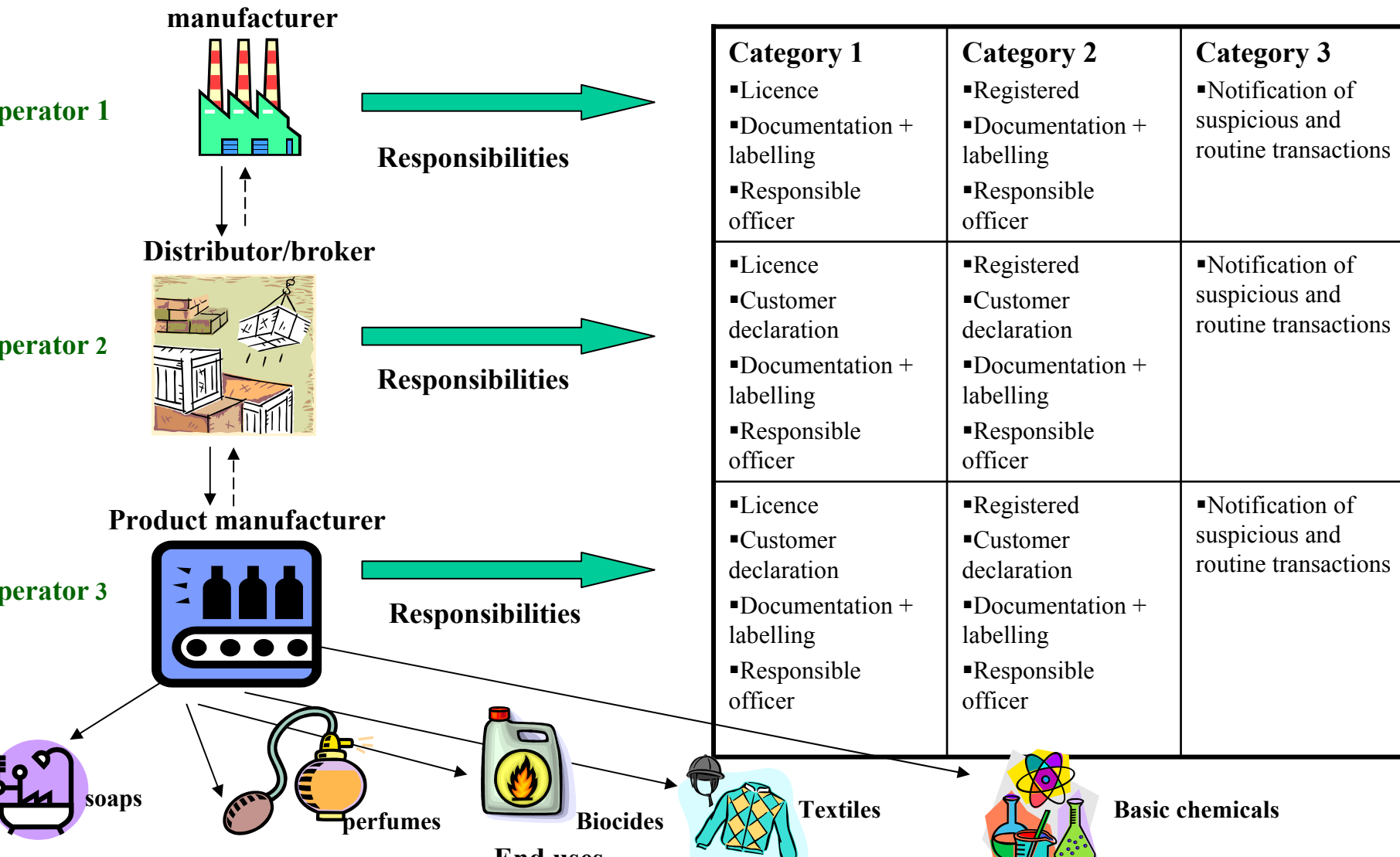
Customer declarations

Customer declaration

- **Obtained from customers**
- **By operators supplying Cat 1 and Cat 2 substances**
- **Specifies the use**
- **One per substance**
 - possibility of a multiple transaction declaration
- **For Cat 1: a copy travels with the substance**

SUMMARY

Controls along the supply chain



PART 3

Other specific features of the Regulation

- 1. The cooperation between authorities and industry**
- 2. Powers and obligation of authorities**

Other Features of the Regulation (1)

Cooperation between authorities and industry

- **Routine reporting obligations**
 - yearly reporting of quantities used or supplied
 - name of third parties (customer declarations)
- **Exchange of information on suspicious transactions**

Other Features of the Regulation (2)

Powers and obligations of authorities:

Powers

- Enter premises to obtain evidence**
- Detain consignments**

Obligations

- Protect confidential business information**



The End

Thank you for your attention !

Contact Points in the European Commission

- Concerning intracommunity trade

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