HANDBOOK

AUTHORIZATION APPLICATION

Of analytical laboratories for cannabinoid quantification

Version 1.0-2019

IRCCA
INSTITUTO DE REGULACIÓN Y CONTROL DEL CANNABIS

HANDBOOK FOR AUTHORIZATION APPLICATION OF ANALYTICAL LABORATORIES FOR CANNABINOID QUANTIFICATION

A. SCOPE OF THE HANDBOOK

The present handbook is under the provisions of resolutions No. 12 and No. 66 approved by the Instituto de Regulación y Control del Cannabis [Cannabis Control and Regulation Institute] (hereinafter IRCCA) Board of Directors.

In accordance with Sections 1 and 9 of Regulatory Decree No. 120/014, and Sections 4 and 42 of Regulatory Decree No. 46/015 of Law No. 19 172, the IRCCA is the entity authorized to grant authorizations to laboratories interested in performing analysis for cannabinoid quantification.

The present handbook sets forth the necessary requirements to be filed before the IRCCA in order for analytical laboratories to be granted authorization to perform cannabinoid quantification assays.

The IRCCA can, during the licensing process, request additional documentation or information that is necessary for the granting of the license.
For inquiries regarding this handbook, go to: proyectos@ircca.gub.uy

B. AUTHORIZATION LICENSE APPLICATION RECEPTION

1 The application —with the documents comprising it— will be received exclusively at the front desk of the IRCCA. Applications sent via e-mail or any other mean that is not set forth in this handbook will not be accepted. Applications must be filed in accordance with the present handbook. In the event that they do not comply with the structure provided therein or are not submitted together with the requested documentation, the evaluation process will not begin.

2 The application must be comprised of the following documents:

a The application will be construed as an affidavit, and the relevant form, filled, dated, and signed by the legal representative must be attached to the application (Attachment 1). It must be filed bearing the appropriate stamp.

b Laboratory Technical Director (TD) Affidavit Form (Attachment 2), filled, dated, signed, and bearing the appropriate stamp.

c Copy of Forms 6351 and 6361 of the Dirección General Impositiva (DGI) [Uruguayan tax authority].

d In the case of legal entities, they must file a notarial certificate dated no more than 30 days from its issuance, stating its existence and representation.

e The Notarial Certificate of valid operational clearance from the Ministerio de Salud Pública (MSP) [Department of Public Health] must be filed.

3 The characteristics of the submitted authorization application shall be as follows:

a The application shall be filed in Spanish.

b The application shall be filed in print and in digital format (USB drive), both versions being the exact same document.

c The application shall be signed by the legal representative and the technical director, and all pages must be numbered.

d An electronic address must be provided in the application, which will be valid for all communications with the IRCCA, in accordance with Board of Directors Resolution No. 23/2019.

e A counterpart responsible before IRCCA must be identified, providing the following information: name, e-mail address and contact telephone number. In addition, personal/institutional contact information to be included in the IRCCA institutional website (e-mail address and/or telephone number) must be provided, once authorization has been obtained.

C. MANDATORY CONTENTS OF AUTHORIZATION APPLICATION

1. Filing of the application:
The application shall be structured in two distinct chapters:

- Chapter 1: Documentation
- Chapter 2: Technical Project

2. Contents of Chapter 1 - Documentation:
Chapter 1 shall contain the documents listed in item B.2.

3. Contents of Chapter 2 - Technical Project:

a Analytical methodology to be used for the cannabinoid quantification, together with documentation of its validation.
b Present the surplus management procedure for possible cannabis leftovers.
c It should be taken into consideration that, in the event that the analytical methodology is altered after the authorization is issued, the laboratory shall send the new version and its revalidation, if applicable, to the IRCCA.

PROJECT EVALUATION

As part of the authorization process, the IRCCA will visit the company and evaluate the submitted documentation. Likewise, it may request clarification regarding the information received, as well as complementary information. In this evaluation, whether the laboratory has the necessary safety measures for the handling of samples and that the responsibility for the samples is clearly defined at all times will also be taken into consideration.
Once this stage has been completed, a report will be submitted to the IRCCA Executive Board, which will approve or deny the authorization application submitted. The result will be

notified to the company at the provided e-mail address.
It should be considered that, after the authorization has been granted, the IRCCA, in compliance with the powers granted by Law No. 19 172, may carry out random inspections, request documentation and information, and enforce the applicable sanctions.

ATTACHMENT 1

AFFIDAVIT OF LEGAL REPRESENTATIVES FOR THE AUTHORIZATION APPLICATION OF ANALYTICAL LABORATORIES FOR THE QUANTIFICATION OF CANNABINOIDS.

The undersigned_____,

holder of ID document (government issued ID card or passport) No._____,

phone No._____, e-mail address_____

with residence for legal purposes at _____

_____ acting as representative/legal

representative/holder of the signature/institution _____

_____ declares under oath that all information submitted to the IRCCA for the purpose of obtaining a license for some of the purposes provided for in Law No. 19 172 and its Regulatory Decree No. 46/015 which includes planting, cultivating, harvesting, stocking and/or commercializing cannabis (psychoactive and/or non-psychoactive); I): will be exclusively destined to the purposes foreseen in the aforementioned legislation II): all the information submitted in the project is true, correct and fit for the purposes of the project submitted and III): once the project is approved, the activities will be developed within the established framework, approved by the IRCCA and the relevant authorities. Moreover, states to be aware of the scope of what has been declared and the provisions of Section 239 of the Criminal Code of the Eastern Republic of Uruguay.

Signature: _____

Full name (print): _____

Date:_____/_____/_____

ATTACHMENT 2

AFFIDAVIT OF THELABORATORY'S TECHNICAL DIRECTOR (TD)

The undersigned (name, last name)_____,

holder of ID document (government issued ID card/passport/other) No._____,

agrees to all liabilities and obligations in connection with the authorization applied for before this Institute, rising from their position as Technical Director (TD) of (company/organization) laboratory._____

	Technical Director	Legal representative(s) for the Company/Insititution (If applicable)
Signature		
Full name (print)		
E-mail address		
Mobile phone		
ID card/passport/other number		

IRCCA
INSTITUTO DE REGULACIÓN Y CONTROL DEL CANNABIS

REGULANDO QUEDA CLARO

INFOCANNABIS
.GUB.UY