



# EXPERIENCE ON CIR 2021/808 IMPLEMENTATION

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# Content

- What has been done
- Current situation
- Next steps

L 180/84	EN	Official Journal of the European Union	21.5.2021
<b>COMMISSION IMPLEMENTING REGULATION (EU) 2021/808</b> of 22 March 2021 on the performance of analytical methods for residues of pharmacologically active substances used in food-producing animals and on the interpretation of results as well as on the methods to be used for sampling and repealing Decisions 2002/657/EC and 98/179/EC (Text with EEA relevance)			
THE EUROPEAN COMMISSION,			
Having regard to the Treaty on the Functioning of the European Union,			
Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 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, amending Regulations (EC) No 999/2001, (EC) No 198/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/423/EEC, 91/496/EEC, 96/23/EC, 98/9/EC and 97/53/EC and Council Decision 92/453/EEC (Official Controls Regulation) <sup>(1)</sup> , and in particular Article 34(6) thereof,			
Whereas:			
<p>(1) Regulation (EU) 2017/625 lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States to verify compliance with Union legislation, inter alia, in the area of food safety at all stages of production, processing and distribution. It provides for specific rules on official controls in relation to substances whose use may result in residues in food and feed and sets general requirements for the methods to be used for sampling, laboratory analyses and tests during official controls and other official activities.</p> <p>(2) Commission Decision 2002/657/EC <sup>(2)</sup> sets requirements for the performance of analytical methods and the interpretation of results of analyses of certain substances and residues thereof in live animals and animal products and Commission Decision 98/179/EC <sup>(3)</sup> lays down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products. Both Decisions were adopted on the basis of Council Directive 96/23/EC <sup>(4)</sup>, which was repealed by Regulation (EU) 2017/625. In view of new scientific developments, those rules should be updated and they should be integrated into the framework for official controls defined by Regulation (EU) 2017/625.</p> <p>(3) In accordance with Article 1(2) of Decision 2002/657/EC, that Decision is not to apply to substances for which more specific rules have been laid down in other Union legislation. Those substances are mycotoxins in foodstuffs, dioxins and dioxin-like polychlorinated biphenyls (PCBs) in foodstuffs and lead, cadmium, mercury and benzotrip yrene in foodstuffs. Mycotoxins in foodstuffs are to fulfil the requirements set by Commission Regulation (EC) No 401/2006 <sup>(5)</sup> laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs, Commission Regulation (EU) 2017/644 <sup>(6)</sup> laying down methods of sampling and</p>			
<p><sup>(1)</sup> OJ L 95, 7.4.2017, p. 1.</p> <p><sup>(2)</sup> Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (OJ L 221, 17.8.2002, p. 5).</p> <p><sup>(3)</sup> Commission Decision 98/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products (OJ L 45, 5.1.1998, p. 31).</p> <p><sup>(4)</sup> Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/338/EEC and 86/449/EEC and Decision 89/187/EEC and 91/664/EEC (OJ L 115, 23.1.1996, p. 10).</p> <p><sup>(5)</sup> Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 70, 8.3.2006, p. 12).</p> <p><sup>(6)</sup> Commission Regulation (EU) 2017/644 of 5 April 2017 laying down methods of sampling and analysis for the control of levels of dioxin, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 589/2014 (OJ L 92, 6.4.2017, p. 9).</p>			

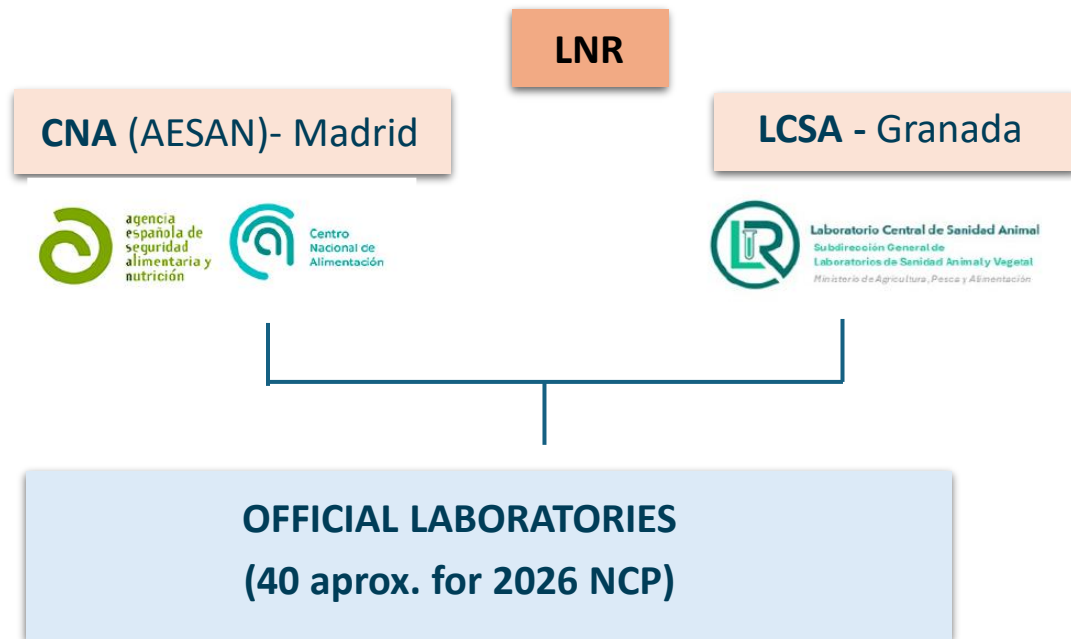
# For which compounds we are NRL

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- A1a. Stilbenes
- A1c. Steroids
- A1d. Resorcylic acid lactones, including zeranol
- A1e. Beta-agonists
  
- A2a. Cloramphenicol
- A2b. Nitrofurans
- A2d. Dapsone
  
- A3a. Dyes
- A3c. Antimicrobial substances
- A3e. Proteín and peptide hormones
  
- B1a. Antimicrobial substances
- B1d. Corticosteroids

Substances listed in Annex I  
CDR (EU) 2022/1644

# Laboratories network in Spain



Laboratories are free to choose their methods:

- Methods developed by:
  - EURL, NRL
  - Official labs themselves
  - Others



In all cases: **validated in each laboratory** to demonstrate that they comply the relevant performances characteristics and criteria fixed in CIR 2021/808 (and previously CD 2002/657)

# Transition CD 2002/657/CE to CIR 2021/808 - CNA

SCOPE validated accord. CD 2002/657 (FLEXIBLE SCOPE)

10/06/2021

21 accredited SOPs



Transition



SCOPE validated accord. CIR 2021/808

10/06/2026



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# Transition CD 2002/657/CE to CIR 2021/808 - CNA

SCOPE validated accord. CD 2002/657 (FLEXIBLE SCOPE)

10/06/2021

21 accredited SOPs!

1º Doubts (EURL Guidance Conf Method Validat. included some differences, comparing to CIR 2021/808). EURL workshops and EURL support.

2º Take decisions, write new validation protocols.

3º Planning (establish priorities)

4º Start validations

Important increase  
of workload

Transition

SCOPE validated accord. CIR 2021/808

10/06/2026



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# Transition CD 2002/657/CE to CIR 2021/808 - CNA

SCOPE validated accord. CD 2002/657 (FLEXIBLE SCOPE)

10/06/2021

Re-evaluation of 657 validation (the so-called “PAPER VALIDATION”) to check if new criteria are fulfilled and complete only what is necessary.

“Paper validation” + extension

Full validation CIR 2021/808

Message for people not working in laboratories:

There is a lot of work behind the validation of a method for VMR analysis.

Transition

SCOPE validated accord. CIR 2021/808

10/06/2026



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# NRLs – CA – AB relationship

Coordination and collaboration have increased since June 2021:

- NRLs meetings every 1-2 weeks (very close contact).
- NRLs + Competent Authorities meetings at least every 2 months
- Spanish Accreditation Body (ENAC): fluid communication
  - Issues in audits
  - NRL Guidances publication,
  - etc.



# NRL GUIDANCES



## NRL Guidance on “Paper validation”

Rev 1 -Dec 2022-



## NRL Guidance on Confirmation Method Validation

Rev 2 -Dec 2024-

- Elaborated by the two NRLs
- Purposes:
  - \* Help for the laboratories
  - \* Harmonization
  - \* Reference documents in audits



# Purely qualitative confirmation methods & CIR 2021/808: are they possible?

Table 5

Classification of analytical methods by the performance characteristics that have to be determined

Method	Confirmation		Screening		
	Qualitative	Quantitative	Qualitative	Semi-quantitative	Quantitative
Substances	A	A, B	A, B	A, B	A, B
Identification in accordance with 1.2	x	x			
CC $\alpha$	x	x			
CC $\beta$	-		x	x	x
Trueness		x			x
Precision		x		(x)	x
Relative matrix effect/absolute recovery *		x			x
Selectivity/Specificity		x	x	x	x
Stability *		x	x	x	x
Ruggedness		x	x	x	x

## NRL Guidance Document on Validation on Confirmation Method Validation:

*“All confirmatory methods have to be validated as quantitative. Only for A substances, in those cases which does not fulfil all requirements for such methods laid down in CIR (EU) 2021/808 could be validated as qualitative”.*

(Information received from EURL Workshops, EURL Guidance...)



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Selectivity/Specificity		x	x	x	x
Stability *		x	x	x	x
Ruggedness		x	x	x	x

Some official laboratories disagree and demand these kinds of methods. Reasons:

- They are included in CIR 2021/808 (table 5).
- For forbidden substances quantitation is not so relevant.
- Qualitative validation is shorter and few performance characteristics have to be determined.



(e-mail to EURLs to ask for advice)

# Survey DC 2002/657 vs CIR 2021/808 in Spain

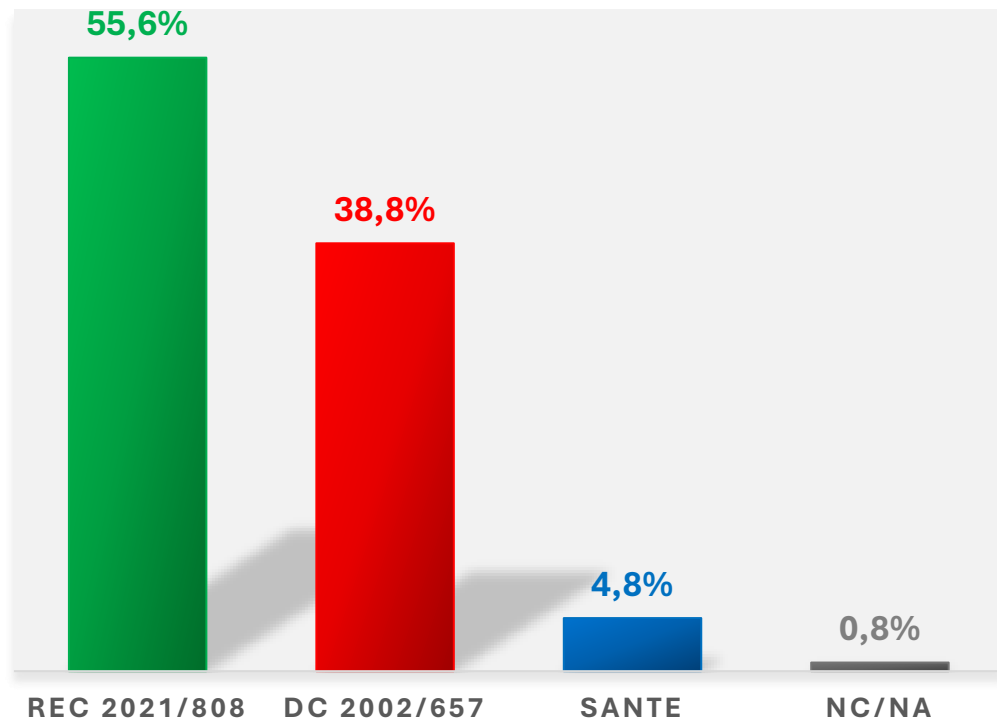
- 2 NRLs collaboration
- Online survey:
  - Validation according to:
    - DC 2002/657
    - REC 2021/808
    - SANTE Document –only possible for A3b-B1b (dual substances)-
  - If 657 was selected: “When is it planned to be validated acc. to 808?”

AD	AE
Validación según:	Previsión de acreditación según REC 2021/808 Observaciones
REC 2021/808	
REC 2021/808	
REC 2021/808	
REC 2021/808	
DC_2002_657	junio-25
DC_2002_657	junio-25
DC_2002_657	junio-25
DC_2002_657	junio-25
DC_2002_657	junio-25
DC_2002_657	junio-25
GUÍA SANTE	
GUÍA SANTE	
GUÍA SANTE	

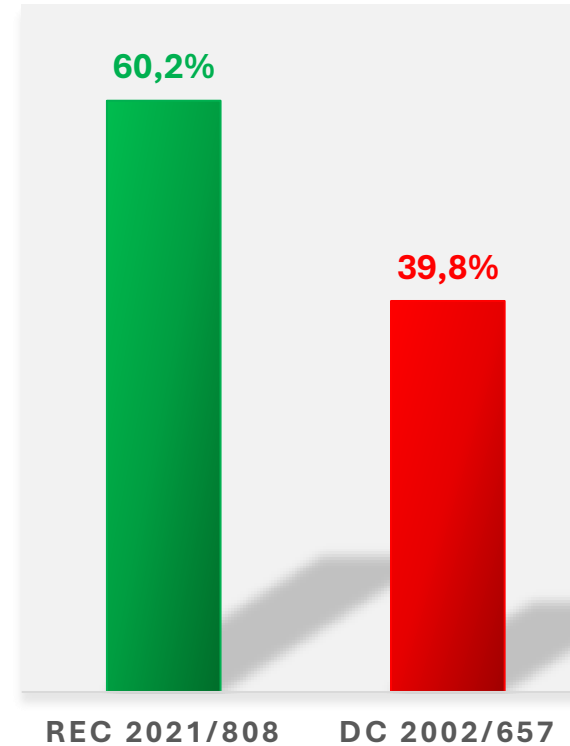


# Current situation - Survey results 10<sup>th</sup> Dec 2025 -

## Global situation in Spain

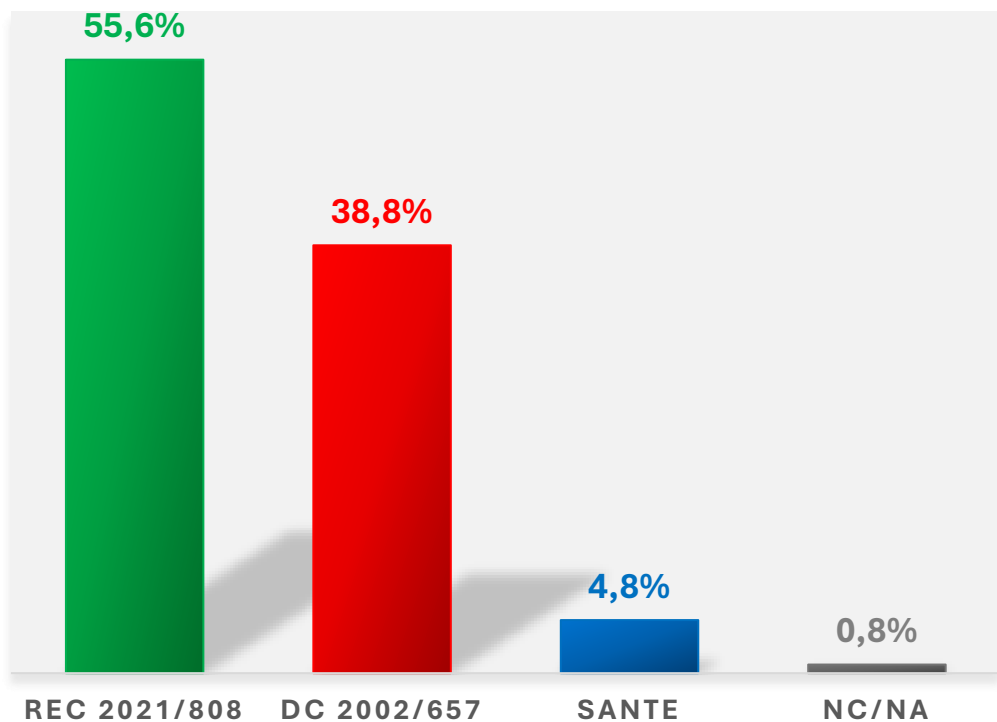


## LNR-CNA (VDR Department)

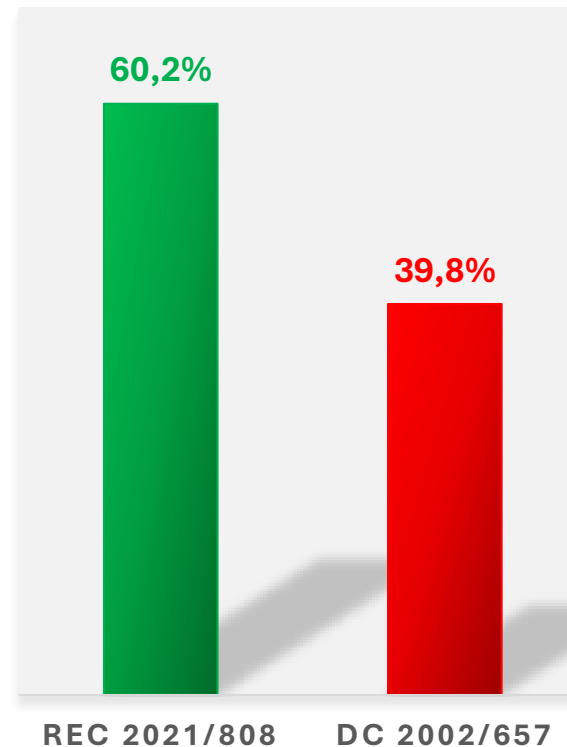


# Current situation - Survey results 10<sup>th</sup> Dec 2025 -

## Global situation in Spain



## LNR-CNA (VDR Department)



### Remarks:

- All the data included are also accredited.
- There is a lot of work and effort behind these figures.



## Current situation – Comments

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- The implementation of the new Regulation has involved more changes than was announced.
- Part of the transitional period was used to clarify what to do.
- Although a lot of work has been done until now...

**An extension of the transitional period is needed**

## Next steps

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- As NRL:

Try to implement Reference Methods in Spain (methods validated in NRL and verified in official laboratories -METHOD TRANSFER-)

↳ **Hybrid system**, in which can live together the current system and Reference Methods.

- Carry on with CIR 2021/808 validations to get the goal

# Challenges in the analysis of VDR

CIR 2021/808: Changes in validation



Changes in NCP (Regulations 2022\_1644 and 2022/1646)

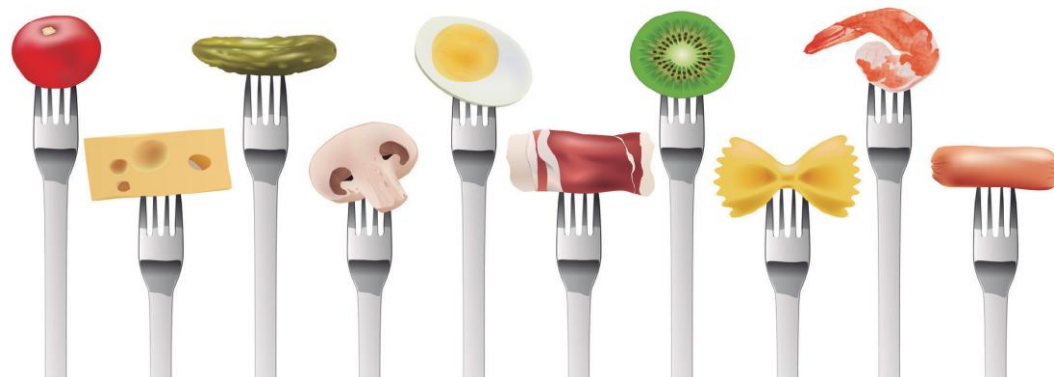
The list of compounds to control is continuously growing

Level of Interests (RPA, MMPR) going down

Accreditation  
ISO 17025:2017



# Thank you for your attention



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