

ETERNAL

Grant Agreement n°: **101057668**

Project acronym: **ETERNAL**

Project name: **Boosting the reduction of the environmental impact of pharmaceutical products throughout their entire life cycle.**

Start Date/Duration: 1st September 2022 /48 Months

Deliverable n° & Title: D6.7 Report on the standardization landscape and applicable standards

Due date: Month 6 (February 2023)

Participant responsible: **UNE**

Type of document		Dissemination Level	
Sensitive (SEN)		Document, report (R)	X
Public (PU)	X	OTHER	
		Websites, patent, filings, videos, etc (DEC)	
		Demonstrator, pilot, prototype (DEM)	

Version	Author	Date	Comments
1.0	UNE	17/02/2023	First draft
1.1	AIMPLAS	24/02/2023	Reviewed first draft
1.2	UNE	28/02/2023	Final version



This project has received funding from the European Union's Horizon Europe Framework Programme (HORIZON) under grant agreement No 101057668. This publication reflects only the author's view and that the Commission is not responsible for any use that may be made of the information it contains.

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1 Summary

This document is a deliverable of the ETERNAL project, funded under the European Union's Horizon Europe Framework programme (HORIZON) under grant agreement No 101057668.

The deliverable D6.7 is produced in the context of ETERNAL-WP6, Task 6.6 – Standardisation activities, in particular with regard to the subtask ST6.6.1 for the analysis of the applicable standardization landscape. This deliverable includes as main contribution the identification and analysis of the standardisation technical committees (TCs) at European and International standardisation level related with the ETERNAL project as well as the published standards (existing and under development) that can be relevant and useful for all the project activities. Using standards as a knowledge source in the earliest possible stages of research and innovation avoids duplication of work and provides the basis for future marketable products.

The Spanish Association for Standardisation (UNE), as a National Standardisation Body, is partner in the ETERNAL project to provide support regarding all the standardisation tasks included in the project. In order to fulfil this commitment, this deliverable has been prepared to guide the partners about the published standards and standards under development that can be applicable and are related to the ETERNAL/WP tasks.

This deliverable will also serve as source to identify, in the near future, the strategy for collaboration and communication with the relevant technical committees and the contribution to standardization in subtask ST6.6.2, and also to recognize the standardisation gaps that can be covered by the results of the project.

2 Glossary of Terms

The following terms and acronyms have been used in this report.

Table 1 Glossary of Terms

Term	Description / Definition
ASTM	American Society for Testing and Materials
CEN	European Committee for Standardization
CENELEC (CLC)	European Committee for Standardization in the Electrical field
CWA	CEN or CENELEC Workshop Agreement
EN	European Standard
ISO	International Organization for Standardization; International Standard
NSB	National Standardization Body
prEN	European Standard under development for public enquiry
SC	Subcommittee
TC	Technical Committee
TR	Technical Report
TS	Technical Specification
WG	Working Group
WI	Work Item
WP	Work Package
UNE	Spanish Association for Standardization

3 Introduction

The Deliverable D6.7 Report on the Standardization landscape and applicable standards contains a detailed study on the relevant Standardization Technical Committees on international and European level in the scope of the ETERNAL project activities as well as relevant standards developed in these committees.

The objective of including the standardization in the project is to facilitate the acceptance and utilisation by the market of the developed solutions. Other objectives are to provide starting information for other WPs, ensure compatibility and interoperability with what already exists in the market through standards, as well as to use the standardization system as a tool for the dissemination of the project results and the interaction with the market stakeholders.

This document contains:

- an overview on the relevant international and European standardization system;
- a detailed list of the standards and normative documents as well as standards and normative documents under development relevant for ETERNAL.

4 The context: ETERNAL project

ETERNAL will contribute to sustainable development of pharmaceutical manufacture, use and disposal, by using and promoting full life cycle approaches covering design, manufacture, usage, and disposal, assessing the environmental risks of not only active pharmaceutical ingredients and residues or metabolites, but other chemicals and by-products of the production process. In other words, safe and sustainable pharmaceutical lifecycles by design. The concept and expected project outcomes are shown in Figure 1. ETERNAL project concept.



Figure 1. ETERNAL project concept

In the ETERNAL project, standardization activities are employed to maximize the impact and to facilitate the acceptance and utilization by the market of the developed solutions. In order to provide starting information for other WPs, ensure compatibility and interoperability with what already exists in the market through standards, this document contains a list of standardization technical committees and standards relevant for the ETERNAL project. This document has been developed as result of subtask ST6.6.1 for the analysis of the applicable standardization landscape, corresponding to the WP6 "Project management and pathway to impact".

No official updates of this document are foreseen in the project plan, i.e. there will not be a deliverable corresponding to an update of this document. Nevertheless, a continuous follow-up of the activities of relevant Standardization Technical Committees and their standardization developments will be provided throughout the project lifetime.

The activities within the scope of ST.6.6.2 "Contribution to the ongoing and future standardization developments" which extends to the end of the project in M48 will be documented by means of an initial report (D6.8), an interim report (D6.15) and a final report (D6.16). The aim is to make the greatest possible contribution to standardization based on the results of the ETERNAL project.

5 Methodology of the document

5.1 Short introduction about standardization

Standards are voluntary technical documents that set out requirements for a specific item, material, component, system or service, or describes in detail a particular method, procedure or best practice. Standards are developed and defined through a process of sharing knowledge and building consensus among technical experts nominated by interested parties and other stakeholders - including businesses, consumers and environmental groups, among others. These experts are organized in Technical Committees (TCs), which are subdivided in Subcommittees (SCs) or Working Groups (WGs). These TCs are included in the structure of the Standardization Organizations (National, European and International, with the respective mirror committees) and work following their internal regulations.

The standardization bodies operate at National (UNE, AFNOR, BSI, DIN, etc.), Regional (CEN, CENELEC, ETSI) or International (ISO, IEC, ITU) level. Sometimes there are different standardization bodies at the same level but covering different fields. This is the case of ISO (general), IEC (electrical) and ITU (telecommunications) at International level, or CEN, CENELEC and ETSI at European level in the same way.

There are also different kinds of standardization documents. The most widespread is the standard, which has a different code depending on the organization under it was developed, e.g. EN for European Standards, ISO for International standards. Other types of documents are Technical Specifications (TS), Technical Reports (TR) and Workshop Agreements (CWA). Further Amendments to the standards are identified by adding A1, A2, etc. at the end of the standard code.

At European level, all the members of CEN shall adopt EN standards as national standards and have to withdraw any existing national standard which could conflict with them. A summary of the characteristics of the different standardization documents can be found in Table 2.

Table 2 Characteristics of different standardization documents

Type	International code	European code	National code	Main characteristics
Standard	ISO IEC	EN	UNE, NF, BS, DIN, UNI, etc. When adopting: UNE-EN, NF-EN, UNE-ISO, NF-ISO etc.	<ul style="list-style-type: none"> • Elaboration: 3 years • 2 steps of member approval • European: compulsory national adoption Review: every 5 years Revision: whenever needed and as result from a systematic review
Technical Specification	ISO/TS IEC/TS	CEN/TS CLC/TS	When adopting: UNE-CEN/TS, NF-CEN/TS, UNE-ISO/TS, NF-ISO/TS, etc.	<ul style="list-style-type: none"> • Elaboration: 21 months • 1 step of member approval or internal approval in TC • European: optional national adoption Review: after 3 years (upgrading to EN or deletion)
Technical Report	ISO/TR IEC/TR	CEN/TR CLC/TR	When adopting: UNE-CEN/TR, NF-CEN/TR, UNE-ISO/TR, NF-ISO/TR, etc.	<ul style="list-style-type: none"> • Elaboration: free timeframe • Internal approval in TC • European: optional national adoption No review required
Workshop Agreement	IWA	CWA	Variable	<ul style="list-style-type: none"> • Elaboration: free timeframe (usually few months) • Internal approval in the Workshop • European: optional national adoption Review: after 3 years (upgrading to EN or deletion)

There is also an agreement established between European and International Organizations (e.g. CEN and ISO, in this case is called Vienna Agreement) in order to avoid duplication of efforts and promote global relevance of standards, which allows to adopt or develop in parallel each other's standards with the same content and code.

National standards could also be proposed as a base for new European or International standards. Figure 2 shows possible tracks of standards adoption.

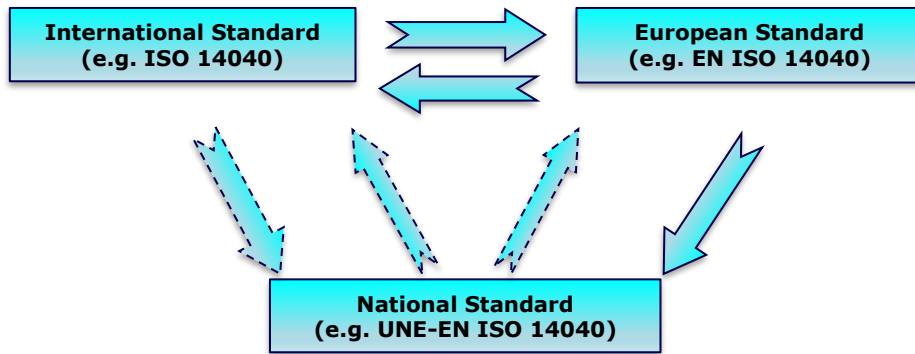


Figure 2. Possible tracks of standards adoption

Therefore, the code of any standard is the combination of the above mentioned issues, and could be explained as shown in Figure 3.

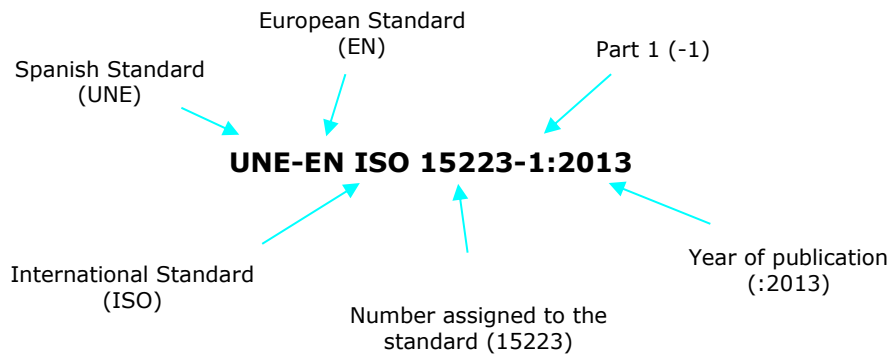


Figure 3. Example of identification of elements in the code of a standard

5.2 Methodology of the identification of relevant standardization areas

This document presents the standardization activity found relevant for the ETERNAL project. In order to structure the research, UNE and AIMPLAS jointly developed a list of key concepts, to act as a starting point for the identification of standardization areas.

For the selection of the key concepts, the aims and goals of the project and the levels in which the project should integrate were taken into account. Also, the needs of the Case Studies were considered.

The final list of key concepts used for the search is shown in Table 3:

Table 3 List of key concepts acting as a starting point for the identification of standardization areas

1	Manufacture: Pharmaceutical manufacture/ Green manufacturing/ Continuous manufacturing
2	Extrusion/compounding/ HME (Hot Melt Extrusion)/TSMEG (Twin screw melt granulation)/sonication/microfluidics/modular flow reactors/ microjet reactor/fermentation
3	Nanoformulations/ nanoparticles/nanoencapsulation/liposomes
4	Bio-based products/ Green solvents
5	Laboratory testing/ stability evaluation/Particle characterization/solvent analysis
6	IR/ Raman spectroscopy/NIR
7	Digitalization: DT (Digital Twins)
8	Digitalization: Machine learning/AI
9	Digitalization: Smart contracts
10	LCA/ Environmental assessment/ environmental risk assessment (ERA)
11	Environmental management/ Quality management/ energy management/ efficiency
12	Ecotoxicity/ toxicity/effluents/disposal/enzymatic degradation
13	Purification/ Membranes/column distillation/impurities capture/diafiltration
14	in-line quality control/PAT (Process analytical tools)

Standards and standards under development were identified for each standardization area, together with the technical committee responsible for the respective standards.

The standardization study covers European standardization developed by the European Committee for Standardization (CEN), the European Committee for electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI), and also the International standardization developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

ASTM (American Society for Testing and Materials) standards have also been considered as several have been identified that address issues of great relevance to the project.

The first result of the research carried out by UNE was shared with the Project Coordinator, AIMPLAS, who was asked to select the interesting documents and to add other interesting missing standards. Then, the submitted feedback was compiled and the list of documents and technical committees was updated according to the Project’s Coordinator expert contribution. The final result of the ETERNAL standardization landscape is described in the section 6 “Standardization related to ETERNAL project” of this deliverable.

6 Standardization related to ETERNAL project

For a better overview of this report, the study has been structured in main technical areas. The relevant standardization technical committees (TCs), the published standards and the standards under development have been clustered within each of these areas.

6.1 Standardization committees' overview

The standards search was carried out considering the agreed key concept list (see Table 3 in section 5.2), and, as a result, several standardization committees were identified as responsible of the development of these standards. These technical committees were therefore selected as the main technical committees in relation to the ETERNAL Project, and they are shown in Table 4 clustered by technical area:

Table 4 Relevant standardization committees for ETERNAL

Technical area	Standardization Technical Committees
Efficient manufacturing	ISO/TC 184 - Automation systems and integration ISO/TC 301 - Energy management and energy savings CEN/CLC/JTC 14 - Energy management and energy efficiency in the framework of energy transition ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products
Digitalization	ISO/IEC JTC 1/SC 41 Internet of things and digital twin ISO/IEC JTC 1/SC 42 Artificial intelligence ISO/TC 184 Automation systems and integration
Ecotoxicity	ISO/TC 282 Water reuse ISO/TC 147 Water quality CEN/TC 230 Water analysis
Environmental aspects	ISO/TC 207/SC 5 Life cycle assessment CEN/CLC/JTC 10 Material efficiency aspects for products in scope of Ecodesign legislation ISO/TC 61 Plastics CEN/TC 249 Plastics
Laboratory testing	ISO/TC 24/SC 4 Particle characterization ISO/TC 201 Surface chemical analysis ISO/TC 48 Laboratory equipment CEN/TC 332 Laboratory equipment
Bio-based products	CEN/TC 411 Bio-based products
Nanotechnologies	ISO/TC 229 Nanotechnologies CEN/TC 352 Nanotechnologies

6.2 Standardization on Efficient manufacturing

Technical committees

ISO/TC 184 - Automation systems and integration

Standardization in the field of automation systems and their integration for design, sourcing, manufacturing, production and delivery, support, maintenance and disposal of products and their associated services. Areas of standardization include information systems, automation and control systems and integration technologies.

The substructure of ISO/TC 184 "Automation systems and integration" is:

- ISO/TC 184/SC 1 Industrial cyber and physical device control
- ISO/TC 184/SC 4 Industrial data
- ISO/TC 184/SC 5 Interoperability, integration, and architectures for enterprise systems and automation applications

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

ISO/TC 301 - Energy management and energy savings

Standardization in the field of energy management and energy savings.

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

CEN/CLC/JTC 14 - Energy management and energy efficiency in the framework of energy transition

Standardization in the field of energy management within the energy transition framework in close coordination with CEN/CENELEC sectorial strategy including, but not limited to, subjects such as:

- Energy management systems
- Energy audits
- Energy efficiency and energy performance improvement
- Energy and savings calculation methodologies
- Energy efficiency improvement financing (For example: Valuation of Energy Related Investments, Energy Performance Contracting minimum requirements, etc.)
- Energy services providers
- Energy measurement and monitoring
- Role of enabling technologies and RES within the energy management and energy efficiency framework

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products

ASTM Committee E55 addresses issues related to process control, design, and performance, as well as quality acceptance/assurance tests for the pharmaceutical manufacturing industry. Stakeholders include manufacturers of pharmaceuticals and pharmaceutical equipment, federal

agencies, design professionals, professional societies, trade associations, financial organizations, and academia.

Information on this subcommittee structure and E55's portfolio of approved standards and Work Items under construction are available [here](#).

Standards to be considered

Table 5 Standards to be considered: Efficient manufacturing

Smart manufacturing	
Standard reference	Title
ISO/IEC TR 63306-1:2020	Smart manufacturing standards map (SM2) – Part 1: Framework
ISO/IEC TR 63306-2:2021	Smart manufacturing standards map (SM2) – Part 2: Catalogue
ISO 10303-1:2021	Industrial automation systems and integration – Product data representation and exchange – Part 1: Overview and fundamental principles
ISO 22400-1:2014	Automation systems and integration – Key performance indicators (KPIs) for manufacturing operations management – Part 1: Overview, concepts and terminology
ASTM E2475-10(2016)	Standard Guide for Process Understanding Related to Pharmaceutical Manufacture and Control
ASTM E2476-22	Standard Guide for Risk Assessment and Risk Control as it Impacts the Design, Development, and Operation of PAT Processes for Pharmaceutical Manufacture
ASTM E2629-20	Standard Guide for Verification of Process Analytical Technology (PAT) Enabled Control Systems
ASTM E2891-20	Standard Guide for Multivariate Data Analysis in Pharmaceutical Development and Manufacturing Applications
ASTM E2898-20a	Standard Guide for Risk-Based Validation of Analytical Methods for PAT Applications
ASTM E2968-14	Standard Guide for Application of Continuous Processing in the Pharmaceutical Industry
ASTM E3177-18	Standard Guide on Sampling for Process Analytical Technology
Efficient energy management	
Standard reference	Title
ISO 20140-1:2019	Automation systems and integration – Evaluating energy efficiency and other factors of manufacturing systems that influence the environment – Part 1: Overview and general principles
ISO 20140-2:2018	Automation systems and integration – Evaluating energy efficiency and other factors of manufacturing systems that influence the environment – Part 2: Environmental performance evaluation process
ISO 20140-3:2019	Automation systems and integration – Evaluating energy efficiency and other factors of manufacturing systems that influence the environment – Part 3: Environmental performance evaluation data aggregation process
ISO 20140-5:2017	Automation systems and integration – Evaluating energy efficiency and other factors of manufacturing systems that influence the environment – Part 5: Environmental performance evaluation data

EN 16212:2012	Energy Efficiency and Savings Calculation, Top-down and Bottom-up Methods
EN 16231:2012	Energy efficiency benchmarking methodology
EN 17463:2021	Valuation of Energy Related Investments (VALERI)
ISO 50001:2018	Energy management systems - Requirements with guidance for use
EN 17267:2019	Energy measurement and monitoring plan - Design and implementation - Principles for energy data collection
ISO 50005:2021	Energy management systems - Guidelines for a phased implementation
ISO/IEC 13273-1:2015	Energy efficiency and renewable energy sources — Common international terminology — Part 1: Energy efficiency
ISO/IEC 13273-2:2015	Energy efficiency and renewable energy sources — Common international terminology — Part 2: Renewable energy sources
ISO 17741:2016	General technical rules for measurement, calculation and verification of energy savings of projects
ISO 17743:2016	Energy savings — Definition of a methodological framework applicable to calculation and reporting on energy savings
ISO 50001:2018	Energy management systems — Requirements with guidance for use
ISO 50004:2020	Energy management systems — Guidance for the implementation, maintenance and improvement of an ISO 50001 energy management system
ISO/TS 50008:2018	Energy management and energy savings — Building energy data management for energy performance — Guidance for a systemic data exchange approach
ISO/PAS 50010:2023	Energy management and energy savings — Guidance for net zero energy in operations using an ISO 50001 energy management system
ISO 50021:2019	Energy management and energy savings — General guidelines for selecting energy savings evaluators
ISO/TS 50044:2019	Energy saving projects (EnSPs) — Guidelines for economic and financial evaluation
ISO 50046:2019	General methods for predicting energy savings
ISO 50047:2016	Energy savings — Determination of energy savings in organizations

Standards under development to be considered

Table 6 Standards under development to be considered: Efficient manufacturing

Smart manufacturing	
Standard reference	Title
IEC/AWI TR 65815	Unified reference model for smart manufacturing
ISO/CD 10303-1	Industrial automation systems and integration — Product data representation and exchange — Part 1: Overview and fundamental principles
Efficient energy management	
Standard reference	Title
ISO/FDIS 50006	Energy management systems — Evaluating energy performance using energy performance indicators and energy baselines
ISO/DTS 50011	Energy management systems — Assessing energy management using ISO 50001:2018

ISO/CD 20140-5.2	Automation systems and integration — Evaluating energy efficiency and other factors of manufacturing systems that influence the environment — Part 5: Environmental performance evaluation data
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6.3 Standardization on Digitalization

Technical committees

ISO/IEC JTC 1/SC 41 Internet of things and digital twin

Standardization in the area of Internet of Things and Digital Twin, including their related technologies.

- Serve as the focus and proponent for JTC 1's standardization programme on the Internet of Things and Digital Twin, including their related technologies.
- Provide guidance to JTC 1, IEC, ISO and other entities developing Internet of Things and Digital Twin related applications.

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

ISO/IEC JTC 1/SC 42 Artificial intelligence

Standardization in the area of Artificial Intelligence:

- Serve as the focus and proponent for JTC 1's standardization program on Artificial Intelligence
- Provide guidance to JTC 1, IEC, and ISO committees developing Artificial Intelligence applications

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

ISO/TC 184 - Automation systems and integration

(See 6.2).

Standards to be considered

Table 7 Standards to be considered: Digitalization

Artificial intelligence	
Standard reference	Title
ISO/IEC TS 4213:2022	Information technology — Artificial intelligence — Assessment of machine learning classification performance
ISO/IEC TR 24027:2021	Information technology — Artificial intelligence (AI) — Bias in AI systems and AI aided decision making
ISO/IEC 24668:2022	Information technology — Artificial intelligence — Process management framework for big data analytics
Digital Twins	
Standard reference	Title

ISO 23247-1:2021	Automation systems and integration — Digital twin framework for manufacturing — Part 1: Overview and general principles
ISO 23247-2:2021	Automation systems and integration — Digital twin framework for manufacturing — Part 2: Reference architecture
ISO 23247-3:2021	Automation systems and integration — Digital twin framework for manufacturing — Part 3: Digital representation of manufacturing elements
ISO 23247-4:2021	Automation systems and integration — Digital twin framework for manufacturing — Part 4: Information exchange
ISO/TR 24464:2020	Automation systems and integration — Industrial data — Visualization elements of digital twins

Standards under development to be considered

Table 8 Standards under development to be considered: Digitalization

Digital Twins	
Standard reference	Title
ISO/IEC AWI 30172	Digital Twin — Use cases
ISO/IEC AWI 30173	Digital twin — Concepts and terminology

6.4 Standardization on Ecotoxicity

Technical committees

ISO/TC 282 Water reuse

Standardization of water reuse of any kind and for any purpose. It covers both centralized and decentralized or on-site water reclamation, and direct and indirect reuse applications, taking into consideration the potential for unintentional exposure or ingestion. It includes technical, economic, environmental and societal aspects of water reuse. Water reuse comprises a sequence of the stages and operations involved in collection, conveyance, processing, storage, distribution, consumption, drainage and other handling of wastewater, and treated effluent, including water that is reused in repeated, cascaded and recycled ways.

The substructure of ISO/TC 282 “Water reuse” is:

- ISO/TC 282/SC 1 Treated wastewater reuse for irrigation
- ISO/TC 282/SC 2 Water reuse in urban areas
- ISO/TC 282/SC 3 Risk and performance evaluation of water reuse systems
- ISO/TC 282/SC 4 Industrial water reuse

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

ISO/TC 147 Water quality

Standardization in the field of water quality, including definition of terms, sampling of waters, measurement and reporting of water characteristics.

The substructure of ISO/TC 147 “Water quality” is:

- ISO/TC 147/SC 1 Terminology
- ISO/TC 147/SC 2 Physical, chemical and biochemical methods

- ISO/TC 147/SC 3 Radioactivity measurements
- ISO/TC 147/SC 4 Microbiological methods
- ISO/TC 147/SC 5 Biological methods
- ISO/TC 147/SC 6 Sampling (general methods)

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

CEN/TC 230 Water analysis

Standardization in the area of water analysis including: definition of terms; sampling of water; measurement; reporting.

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

Standards to be considered

Table 9 Standards to be considered: Ecotoxicity

Toxicity - Water	
Standard reference	Title
ISO 20426:2018	Guidelines for health risk assessment and management for non-potable water reuse
ISO 20469:2018	Guidelines for water quality grade classification for water reuse
ISO 22447:2019	Industrial wastewater classification
EN 16101:2012	Water quality - Guidance standard on interlaboratory comparison studies for ecological assessment
ISO 21676:2018	Water quality — Determination of the dissolved fraction of selected active pharmaceutical ingredients, transformation products and other organic substances in water and treated waste water — Method using high performance liquid chromatography and mass spectrometric detection (HPLC-MS/MS or -HRMS) after direct injection
ISO 5815-2:2003	Water quality — Determination of biochemical oxygen demand after n days (BOD _n) — Part 2: Method for undiluted samples
ISO 5815-1:2019	Water quality — Determination of biochemical oxygen demand after n days (BOD _n) — Part 1: Dilution and seeding method with allylthiourea addition
ISO 9439:1999	Water quality — Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium — Carbon dioxide evolution test
ISO 9887:1992	Water quality — Evaluation of the aerobic biodegradability of organic compounds in an aqueous medium — Semi-continuous activated sludge method (SCAS)
ISO 9888:1999	Water quality — Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium — Static test (Zahn-Wellens method)
ISO 11733:2004	Water quality — Determination of the elimination and biodegradability of organic compounds in an aqueous medium — Activated sludge simulation test
ISO 14592-1:2002	Water quality — Evaluation of the aerobic biodegradability of organic compounds at low concentrations — Part 1: Shake-flask batch test with surface water or surface water/sediment suspensions

ISO 14592-2:2002	Water quality — Evaluation of the aerobic biodegradability of organic compounds at low concentrations — Part 2: Continuous flow river model with attached biomass
ISO/TR 15462:2006	Water quality — Selection of tests for biodegradability
ISO 16221:2001	Water quality — Guidance for determination of biodegradability in the marine environment

Standards under development to be considered

Table 10 Standards under development to be considered: Ecotoxicity

Toxicity - Water	
Standard reference	Title
ISO/CD 5667-27	Water quality — Sampling — Part 27: Sampling for microplastic particles and fibres in water

6.5 Standardization on Environmental aspects

Technical committees

ISO/TC 207/SC 5 Life cycle assessment

Standardization in the field of life cycle assessment and related environmental management tools for products and organizations. It includes life cycle based resource efficiency and eco-efficiency assessment, and encompasses consideration of a life cycle perspective in the assessment of impacts from the extraction of raw materials to the final disposal of waste.

The homepage of the technical committee SC with further information can be found [here](#).

CEN/CLC/JTC 10 Material efficiency aspects for products in scope of Ecodesign legislation

Material efficiency aspects for products in scope of the Ecodesign Directive 2009/125/EC and its future revisions.

Producing generic and horizontal CEN-CENELEC publications covering aspects such as assessment methods, design rules, dematerialization, digitalization and transfer of information on a variety of material efficiency topics, in particular (but not limited to):

- Extending product lifetime
- Ability to reuse components or recycle materials* from products at End-of-Life
- Use of reused components and/or recycled materials* in products

* Includes coverage of the European Commission defined list of Critical Raw Materials (CRM).

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

ISO/TC 61 - Plastics

Standardization of nomenclature, methods of test, and specifications applicable to materials and products in the field of plastics including processing (of products) by assembly in particular, but not limited to, polymeric adhesives, sealing, joining, welding.

The substructure of ISO/TC 61 "Plastics" is:

- ISO/TC 61/SC 1 Terminology
- ISO/TC 61/SC 2 Mechanical behaviour
- ISO/TC 61/SC 4 Burning behaviour
- ISO/TC 61/SC 5 Physical-chemical properties
- ISO/TC 61/SC 6 Ageing, chemical and environmental resistance
- ISO/TC 61/SC 9 Thermoplastic materials
- ISO/TC 61/SC 10 Cellular plastics
- ISO/TC 61/SC 11 Products
- ISO/TC 61/SC 12 Thermosetting materials
- ISO/TC 61/SC 13 Composites and reinforcement fibres
- ISO/TC 61/SC 14 Environmental aspects

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

CEN/TC 249 Plastics

Standardization of: 1) terminology, 2) test methods, 3) specifications, classifications and designation systems, 4) environmental aspects, 5) joining systems and techniques, of plastics, plastic-based materials, semi-finished products and products (thermoplastics, thermosets, degradable plastics, bio-based polymers, thermoplastic elastomers, composites, reinforcement products for plastics, recyclates).

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

Standards to be considered

Table 11 Standards to be considered: Environmental aspects

Life Cycle Assessment (LCA)	
Standard reference	Title
ISO 14040:2006	Environmental management – Life cycle assessment – Principles and framework
ISO 14040:2006/Amd 1:2020	Environmental management – Life cycle assessment – Principles and framework – Amendment 1
ISO 14044:2006	Environmental management – Life cycle assessment – Requirements and guidelines
ISO 14044:2006/Amd 1:2017	Environmental management – Life cycle assessment – Requirements and guidelines – Amendment 1
ISO 14044:2006/Amd 2:2020	Environmental management – Life cycle assessment – Requirements and guidelines – Amendment 2
ISO 14045:2012	Environmental management – Eco-efficiency assessment of product systems – Principles, requirements and guidelines
ISO 14046:2014	Environmental management – Water footprint – Principles, requirements and guidelines
ISO/TR 14047:2012	Environmental management – Life cycle assessment – Illustrative examples on how to apply ISO 14044 to impact assessment situations
ISO/TS 14048:2002	Environmental management – Life cycle assessment – Data documentation format

ISO/TR 14049:2012	Environmental management — Life cycle assessment — Illustrative examples on how to apply ISO 14044 to goal and scope definition and inventory analysis
ISO/TS 14071:2014	Environmental management — Life cycle assessment — Critical review processes and reviewer competencies: Additional requirements and guidelines to ISO 14044:2006
ISO/TS 14072:2014	Environmental management — Life cycle assessment — Requirements and guidelines for organizational life cycle assessment
ISO/TR 14073:2017	Environmental management — Water footprint — Illustrative examples on how to apply ISO 14046
ISO/TS 14074:2022	Environmental management — Life cycle assessment — Principles, requirements and guidelines for normalization, weighting and interpretation
Plastics biodegradability	
Standard reference	Title
ISO 14851:2019	Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium - Method by measuring the oxygen demand in a closed respirometer
ISO 14855-1:2012	Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions - Method by analysis of evolved carbon dioxide - Part 1: General method
ISO 22766:2020	Plastics - Determination of the degree of disintegration of plastic materials in marine habitats under real field conditions

Standards under development to be considered

Table 12 Standards under development to be considered: Environmental aspects

Life Cycle Assessment (LCA)	
Standard reference	Title
ISO/CD 14071	Environmental management — Life cycle assessment — Critical review processes and reviewer competencies: Additional requirements and guidelines to ISO 14044:2006
ISO/CD 14072	Environmental management — Life cycle assessment — Requirements and guidelines for organizational life cycle assessment
ISO/CD 14075	Principles and framework for social life cycle assessment
prEN 45560	Method to achieve circular designs of products
Plastics biodegradability	
Standard reference	Title
ISO/DIS 24187:2021	Principles for the analysis of plastics and microplastics present in the environment

6.6 Standardization on Laboratory testing

Technical committees

ISO/TC 24/SC 4 Particle characterization

Standardization pertaining to equipment and methods used in characterization or size classification of particulate material, where particles may be considered to include grains, flakes, fibres, droplets, bubbles or pores from the nanometre to the millimetre scale.

Covering the following:

- Particle and particle ensemble characterization, mainly by determination of physical properties of the particles including, for example, size distribution, particle shape and morphology, weight, density, surface area or porosity, and mobility;
- Particle systems characterization comprises particle-fluid and particle-particle interactions in suspensions, emulsions, aerosols or powders by determining their properties including concentration, electric charge, zeta potential, state of agglomeration, stability and rheology.

Each of the above areas will comprise standardization in the field of laboratory or process environment including terminology, reference materials, guidance for sampling, sample preparation, interpretation of results and uncertainty determination.

The homepage of technical committee with further information on, for example, the Business Plan can be found [here](#).

ISO/TC 201 Surface chemical analysis

Standardization in the field of surface chemical analysis. Surface chemical analysis includes analytical techniques in which beams of electrons, ions, neutral atoms or molecules, or photons are incident on the specimen material and scattered or emitted electrons, ions, neutral atoms or molecules, or photons are detected. It also includes techniques in which probes are scanned over the surface and surface-related signals are detected.

The substructure of ISO/TC 201 "Surface chemical analysis" is:

- ISO/TC 201/SC 1 Terminology
- ISO/TC 201/SC 2 General procedures
- ISO/TC 201/SC 3 Data management and treatment
- ISO/TC 201/SC 4 Depth profiling
- ISO/TC 201/SC 6 Secondary ion mass spectrometry
- ISO/TC 201/SC 7 Electron spectroscopies
- ISO/TC 201/SC 8 Glow discharge spectroscopy
- ISO/TC 201/SC 9 Scanning probe microscopy
- ISO/TC 201/SC 10 X-ray Reflectometry (XRR) and X-ray Fluorescence (XRF) Analysis

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

ISO/TC 48 Laboratory equipment

Standardization of devices and furniture for laboratory purposes, with respect to principles and to materials of construction, performance, dimensions and testing, as well as the terms and definitions used in connection therewith.

The standardization of laboratory devices includes laboratory supplies, apparatus, electrical and non-electrical instruments.

The standardization of laboratory furniture includes benches, specialist seating, laboratory storage units, media supply, taps, fittings and fume cupboards.

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

CEN/TC 332 Laboratory equipment

Standardization of laboratory equipment except the following exclusions: - Electrical safety and electromagnetic compatibility; - Basic laboratory furniture; - Apparatus and equipment exclusively intended for biotechnological or in vivo and in vitro diagnostic use for medical applications.

The homepage of technical committee with further information on, for example, the Business Plan of the TC can be found [here](#).

Standards to be considered

Table 13 Standards to be considered: Laboratory testing

Particle characterization	
Standard reference	Title
ISO/TS 4807:2022	Reference materials for particle size measurement — Specification of requirements
ISO 9277:2022	Determination of the specific surface area of solids by gas adsorption — BET method
ISO/TR 13097:2013	Guidelines for the characterization of dispersion stability
ISO 13320:2020	Particle size analysis — Laser diffraction methods
ISO 22412:2017	Particle size analysis — Dynamic light scattering (DLS)
ISO/TR 22814:2020	Good practice for dynamic light scattering (DLS) measurements
Others	
Standard reference	Title
ISO 18115-1:2013	Surface chemical analysis — Vocabulary — Part 1: General terms and terms used in spectroscopy
ISO 22916:2022	Microfluidic devices — Interoperability requirements for dimensions, connections and initial device classification

Standards under development to be considered

Table 14 Standards under development to be considered: Laboratory testing

Particle characterization	
Standard reference	Title

ISO 21501-4:2018/Amd 1	Determination of particle size distribution — Single particle light interaction methods — Part 4: Light scattering airborne particle counter for clean spaces — Amendment 1
ISO/CD TS 5973	Good practice for laser diffraction measurements
ISO/FDIS 23484	Determination of particle concentration by small-angle X-ray scattering (SAXS)
ISO/WD 22412	Particle size analysis — Dynamic light scattering (DLS)
Others	
Standard reference	Title
ISO/CD TS 6417	Microfluidic pumps — Symbols and performance communication
ISO/DIS 10991	Microfluidics — Vocabulary

6.7 Standardization on Bio-based products

Technical committees

CEN/TC 411 Bio-based products

- i. Development of standards for bio-based products covering horizontal aspects. This includes consistent terminology, sampling, certification tools, bio-based content, application of and correlation towards life cycle analysis, sustainability criteria for biomass used and for final products, and aspects where further harmonization is needed on horizontal level;
- ii. Development of standards for bio-solvents, covering product functionality, biodegradability and, if necessary, product specific aspects not covered under i.

The homepage of technical committee with further information on, for example, the Business Plan can be found [here](#).

Standards to be considered

Table 15 Standards to be considered: Bio-based products

Bio-based products - Sustainability	
Standard reference	Title
CEN/TR 16957:2016	Bio-based products - Guidelines for Life Cycle Inventory (LCI) for the End-of-life phase
CEN/TR 17341:2019	Bio-based products - Examples of reporting on sustainability criteria
EN 16751:2016	Bio-based products - Sustainability criteria
EN 16760:2015	Bio-based products - Life Cycle Assessment
EN 16935:2017	Bio-based products - Requirements for Business-to-Consumer communication and claims

6.8 Standardization on Nanotechnologies

Technical committees

ISO/TC 229 Nanotechnologies

Standardization in the field of nanotechnologies that includes either or both of the following:

1. Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications,
2. Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties.

Specific tasks include developing standards for: terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulations; and science-based health, safety, and environmental practices.

The homepage of technical committee with further information on, for example, the Business Plan can be found [here](#).

CEN/TC 352 Nanotechnologies

Standardization in the field of nanotechnologies that includes either or both of the following:

- i. understanding and control of matter and processes at the nanoscale, typically, but not exclusively below 100 nanometres in one or more dimensions, where the onset of size dependent phenomena usually enables novel applications;
- ii. utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules or bulk matter, to create improved materials, devices and systems that exploit these new properties.

Specific tasks include developing standards for: classification, terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; science-based health, safety and environmental practices; and nanotechnology products and processes. Standards in each of these areas could be specific to a product, process or industry.

The homepage of technical committee with further information on, for example, the Business Plan can be found [here](#).

Standards to be considered

Table 16 Standards to be considered: Nanotechnologies

Nanotechnologies	
Standard reference	Title
CEN/TS 16937:2016	Nanotechnologies - Guidance for the responsible development of nanotechnologies
CEN/TS 17275:2018	Nanotechnologies - Guidelines for the management and disposal of waste from the manufacturing and processing of manufactured nano-objects
CEN/TS 17276:2018	Nanotechnologies - Guidelines for Life Cycle Assessment - Application of EN ISO 14044:2006 to Manufactured Nanomaterials
ISO/TR 11360:2010	Nanotechnologies — Methodology for the classification and categorization of nanomaterials
ISO/TS 12025:2021	Nanomaterials — Quantification of nano-object release from powders by generation of aerosols
ISO/TR 12885:2018	Nanotechnologies — Health and safety practices in occupational settings
ISO/TR 13121:2011	Nanotechnologies — Nanomaterial risk evaluation

ISO/TR 13329:2012	Nanomaterials — Preparation of material safety data sheet (MSDS)
ISO/TS 13830:2013	Nanotechnologies — Guidance on voluntary labelling for consumer products containing manufactured nano-objects
ISO 17200:2020	Nanotechnology — Nanoparticles in powder form — Characteristics and measurements
ISO/TS 19337:2016	Nanotechnologies — Characteristics of working suspensions of nano-objects for in vitro assays to evaluate inherent nano-object toxicity
ISO 19749:2021	Nanotechnologies — Measurements of particle size and shape distributions by scanning electron microscopy
ISO/TS 21357:2022	Nanotechnologies — Evaluation of the mean size of nano-objects in liquid dispersions by static multiple light scattering (SMLS)
ISO 21363:2020	Nanotechnologies — Measurements of particle size and shape distributions by transmission electron microscopy
ISO/TS 80004-5:2011	Nanotechnologies — Vocabulary — Part 5: Nano/bio interface
ISO/TS 80004-7:2011	Nanotechnologies — Vocabulary — Part 7: Diagnostics and therapeutics for healthcare
ISO/TS 80004-8:2020	Nanotechnologies — Vocabulary — Part 8: Nanomanufacturing processes

Standards under development to be considered

Table 17 Standards under development to be considered: Nanotechnologies

Nanotechnologies	
Standard reference	Title
ISO/AWI TS 4958	Nanotechnologies — Liposomes terminology
ISO/AWI 4962	Nanotechnologies — In vitro nanoparticle acute phototoxicity assay
ISO/DIS 19337	Nanotechnologies — Characteristics of working suspensions of nano-objects for in vitro assays to evaluate inherent nano-object toxicity
ISO/AWI 21362	Nanotechnologies — Analysis of nano-objects using asymmetrical-flow and centrifugal field-flow fractionation
ISO/CD TS 24672.2	Nanotechnologies — Guidance on the measurement of nanoparticle number concentration

7 Conclusions and perspectives

This report brings together the technical standardization committees of interest for the ETERNAL project at European and international level on the basis of a detailed analysis carried out with input from the Project Coordinator AIMPLAS. By making this report available, the awareness of all partners in the project is raised that there is an extensive basis of potentially relevant standards. This can also prevent any duplication of work.

This document D6.7 as result of the subtask ST6.6.1 forms the basis for the activities of subtask ST6.6.2 on the contribution to the ongoing and future standardization developments, which extends to the end of the project. The developments within the relevant technical committees will be monitored and reported to the project partners. This information will be included in deliverables: "D6.8 Report on the contribution to standardization" (M12), "D6.15 First update of Report on the contribution to standardization" (M30) and "D6.16 Second update of Report on the contribution to standardization" (M48).

Subtask ST6.6.2 will now aim to investigate the standardization potential of the results being generated in ETERNAL, enabling the project to interact with the related technical standardization committees, assessing to what extent the relationships with the committees should be and using the standardization system as a rapid and much more focused dissemination tool to market stakeholders.

Based on the above results, ETERNAL will seek if there is an option to contribute to the development of new standards on specific topics, related to the project objectives. In case the inclusion of the project results in new or future standards that can be easily used by European or international industry and research is achieved, it will increase the impact of the project and contribute positively to the transfer of the knowledge generated in the framework of the project to industry and society.

In order to be able to use the standardisation system as a tool for dissemination of project results and interaction with market actors, it will be necessary to decide on the type of interaction with the technical standardisation committees relevant to ETERNAL (see Table 4). UNE will provide the necessary technical support for such interaction.

Specific tasks may be performed in relation with the standardisation works of the identified TCs. Depending on the assessment by ETERNAL partners of the impact of the identified standardisation TCs on their tasks and the level of contribution that their results can represent for these committees, several actions can be performed, for example:

- the follow up of the standardisation activity through updates reported by UNE, supported by the technical partners;
- the dissemination of the ETERNAL project progress by delivering reports to the relevant TCs Secretaries or by attending relevant technical committees' meetings;
- the proposal of standardisation activities to relevant TCs, e.g. revision or modification of existing standards, participation in the development of ongoing standards, proposals of new standards, etc. In the case of new standards, the most appropriate option in the framework of a Horizon Europe project is the development of fast-track standards, such as CEN-CENELEC Workshop Agreements (CWA).

Consequently, the following objectives have been achieved with the production of this deliverable:

- Identification of documents (Standards, Technical Specifications and Technical Reports) that can be directly applied in the ETERNAL activities, or/and that can be used as valuable information source.

- Identification of relevant standardization Technical Committees for ETERNAL project, allowing the monitorization of their future activities.
- Awareness of the present standardization framework around the ETERNAL knowledge areas, that will allow in the next steps to identify possible contributions of the ETERNAL project to the on-going and future standardization developments.
- Insight into the state of the art, that will be the base for the specification of a ETERNAL strategy concerning its interaction with the European standardisation system

8 References

- ASTM Website (www.astm.org)
- CEN Website (www.cen.eu)
- CENELEC Website (www.cenelec.eu)
- CEN/CENELEC Projex Online database (projex.cen.eu) (restricted to authorized users)
- ISO Website (www.iso.org)
- ISO Project Portal (isotc.iso.org) (restricted to authorized users)
- IEC Website (www.iec.ch)