



SLOVENSKI STANDARD
oSIST prEN 18029:2024
01-januar-2024

Diagnostične analize zdravja živali - Elektronska izmenjava podatkov v laboratorijskih analizah

Animal health diagnostic analyses - Electronic data exchange in laboratory analysis

Tiergesundheit - Elektronischer Datenaustausch bei Labortests

Analyses de diagnostic en santé animale - Échange de donnée électronique dans les analyses de laboratoire

Ta slovenski standard je istoveten z: prEN 18029

[oSIST prEN 18029:2024](https://standards.iteh.ai/catalog/standards/sist/b7610eb1-dd0d-4f7f-840e-91c02cf0257a/osist-pren-18029-2024)

<https://standards.iteh.ai/catalog/standards/sist/b7610eb1-dd0d-4f7f-840e-91c02cf0257a/osist-pren-18029-2024>

ICS:

11.220	Veterinarstvo	Veterinary medicine
35.240.99	Uporabniške rešitve IT na drugih področjih	IT applications in other fields

oSIST prEN 18029:2024

en,fr,de

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
prEN 18029

November 2023

ICS 11.220; 35.240.99

English Version

Animal health diagnostic analyses - Electronic data exchange in laboratory analysis

Analyses de diagnostic en santé animale - Échange de
donnée électronique dans les analyses de laboratoire

Tiergesundheits - Elektronischer Datenaustausch bei
Labortests

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 469.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

<https://standards.iteh.ai/catalog/standards/sist/b7610eb1-dd0d-4f7f-840e-91c02cf0257a/osist-pren-18029-2024>



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents	Page
European foreword	4
Introduction	5
1 Scope.....	6
2 Normative references.....	6
3 Terms and definitions	6
4 e-Labs	7
5 The partners in the exchanges	8
6 Scope of the exchanges.....	8
7 General exchange system.....	9
8 Exchange scenarios	9
9 Simplified data diagram	11
9.1 Description of the exchanged files.....	11
9.1.1 The “Request” file	11
9.1.2 The “Result” file	13
9.1.3 The “Acknowledgement” file	15
9.2 The exchange parameters	15
9.3 Service requests	16
9.4 Sampling location and sampler	16
9.5 The sample	17
9.6 Instruction.....	18
9.7 The analyses	18
9.8 Analysis results.....	19
10 Data dictionary	20
10.1 The principles	20
10.2 Definitions and glossary	20
10.3 Request and result messages.....	21
10.3.1 General tags	21
10.3.2 “Function” tags.....	23
10.4 Acknowledgement message.....	38
11 Management of the reference lists	39
11.1 Reference lists.....	39
11.2 The reference framework.....	39
11.3 Nomenclatures.....	41
12 Management of the parties.....	43
12.1 General.....	43
12.2 Identification of the parties	43
12.3 Party contacts.....	43
13 Points requiring attention for the implementation of the standard.....	44
13.1 General.....	44
13.2 Exchange scenarios	44
13.3 Scope of exchanged data.....	44

13.4	Organization of the exchanges	44
13.5	Communication protocol	45
Annex A	(informative) The entities in the data dictionary	46

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[oSIST prEN 18029:2024](https://standards.iteh.ai/catalog/standards/sist/b7610eb1-dd0d-4f7f-840e-91c02cf0257a/osist-pren-18029-2024)

<https://standards.iteh.ai/catalog/standards/sist/b7610eb1-dd0d-4f7f-840e-91c02cf0257a/osist-pren-18029-2024>

prEN 18029:2023 (E)

European foreword

This document (prEN 18029:2023) has been prepared by Technical Committee CEN/TC 469 “Animal health diagnostic analyses”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

iTeh Standards (<https://standards.iteh.ai>) Document Preview

[oSIST prEN 18029:2024](https://standards.iteh.ai/catalog/standards/sist/b7610eb1-dd0d-4f7f-840e-91c02cf0257a/osist-pren-18029-2024)

<https://standards.iteh.ai/catalog/standards/sist/b7610eb1-dd0d-4f7f-840e-91c02cf0257a/osist-pren-18029-2024>

Introduction

Numerous partners are involved in animal health monitoring/surveillance, from the competent authorities and public establishments to the professional organizations.

Sharing electronic information on animal health knowledge is a major issue. This sharing process involves exchanging information and making sure that the information is comparable and coherent, and it requires that the informatic systems of the various players in this field are interoperable.

To do so, the use of a common language based on a standard data exchange format that is open and accessible to all and that uses lists of common codes is the most appropriate response to this need.

This standardization offers numerous advantages:

- to be able to process data from a large number of laboratory tests in a short period of time, especially in the context of a health crisis;
- to facilitate animal health data reporting and analysis;
- to guarantee interoperability within the animal health community on the laboratory test data;
- to improve data reliability and data quality.

The ultimate goal is to propose a common data exchange language (format of the messages and the dictionary of all the items that compose the message) between the prescribers and the laboratories in the animal health sector. This document provides only the format of the common data exchanges language. It can be considered as the first step in standardization of electronic data exchange in laboratory analysis. A subsequent step could be the development of code lists.

This standardization is based on the e-Labs format, which consists of a set of files, processes and rules allowing for the standardization of data exchanges between prescribers and laboratories.

This standard exchange format has been developed using tools designed by UN/CEFACT (United Nations Centre for Trade Facilitation and Electronic Business). UN/CEFACT is a United Nations organization that promotes and establishes the interoperability of information exchanges through the definition of data exchange format standards. These standards are available on the UN/CEFACT website: <http://www.unece.org/cefact/>.

UN/CEFACT designed an **e-Labs** exchange format to standardize transactions of analytical data in agriculture in the broadest sense.

By supporting animal health and reducing severe diseases and losses in animal production, the standard will also have a positive effect on Goal 12 zero responsible consumption and production, see <https://www.fao.org/common-pages/search/en/?q=sustainable%20development%20goals%20food%20production%20>
<https://www.fao.org/sustainable-development-goals/en/>

By supporting animal health and thus a sustainable production the standard will also have a positive effect on Goal 2 zero Hunger

A sustainable production does also contribute to goal 13.

<https://www.fao.org/sustainable-development-goals/en/>

prEN 18029:2023 (E)

1 Scope

This document specifies a common data exchange format (i.e. format of the messages and the dictionary of all the items that compose the message) between the prescribers and the laboratories in the animal health sector.

This document is intended for prescribers (purchasers) and service providers in charge of collecting samples and conducting analyses (including analysis laboratories) that want to computerize and standardize their data exchanges, particularly in the animal health sector.

This document excludes the code lists that are required for unambiguous data exchange.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp/>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 reference

structured additional information that specifies the characteristics of an entity

Note 1 to entry: References may be provided for the following entities: the sample, the sampling location, the contract, the sampled object, the analysis request, the result of the analysis.

3.2 contract

formally defines the analytical services expected by the prescribers and that are delivered by the laboratory

3.3 sample

result of the sampling process, used by the laboratory to perform the analysis according to the prescribers' requests

3.4 laboratory

party that analyses the samples according to the analysis request received

Note 1 to entry: The laboratory issues the results in an electronic format. For subcontracting, the e-Labs format identifies the analyses concerned by identifying the subcontractor laboratory. When the subscriber chooses to call on several laboratories (for example, a first-line laboratory for screening analyses and a second-line laboratory for confirmation analyses), each laboratory receives a request for an analysis and the sender of the message receives the results of the relevant analyses.

3.5**sampled object**

object from which the samples are collected

Note 1 to entry: The sampled object may be an animal or a lot of animals (biological samples) or a building housing livestock – production unit (environmental samples). Livestock or wildlife animals can be concerned.

3.6**sampling**

operation that produces one or more samples that are taken from the sampled object

3.7**sampler**

party that collects the samples

Note 1 to entry: The sampler may be the prescriber or an external party receiving a sampling request from the prescriber corresponding to the analysis request sent to the laboratory.

3.8**prescriber**

party that issues the analysis request or the request for samples and analyses

Note 1 to entry: By definition, the prescriber is also the issuer of the computerized request (requests can only be raised by one prescriber). The prescriber doesn't need to be the sole receiver of the results of a request that he/she has made.

3.9**owner**

sampled object from which the sample was collected is the property of the owner

Note 1 to entry: One sampled object can have several owners.

3.10**operator**

in charge of the sampled object from which the sample is collected and responsible for carrying out the laboratory tests

4 e-Labs

Animal health e-Labs is a subset of the e-Labs format adapted to the needs of information exchanges between the prescribers of analyses and the laboratories in the animal health field.

Animal health e-Labs is made up of two elements:

- the data dictionary that is used to precisely describe the definition and the terminology of all the data used in the format. The purpose of this dictionary is to define a common language between the various partners using this data exchange system. The dictionary covers several aspects of the data:
 - ✓ the meaning;
 - ✓ the essential rules for codification;

prEN 18029:2023 (E)

- the electronic exchange formats intended to describe an interface between the computer systems and the organization of the exchanged data. For Animal health e-Labs, these formats are defined in three XSD files (XML Schema Definition) describing the different types of exchanged messages (requests, results and acknowledgements):
 - ✓ LaboratoryObservationReport_1.xsd: this file is used for sending the results;
 - ✓ LaboratoryAnalysisRequest_1.xsd: this file is used for requesting an analysis;
 - ✓ LaboratoryAcknowledgement_1.xsd: acknowledgement file.

Animal health e-Labs intends to implement the changes to the e-Labs format. This close link between Animal health e-Labs and e-Labs ensures that Animal health e-Labs is internationally recognized, while also focusing on the needs of operators in animal health field.

5 The partners in the exchanges

The partners in this system of data exchanges are:

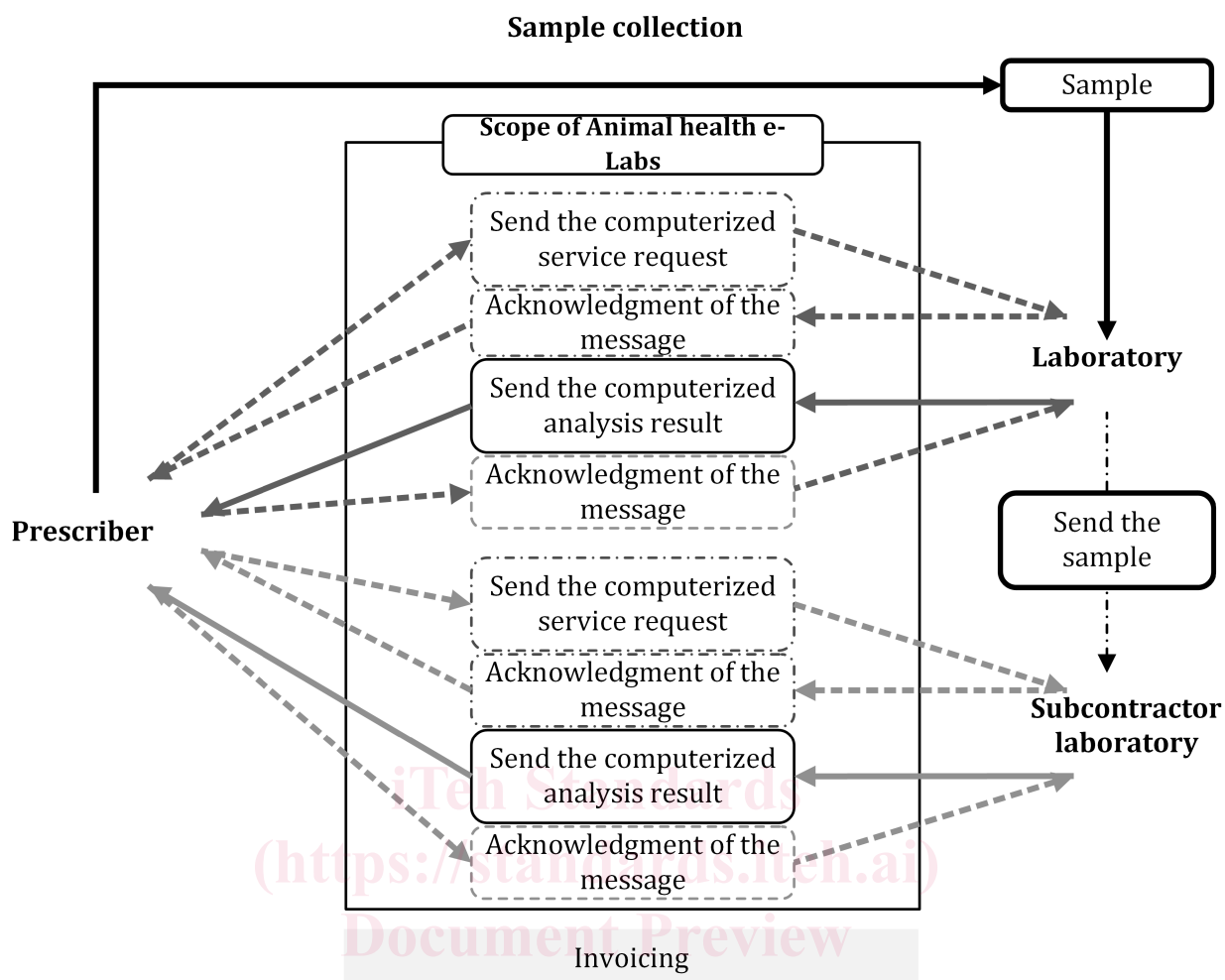
- **Prescribers** with an information system that is able to import the data of analysis results sent in an XML file structured according to the Animal health e-Labs standard. The analysis request files (creation of the request files) and acknowledgement files (sending and receiving) should be controlled, but this is not mandatory, depending on the exchange rules defined with partners.
- **Laboratories** with a computer system able to create files containing the analysis results data in XML format structured according to the Animal health e-Labs standard. The analysis request files (import of the request files) and acknowledgement files (sending and receiving) should be controlled, but this is not mandatory, depending on the exchange rules defined with partners.

6 Scope of the exchanges

The scope of exchanges of the Animal health e-Labs format covers veterinary **analytical services**, including sampling and quantitative or qualitative analyses of all types. Several exchange configurations can be managed, according to the number of parties in the exchanges: prescribers, samplers, first-line laboratories (for example, for screening analyses), second-line laboratories (for confirmation of analyses, for example) and the computerized management of service requests.

Exchanges related to invoicing or pricing are not modelled in the Animal health e-Labs format.

7 General exchange system



Key

continuous line: exchanges of results

dotted line: exchanges of acknowledgement requests

Figure 1 — Scheme of exchanges

This scheme is an example of some scenarios that can be operated thanks to the e-Labs format. Other data exchange scenarios may be supported by this format: for example, the first line laboratory can forward the request to the subcontractor laboratories and can receive the results directly from the subcontractor laboratory.

8 Exchange scenarios

The Animal health e-Labs format manages several exchange configurations. However, this standard is not intended to present and describe in detail the exchange scenarios specific to every prescriber and their organization. The goal of this subclause is to show the possible flows that can be managed by the Animal health e-Labs format.

- **Scheduled Intervention mode – IP** (blue diagram): In this exchange configuration, the prescriber sends a computerized analysis request containing details of the request to the laboratory: information on the sampling, the intervention and the analyses to be made. An acknowledgement

prEN 18029:2023 (E)

file may be sent when the laboratory receives the analysis request. In this scenario, the results subsequently sent by the laboratory contain the identifiers included in the request: request No., sample No., etc.

- **Unscheduled Intervention – INP:** In this exchange configuration, the laboratory sends the results without having previously received and accepted a computerized analysis request. In this case, the results do not refer to a request or a sample number sent by the prescriber.
- The Animal health e-Labs format can also manage **dual flows** of requests and results:
 - a sampling request is sent to the sampler, who returns a result that may contain the results of field observations and information on the collected samples;
 - the prescriber then sends an analysis request for the collected samples in response to the initial computerized request to the analysis laboratory. This analysis request may contain the field results sent by the sampler, if they are of any interest to the laboratory. The laboratory then sends the results of the analyses performed by the laboratory;
 - this dual flow may include flows of acknowledgements of the request and results files;
 - this dual flow may also be useful when a second-line laboratory is involved (green diagram).

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

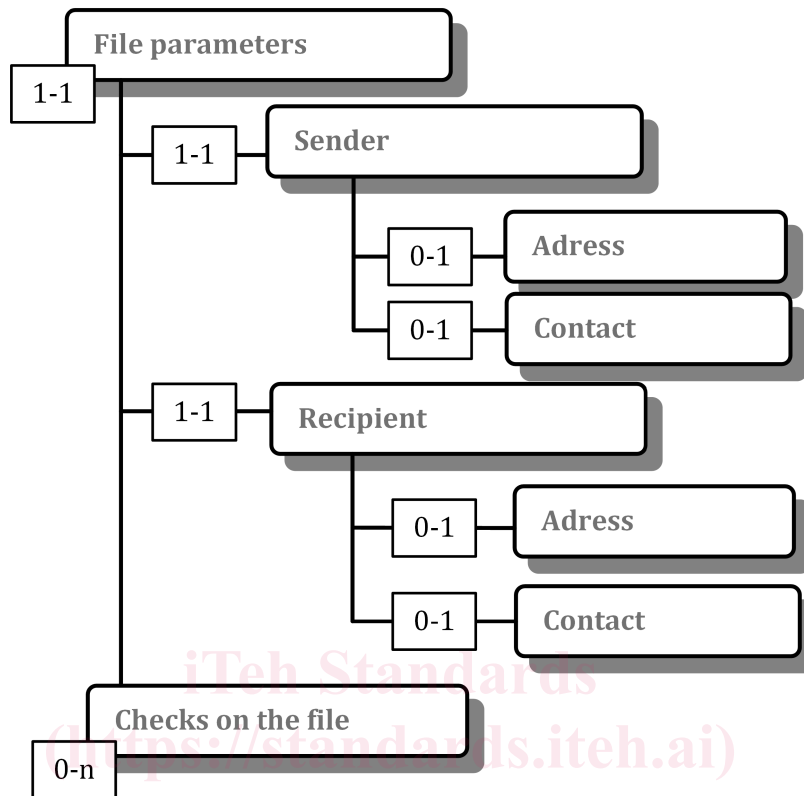
[oSIST prEN 18029:2024](https://standards.iteh.ai/catalog/standards/sist/b7610eb1-dd0d-4f7f-840e-91c02cf0257a/osist-pren-18029-2024)

<https://standards.iteh.ai/catalog/standards/sist/b7610eb1-dd0d-4f7f-840e-91c02cf0257a/osist-pren-18029-2024>

9 Simplified data diagram

9.1 Description of the exchanged files

9.1.1 The "Request" file



[oSIST prEN 18029:2024](https://standards.itih.ai/catalog/standards/sist/b7610eb1-dd0d-4f7f-840e-91c02cf0257a/osist-pren-18029-2024)

<https://standards.itih.ai/catalog/standards/sist/b7610eb1-dd0d-4f7f-840e-91c02cf0257a/osist-pren-18029-2024>

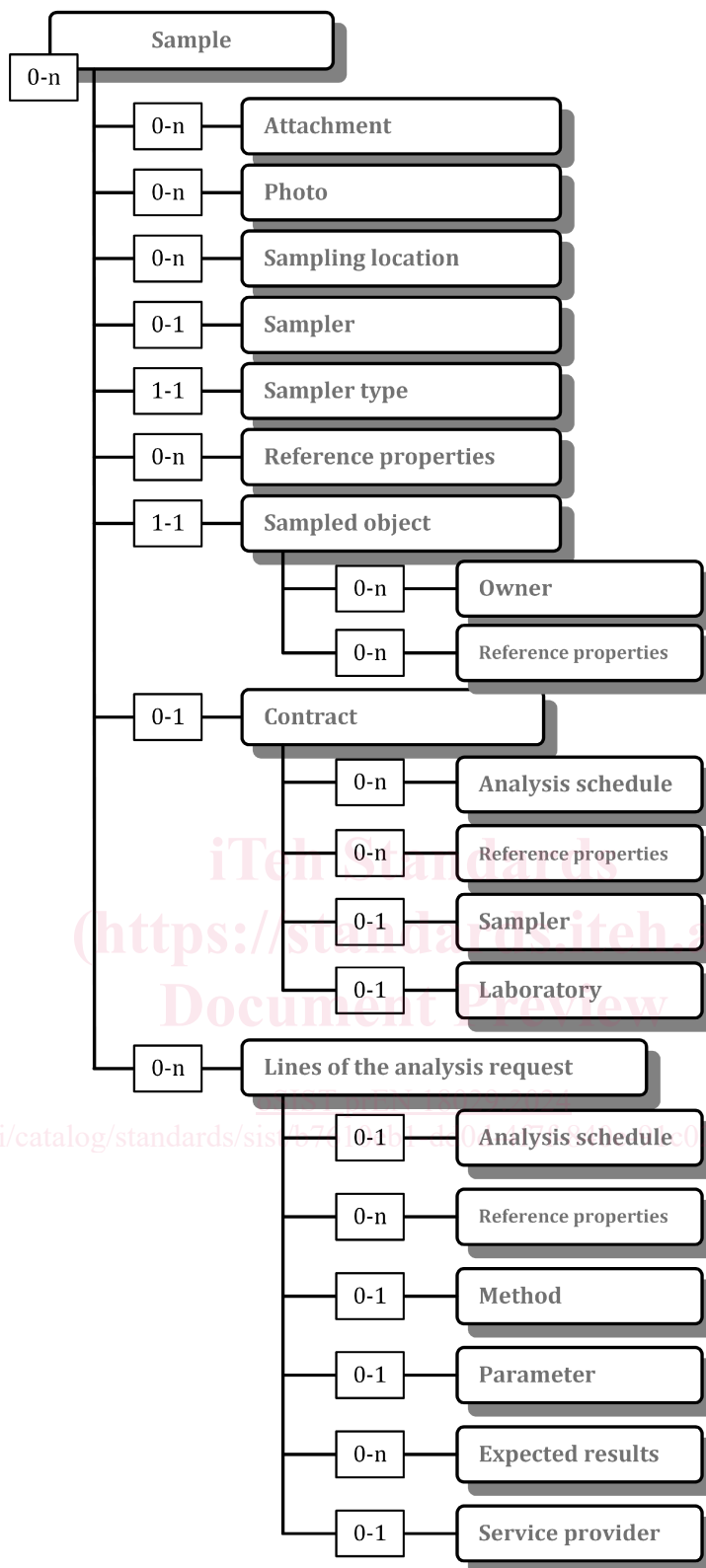


Figure 2 — The request file overview