

Accreditation of laboratories for the analysis of pesticide residues in Spain

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Accreditation of laboratories for the analysis of pesticide residues in Spain: **Contents**

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Spanish National Reference Laboratories

- **Regulation (EU) 2017/625** on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (**Official Control Regulations**):
 - Article 100: Designation of National Reference Laboratories
 - Article 101: Responsibilities and tasks of National Reference Laboratories



Centro Nacional de Alimentación



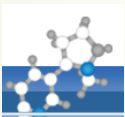
Fruits and Vegetables



Cereals and Feedingstuffs



Food of Animal Origin



Single Residue Methods



Laboratorio Arbitral Agroalimentario

Spanish National Reference Laboratories

► Spanish Official Laboratories Network (CNA)

Servicio de Seguridad y Control de la Producción Agraria de la Generalitat Valenciana-EURL	Valencia
Centro Nacional de Alimentación (AECOSAN) - LNR	Majadahonda (Madrid)
Laboratorio Arbitral Agroalimentario (MAPAMA) - LNR	Madrid
Laboratorio Regional del Gobierno de La Rioja	Logroño
Navarra de Servicios y Tecnología, S.A. (Nasertic)	Villava (Navarra)
Laboratorio Agrario Regional. Consejería de Agricultura y Ganadería de la Junta de Castilla y León	Burgos
Laboratorio Regional Agroalimentario y Ambiental de Castilla La Mancha. Consejería de Agricultura	Toledo
Agència Salut Pública de Barcelona	Barcelona
Laboratorio de Salud Pública (Madrid Salud). Ayuntamiento de Madrid	Madrid
Laboratorio de Salud Pública de Valencia	Valencia
Laboratori de Salut Pública de Palma	Palma de Mallorca
Laboratorio de salud Pública de Cuenca	Cuenca
Laboratorio de salud Pública de Almería	Almería
Laboratorio de salud Pública de Badajoz	Badajoz
Laboratorio Normativo de salud Pública de Bilbao	Derio (Bilbao)
Laboratorio de Saúde Pública de Galicia. Laboratorio de Lugo	Lugo

Spanish National Reference Laboratories

► Spanish Official Laboratories Network (LAA)

Servicio de Seguridad y Control de la Producción Agraria de la Generalitat Valenciana-EURL	Valencia
Centro Nacional de Alimentación (AECOSAN) - LNR	Majadahonda (Madrid)
Laboratorio Arbitral Agroalimentario (MAPAMA) - LNR	Madrid
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Navarra de Servicios y Tecnologías, S.A. (Nasertic)	Villava (Navarra)
Laboratorio Agrario Regional. Consejería de Agricultura y Ganadería de la Junta de Castilla y León	Burgos
Laboratorio Regional Agroalimentario y Ambiental de Castilla La Mancha. Consejería de Agricultura	Toledo
Instituto Tecnológico de Canarias. S.A. Laboratorio de Residuos	Agüimes (Las Palmas)
Laboratori Agroalimentari. Generalitat de Catalunya	Cabrils (Barcelona)
Laboratorio Agrario y Fitopatológico de Galicia	Mabegondo (A Coruña)
Laboratorio Agroalimentario de Extremadura	Cáceres
Laboratorio Agroalimentario de Córdoba. Junta de Andalucía	Córdoba
Laboratorio Agroalimentario de Granada. Junta de Andalucía	Atarfe (Granada)
Laboratorio Agroambiental de Aragón	Zaragoza
Laboratorio Agroalimentario y de Sanidad Animal de Murcia	Murcia
Laboratorio de pesticidas de Fraisoro (Zizurkil)	Zizurkil (Guipuzcoa)
Laboratorio de Producción y Sanidad Vegetal de Almería. Junta de Andalucía	Mojonera (Almería)
Laboratorio de Producción y Sanidad Vegetal de Jaén. Junta de Andalucía	Mengibar (Jaén)
Laboratorio de Sanidad Vegetal de Asturias	Oviedo (Asturias)
Servicio Laboratorio y Control de Cantabria	Santander
Laboratorio del Servicio de Inspección de la Dirección Provincial de Comercio de Almería	Almería
Laboratorio del Servicio de inspección SOIVRE de Valencia	Valencia
Laboratorio del Servicio de Inspección SOIVRE. Dirección Territorial de Comercio de Santa Cruz deTenerife	Sta. Cruz de Tenerife

Accreditation of Spanish laboratories for the analysis of pesticide residues

► Regulation (EU) 2017/625 (Official Control Regulations):

► Article 37: Designation of Official Laboratories

4e. The competent authorities may only designate as an **official laboratory** a laboratory which operates in accordance with the standard **EN ISO/IEC 17025** and is **accredited** in accordance with that standard **by a national accreditation body** operating in accordance with Regulation (EC) No 765/2008.

► Spanish National Accreditation Body: Entidad Nacional de Acreditación (ENAC): www.enac.es

► ENAC is a signatory of all international agreements of the EA ([European Cooperation for Accreditation](#)), ILAC ([International Laboratory Accreditation Cooperation](#)) and IAF ([International Accreditation Forum](#)).



► Standard EN ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.

Accreditation of Spanish laboratories for the analysis of pesticide residues: relevant documents

- **Standard EN ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.**
- [CGA-ENAC - LEC](#) Rev. 8 General criteria for the accreditation of testing and calibration laboratories according to Standard UNE-EN ISO/IEC 17025 (September 2018)
- [PAC-ENAC - LEC](#) Rev. 6 Laboratory accreditation procedure (May 2018)
- [NT - 03](#) Rev. 6 ENAC policy on Proficiency Testing (June 2018)
- [G-ENAC - 14](#) Rev. 1 Guide on participation in proficiency tests schemes (September 2008)
- [NT - 18](#) Rev. 1 Testing laboratories: Accreditation for testing categories (June 2004)
- [NT - 19](#) **Rev. 3 Testing laboratories: Accreditation for pesticide residue analysis in agrifood products** (June 2011)
- [NT - 55](#) **Rev. 2 Reference laboratories in agrifood area: policy on participation in the accreditation system** (March 2018)
- [NT - 86](#) Rev. 2 Test methods: expression and modification of the scope of accreditation in accredited laboratories according to ISO/IEC 17025 (September 2018)

Accreditation of Spanish laboratories for the analysis of pesticide residues: scope types

Pesticides	Commodities	Scope
Fixed	Fixed	FIXED
Fixed	Open	FLEXIBLE
Open	Fixed	
Open	Open	

► General requirements:

FIXED SCOPE →

- **Standard EN ISO/IEC 17025:2017** General requirements for the competence of testing and calibration laboratories.
- **NT - 19** Rev. 3 Testing laboratories: Accreditation for pesticide residue analysis in agrifood products

← **FLEXIBLE SCOPE**

Accreditation of Spanish laboratories for the analysis of pesticide residues. Fixed scope: advantages and drawbacks

- **Scope of accreditation: simpler management**



- **Analyzing pesticides and/or commodities not included in the scope of accreditation is not possible (Official Control Programs, private customers).**



- **Extension of the scope of accreditation: audit of the accreditation body (ENAC) required**

- **Increase in response time**
- **Additional costs**



Accreditation of Spanish laboratories for the analysis of pesticide residues. Flexible scope: testing categories

- [NT - 18](#) Rev. 1 Testing laboratories: Accreditation for testing categories
- [NT - 19](#) Rev. 3 Testing laboratories: Accreditation for pesticide residue analysis in agrifood products

Accreditation of Spanish laboratories for the analysis of pesticide residues. Flexible scope: NT-19

- **Purpose:** to describe **ENAC criteria** to be taken into account in the **evaluation of testing laboratories** requesting **flexible accreditation for analysis of pesticide residues in agri-food products** (plant products, food, feedingstuffs, plant material such as leaves, branches, etc.) as testing categories.
- Also applies to accreditation requests considered as an **intermediate situation**:
 - only commodities
 - only pesticides
- **The laboratory must have an extensive experience in carrying out a number of specific analyses sufficiently representative of the category to qualify for this type of flexible scope.**



Accreditation of Spanish laboratories for the analysis of pesticide residues. Flexible scope (NT-19): scope of accreditation

- **Technical accreditation annex** will include:
 - Product to be tested: **commodity group(s)**
 - Test: 'pesticide residues' and analytical technique
 - Analytical method: **Standard Operating Procedure (SOP)**, according to internal rules of the laboratory
 - Reference to '**Public List of Tests**' (*Lista Pública de Ensayos, LPE*)



AGENCIA ESPAÑOLA DE CONSUMO, SEGURIDAD ALIMENTARIA Y NUTRICIÓN (AECOSAN)
Centro Nacional de Alimentación (CNA)
 Dirección: C/da. Perseida s/n, 28002 Madrid (España)
 Actividad: Ensayos
 Acreditación Nº 7020/2018
 Fecha de entrada en vigor: 23/07/2018

ALCANCE DE LA ACREDITACIÓN
 Categoría 01 Ensayos en los laboratorios del laboratorio

ÁREA QUÍMICA Y EVALUACIÓN NUTRICIONAL. UNIDAD DE PLASQUICIDAS Y ENXERMA. RESIDUOS FITOFÁRMACOS.

Análisis mediante métodos basados en técnicas cromatográficas

PRODUCTOS/GRUPOS DE ENSAJO	ENSAJO	MÉTODOS/REFERENCIAS DE ENSAJO
Arroz	01.01 mg/kg	01.01 mg/kg
Arroz	01.02 mg/kg	01.02 mg/kg
Arroz	01.03 mg/kg	01.03 mg/kg
Arroz	01.04 mg/kg	01.04 mg/kg
Arroz	01.05 mg/kg	01.05 mg/kg
Arroz	01.06 mg/kg	01.06 mg/kg
Arroz	01.07 mg/kg	01.07 mg/kg
Arroz	01.08 mg/kg	01.08 mg/kg
Arroz	01.09 mg/kg	01.09 mg/kg
Arroz	01.10 mg/kg	01.10 mg/kg
Arroz	01.11 mg/kg	01.11 mg/kg
Arroz	01.12 mg/kg	01.12 mg/kg
Arroz	01.13 mg/kg	01.13 mg/kg
Arroz	01.14 mg/kg	01.14 mg/kg
Arroz	01.15 mg/kg	01.15 mg/kg
Arroz	01.16 mg/kg	01.16 mg/kg
Arroz	01.17 mg/kg	01.17 mg/kg
Arroz	01.18 mg/kg	01.18 mg/kg
Arroz	01.19 mg/kg	01.19 mg/kg
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Arroz	01.94 mg/kg	01.94 mg/kg
Arroz	01.95 mg/kg	01.95 mg/kg
Arroz	01.96 mg/kg	01.96 mg/kg
Arroz	01.97 mg/kg	01.97 mg/kg
Arroz	01.98 mg/kg	01.98 mg/kg
Arroz	01.99 mg/kg	01.99 mg/kg
Arroz	02.00 mg/kg	02.00 mg/kg



PRODUCTOS/GRUPOS DE ENSAJO	ENSAJO	MÉTODOS/REFERENCIAS DE ENSAJO
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Arroz	01.37 mg/kg	01.37 mg/kg
Arroz	01.38 mg/kg	01.38 mg/kg
Arroz	01.39 mg/kg	01.39 mg/kg
Arroz	01.40 mg/kg	01.40 mg/kg
Arroz	01.41 mg/kg	01.41 mg/kg
Arroz	01.42 mg/kg	01.42 mg/kg
Arroz	01.43 mg/kg	01.43 mg/kg
Arroz	01.44 mg/kg	01.44 mg/kg
Arroz	01.45 mg/kg	01.45 mg/kg
Arroz	01.46 mg/kg	01.46 mg/kg
Arroz	01.47 mg/kg	01.47 mg/kg
Arroz	01.48 mg/kg	01.48 mg/kg
Arroz	01.49 mg/kg	01.49 mg/kg
Arroz	01.50 mg/kg	01.50 mg/kg
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Arroz	01.65 mg/kg	01.65 mg/kg
Arroz	01.66 mg/kg	01.66 mg/kg
Arroz	01.67 mg/kg	01.67 mg/kg
Arroz	01.68 mg/kg	01.68 mg/kg
Arroz	01.69 mg/kg	01.69 mg/kg
Arroz	01.70 mg/kg	01.70 mg/kg
Arroz	01.71 mg/kg	01.71 mg/kg
Arroz	01.72 mg/kg	01.72 mg/kg
Arroz	01.73 mg/kg	01.73 mg/kg
Arroz	01.74 mg/kg	01.74 mg/kg
Arroz	01.75 mg/kg	01.75 mg/kg
Arroz	01.76 mg/kg	01.76 mg/kg
Arroz	01.77 mg/kg	01.77 mg/kg
Arroz	01.78 mg/kg	01.78 mg/kg
Arroz	01.79 mg/kg	01.79 mg/kg
Arroz	01.80 mg/kg	01.80 mg/kg
Arroz	01.81 mg/kg	01.81 mg/kg
Arroz	01.82 mg/kg	01.82 mg/kg
Arroz	01.83 mg/kg	01.83 mg/kg
Arroz	01.84 mg/kg	01.84 mg/kg
Arroz	01.85 mg/kg	01.85 mg/kg
Arroz	01.86 mg/kg	01.86 mg/kg
Arroz	01.87 mg/kg	01.87 mg/kg
Arroz	01.88 mg/kg	01.88 mg/kg
Arroz	01.89 mg/kg	01.89 mg/kg
Arroz	01.90 mg/kg	01.90 mg/kg
Arroz	01.91 mg/kg	01.91 mg/kg
Arroz	01.92 mg/kg	01.92 mg/kg
Arroz	01.93 mg/kg	01.93 mg/kg
Arroz	01.94 mg/kg	01.94 mg/kg
Arroz	01.95 mg/kg	01.95 mg/kg
Arroz	01.96 mg/kg	01.96 mg/kg
Arroz	01.97 mg/kg	01.97 mg/kg
Arroz	01.98 mg/kg	01.98 mg/kg
Arroz	01.99 mg/kg	01.99 mg/kg
Arroz	02.00 mg/kg	02.00 mg/kg

<https://www.enac.es/documents/7020/8a0f5a13-a3b6-41a4-8919-ceb9c671aad0>

Accreditation of Spanish laboratories for the analysis of pesticide residues. Flexible scope (NT-19): Public List of Tests (LPE)

- Public document prepared, reviewed and controlled by the laboratory
- Validated or checked commodities and pesticides
- Limit of quantification pesticide/commodity
- It must be provided by the laboratory to customers who request it
- Systematic update based on the validations and checks made
- Testing procedure and analytical technique
- As many LPEs as accredited commodity groups

[documentos\LPE CNA.pdf](#)

Accreditation of Spanish laboratories for the analysis of pesticide residues. Flexible scope (NT-19): Analytical method validation

1. Initial full validation of the analytical method

- ▶ Representative commodities for each commodity group (commodities more frequently analyzed).
- ▶ Validation parameters:
 - ▶ Limit of quantification
 - ▶ Linearity
 - ▶ Precision and trueness at different levels which justify the accredited range (including limit of quantification but not only)
 - ▶ Specificity/selectivity
- ▶ ENAC considers as guidelines requirements from SANTE document (other reference documents with an equivalent acknowledgement are accepted)

Accreditation of Spanish laboratories for the analysis of pesticide residues. Flexible scope (NT-19): Analytical method validation

2. Extension of the scope of the method: new commodities

- ▶ Other matrices from the same commodity group included in LPE from a group of commodities with a full initial validation
 - ▶ Checking limit of quantification:
 - ▶ Recovery
 - ▶ List of pesticides included in LPE from that group of commodities

3. Extension of the scope of the method: new pesticides

- ▶ Need to be validated using the same procedure as the full initial validation
 - ▶ New pesticide not included in existing Public List of Tests (LPEs)
 - ▶ Pesticide included in a different LPE from the one corresponding to the requested commodity

Accreditation of Spanish laboratories for the analysis of pesticide residues. Flexible scope (NT-19): Quality control

1. Routine quality control activities

- ▶ Each batch of analyses:
 - ▶ Extraction control: recovery experiments
 - ▶ Testing detector response with representative pesticides
(all pesticides must be included throughout the year)
- ▶ Other routine control activities:
 - ▶ Blank control analyses (reagents, samples)
 - ▶ Linearity control
 - ▶ ...

Accreditation of Spanish laboratories for the analysis of pesticide residues. Flexible scope (NT-19): Quality control

2. Periodic quality control activities

- ▶ Blind samples, replicate samples and/or reference materials
(positive samples must be included: limit of quantification, maximum residue levels)
- ▶ Commodities included in LPEs from a LOQ checking (not fully validation) require special care
- ▶ Control frequency depends on the number of samples and on the variety of usual commodities

Accreditation of Spanish laboratories for the analysis of pesticide residues. Flexible scope (NT-19): Quality control

3. Participation in Proficiency Testing

- ▶ Official Control Laboratories: EUPTs
- ▶ **Other Proficiency Testing schemes: when EUPTs are not representative for all accredited commodity groups (<https://www.enac.es/documents/7020/8a0f5a13-a3b6-41a4-8919-ceb9c671aad0>)**
- ▶ Not only for usual pesticides and commodities.



Proficiency Tests must include different commodities included in the scope of accreditation

Quality control results can be used to complete analytical methods validation (On going validation)

Accreditation of Spanish laboratories for the analysis of pesticide residues. Flexible scope (NT-19): Analyses requests

- ▶ The laboratory must report to the client of its competence (LPEs) when an analysis requests is received.
- ▶ **The laboratory must contact the client if additional validation are required.**
- ▶ **Flexible scope implies the laboratory commitment to offer accredited analyses for any pesticide or commodity included in the technical accreditation annex, even if they are not included in the Public Lists of Tests (LPEs) when the request is received.**

The laboratory must communicate to the client:

- 1. Additional validation is required.**
- 2. If validation results do not fulfil the requirements, an accredited report will not be issued.**
- 3. The period of time needed to issue the analysis report will be longer than usual.**



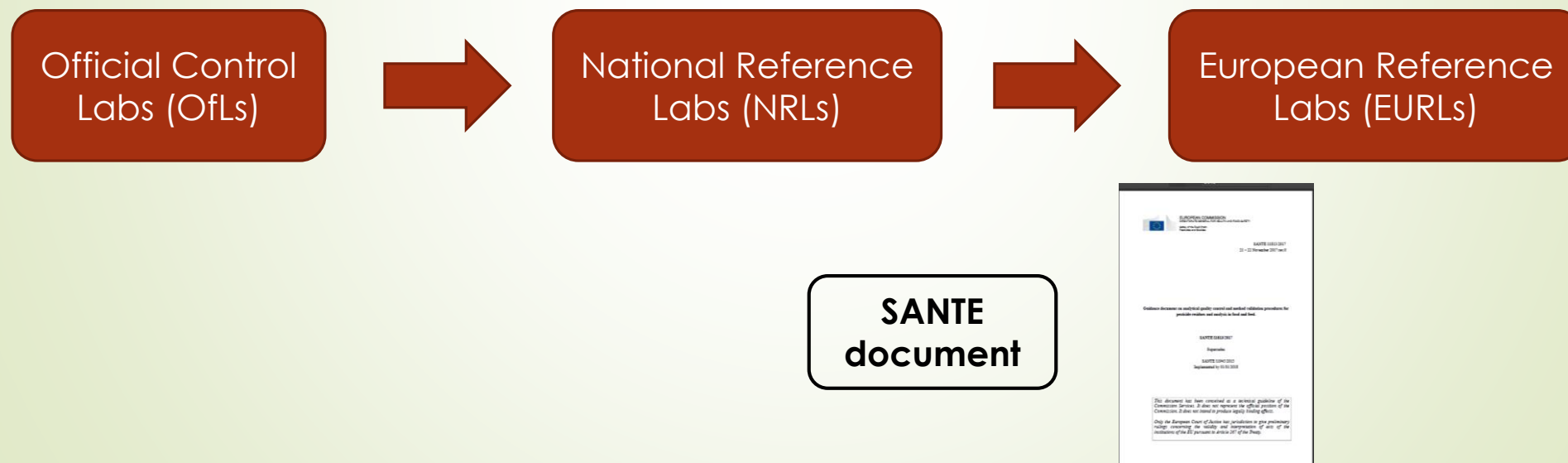
Accreditation of Spanish laboratories for the analysis of pesticide residues. Flexible scope (NT-19): Audits

- **Analyses in the presence of the auditor team: commodities and/or pesticides analyses included in the scope but not previously validated (not included in LPEs) could be required:**
 - **15 days in advance**
 - **During the audit:**
 - **Verification of validation results**
 - **Analysis**
- Verification of implementation and effectiveness in management control of LPEs.



Accreditation of Spanish laboratories for the analysis of pesticide residues. NT-55: Reference laboratories in agrifood area: policy on participation in the accreditation system

- ENAC will consider suitable decisions, practices and analytical procedures used by Official Control Laboratories (OfLs) which follow instructions, guidelines, recommendations or published documents from NRLs or EURLs





Accreditation of Spanish laboratories for the analysis of pesticide residues. Main difficulties encountered with the accreditation bodies: summary

► Fixed scope:

- Analyzing pesticides/commodities not included in the scope is not allowed
- Extension of the scope requires ENAC audit
- PTs different from EUPTs (when not representative)



► Flexible scope:

- Extensive experience of the lab required
- Management control of LPEs: hard-working, time consuming, personnel required
- PTs different from EUPTs (when not representative)
- Laboratory commitment to offer accredited analyses for any pesticide or commodity included in the technical accreditation annex (LPEs) when requested (additional validations): clients/audits

EUPT-FV19: 58% (18 of 31)

► Different criteria among auditors (e.g.: SOPs, QCs, extension of the scope, ...)



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