

STANDARDIZATION

A FRAMEWORK
OF PROGRESS
FOR ALL

EVOLUTION AND IMPLEMENTATION
OF ELABS - NF U 47-700 STANDARD
(ELABS "ANIMAL HEALTH") AND ITS
OPERATIONAL IMPLEMENTATION IN
FRANCE AND FUTURE IN EUROPE)

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Viviane MOQUAY – CGAER - Min. Agri., FR
General Council for Food, Agriculture and Rural Areas



Daniel LAFON
DRAAF Occitanie - Min. Agri., FR
Occitania Regional Directorate of Food, Agriculture
and Forestry

Bruno GARIN-BASTUJI – ANSES, FR
French Agency for Food, Environmental and Occupational Health & Safety



Hélène ROUCH- PHYLUM, FR



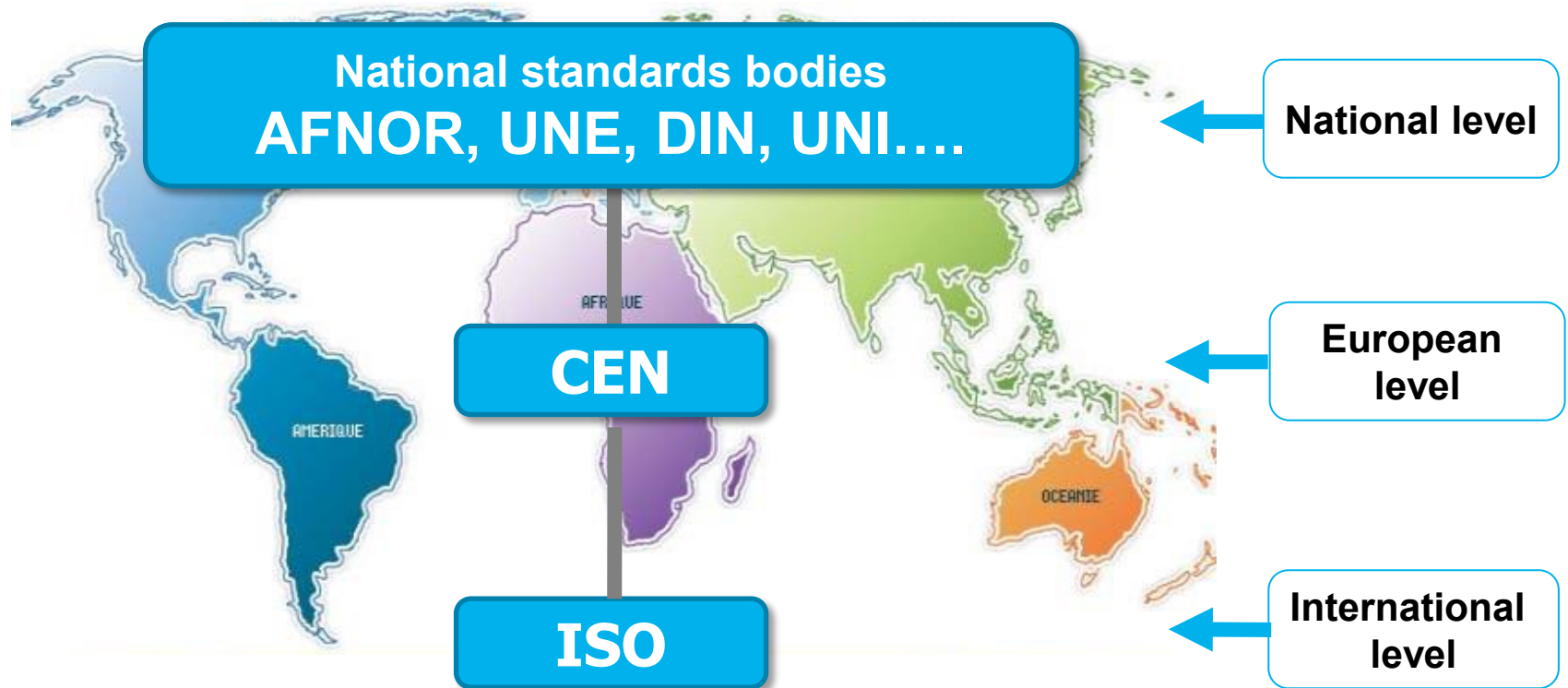
Outline



- 1. Focus on the E-Labs standard in animal health at national level**
- 2. Focus on the new CEN technical committee on animal health**

The standardization system

STANDARDIZATION IN FRANCE, EUROPE AND IN THE WORLD





**1- FOCUS ON THE E-LABS STANDARD
IN ANIMAL HEALTH AT NATIONAL
LEVEL**

The E-Labs French standard in animal health

NF U47-700:2019 - Animal health analysis methods - Dematerialised data exchange system in laboratory analyses - ELabs Animal Health

- **Background:**

- ✓ **2010 : Publication of Electronic Laboratory Observation Reporting (eLabs) in the UN/CEFACT Commission on Agriculture**
 - Enables the electronic exchange of data between testing laboratories and prescribers in the agricultural field.
- ✓ **2017 : Creation of a working group within AFNOR composed of representatives of the various stakeholders (prescribers, laboratories)**
 - Works on the adaptation of the UN/CEFACT document to the specific challenges of animal health analysis.
- ✓ **2019 : Publication of the standard NF U47-700 in the French national committee on animal health**
 - France has enacted a new national standard dedicated to animal health, based on UN/CEFACT Elabs format.

The E-Labs French standard in animal health

NF U47-700:2019 - Animal health analysis methods - Dematerialised data exchange system in laboratory analyses - ELabs Animal Health

- **Objectives of the French standard:**

- ✓ To propose a common language for the implementation of an electronic data exchange system in the field of laboratory analyses in animal health.
- ✓ To facilitate and secure the exchange of information in this field where a very large number of analyses may be prescribed and carried out in a short time.

This topic is strategic in order to ensure the management of information resulting from analysis, testing and diagnosis.

The E-Labs French standard in animal health

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- **Use of the standard:**

- ✓ To be able to process data from a large number of analyses in a short period of time, especially in the context of a health crisis,
- ✓ To have access to a complete documentation of the eLabs standard by translating and defining precisely the structure of the messages exchanged in this domain.
- ✓ To guarantee interoperability within the animal health community. Beyond animal health, this standard can serve as a basis for building an exchange system between prescribers and analysis laboratories.

The recent Covid-19 health crisis is an example of where the use of a paperless data exchange system can be used to improve the collection of data from a large number of laboratories.

The E-Labs French standard in animal health

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- **Not in the scope of the standard:**
 - ✓ Technical recommendation to implement the exchanges such as transfer protocol, security (authentication, encryption).
 - ✓ The system governance including the maintenance of the standard, the master data management concerning all stakeholders in the exchanges (prescribers and analysis laboratories).
 - ✓ Everyone has to look at these topics. In France, in the field of animal health, these subjects concern several organizations. A common approach must be found.

The E-Labs French standard in animal health

Implementation of the E-Labs French standard by Directorate-General for Food at the French Ministry of Agriculture

- ✓ **2010: The Directorate-General for food at the French ministry of agriculture decides to renew its information system**
 - To be able to manage all process (inspection, monitoring)
 - ❖ Involving samples and analyses (outsourced process)
 - ❖ In the fields of animal health, plant health and food chain control
- ✓ In this context, the E-Labs standard was chosen to manage exchanges with analysis laboratories.
- ✓ This choice guided our analysis of the process (for example, the data modelling is compliant with E-Labs standard).
- ✓ This choice will allow the implementation of dematerialized exchanges with analysis laboratories, replacing our current EDI system ... still operational but old (soon 20 years old !)

The E-Labs French standard in animal health

Implementation of the E-Labs French standard by the French Biodiversity Office (OFB)

- ✓ **Epifaune: wildlife animal health database**
 - To collect data on wildlife animals and on laboratory tests
 - To analyze data: diseases, locations ...

- ✓ The need: to organize dematerialized exchanges with analysis laboratories

- ✓ Why eLabs?
 - ✓ International standardized messages
 - ✓ Used by other organizations in France like the French Ministry of Agriculture
 - ✓ Sustainability of the standard

The E-Labs French standard in animal health

Implementation of the E-Labs French standard by the French Biodiversity Office (OFB)

✓ Interoperability also needs data dictionary

- To share the same definition
 - Diseases
 - Laboratory tests
 - Test results
- To use the same codes to exchange information on animal health

✓ The key points

- The methodology to construct the codes
- The procedures to administrate the codes
- The conditions to store and to publish the data,
- The organization of the governance of the repository



**2-FOCUS ON THE NEW CEN
TECHNICAL COMMITTEE**

CEN/TC 469 ON ANIMAL HEALTH

1. What about Animal health ?

➤ The existing technical and legal framework:



- **World Organisation for Animal Health (OIE):**
 - The "Terrestrial Manual" and the "Aquatic Manual"



- **European Commission (EU):**
 - European Union Reference Laboratories (EURLs)
 - Animal Health Law (April 2021)
 - Official Control Regulation (2017/625)



- **United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT):**
 - "Electronic Laboratory Observation Report" or "eLabs": data exchange standard for laboratory analyses in agriculture



Proposal: Creation of a European Technical Committee (CEN/TC) in animal health with the following main objectives:

- ➔ To harmonize technical practices, particularly when OIE documents are not detailed
- ➔ To facilitate European and international trade

2. Why addressing animal health content now in CEN?

- To contribute to these objectives: focus on the following:

Quality control of diagnostic reagents

No common or consistent methodologies across Europe

To harmonise control methods in Europe



Digitalisation of data exchange

Large number of analyses to be carried out in a short period of time

To facilitate and secure the transmission of test results



3. The scope

Standardization in the field of animal health.



It includes:

- ✓ Guidelines for implementation of diagnostic methods and quality control of diagnostic reagents;
- ✓ Data management and analytical technologies used for diagnostic methods.

It excludes:

- ✓ Terminology and methods for specific disease diagnosis already covered by the World Organisation for Animal Health (OIE) and European Union Reference Laboratories (EURLs);
- ✓ Standards on primary production in microbiology of the food chain as dealt with in CEN/TC 463 and related standards applicable inter alia in the field of animal health;
- ✓ Zootechnics;
- ✓ Animal welfare.

4. The work programme



The purpose of the new technical committee is to develop standards complementary to OIE and UN/CEFACT documents.

The initial work program will cover the following topics:

- Biological reagents performance control
- Dematerialized data exchange system in laboratory analysis

Other deliverables could be developed later on, upon decision by the new TC:

- Specific requirements and recommendations for the implementation of diagnostics based on cell cultures, molecular methods, immunological techniques or any other relevant technologies fully in the scope.
- A list of the relevant analytical methods recognized as appropriate for the European context.
- Analytical methods for animal diseases not covered by EURLs nor OIE.

5. Links with existing standards



In France, the following standards are available:

- NF U47-301:2001 - Animal health analysis methods - **Application file for performance control of biological reagents used in animal health**
- NF U47-310:2013 - Animal health analysis methods – **Performance control of biological reagents for the immunological techniques used in animal health**
- NF U47-311:2014 - Animal health analysis methods - **Performance control of PCR reagents used in animal health**
- **NF U47-700:2019 - Animal health analysis methods - Dematerialized data exchange system in laboratory analyses - ELabs Animal Health**

➔ Any national contributions will be welcome to promote good animal health practices and harmonize them at European level

Diagnostic reagents

ELabs

6. Stakeholders

Main categories of stakeholders are:

- ✓ Laboratories:
 - European Union Reference Laboratories
 - Diagnostic laboratories
 - National reference laboratories
- ✓ Industry (livestock, diagnostics, IT)
- ✓ Government
- ✓ Veterinarians
- ✓ Consumers
- + International organizations as liaison :
OIE, UN/CEFACT, Diagnostics For Animals, FESASS, EFSA



Why building collectively new standards in animal health ?



To enhance and sharing the expertise in Europe among CEN members



To promote good animal health diagnostic practices at European level



To harmonise practices



To support stakeholders, e.g. livestock and diagnostics industry and also veterinarians



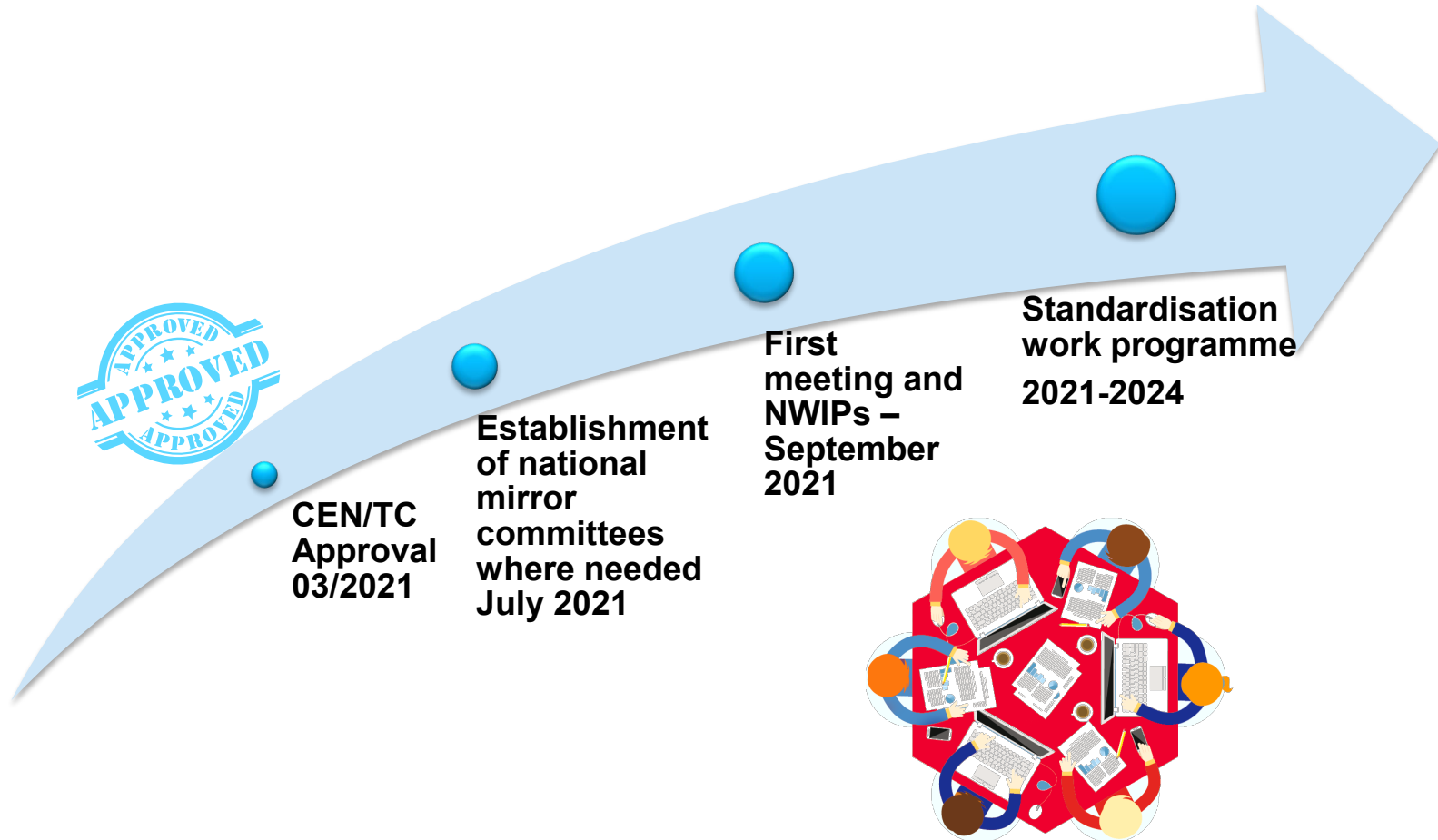
To ensure common requirements or guidelines to increase European competitiveness in international trade



And to enhance protection of animal and public health

3-7 Proposed planning

- **Kick-off meeting : September 2021**



Questions and discussion



CONTACTS :

perrine.leroy@afnor.org

bruno.garin-bastuji@anses.fr

viviane.moquay@agriculture.gouv.fr

**THANK YOU
MERCI !**

11 rue Francis de Pressensé
93 571 La Plaine Saint-Denis Cedex
Tél. 01 41 62 80 00
Fax. 01 49 17 90 00

