ORDER SCO/127/2004, OF JANUARY 22nd IN DEVELOPMENT OF ARTICLES 4 AND 6 OF ROYAL DECREE 1079/2002, OF OCTOBER 18TH IN RELATION TO THE TAR, NICOTINE AND CARBON MONOXIDE YIELDS OF CIGARETTES, THE LABELLING OF TOBACCO PRODUCTS, AND MEASURES RELATING TO INGREDIENTS AND THE DENOMINATION OF TOBACCO PRODUCTS

Royal Decree 1079/2002 of 18 October which regulates the maximum nicotine, tar and carbon monoxide yield of cigarettes, the labelling of tobacco products, and measures relating to ingredients and the denomination of tobacco products, provides in its Article 3 for the maximum tar, nicotine and carbon monoxide yield of cigarettes. In Article 4 it lays down the ISO rules that are applicable for exactly measuring these yields and it is laid down that the measurements made by manufacturers or importers, in accordance with such control methods, must be verified by laboratories specified by the Ministry of Health and Consumer Affairs.

Further, Article 6 of the Royal Decree lays down a duty on tobacco manufacturers, importers and trademark holders (*marquistas*) to declare the list of all ingredients used in the manufacture of their products together with the quantities thereof, specified according to brand and type of product.

This Order is to develop these provisions of the said Royal Decree.

Thus, in accordance with the provisions of the second final provision of Royal Decree 1079/2002 of 18 October, I hereby promulgate as follows:

FIRST.- Duties of manufacturers, importers and trademark holders (*marquistas*) of tobacco products.

1.- The manufacturers and importers of tobacco products shall verify cigarette tar, nicotine and carbon monoxide yields, in accordance with the provisions contained in Article 4 of Royal Decree 1079/2002, by analysis of representative samples of the cigarettes they offer for sale, distinguished according to brand and type, carried out in laboratories authorised on the terms set forth in this Order.

2.- Annually, prior to 1 November of each year, the manufacturers and importers shall submit to the Directorate General of Public Health of the Ministry of Health and Consumer Affairs the verification controls set forth in the foregoing paragraph, indicating: samples

analysed, sampling criteria used for selection of the same, and the laboratory which performed the verification.

3.- The Directorate General of Public Health may require, by resolution stating its grounds, the tobacco manufacturers and importers to submit other complementary tests, for the evaluation of the yield of other substances produced by their tobacco products, as well as their effects on health, on the terms set forth in Section 2 of Article 4 of Royal Decree 1079/2002. In this case, said tests shall be verified by the laboratories recognised pursuant to this Order.

4.- Independently of these, verifications, the Directorate General of Public Health reserves the possibility to carry out the pertinent verification of tobacco products offered for sale.

5.- Likewise, in accordance with the provisions of Article 6 of the said Royal Decree, manufacturers, importers and trademark holders (*marquistas*) of tobacco products shall on an annual basis, prior to 1 November of each year, provide the Directorate General of Public Health of the Ministry of Health and Consumer Affairs with a list of ingredients and quantities used in the manufacture thereof on the terms set forth in Annex I to this Order.

SECOND.- Laboratories authorised for verification of yields of tobacco products.

1.- The laboratories for the verification of cigarette yields shall be independent from the manufacturers, importers and trademark holders (*marquistas*) of tobacco products, whether public or private, and shall be authorised by the Directorate General of Public Health of the Ministry of Health and Consumer Affairs and registered in the Register of Laboratories Authorised for the Verification of Tobacco Products.

For the purposes laid down in this Order, the *Centro de Investigación y Control de la Calidad* of the *Instituto Nacional de Consumo* shall be deemed to be an authorised laboratory, which shall act as a reference laboratory and for the purposes set forth in the first additional provision, section 4.

2.- Applications for authorisation must contain all information referred to in Annex II.

3.- It shall rest with the Directorate General of Public Health to deal with and decide upon any applications that are made in accordance with the minimum requirements contained in Annex III with the support and advice of the reference laboratory referred to in point 1 of this section, and of other public and private entities.

4.- Authorisations shall be for a period of time of two years as from the date of recording in the Register and may be extended for a like period of time provided always the laboratory continues to comply with the required conditions, and requests such an extension.

5.- The Directorate General of Public Health shall, throughout the period of the validity of an authorisation, oversee compliance with the conditions laid down for the grant thereof and, if pertinent, it may revoke such authorisation if such conditions are not complied with.

THIRD.- Register of Laboratories Authorised for the Verification of Tobacco Products.

A Register of Laboratories Authorised for the Verification of Tobacco Products is hereby created under the control of the Directorate General of Public Health, in which all authorised laboratories shall be registered.

FOURTH.- Information to be made public by the Ministry of Health and Consumer Affairs.

The information to be made public by the Ministry of Health and Consumer Affairs regarding the maximum yield of the products and the list of their ingredients, as provided for under Articles 4 and 6 of Royal Decree 1709/2002, must in each case contain a reference to the laboratory which has carried out the verification in question.

FIFTH.- Coming into force.

This Order shall come into force on the day following its publication in the Official State Gazette.

Madrid,

THE MINISTER OF HEALTH AND CONSUMER AFFAIRS

Ana María Pastor Julián

ANNEX I (A)

List of Ingredients of Tobacco Products***

Name: Manufacturer, Importer, Holders of Trademark: .....

Brand: .....

Individual Type: .....

Ingredients	Amounts *	Toxicological Data**	Health Effects	Addictive Effects	Function - Category

* In decreasing order of weight.

** any other information of complementary interest may be attached

*** this information must be provided in hardcopy, computer media and in the Spanish language.

ANNEX I (B)

Declaration stating the reasons for inclusion of these ingredients in the tobacco products.

Brand..... Individual Type .....

Name of Ingredient .....

Reasoned justification for inclusion, according to category, function, toxicity (with and without combustion), other health effects, including addictive effects if any:

Signature of industrial manager

ANNEX II

Application for authorisation as a Laboratory for Verification of Tobacco Products

Details of the Laboratory

Name: .....

Address: ..... Telephone ..... e-mail .....

Company Name .....

Director / Person in Charge .....

Data probative of organisational, functional and economic independence: .....

Technical and Professional Qualifications

Technical Personnel in Charge

Qualifications .....

Description of installations, equipment, techniques and laboratory procedures

Complete list of specific equipment necessary

Directorate General of Public Health. Ministry of Health and Consumer Affairs

ANNEX III

Minimum requirements to be met by laboratories for verification of tobacco products

- Installations required for a general chemistry lab
- Smoking room with environmental conditions in accordance with the needs and requirements of the ISO 4387 STANDARD
- Compliance with the pertinent UNE Standards
- Equipment necessary to perform the required measurements and verifications.
- Installations authorised by the Regional Government of the place where the laboratory is located