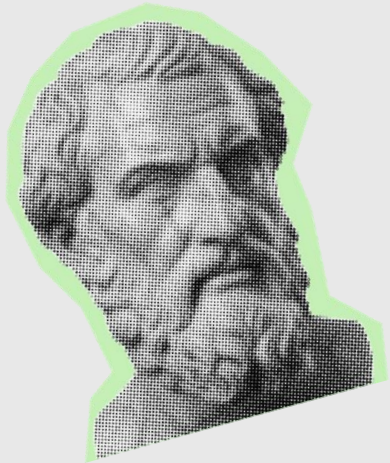
Webinar

Harmonised standards for the AI Act

Helping you make AI Act compliance simple

02.09.2026 / 14:00 – 15:00



Harmonised standards for the AI Act

Helping you make AI Act compliance simple

2 September 2026

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Digital Austria

European Commission

Agenda

- Why we are here today
- What is a harmonised standard?
- Diving into the presumption of conformity
- How to read a harmonised standard
- Applying harmonised standards
- Deep dive: EN 18228:2026 for quality management
- Overview and timeline of harmonised standards
- Further information
- Questions and discussion

Why we are here today

We empower Austria‘s digital transformation

AI Act
+ national implementation

Austrian AI Strategy
AIM AT 2030

Austrian Data Strategy

Grants4Companies

AI Literacy Programme

Measures in support of innovation (AI Act)

AIM AT 2030 Implementation Plan 2024

AI Marketplace (aws)

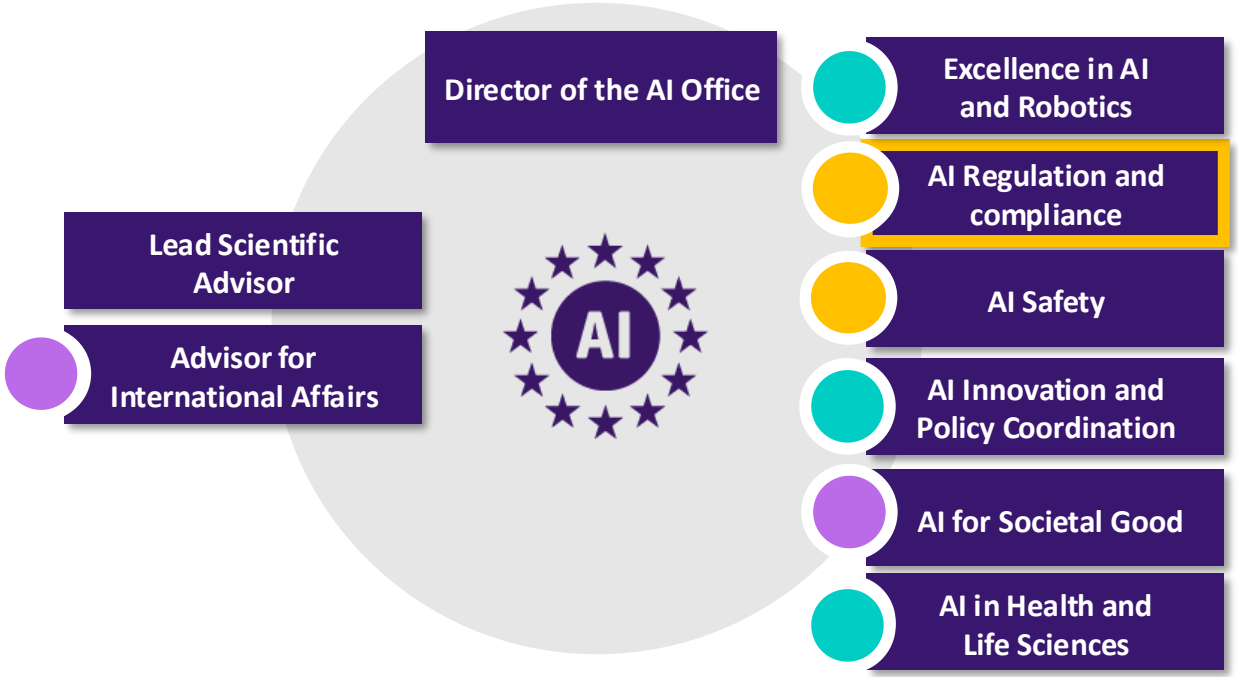
Labelling of AI systems in federal government

AI Monitor

The EU Commission's AI Office

360-degree vision on AI:

- Key role in the implementation of the AI Act
- Fosters research and innovation in trustworthy AI
- Positions the EU as a leader in international discussions and contributor to AI for good



What is a harmonised standard?

Diving into the presumption of conformity

What is a standard?

- **Standard** (Regulation 1025/2012)

  A technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory

  - International standards
  - European standards
  - Harmonised standards
  - National standards

- **Technical Specification** (Regulation 1025/2012)

  A document that prescribes technical requirements to be fulfilled by a product, process, service or system

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Legislation vs. Standards

Legislation (AI Act)

- Adopted by a public authority
- **Mandatory application**
- Specify legal obligations
- In product safety legislation:
  - Specify essential requirements
  - Only **safe** or otherwise **compliant** products may enter the EU market
  - Do not specify technical solutions

European Standards

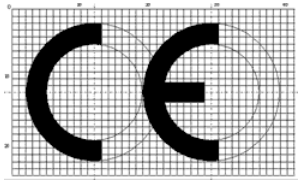
- Prepared by interested parties and adopted by recognised standardisation bodies (e.g. CEN, CENELEC, ETSI)
- Based on principles of openness, transparency, consensus
- **Voluntary use**
- Specify technical solutions
- In product safety legislation:
  - Harmonised standards **operationalise** legal requirements

The gap between legal and technical is bridged using **Harmonised Standards (hENs)**

Harmonised standards

- A **Harmonised standard** is a European standard adopted specifically on the basis of a **Standardisation Request (SR)** by the European Commission

- Harmonised standards may give **Presumption of Conformity (PoC)**
  - Clear technical path to achieving compliance with essential requirements
  - Simplified **conformity assessment** procedure



- After delivery of standards conform the SR, the **Commission evaluates whether it can give PoC** to legal requirements
  - Harmonised standard **must** be cited in Official Journal of the European Union (OJEU) for PoC

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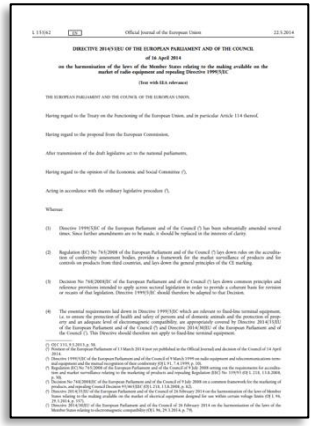
Standards for Presumption of Conformity (hEN)



DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014
on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC
(Text with EEA relevance)

EUROPEAN COMMISSION

M/565

Brussels, 15.5.2020
C(2020) 2532 final

COMMISSION IMPLEMENTING DECISION

of 15.5.2020

on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council

The EU sets essential requirements in harmonised regulation

The Commission issues a Standardisation Request to the ESOs

The ESOs draft and publish the standards

The Commission publishes the reference of the standard in the OJ

- Conformity assessment
- Declaration of conformity
- CE marking

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The New Legislative Framework (NLF)

31 pieces of **Union harmonisation legislation** (“sectoral” legal acts), including the **AI Act**

Regulation 1025/2012 on European standardisation

Regulation 2019/1020 on market surveillance

Regulation 765/2008
- Accreditation
- Market surveillance
- CE marking principles

Decision 768/2008
- Common definitions & reference provisions
- Conformity assessment (modules)
- Notification

Standardisation requests for the AI Act

- **Standardisation request was issued** by the Commission in May 2023 for requirements for high-risk AI systems
  - Development by experts in Joint Technical Committee (JTC) 21 of CEN and CENELEC

- The AI Act foresees additional **standardisation requests** on:
  - **general-purpose AI models**
  - reporting and documentation processes to improve **AI system's resource performance** and on the **energy-efficient development** of general-purpose AI models

Conformity assessment

The process of **demonstrating** whether the requirements set out in EU legislation have been fulfilled

Conformity assessment can:

- be self-assessed
- require the involvement of a notified body (third-party assessment)

After the conformity assessment, the provider is responsible for:

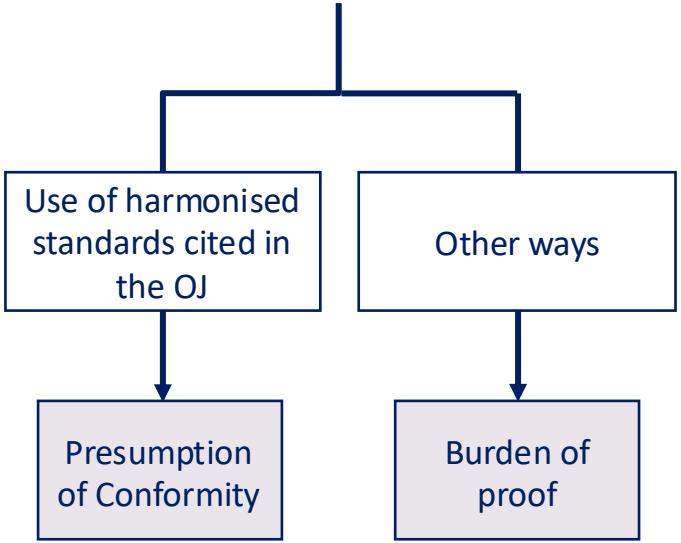
- the declaration of conformity
- CE marking

- In the AI Act, the conformity assessment procedure (self-assessment or third-party) depends on the type of high-risk AI system and is specified in **Article 43**
- For AI systems related to product which are covered by existing Union harmonisation legislation, compliance to the AI Act is assessed as **part of the conformity assessment already provided for in the relevant legislation**

Presumption of conformity

Compliance with a harmonised standard => Compliance with the law
(cited in the Official Journal)

Conformity Assessment



The use of harmonised standards…

- Simplifies conformity assessment procedures
- Reduces resource requirements for:
  - Providers
  - Deployers
  - Notified bodies
  - Market surveillance authorities
- Simplifies market access

PoC applies to the parts of the harmonised standard that have been applied (**modularity**)

How to read a harmonised standard

Your navigation path through a harmonised standard

Scope + Normative references

What is this standard for?
Who is this standard for?
What other standards do you need to apply in order to apply this standard?

Annex ZA

Which regulatory requirements are covered by which clause of the standard?
Which restrictions to the presumption of conformity do I need to be aware of?

Definitions

Are the definitions applicable to my organisation / my product / my existing processes?
Do I need to establish a hierarchy between certain standards?

All of these sections are publicly available in addition to the table of contents

Annex ZA – Table ZA

... illustrates the relationship between a European Standard and the regulation

Requirements of Regulation (EU) 2024/1689 [AI Act]	Clause(s)/subclause(s) of this EN [18286:2026]	Remarks/Notes
Article 11(1) – first sentence	8.9.2	Covered provided the technical documentation contains all elements listed in Annex IV of Regulation (EU) 2024/1689.
Article 17(1) – first sentence	8.1.1, 8.1.4, 8.1.5, 4.1, 4.2, 4.3, 4.4.1, 4.4.3, 5, 6, 8.3.1.1, 9.7, 10.1.1.1, 10.1.3, 10.2	The application of this European Standard does not by itself ensure the fulfilment of all regulatory requirements of the Regulation. The legal requirements must be examined, applied and verified one by one and the solutions adopted become part of the quality management system in the meaning of the Regulation.
Article 17(1) – second sentence, first part	4.1, 4.2, 4.5, 5.2, 6, 8.3.1.1, 10.1.1.1, 10.1.3, 10.2	Covered provided that at least the aspects included in Article 17(1)(a) to Article 17(1)(m) are documented
Article 17(1)(a)	4.4.1, 9.4, 8.3.1.1, 8.8	
Article 17(1)(b)	8.1.1, 8.1.4, 8.1.5, 8.2, 8.3.1.1, 8.3.2, 8.4.2	

Applying harmonised standards

The basics

Four key verbal forms:

- „shall“ = requirement
- „should“ = recommendation
- „may“ = permission
- „can“ = possibility or capability

Verbs can also be used to describe (X consists of Y). In this case, they function in a manner similar to definitions.

Terms in standards are:

- either defined in the standard
- or the dictionary definition of a term applies

European standards have three official language versions:

- English
- German
- French

Standards contain three different types of text:

- Only main body text can contain requirements
- Notes can provide further relevant information.
  Not binding unless they are part of a definition.
- Examples can show how a specific requirement is implemented in a particular context

Practical considerations for applying your first standard

- **Mind the definitions.**
  A definition makes or breaks your compliance: both the process and the object of that process need to be followed.
- **Normative references are relevant for compliance, informative references provide guidance.**
  Informative references give you pointers to other widely-used standards, helpful further information or other types of guidance, but they are not relevant for conformity assessment. Normative and informative references can be made between clauses (also in the same document) and between standards.
- **Implementation is modular but specific.**
  Normative references need to be followed to the extent they are referenced. If clause A gives you a presumption of conformity for Article X and contains a normative reference to clause B, this presumption of conformity for clause A only applies when you also implement clause B.

On the road to applying multiple standards

- **Which parts do you need?**
  Modularity is a feature that allows you to prioritise standards based on which parts you want to obtain a presumption of conformity for.
- **Do the definitions of required parts match?**
  If terms are defined differently in two standards, they are not interchangeable.
- **Which standard allows more flexibility and which requires a more specific approach?**
  If standard A allows you to do a process in five different ways, and standard B requires you to take one of those five approaches, you can follow standard A and standard B by taking the required one of the five permitted approaches.

AI Board Report on sector-specific standards (2026 – forthcoming)

Why read or apply standards?

Standards spell out what to do and how you shall/should/may/can do it.

Whether or not you apply a standards is objectively verifiable. Conformity assessment

Deep dive: EN 18228:2026 for quality management

Deep dive into EN 18286:2026 – part I

Contents

Quality

Risk

Deep dive into EN 18286:2026 – part II

Top management

Competence of personnel

Deep dive into EN 18286:2026 – part III

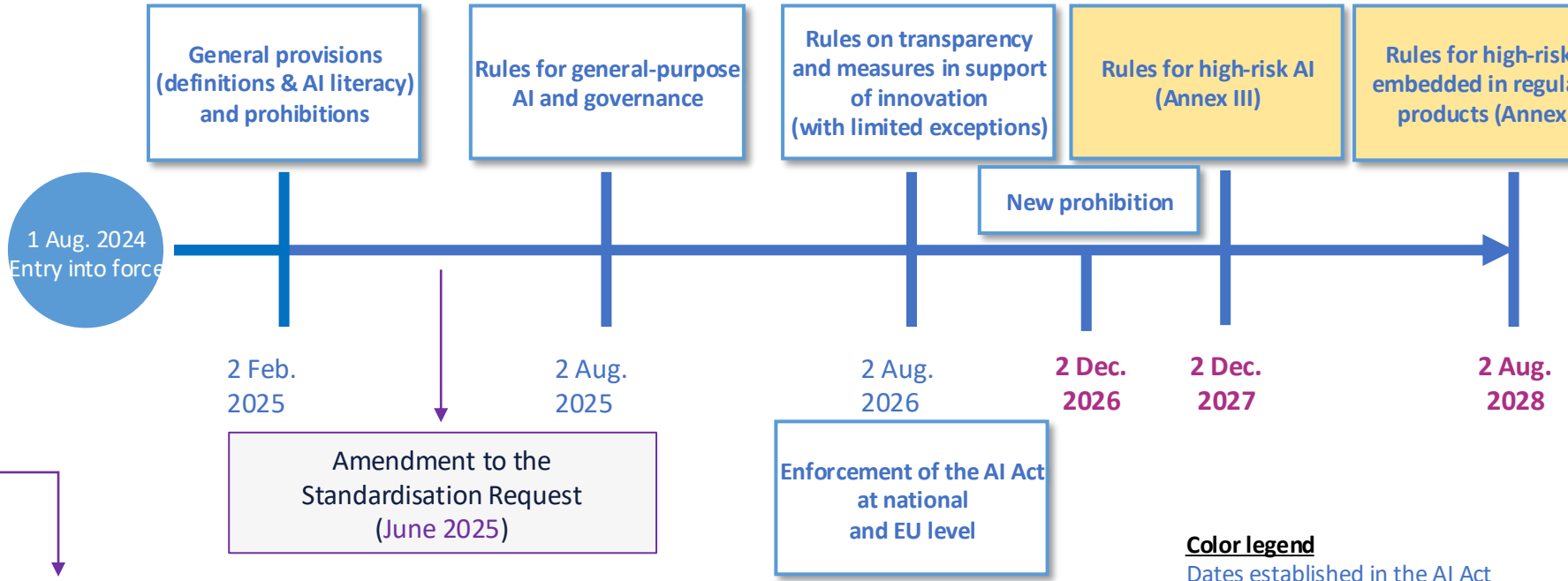
Performance

Overview and timeline of harmonised standards

Overview of JTC 21 work

Legal requirements SR, AI Act)	Draft standards	JTC 21 WG
Risk management (SR 1, Art. 9)	prEN 18228 – AI Risk Management	WG2 – operational aspects
Data (SR 2, Art. 10)	prEN 18284 – Quality and governance of datasets in AI	WG3 – engineering aspects
	prEN 18283 – Concepts, measures and requirements for managing bias in AI systems	
Record Keeping (SR 3, Art. 12)	prEN 18229-1 – AI trustworthiness framework – Part 1: Logging	WG4 – foundational and societal aspects
Transparency (SR 4, Art. 13)	prEN 18229-2 – AI trustworthiness framework – Part 2: Transparency	
Human oversight (SR 5, Art. 14)	prEN 18229-3 – AI trustworthiness framework – Part 3: Human oversight	
Accuracy (SR 6, Art. 15)	prEN 18229-4 – AI trustworthiness framework – Part 4: Accuracy	
Robustness (SR 7, Art. 15)	prEN 18229-5 – AI trustworthiness framework – Part 5: Robustness	
Cybersecurity (SR 8, Art. 15)	prEN 18282 – Cybersecurity specifications for AI systems	WG5 – cybersecurity for AI systems
Quality management (SR 9, Art. 15)	EN 18286 – Quality management system for EU AI Act regulatory purposes	WG2 – operational aspects
Conformity assessment (SR 10)	prEN 18285 – AI Conformity assessment framework	

(Revised) Timeline



Why and how to get involved in standardisation

How to get started

Onwards into standardisation

How?

Join your national mirror comittee

OR

Send your comments during public enquiry phases

Write about law *and standards*

How?

Cite standards in your academic writing.

(and please read the Blue Guide!)

Evaluate standards

How?

Check the definitions and scopes of different standards (always publicly available).

Learn, baby, learn

How?

Understand who implements different types of standards in different organisations.

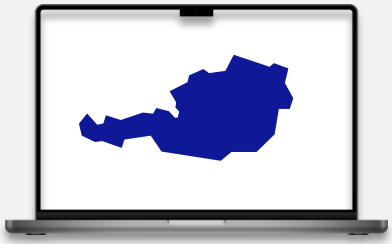
Wait

How?

Do not jump to conclusions.

Standardisation organisations

for Austria, Europe and beyond



Austria

Austrian Standards International

AG 001.42

Europe

CEN / CENELEC

ETSI

JTC-21
OCG AI

International

ISO / IEC

ITU

IEEE

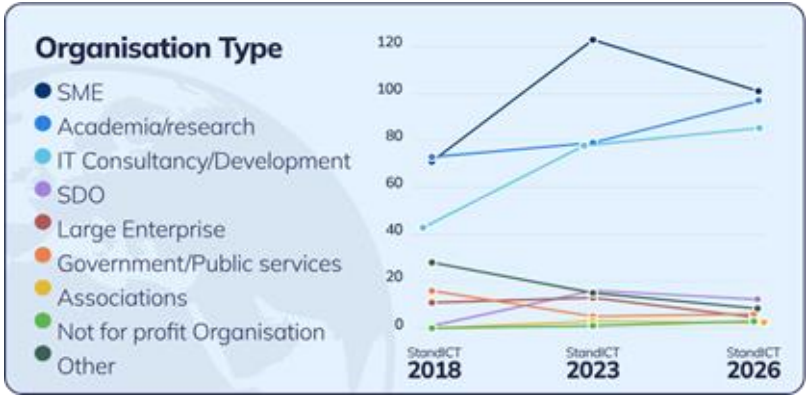
JTC 1/SC 42
SG 3, 5 & 17
project-based

Open Calls for participation in standardisation activities

- **6 open calls:** December 2025 – June 2027
- **Budget for open calls:** 4.2 M€

Typology	Description	Max duration	Max funding range
Long term contribution (LT)	Contribution to ongoing standards development as a chair, convener, rapporteur or member of an SDO WG. For example, commenting on standards development and drafts, attending meetings as an observer, and paying membership fees.	9 months	Up to 10.000 €
Short term contribution (ST)	Contribution to standards documentation e.g. liaison to WG, comments on standards drafts, participation at meeting paying membership fees	3 months	Up to 5.000 €
Organisation of Standardisation Meetings (SM)	Pilot type. Support to the organisation of strategic standardisation meetings in Europe, endorsed by an international SDO, global forum, or consortium. Eligible costs include venue and equipment rental, catering, communication materials, and travel and accommodation for key participants.	Max 6 months, depending on the scale and timing of the meeting	Up to 50.000 €

Key achievements since 2018:



Top 3 Most Targeted Topics	StandICT 2018	StandICT 2023	StandICT 2026	Total	
CYBERSECURITY	74	56	60	190	20%
ARTIFICIAL INTELLIGENCE	9	46	66	121	13%
5G & BEYOND 6G	19	31	17	67	7%

- Priorities for each Open Call are **defined in coordination with the EC**
- Guidelines for application process: StandICT.eu 2029 - Guidelines for Applicants to Fellowship

Further information

For reading, watching and listening

Type and link	Content
Conference	**UK AI Standards Hub** Global Summit Advancing AI governance through standards
Webinar	**European Commission** Risk management logic of the AI Act and related standards
Newsletter	**CEN-CENELEC** AI Standardization Inclusiveness Newsletter
Commission Notice	**European Commission** The ‘Blue Guide’ on the implementation of EU product rules 2022
Policy Brief	**Joint Research Center** Science for Policy Brief: Harmonised standards for the EU AI Act

Stakeholder outreach and support in compliance
Introducing the AI Act Service Desk

Possibility for stakeholders to **submit queries about the AI Act to the AI Office** and **receive tailored feedback**

- **Multilingual** support
- **Complementary** to other schemes such as the Regulatory sandboxes, EDIHs, and national helpdesks

Integrated into a **Single Information Platform**
(launch in EN only – multilingual support to be available soon)

- **AI Act Explorer**
- **Compliance Checker**
- **FAQs**
- Repository of **Commission's and national resources**

https://ai-act-service-desk.ec.europa.eu/en

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Let’s discuss

Thank you for your curiousity!

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Digital Austria

European Commission

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and Infrastructure
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FFG
Promoting Innovation.

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