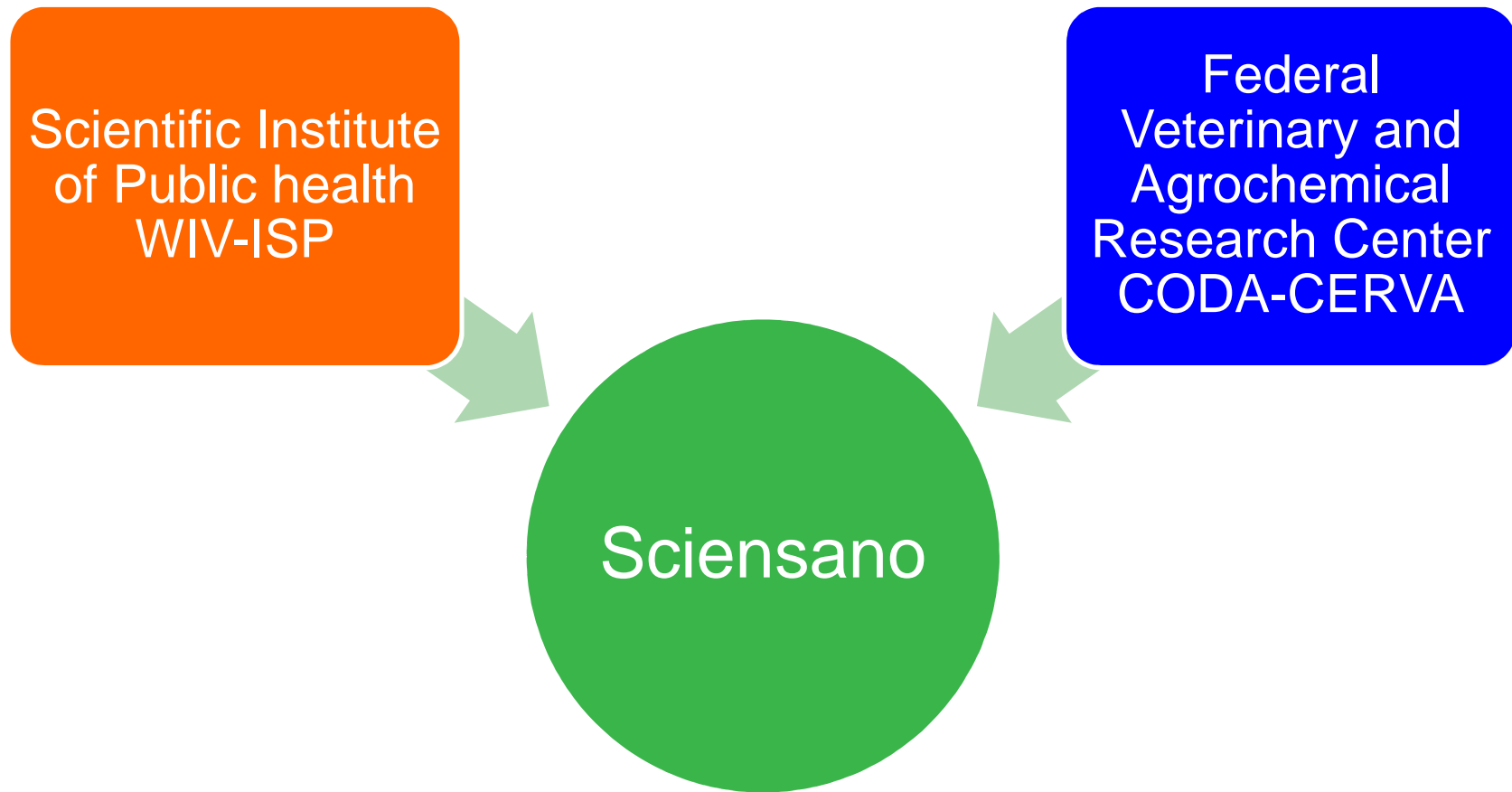




**MAIN DIFFICULTIES ENCOUNTERED
WITH THE ACCREDITATION BODIES
THE BELGIAN CASE**

Laure Joly



Sciensano was created 1st of April 2018

700 staff members are divided in 6 fields of actions



Animal health



Effectiveness and safety of vaccines, medicines and health products - Quality of medical laboratories



Food consumption and food safety



Health and disease monitoring



Health and environment



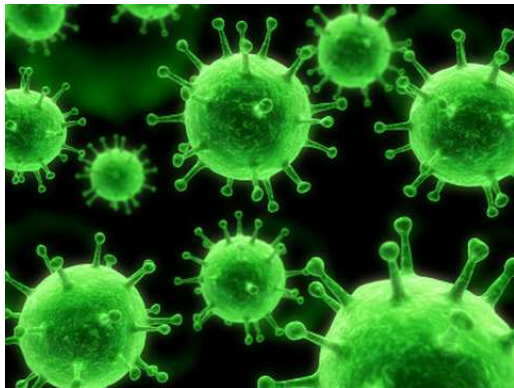
Quality of healthcare

Contaminants & additives
service

Toxins Unit

Contact material
& additives Unit

Pesticides &
contaminants Unit



Head of service : Els Van Hoeck, staff 30 persons

BELAC : Belgian accreditation body

Since **2006**, BELAC is the only Belgian Accreditation Body
Depends on the **Federal Public service of Economy**

BELAC **operates according to the international requirements**
with regard to the management of the accreditation bodies

Accreditations issued under the BELAC roof are **recognized by
the Belgian State**

BELAC is a signatory of all existing **multilateral
agreements** with equivalent accreditation bodies



BELAC activities

1. CALIBRATION LABORATORIES (EN ISO/IEC 17025)
2. **TESTING LABORATORIES (EN ISO/IEC 17025)**
3. MEDICAL LABORATORIES (EN ISO 15189)
4. PROFICIENCY TESTING ORGANIZERS (EN ISO/IEC 17043)
5. REFERENCE MATERIALS PRODUCERS (ISO Guide 34 –ISO 17034)
6. INSPECTION BODIES (EN ISO/IEC 17020)
7. MANAGEMENT SYSTEMS CERTIFICATION BODIES (EN ISO/IEC 17021-1)
8. ENVIRONMENTAL VERIFIERS (Regulation (CE) N° 1221/2009 + EN ISO/IEC17021-1)
9. CERTIFICATION BODIES FOR PRODUCTS (EN ISO/IEC 17065)
10. CERTIFICATION BODIES FOR PERSONS (EN ISO/IEC 17024)
11. BODIES ACTIVE AS NOTIFIED BODIES
12. VALIDATION AND VERIFICATION BODIES (EN ISO 14065)

SOME BELGIAN “SPECIFICITIES”

- Flexible scope
- Proficiency test management
- Sleeping activity

Which kind of flexible scope you can ask?

| Matrix | parameter | Method |
|---------------------------------------|---|-------------------------|
| Sub-matrix : pome fruit | Specific : Chlormequat, bromure | Specific : GC-ECD |
| Main matrix : high water content | Main parameter : organochlorinated pesticides | Main method : LC-MS/MS |
| Group of matrix : vegetable matrix | Group of parameter : pesticides | Group of method : LC-MS |

How will you manage with your scope ?

| Parameters | | |
|--------------------------------|--|---|
| Primary validation | For each group of matrix | linearity, matrix effect, LOQ, specificity, precision (RSD_r and RSD_{wR}), robustness, trueness: LOQ and higher level |
| Secondary validation | For each sub-group of matrix | 2 recovery tests Specificity (blanco matrix) |

→ **Criteria according to SANTE document**

Belgian flexible scope evolution

1st version = 2004 based on veterinary drugs (not really flexible)

2nd version = actual (from 2009) based on SANCO document of 2007

3rd version = on writing, proposition of private lab PRIMORIS

- involvement of BELAC, food agency, NRL, private lab

What is it under discussion ?

- Matrix on the BELAC document :
 - classification is the same than in SANCO 2007 (old version)
 - **follow SANTE document** (proposition)
 - introduction of **feed** in BELAC document (prop)
 - **non food products** (bees, soils): flexible or fix scope?(prop)
- Get a flexible scope :
 - stay to the “appreciation of auditor” (old one)
 - Or link to a % of already accredited pesticides (proposition)
- Secondary validation :
 - 2 samples (old version)
 - or 3 samples (proposition)

Proficiency test management

1 / Proficiency testing

2/ **Interlaboratory comparisons** used for different purposes (e.g. **method validation or characterization of reference materials**). (interpretation with cautions)

3/ In specific sectors where no proficiency testing is available, the laboratory should use alternative resources to prove its technical competence. These include

- o The regular use of **(certified) reference materials**;
- o Comparison of results obtained **by independent techniques**;
- o Comparison of the results of **2 or more laboratories** on their own initiative.

4/ **blind sample** (spiked by a person not involved in the analysis) if no other possibility exists.

Sleeping activity



BELAC allows for the maintenance of dormant activities in the accreditation scope, provided that the following conditions are met:

- having a **documented procedure** for the administrative management of the "dormant" activities
- keeping available **human and material resources** required for the performance of the activities and for the follow-up of standards
- **establishing measures to be taken in case the activities are resumed**, to ensure that the performance remains under control
- **informing BELAC** before each assessment about the activities that have become dormant since the last assessment

WHAT IS THE PROFILE OF A BELGIAN AUDITOR?



Auditors have to speak languages of audited lab



3 official languages :

- French
- Dutch
- German

Translation of all the BELAC documents

Auditors come from Belgium but also from neighbouring countries

The Netherlands



Training



Requirements are different from 1 country to another

Auditors have to know regulations

International regulations :

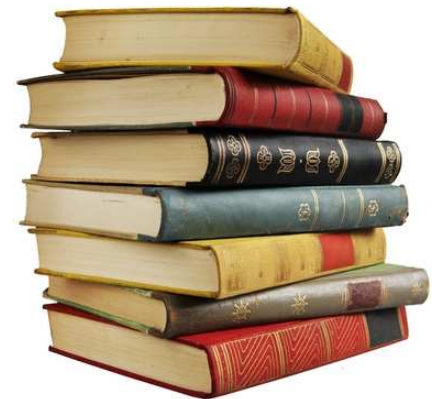
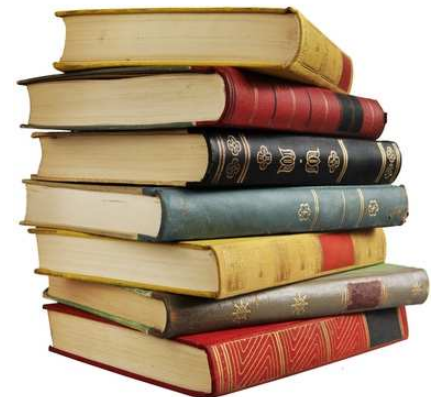
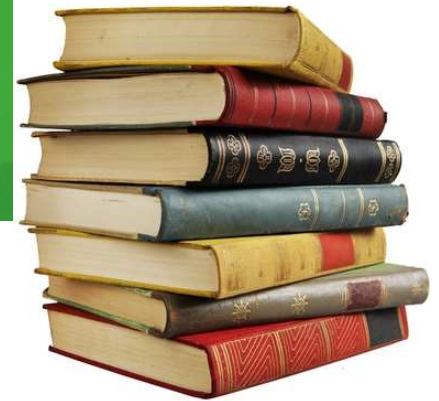
- General : ISO 17025
- Regulation : 396/2005 and amendment
- Recommendation :
- Guideline : SANTE/11813/2017

National regulation

- Some specific criteria for pesticide in water

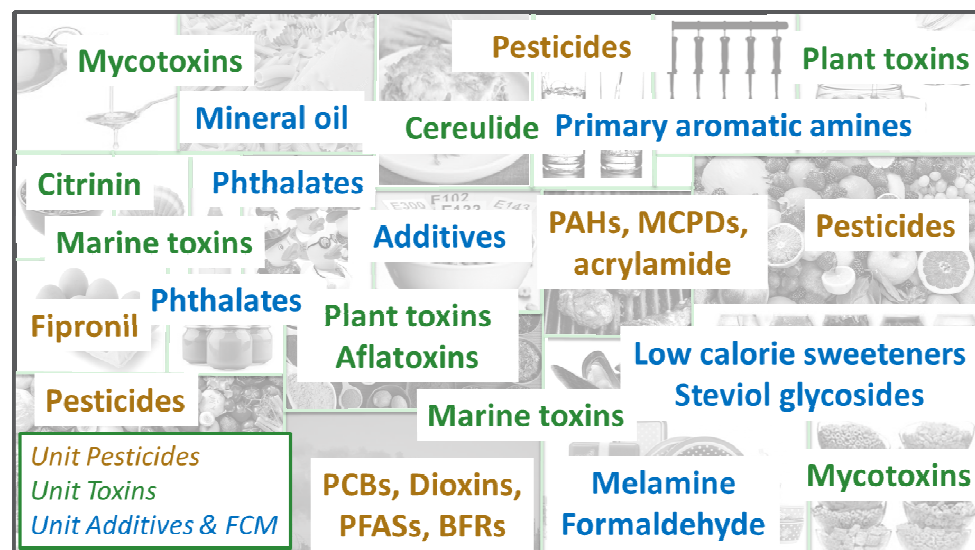
Specific BELAC documents :

- Flexible scope for pesticides, sleeping method ...



Belac auditors in our service

1. Have to speak Dutch and French (federal)
2. May come from neighbouring countries but need to know specific Belgian regulations
3. Have to manage with a very large scope



**LACK OF HARMONISATION IN EU
CONCERNING THE “VALIDATION
OF AN IMPROVED METHOD”**

When do you need to revalidate your method ?

And which kind of validation : mini or full ? On all matrixes?

- When you add a new compound in your multi ?
- When you change the gradient of your instrument ?
- When you change the buffer of your extraction procedure ?
- When you change your instrument (buy new one for example) ?
- When you reach lower LOQs to be in agreement with the 2 years old LOQ/MRL definitions on sum ?

**THANK YOU FOR
YOUR ATTENTION**