



TECHNICAL BOARD

CEN/BT by correspondence

For vote in line with IR2 Clause 6.1.4

Issue date: 2021-01-06

Deadline: 2021-03-30

SUBJECT

New CEN/TC 'Animal Health'

BACKGROUND

On 5 January 2021, AFNOR submitted a proposal to CCMC for the creation of a new Technical Committee (CEN/TC) 'Animal Health'. A detailed explanation is provided in the 'proposal for a new field of activity' form (Annex I).

Rationale

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. More recently, the Covid-19 pandemic is thought to originate in the transmission of a bats' disease to humans, via pangolins. In addition, animal health can also have economic impacts, for example by reducing the productivity of livestock farming or by hindering animal trade, both nationally and internationally.

European standardization in the field of animal health will provide clear, accessible and recognized documents for all steps of the animal disease control chain, complementing the manuals of the World Organisation for Animal Health (OIE). The TC 'Animal Health' will ensure that it does not interfere with OIE work but rather possibly contributes to it. Its work will be based on existing OIE work to produce recommendations on the implementation of existing methods but would also address complementary issues such as reagent quality control and dematerialized data exchange.

AFNOR is committed to providing the secretariat of the proposed TC and to providing Professional Standardization Support to the Working Group to be created.

Criteria for approval

By Resolution BT 65/2017, BT decided that the following criteria are to be met for acceptance of such a proposal for new work (in a new area):

- Vote according to Internal Regulations Part 2 clause 6.1.4; Note: Possible votes are 'Agrees', 'Disagrees with comments' and 'Abstains'. Any vote indicating 'Deferred decision' will be counted as 'Disagrees with comments'.
- At least 5 members express commitment to participate. As a consequence, BT Members are requested to state explicitly, by means of the commenting field provided in the BT-balloting tool, whether or not they are committed to participate in the work.

Information Sessions

In order to give the opportunity to ask questions and raise issues, while the consultation is ongoing, AFNOR invites CEN members to participate in an informative webinar session. Two

sessions are proposed. It is open to CEN member bodies but is not limited to NSB staff: any representative or stakeholder CEN members would like to include are welcome.

These web sessions will be held on:

- Webinar 1: Friday, 26 February, 10:00 - 11:00 am (CET - Paris time)

Registration link :

<https://afnor.zoom.us/meeting/register/tJwqc-ipcT0iHNxdyld1Usn8xx3brKGio13>

- Webinar 2: Thursday, 11 March, 3:00 - 4:00 pm (CET – Paris time)

Registration link :

<https://afnor.zoom.us/meeting/register/tJYtdeusqDwrGNcVwSQcTljinMeeWWJsbPka9>

PROPOSAL(S)

BT,

- having considered the proposal for a new field of technical activity on ‘Animal Health’ submitted by AFNOR as included in Annex I;
- considering that the following members have expressed commitment to participate:
 - o <members>
- decides to create a new CEN/TC XXX with the following preliminary title and scope:

Title: ‘Animal Health’

Scope:

‘Standardization in the field of animal health.

Including:

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

Excluding:

- 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;
 - Animal welfare and zootechnics.’;
- allocates the secretariat of CEN/TC XXX to AFNOR;
 - asks the new CEN/TC XXX to submit its final title and scope for BT approval, following its first kick-off meeting.

2021-01-05 – CHT – CM



PROPOSAL for a NEW FIELD OF TECHNICAL ACTIVITY	
Date of circulation	CEN/TC / SC N (where appropriate)
Secretariat	CENELEC/TC / SC (Sec) (where appropriate)
Type of technical body proposed (TC / SC / BTTF)

IMPORTANT NOTE: Incomplete proposals risk rejection or referral to originator.

The proposer has considered the guidance given in Annexes 1 and 2 during the preparation

Proposal (to be completed by the proposer)

<p>Title of the proposed new subject (The title shall indicate clearly and unambiguously, yet concisely, the new field of technical activity which the proposal is intended to cover.)</p> <p>Animal health</p>
<p>Scope statement of the proposed new subject (The scope shall precisely define the limits of the new field of technical activity. Scopes shall not repeat general aims and principles governing the work of the organization but shall indicate the specific area concerned.)</p> <p>Standardization in the field of animal health.</p> <p>It includes:</p> <ul style="list-style-type: none"> • Guidelines for implementation of diagnostic methods and quality control of diagnostic reagents; • Data management and analytical technologies used for diagnostic methods. <p>It excludes:</p> <ul style="list-style-type: none"> • 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 <i>inter alia</i> in the field of animal health; • Animal welfare and zootechnics.

Purpose and justification for the proposal

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. More recently, the Covid-19 pandemic is thought to originate in the transmission of a bats' disease to humans, *via* pangolins. In addition, animal health can also have economic impacts, for example by reducing the productivity of livestock farming or by hindering animal trade, both nationally and internationally.

The existing technical and legal framework

Issues regarding animal diseases, including zoonoses, are a global concern and need to be monitored. The key player for that issue is the World Organization for Animal Health (OIE) : <https://www.oie.int/en/>

The OIE 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. However, they do not provide detailed information on all diagnostic methods and reagents used in the field of animal health. Moreover, these manuals do not always include guidelines for the implementation of some of the diagnostic technologies that are used independently of the disease (e.g. ELISA, PCR, Maldi-tof technologies) and do not always cover the critical area of the quality of the reagents used.

Another document to take into account has been developed, in 2010, by the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT: <https://www.unece.org/fileadmin/DAM/cefact/about.htm>): the "Electronic Laboratory Observation Report" or "eLabs". It is a data exchange standard for laboratory analyses in the wider agricultural sector. It enables the implementation of a dematerialized data exchange system guaranteeing interoperability within the network of players. However, it has not yet been specifically applied in the field of animal health at European level.

At European level, to ensure high quality testing across the EU, the European Commission has established European Union Reference Laboratories (EURLs) in areas where there is a need for harmonized practices and reliable diagnostic methods and tests. This is in line with the Official Control Regulation (2017/625), entered into force late 2019, and the European Animal Health Law, which will enter into force in April 2021 and aims at limiting the social and economic consequences of the animal disease crises and thus ensure the competitiveness and safety of European animal production. In this context, EURLs have been given, among other things, the task of harmonizing a number of methods relating to the animal diseases for which they hold a mandate. The European Animal Health Law will also promote the digitalization of animal health data exchange at European level.

However:

- EURLs cover a limited number of diseases,
- There is no existing plan to develop standards or recommendations
 - that are generic, i.e. applying to the entire field of animal health,
 - for the implementation of diagnostic techniques,
 - and to ensure the quality of reagents.

Standardization needs at European level on diagnostic reagents, data management and analytical technologies used for diagnostic methods

The proposed technical committee will focus on the following:

1. Quality control of diagnostic reagents:

At this stage, there are no common or consistent methodologies across Europe to ensure that reagents used are of appropriate quality.

2. Digitalization of data exchange:

Management of data aims at facilitating and securing the exchange of information. 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 dematerialized data exchange system can be useful to standardize the data collection from a large number of laboratories.

To sum up, the creation of a European technical committee dedicated to animal health aims at:

- promoting good animal health diagnostic practices at European level,
- harmonizing practices,
- 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 the countries of CEN members,
- and, eventually, enhancing protection of consumers.

Our goal: European standard contributing to the animal health control chain in collaboration with OIE and relevant European institutions.

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

Is the proposed new subject actively, or probably, in support of European legislation or established public policy?

Yes No

If Yes, indicate if the proposal is

▪ in relation to EC mandate(s):(which one(s))

▪ in relation to EC Directive(s)/Regulation(s):(which one(s))

- Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health - 'Animal Health Law' and associated implementing and delegated regulations.
- Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 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 protection product.

▪ in relation to other legislation or established public policy:(give details)

Proposed initial programme of work

The proposed programme of work shall correspond to and clearly reflect the aims of the standardization activities and shall therefore show the relationship between the subjects proposed.

Each item on the programme of work shall be defined by both the subject aspect(s) to be standardized (for products, for example, the items would be the types of products, terminology, characteristics, other requirements, data to be supplied, test methods, performance requirements, etc.). Supplementary justification may be combined with particular items in the programme of work (e.g. output from a research project).

The proposed programme of work shall also suggest priorities, target dates and the most appropriate type of deliverable (e.g. EN, TS) for each item

The initial work program will cover the following topics:

- **Biological reagents control of performance:** some European countries have already developed their own control methods. Harmonized 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;
- **Dematerialized 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 dematerialized 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 diagnostics based on:

- Cell cultures;
- Molecular methods;
- Immunological techniques;
- Mass spectrometry (MALDI-TOF);
- Any other relevant technologies fully in the scope of the Technical Committee.

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

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing CEN, CENELEC, ISO and IEC deliverables

The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized. If seemingly similar or related work is already in the scope of other committees of the organization, or in other organizations, the proposed scope shall distinguish between the proposed work and the other work. The proposer shall indicate whether his or her proposal could be dealt with by widening the scope of an existing committee or by establishing a new committee.)

The purpose of the new technical committee is to develop standards complementary to those developed by the OIE.

The following committees are not directly working on animal health, but their work and deliverables should be taken into account in the work of the future technical committee:

→ **Primary production in food chain microbiology:**

- **ISO/TC 34/SC 9, Microbiology**, which standardizes horizontal methods in the field of microbiological analysis of the food chain from primary production stage to food and animal feed products, including the environment of food production and handling. ISO/TC 34/SC 9 is in liaison with the OIE where their standardized methods cover samples from animals and primary production. EN ISO standards for food chain microbiology are referenced in the OIE terrestrial manual.

- **CEN/TC 463, Microbiology of the food chain**, which standardizes horizontal methods in the field of microbiological analysis of the food chain from primary production stage to food and animal feed, including the environment of food production and handling. EN ISO standards for food chain microbiology are referenced in the OIE terrestrial manual.

→ **Laboratory analysis conditions:**

- **ISO/TC 212, Clinical laboratory testing and in vitro diagnostic test systems**, which standardizes in the field of laboratory medicine and in vitro diagnostic test systems. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance.

→ **Biotechnologies:**

- **ISO/TC 276, Biotechnology**, which standardizes in the field of biotechnology including analytical methods.

The work will also be carried out in close collaboration with :

- OIE;
- Relevant European institutions including EURLs;
- Diagnostics For Animals, which federate and represent manufacturers of animal health diagnostics, they work with the OIE and UE on the control of reagents;
- UN-CEFACT;
- Any other relevant stakeholders.

A listing of relevant existing documents at the international, regional and national levels

Any known relevant documents (such as standards and regulations) shall be listed, regardless of their source, and should be accompanied by an indication of their significance.

The following preexisting documents have been identified, without being limited to:

- **In OIE:**
 - Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)
 - Manual of Diagnostic Tests for Aquatic Animals (Aquatic Manual)
- **In UN-CEFACT:**
 - Electronic Laboratory Observation Reporting (*eLabs*)
- **In CEN/ISO:**
 - EN ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories
 - EN ISO 22117 - Microbiology of food chain - Specific requirements and guidance for proficiency testing by interlaboratory comparison
 - EN ISO 19036 - Microbiology of food chain - Guidelines for the estimation of measurement uncertainty for quantitative determinations
 - EN ISO 22174 - Microbiology of food - Polymerase chain reaction (PCR) for the detection of food-borne pathogens - General requirements and definitions
- **In CEN:**
 - No document identified on biological reagents control and data exchange system
- **In France, the following standards**
 - NF U47-301 - Animal health analyse methods - Presentation file for control of biological reagents used in the animal health sector
 - NF U47-310 - Animal health analysis methods - Biological reagents control for the immunological techniques used in animal health
 - NF U47-311 - Animal health analysis methods - PCR reagent control used in animal health
 - NF U47-700 - Animal health analysis methods — Dematerialised data exchange system in laboratory analysis — ELabs Animal Health

Known patented items

Yes No If "Yes", see CEN-CENELEC Guide 8 and provide full information in an annex

A simple and concise statement identifying and describing relevant affected stakeholder categories (including small and medium sized enterprises) in particular those who are immediately affected from the proposal (see Annexes 1 and 2) and how they will each benefit from or be impacted by the proposed deliverable(s)

Main categories of stakeholders are, by decreasing order of desirable involvement:

- **Laboratories:**
 - o **European Union Reference Laboratories:** they are responsible for carrying out scientific and technical studies; for developing and validating reference methods for official control, for organising proficiency tests for the networks of National Reference Laboratories, for conducting training courses and disseminating research findings and technical innovations; and for providing scientific and technical advice for the development and application of animal welfare indicators. New standards are expected to bring benefits in terms of harmonization of practices and enhancement of effectiveness. This new technical committee could also provide the opportunity to promote research results and innovations.
https://ec.europa.eu/food/ref-labs_en
 - o **National reference 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 harmonized, 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 ...) 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:** World Organisation for Animal Health (OIE) and Diagnostics For Animals. 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.

Liaisons:

A listing of relevant external European or international organizations or internal parties (other CEN, CENELEC, ETSI, ISO and/or IEC committees) to which a liaison should be established (in the case of ISO and IEC committees via the Vienna or Dresden Agreements).

World Organisation for Animal Health
 CEN/TC 463 - Microbiology of the food chain
 ISO/TC 34/SC 9 – Food products - Microbiology
 Diagnostics For Animals
 FESASS
 European Food Safety Authority (EFSA)

Joint/parallel work:

Possible joint/parallel work with:

- CEN (please specify committee ID)
- CENELEC (please specify committee ID)
- ISO (please specify committee ID)
- IEC (please specify committee ID)
- Other (please specify)

Name of the Proposer
(include contact details)

AFNOR

Contact details :

Perrine LEROY

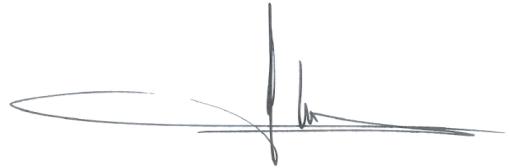
Standardization Project Manager

perrine.eroy@afnor.org

An expression of commitment from the proposer to provide the committee secretariat if the proposal succeeds.

If the proposal is accepted, AFNOR is willing to undertake the secretariat of the new TC, and is committed to providing all resources to successfully run the secretariat.

Signature of the proposer

A handwritten signature in black ink, appearing to read 'Franck Lebeugle', with a long horizontal stroke extending to the right.

Franck LEBEUGLE
AFNOR Standardization Director

Annex(es) are included with this proposal (give details)