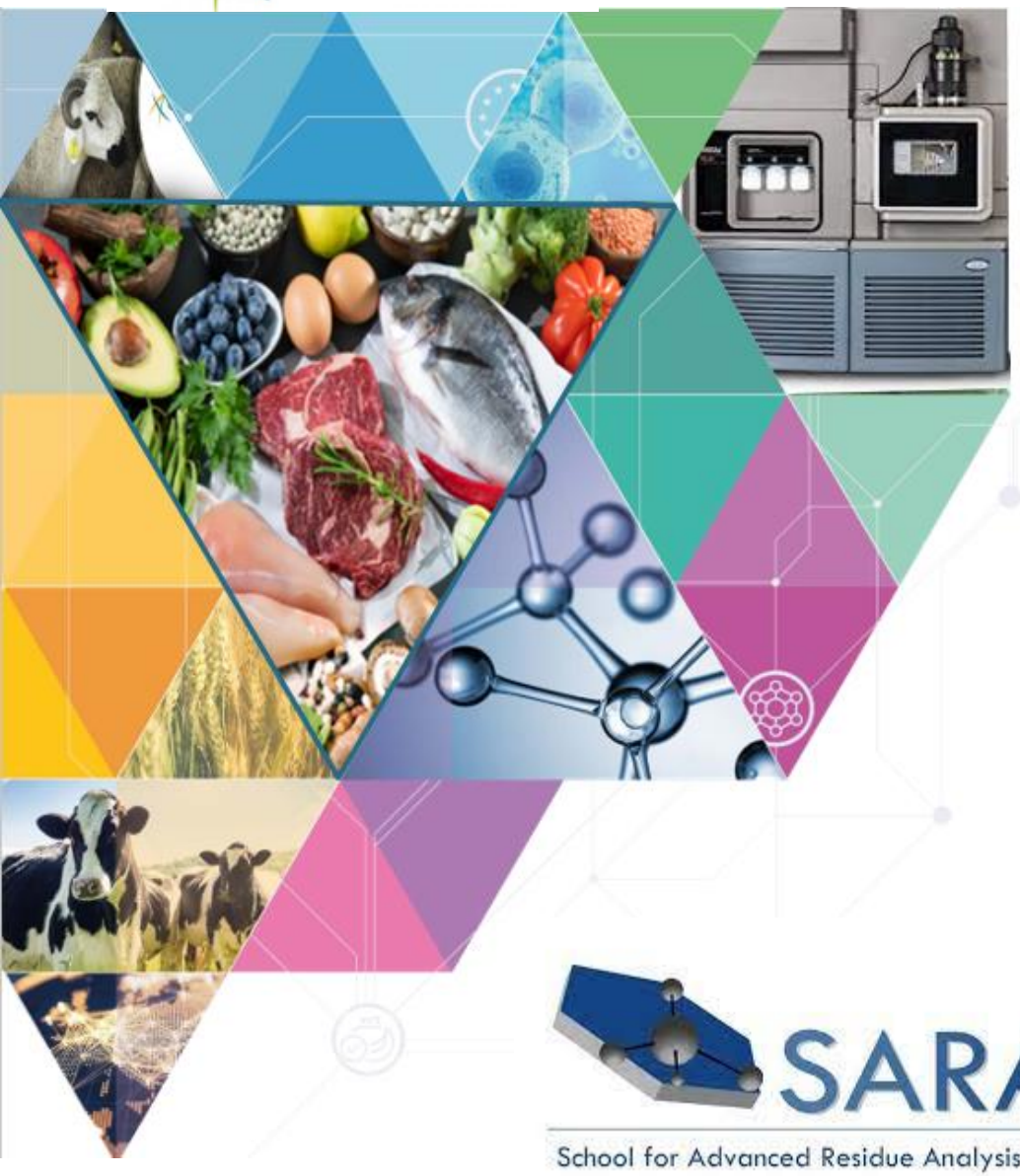


Implementation of regulation 2021/808 issues and challenges -Moroccan experience-

Presented by: Sami DARKAOUI, DVM PhD

December 20, 2023

Overview

- ONSSA Presentation
- Implementation of the Regulation (EU) 2021/808
- The transition to the new regulation
- Validation and revalidation plans according to regulation 2021/808
- Faced challenges
- Experienced Solutions

ONSSA PRESENTATION

ONSSA is the Moroccan food safety authority, under supervision of Agriculture Ministry

Health protection of animals and plants against diseases

Protection of public health by limiting the risks of food-borne diseases

Ensure the safety of food products that are sold on markets including fisheries and aquaculture products

Improvement of sanitary and phytosanitary support

Ensure the safety, quality and compliance of imported and exported food products

Establish a legal environment encouraging investment into the agro-industrial sector

Implementation of the regulation

from Decision (EC) 657/2002 to Regulation (EU) 2021/808

The transition to the new regulations

The way we began

- Comparison between decision 2002/657 and regulation 2021/808

➡ What does not change with the new regulation

➡ What changes will impact the future validations

- Impact analysis of the new regulation on the development process, validation, analysis and results

The transition to the new regulations

The way we worked

- Improve analysts' knowledge of the new regulatory requirements
- Update of validation spreadsheet in accordance with regulation 2021/808
- Verification of equipment performance against the RPA and MMPR, taken into account the technical progress
- Evaluation of matrix effect on results

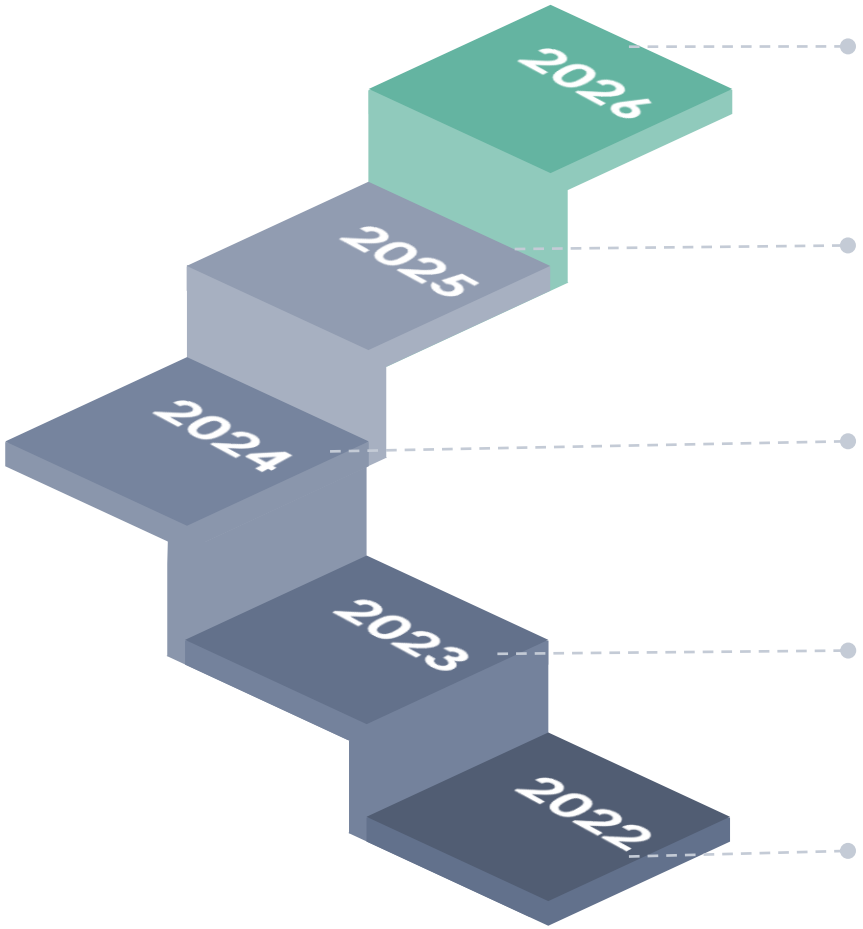
Transition to the new regulations

The way we worked

- Updating of analysis methods and validation reports
- Internal verification of the reliability of validation spreadsheet results
- Comparison of the results of our spreadsheets with LABERCA (reference laboratory)
- Evolution of identification and confirmation spreadsheets according to regulation 2021/808 and comparison with LABERCA spreadsheets.

Validation and revalidation schedule according to regulation 2021/808

up to 2026



Deadline for method validation according to the regulation 2021/808

Multi-class multi-residus method in muscle by LC-MS/MS
Antibiotic confirmation methods by LC-MS/MS

Hormones by LC-MS/MS and GC-MS/MS
NSAIDs, Florfenicol and colistine by LC-MS/MS
Research of veterinary drugs in feed by LC-MS/MS

Antibiotics (Sreening method), anthelmintics, avermectins, anticoccidials and nitroimidazole by LC-MS/MS (in progress)

Chloramphenicol, nitrofurans and triphenylmethane dyes and B-agonists by LC-MS/MS (done)

Challenges

We have faced

Establish the evaluation levels and achieve the lowest possible concentrations for unauthorized compounds

Verification of validation parameters (trueness and reliability) at 3 concentration levels

Stability and robustness studies

Implementation of a new "matrix effect" parameter to be examined

Revalidation of all methods according to the new regulations

Challenges

- Availability of validation guidance of reference laboratories : Version 0 published on 01/01/2023 (20 months after publication of the regulation)
- The choice of the CCα and CCβ calculation method : 3 methods described in the regulation
- The number of analyses for full validation has increased
- Study of the matrix effect of nitrofurans required the use of pre-derived standards (availability, price)
- The new classification of molecules in regulation 1644/2022 obliged us to revalidate methods and validate new methods (compounds identification, method availability, analytical stantards availability)

Experienced Solutions

Participate in workshops of EURL Lab / SARAF Webinar

Organization of training courses regarding the new regulation for laboratory staff

Invest in high-performance instruments (increased sensitivity)

Subcontracting of new analyses requested by regulation 2022/1644 pending their implementation/validation

Networking with experts from EU Reference laboratories (ANSES, BVL, LABERCA, WFSR) and international networks (AFOSAN/AIEA)

Invest in analytical standards especially pre-derived Nitrofuran standards


شكرا
THANK YOU
DANKE
MERCI
GRAZIE
OBRIGADO
TACK
ARIGATÔ
GRACIAS
NGIYABONGA
DHANYAVĀD
KÖSZÖNÖM
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