


Commission Implementing Regulation (EU) 2021/808

- ✓ Testimony from an EU member state NRL, Czech Republic.



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NRL ÚSKVBL Brno, Czech Republic

 National Reference Laboratory for residues of banned substances.

 30 confirmatory methods for various analytes.

 Majority of methods validated for multiple matrices.

The Appendix is an integral part of
Certificate of Accreditation No: 201/2025 of 29/04/2025

Accredited entity according to ČSN EN ISO/IEC 17025:2018:

Ústav pro státní kontrolu veterinárních biopreparátů a léčiv
CAB number 1219, Testing Laboratory
Hudcova 232/56a, Medlánky, 621 00 Brno

Ordinal number ¹	Test procedure / method name	Test procedure / method identification ²	Tested subject	Degrees of freedom ³
17	Determination of β -agonists by LC-MS/MS method	SOP 82 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, milk, feedstuffs, liver, hair, lungs	A, B
18	Determination of stanozolol and 16- β -hydroxystanozolol by LC-MS/MS method	SOP 77 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, muscle	A
19	Determination of nitroimidazoles by LC-MS/MS method	SOP 81 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Blood plasma, eggs, muscle, honey, feathers, milk, feedstuffs, feed water, egg shells	A, B
20	Determination of dapsone by LC-MS/MS method	SOP 84 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Muscle, milk, honey	A
21	Determination of nitrofurans by LC-MS/MS method	SOP 72 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Muscle, milk, honey, eggs	A, B
22	Determination of thyreostatics by LC-MS/MS method	SOP 73 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, muscle, milk	A, B
23	Determination of corticosteroids by LC-MS/MS method	SOP 74 (Commission Implementing Regulation (EU) 2021/808, cl. 3)	Urine, animal tissue	A, B

NRL ÚSKVBL Brno, Czech Republic

✓ Accreditation since 1999.

✓ Current instrumentation:

✓ 4 x LC-MS/MS

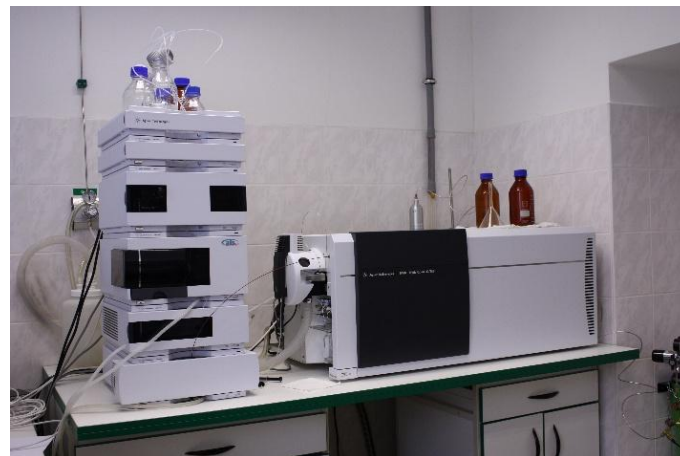
✓ Triple quadrupoles

✓ 5 x GC-MS(/MS)

✓ Personnel:

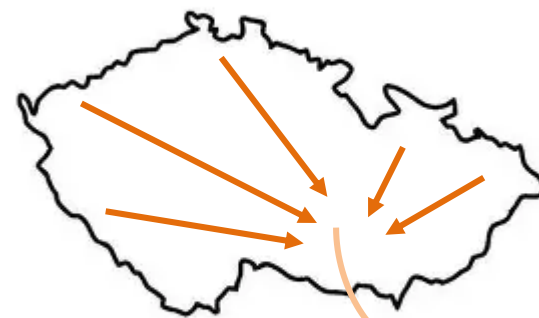
✓ 7 analysts

✓ 4 technicians



NRL ÚSKVBL Brno, Czech Republic

- ✔ As for A1, A2 and selected A3 substances our NRL tests all routine samples.
- ✔ No further field laboratories for our methods in the country.
- ✔ Closed contact with analytical reality.
- ✔ Samples analysed regularly.



Commission Decision 2002/657/EC

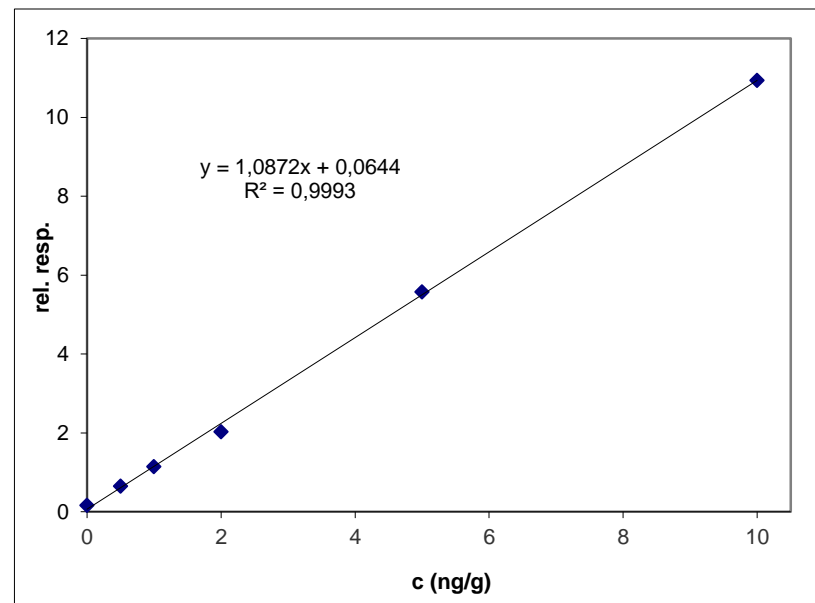
- ✔ From 2002 we validated all methods according to Commission Decision and EURL implementing guidelines.
- ✔ Precision, trueness, linearity, ruggedness
- ✔ Stability in solution, extract, matrix
- ✔ Decision limit CC_{α} , detection capability CC_{β}
 - ✔ Determination by matrix calibration curves procedure (ref. ISO 11 843) from within-laboratory reproducibility.
 - ✔ Verification of calculated concentration values by fortification of matrix.

Ongoing method performance verification

- ✔ **Isotopically labeled internal standards are included in all methods.**
- ✔ **Matrix-fortified calibration curves were prepared with each set of analyte/matrix samples.**

Example: Methyltestosterone in fish muscle by GC-MS/MS, 2012

Significant number of robust data were collected over years for analytes, matrices, species, instruments.



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- ✔ Analogous requirements for method validation as in previous legislation.
 - ✔ Banned substances – minor changes.
 - ✔ Permitted substances with MRL (maximum residue limits) – new requirement for 0.1 MRL concentration level – need of additional sample measurement at low levels, when reasonably achievable.
- ✔ Transition period till June 2026 (now postponed till 1.1.2028) – time for additional measurements within ongoing method performance verification.

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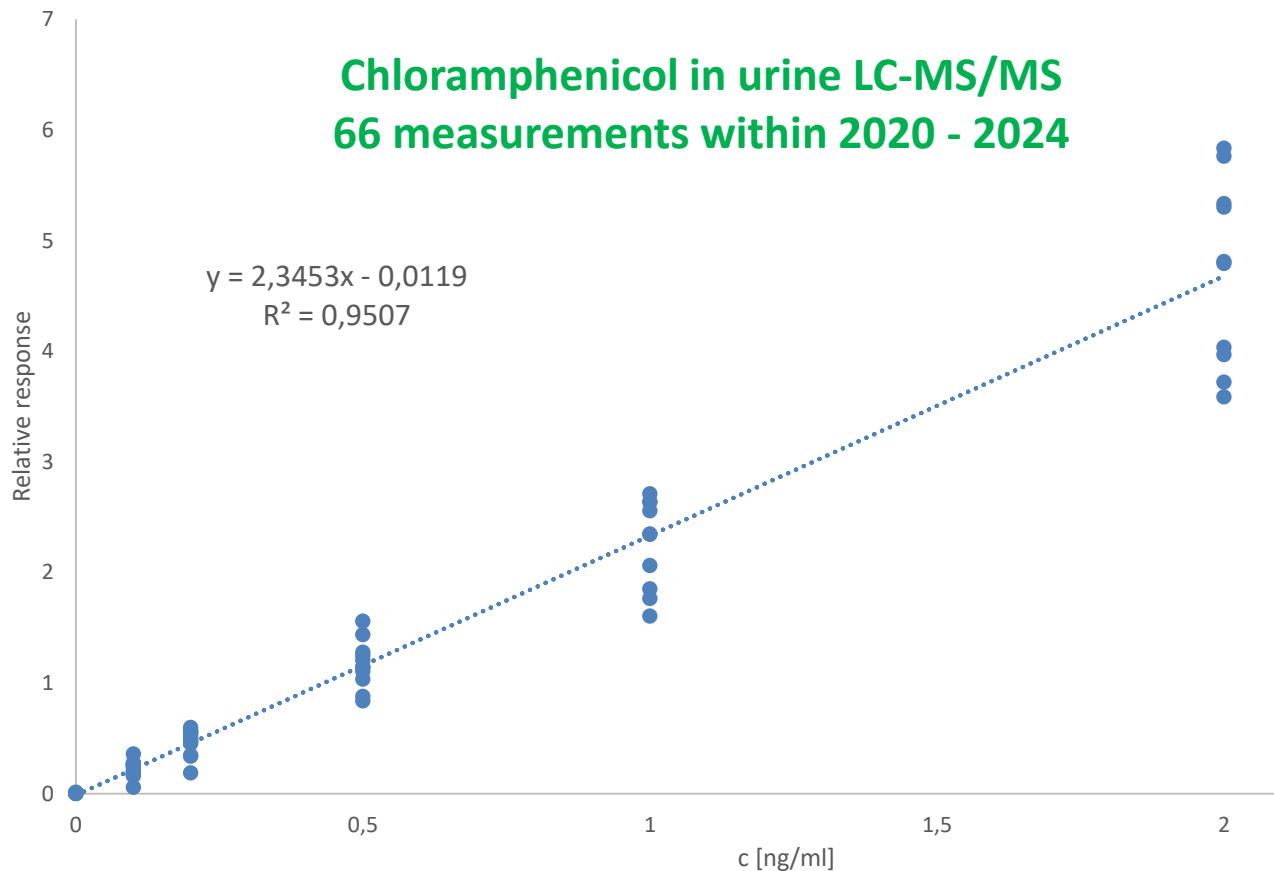
- ✔ **Paper validation** for majority of existing methods - updated validation files were created from gathered data throughout previous years.
- ✔ EURL guidelines prefer long-term collected data as more robust for method suitability testing.
- ✔ Updated validation parameters were compared to previous.
- ✔ SOPs were properly adjusted.

Paper validation

Within-laboratory reproducibility

Chloramphenicol in urine LC-MS/MS
66 measurements within 2020 - 2024

$$y = 2,3453x - 0,0119$$
$$R^2 = 0,9507$$



Initial
CC α = 0.07 $\mu\text{g/L}$
(2011)

Updated
CC α = 0.06 $\mu\text{g/L}$
(2024)

Current status

- ✔ **All previously used methods already re-validated according to CIR (EU) 2021/808.**
- ✔ **Newly implemented methods (SARMs, antivirals, additional analytes, matrices) initially validated, performance verification data are continuously collected.**
- ✔ **National accreditation body accepted all changes (flexible scope of accreditation).**

Conclusions

- ④ Updated validation parameters were communicated to national competent authority and implemented into national control plans.
- ④ Validation parameters given by CIR (EU) 2021/808 are definitely more explicit and clear than in CD 2002/657/EC.
- ④ Better comparison of official methods within the network (esp. for limits $CC\alpha$).

Thank you for your attention.

PF 2026

Veselé Vánoce a šťastný nový rok

Merry Christmas and happy new year

*Frohe Weihnachten
und ein glückliches neues Jahr*

Joyeux Noël et bonne année



Martina Rejtharová

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