BT N 15578

Draft BT C055/2024

TECHNICAL BOARD

CEN/BT by correspondence

For decision **Issue date:** 2024-03-13

Deadline: 2024-04-09

SUBJECT

CEN/TC 469 **Animal health diagnostic analyses**

Approval of Business Plan

BACKGROUND

By Decision BT C203/2021, the CEN Technical Board approved the new title and scope of CEN/TC 469 ‘Animal health diagnostics analyses’.

During their last plenary meeting, on 5 October 2023, CEN/TC 469 decided to approve its first Business Plan (see Annex 1). The decision was taken by unanimity. The revised Business Plan is reproduced in Annex 2.

PROPOSAL(S)

BT,

- noting the first edition of the Business Plan of CEN/TC 469 ‘Animal health diagnostics analyses’ as presented in Annex 1;
- approves the Business Plan CEN/TC 469.

2024-03-05 – CHT – CV

Decisions and actions taken at the 3rd meeting of CEN/TC 469 on 5th October 2023 (Paris, Hybrid)

DECISION 01/2023 taken by CEN/TC 469 on 2023-10-05

Subject: CEN/TC 469 – Confirmation of the Business Plan

The CEN/TC 469,

- having considered the guidance 'Establishing the business plan of a Technical Committee' as included in CEN BOSS;
- confirms its current Business Plan, dated 2023-09-07, with the update of the WG2 title included (see Decision 02/2023).

The decision was taken by unanimity.

DECISION 02/2023 taken by CEN/TC 469 on 2023-10-05

Subject: CEN/TC 469 – Title of CEN/TC 469/WG 2

The CEN/TC 469 approves the new title of WG2, discussed at the 1st meeting of WG2 on 8 November 2022, as follows: Electronic laboratory data exchange.

The decision was taken by unanimity.

Action 1/2023: *The secretariat will contact European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) to share the WG2 project "Animal health diagnostic analyses - Electronic data exchange in laboratory analysis" during the CEN Enquiry.*

Action 2/2023: *The secretariat will share the project EN ISO 22174 "Microbiology of the food chain — Polymerase chain reaction (PCR) for the detection and quantification of microorganisms — General requirements and definitions" for members to comment during the preFDIS stage. Technical comments are still possible at this stage.*

Action 3/2023: *The secretariat will launch a call for experts and for a project leader if the revision of EN ISO 6887-6:2013 "Microbiology of food and animal feed — Preparation of test samples, initial suspension and decimal dilutions for microbiological examination — Part 6: Specific rules for the preparation of samples taken at the primary production stage" is approved.*

Action 4/2023: *CEN/TC 469 asks the secretariat to share for information the project EN ISO 7218 "Microbiology of the food chain — General requirements and guidance for microbiological examinations" at the Formal vote stage and the document "Guidance Document from ISO/TC 34/SC 9 and CEN/TC 463: Microbiology of the food chain — Template and guidance for drafting ISO/CEN standards".*

DECISION 03/2023 taken by CEN/TC 469 on 2023-10-05

Subject: CEN/TC 469 – Next plenary meeting in 2024

CEN/TC 469 will hold its next plenary meeting on 17 October 2024 in hybrid format. The location will be decided later. WG1 will hold its meeting the day before on 16 October 2024.

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BUSINESS PLAN

CEN/TC 469
Animal health diagnostic analyses

EXECUTIVE SUMMARY

Business Environment

- CEN/TC 469 addresses laboratory analyses in animal health. The business environment is therefore essentially the livestock and poultry industry, the biological industry, the laboratories and the animal health authorities.
- Livestock production and product value in the EU-28 was, in 2017, equal to € 170 billion, representing 40% of the total agricultural activity. The EU-28 is a net exporter on the world market and international trade surplus in livestock commodities reached € 33.7 billion in 2019.
- Standardization in this domain becomes of utmost importance due to the actual EU regulatory framework: (i) the Official control regulation 2017/625 that requires the reliability of diagnostic methods and laboratory activites across the Union, and accreditation according to ISO/IEC 17025 standard of all EU laboratories that implement official analyses in the area as well (ii) the Animal Health Law (2016/429) that defines, amongst others, health statuses for holdings, regions or Member states and/or animal/animal product trade health controls for listed diseases; statuses and controls being based on results of laboratory analyses.
- Parties involved:
  - Laboratories: Animal health European Union (EURLs) and National (NRLs) reference laboratories, Diagnostic laboratories – *Quality control of diagnostic reagents; Performing diagnostic methods; Data management*;
  - Industry: manufacturers and suppliers of animal health diagnostic reagents;
  - National and local authorities ministries and associated public authorities/agencies;
  - European and international organizations: European Commission (EC), European Food Safety Authority (EFSA); World Organisation for Animal Health (WOAH formerly OIE), UN/CEFACT; Biological industry: Diagnostics For Animals, AnimalhealthEurope; Livestock industry: European Federation for Animal Health and Safety (FESASS);
  - Consumers.

Benefits

- Promoting good laboratory diagnostic practices in animal health at European level;
- Harmonising practices as regards the diagnostic reagent control, the implementation of diagnostic methods as well as the management of result data;
- Ensuring common international requirements or guidelines to increase European competitiveness in international trade;
- Supporting stakeholders, e.g. livestock and diagnostics industry;
- Enhancing the expertise in this field in CEN member countries;
- Moreover, eventually, enhancing protection of consumers.

For EURLs, new standards are expected to bring benefits in terms of harmonisation of practices and enhancement of effectiveness. This new TC could also provide opportunity to promote innovation. For the NRLs and other official animal health laboratories mostly veterinary laboratories, new standards will give clear instructions on how to apply various analytical methods. Therefore, laboratories could use validated and harmonised methods, making their implementation easier with a higher level of quality assurance. For international organizations, new standards will improve animal health by sharing and disseminating good practices to complement their work and avoid generating conflicting results in the sector.

Priorities

CEN/TC 469 sets priorities for quality control of diagnostic reagents and for the dematerialisation of data exchange. Depending on future discussions within the TC, other guidelines or standards might be established for the performance of the most common diagnostic methods in animal health (e.g. immunological or molecular).

1. BUSINESS ENVIRONMENT OF THE CEN/TC 469

1.1. Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment related to the scope of this CEN/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards.

International trade of animals, climate change and the alteration of ecosystems are the main factors favouring the emergence or re-emergence of animal diseases, including zoonoses that can be transmitted from animal, both domestic and wild, to human beings. The Bovine Spongiform Encephalopathy, *Salmonella* and Avian Influenza crises are illustrations of this reality. In addition, animal health can also have economic impacts, e.g. by reducing the productivity of livestock farming or by hindering animal trade, both nationally and internationally.

These issues raise three main objectives for the animal health sector:

- To have reliable and recognised methods enabling diagnosis on animal health status,
- To diagnose and to guarantee animal health, thanks in particular to the reliability of the laboratories which use and provide the results of these methods,
- To anticipate diseases (emerging or not) for their surveillance and control.

The work of CEN/TC 469 primarily concerns the harmonisation of the procedures for the control of the diagnostic reagents and the electronic exchange of data in animal health. It could also adress, where relevant, the performance of diagnostic methods. The interested parties in the standardization process are all institutions that deal with the animal disease control chain, e.g laboratories, reagent manufacturers and all animal trade organizations.

CEN/TC 469 covers all animals (e.g. pets, farm animals, wild animals).
CEN/TC 469 does not work on:

- Terminology and methods for specific disease diagnosis already covered by the WOAH;
- Primary production in microbiology of the food chain covered by CEN/TC 463;
- Animal welfare and zootechnics.

The proposal is strongly linked to the Animal Health Law (Regulation (EU) -2016/429) that came into force in April 2021. This regulation, which lists 63 diseases, supersedes the existing directives (where standardization parameters were described for important diseases such as brucellosis, EBL, HPAI, FMD, etc.) and will reinforce the need for harmonisation of laboratory practices.

Regulation (EU) -2017/625 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 is specifically related to animal health.

The European Union Reference Laboratories (EURLs), established by the EC, have been given, among other things, the task of harmonising a number of methods relating to the animal diseases for which they hold a mandate.

The WOAH has established two manuals regarding animal disease diagnostic methods (and vaccines): the "Terrestrial Manual" and the "Aquatic Manual". Their aim is to facilitate international trade in animals and animal products and to contribute to the improvement of animal health services worldwide. To this effect, they provide relevant guidelines and information on diagnostic methods.

Therefore, the work of CEN/TC 469 will also take into account, without contradicting:

- requirements and recommendations already covered by the WOAH, European Union regulations and 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.

Concerning the electronic exchange of data, the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) developed a data exchange standard for laboratory analyses in the wider agricultural sector in 2010: the "Electronic Laboratory Observation Report" or "eLabs".

1.2. Quantitative Indicators of the Business Environment

The following quantitative indicators describes the business environment in order to provide adequate information to support actions of the CEN/TC:

- Livestock production and product value in the EU-28 was, in 2017, equal to € 170 billion, representing 40% of the total agricultural activity.
- The EU-28 is a net exporter on the world market and international trade surplus in livestock commodities reached € 33.7 billion in 2019.

2. BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC 469

European standardization in the field of animal health will provide clear, accessible and recognised documents for all steps of the animal disease analysis chain, complementing the WOAH manuals. The TC will ensure that it does not interfere with WOAH work but may possibly contribute to it. Its work will be based on existing WOAH work to produce recommendations on the implementation of existing methods but would also address complementary issues such as reagent quality control and dematerialised data exchange.

With regard to reagents, the WOAH manuals describe how to validate diagnostic methods and/or reagents but do not provide procedures for the examination of applications for the placing on the market of reagents as well as the control of batches of approved reagents. Similarly, the WOAH documents cover reagents validation records but do not give the control parameters that reference laboratories should use. Indeed, there are no common or consistent methodologies for diagnostic reagent control across Europe. The benefit of the work of the new Technical Committee will be to agree at European level on the control parameters to be used and then to harmonise the procedures for the control of the diagnostic reagents. One of the first objectives is thus to harmonise and make consistent the level of the quality control of diagnostic reagents in Europe.

In addition, the work of this CEN/TC could lead to a consensus on guidelines at European level for the implementation of the main diagnostic techniques in animal health (e.g. ELISA, PCR, Cell cultures, neutralisation tests, MALDI-TOF, etc.).

Concerning the digitalisation of data exchange, the specific challenges of animal health analyses would require an adaptation of the UN/CEFACT document, especially for the implementation of the Animal Health Law. This will allow for a larger number of analyses to be carried out in a short period of time, in particular in the context of a health crisis. In the field of human health, the Covid-19 crisis has provided an example where the use of a dematerialised data exchange system can be useful to standardize the data collection from a large number of laboratories.

Main categories of stakeholders can expect benefits from the work of CEN/TC 469:

- **Laboratories**:
    - **European Union and National Reference Laboratories:** new standards are expected to bring benefits in terms of harmonisation of practices and enhancement of effectiveness. This new technical committee could also provide the opportunity to promote research results and innovations.
    - **Diagnostic laboratories:** these are mostly veterinary laboratories. The new work will give clear instructions how to apply various methods, so laboratories can use methods that are validated and harmonised, making their implementation easier.
- **Businesses:** these are mostly the reagent manufacturers, which are mainly SMEs. Having a coherent set of standards to answer legal requirements will improve and foster the development of and access to the market. One of the expected benefits is the reduction of compliance costs against national or local requirements.
- **Government**: national ministries and associated public authorities/agencies; regional/federal and local governments (cities, communities, etc) are expected to benefit from the availability of complementary tools to ensure compliance with the EU Animal Law.
- **Consumers**: as the ultimate end-user beneficiary of an enhanced sanitary environment.
- **International organizations**: the new work will improve animal health by sharing and disseminating good practices to complement their work, and avoid generating conflicting results in the sector.

3. PARTICIPATION IN THE CEN/TC

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to WGs, ensuring a balance of all interested parties. Participation as observers of recognised European or international organizations is also possible under certain conditions. To participate in the activities of this CEN/TC, interested people are requested to contact their national standard organizations.

The collaboration and communication with the identified structures, whose work themes are complementary to the work proposed in this committee, is crucial. Obviously, the new proposed work will take into account their work and results, as there will be interaction between them but in no way overlapping.

As mentioned in the scope, terminology and methods for specific disease diagnosis already covered by the WOAH and EURLs are excluded, as are standards on primary production in microbiology of the food chain covered by CEN/TC 463.

Furthermore, experts of the following institutions/organizations should be invited to participate in the proposed CEN/TC:

- AnimalhealthEurope (AHE)
- Diagnostics For Animals (D4A)
- European Food Safety Authority (EFSA)
- European Federation for Animal Health and Safety (FESASS)
- UN/CEFACT
- World Organisation for Animal Health (WOAH)

4. OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1. Defined objectives of the CEN/TC 469

The objective of CEN/TC 469 is the elaboration of standards in the field of animal health.
The scope of the TC is as follows:

Standardization in the field of animal health,
Including:

- Performing diagnostic methods;
- Quality control of diagnostic reagents;
- Data management;

Excluding:

- Animal welfare and zootechnics;

Taking into account without contradicting:

- Requirements and recommendations already covered by the WOAH and 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.

4.2. Identified strategies to achieve the CEN/TC.s defined objectives.

CEN/TC 469 will mainly elaborate European Standards, but also Technical Specifications and, in some exceptional cases, Technical Reports.

The initial work program will cover the following topics:

- Biological reagents control of performance: some European countries have already developed their own control methods. Harmonised criteria and control methods at European level could help in referencing and benchmarking laboratories and be of interest to reagent suppliers. The objective is to propose a standardized control of diagnostic reagents (immunology and molecular biology) used in the animal health diagnostic sector;
- Dematerialised data exchange system in laboratory analyses: this topic is strategic in order to ensure the management of information resulting from analysis, testing and

diagnosis. The objective is to propose a standardized language for the implementation of a system for the dematerialised data exchange in the field of laboratory analyses in animal health.

Other deliverables could be developed later on, upon decision by the Technical Committee. This could include specific requirements and recommendations for the implementation of diagnostic methods and interpretation of diagnostic results based on:

- Immunological methods;
- Molecular methods;
- Other relevant diagnostic methods.

The TC could also address, where relevant and based on WOAH documents a list of the relevant analytical methods recognised as appropriate for the European context, as well as analytical methods for animal diseases not covered by EURLs nor WOAH.

Structure:

There are two main subjects proposed in the initial work program, the CEN/TC 469 has therefore established appropriate WGs:

WG 1 “Reagents and methods”
WG 2 “Electronic laboratory data exchange”

Liaisons with the following "internal" institutions should be established:

CEN/TC 463 "Microbiology of the food chain” (done)
ISO/TC 34/SC 9 "Microbiology”
ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems"
CEN/TC 140 “In vitro diagnostic medical devices”
ISO/TC 276 "Biotechnology"

Liaisons with the following "external" institutions should be established:

AnimalhealthEurope (done)
Diagnostics For Animals (done)
European Federation for Animal Health and Safety (FESASS) (done)
UN/CEFACT
World Organisation for Animal Health (WOAH) (done)

4.3. Environmental aspects

CEN/TC 469 will not elaborate standards which are definitely addressed to environmental issues. However, the aspect of hazardous materials and respect for REACH Directive will be taken into account for the elaboration of standards, as well as biosafety/biosecurity and protection of workers.

For its first meeting, CEN/TC 469 circulated the environmental checklist and distributed the CEN Guide 33 Guide for addressing environmental issues in testing standards.

The secretariat will inform its members on all environmental topics of CEN regularly.

If new work items are proposed, who would encounter the use of hazardous material or reagents, the providers would need a good justification to let their projects be adopted. One method which makes use of a (meanwhile unnecessarily) hazardous reagent should be withdrawn and replaced by a safer alternative.

Moreover, CEN/TC 469 will use electronic means (e-committees, webmeetings) to preserve the environment as much as possible.

5. FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC WORK PROGRAMME

Financial resources for the validation of methods in animal health are limited and may be not in the terms of reference of nominated EURLs, that is why it could be difficult at the beginning to upgrade new methods in new WGs. A financial contribution from key players (private and public) in the field could therefore be an accelerator to build new projects in this TC.

Mandated projects, funded by the EC, could be a way out combined with research and development results of scientific projects funded by the EC to improve existing or new EN standards.

Involvement of experts in sufficient numbers and various skills in convening WGs, leading projects or participating in the drafting is sometimes lacking, which could affect the project's development timeline.