

EU Regulations and Manufacturing-X

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EU Regulations:

- Digital Product Passport
- EU Data Act
- Cyber Resilience Act

In June 2024, there were in total 116 EU laws for the digital sector

EU Regulation Overview

Table 1: Overview of EU Legislations in the Digital Sector

Research & Innovation	Industrial Policy	Connectivity	Data & Privacy	IPR	Cybersecurity	Law Enforcement	Trust & Safety	E-commerce & Consumer Protection	Competition	Media	Finance
Digital Europe Programme Regulation, (EU) 2021/594	Recovery and Resilience Facility Regulation, (EU) 2021/241	Frequency Bands Directive, (EEC) 1987/272	ePrivacy Directive, (EC) 2002/58, 2017/0008(COD)	Database Directive, (EC) 1996/9	Regulation for a Cybersecurity Act, (EU) 2019/831, 2023/0108(COD)	Law Enforcement Directive, (EU) 2016/680	Product Liability Directive (PLD), (EC) 1985/274, 2022/0302(COD)	Unfair Contract Terms Directive (UCTD), (EEC) 1993/13	EC Merger regulation, (EC) 2004/39	Satellite and Cable Directive, (EEC) 1993/63	Common VAT system, (EC) 2006/112, 2022/0407(CNS)
Horizon Europe Regulation, (EU) 2021/695, (EU) 2021/754	InvestEU Programme Regulation, (EU) 2021/523	Radio Spectrum Decision, (EC) 2002/676	European Statistics, (EC) 2009/223, 2023/0237(COD)	Community Design Directive, (EC) 2009/16, 2022/0391(COD)	Regulation to establish a European Cybersecurity Competence Centre, (EU) 2021/687	Directive on combating fraud and counterfeiting of non-cash means of payment, (EU) 2019/713	Toys Regulation, (EC) 2009/48, 2023/0290(COD)	Price Indication Directive, (EC) 1998/8	Technology Transfer Block Exemption, (EU) 2014/316	Information Society Directive, (EC) 2001/29	Administrative cooperation in the field of taxation, (EU) 2011/16
Regulation on a pilot regime for distributed ledger technology, (EU) 2022/859	Connecting Europe Facility Regulation, (EU) 2021/1153	Open Internet Access Regulation, (EU) 2015/2120	General Data Protection Regulation (GDPR), (EU) 2016/679	Enforcement Directive (IPR), (EC) 2004/48	NIS 2 Directive, (EU) 2022/2555	Regulation on interoperability between EU information systems in the field of borders and visa, (EU) 2019/817	European Standardization Regulation, (EU) 2017/1025	E-commerce Directive, (EC) 2000/31	Company Law Directive, (EU) 2017/1132, 2023/0089(COD)	Audio-visual Media Services Directive (AVMSD), (EU) 2010/13	Payment Service Directive 2 (PSD2), (EU) 2015/2366, 2022/0209(COD)
	Regulation on High Performance Computing Joint Undertakings, (EU) 2021/1173, 2023/0018(CNS)	European Electronic Communications Code Directive (EECC), (EU) 2018/1972	Regulation to protect personal data processed by EU institutions, bodies, offices and agencies, (EU) 2018/1724	Directive on the protection of trade secrets, (EU) 2016/943	Cybersecurity Regulation, (EU) 2023/2841	Regulation on terrorist content online, (EU) 2021/784	Radio Equipment Directive (RED), (EU) 2014/53	Unfair Commercial Practices Directive (UCPD), (EC) 2005/29	Market Surveillance Regulation, (EU) 2019/1020	Portability Regulation, (EU) 2017/1128	Digital Operational Resilience Act (DORA) Regulation, (EU) 2022/2554
	Regulation on Joint Undertakings under Horizon Europe, (EU) 2021/2085, 2022/0033(RLE)	Regulation on the free flow of non-personal data, (EU) 2019/817	Regulation on the free flow of non-personal data, (EU) 2019/817	Design Directive, 2022/0392(COD)	Information Security Regulation, 2022/0084(COD)	Temporary CSAM Regulation, (EU) 2021/1232, 2022/0135(COD)	eIDAS Regulation (European Digital Identity Framework), (EU) 2014/910	Directive on Consumer Rights (CRD), (EU) 2011/63	P2B Regulation, (EU) 2019/1150	Satellite and Cable II Directive, (EU) 2019/789	Crypto-assets Regulation (MICA), (EU) 2023/1114
	Decision on a path to the Digital Decade, (EU) 2022/2481	Roaming Regulation, (EU) 2022/612	Open Data Directive (PSI), (EU) 2019/1024	Compulsory licensing of patents, 2023/0129(COD)	Cyber Resilience Act, 2022/0272(COD)	E-evidence Regulation, (EU) 2023/1543	Regulation for a Single Digital Gateway, (EU) 2018/1724	e-invoicing Directive, (EU) 2014/55	Single Market Programme, (EU) 2021/690	Copyright Directive, (EU) 2019/790	Financial Data Access, 2023/0205(COD)
	European Chips Act (Regulation), (EU) 2023/1781	Union Secure Connectivity Programme, (EU) 2023/588	Data Governance Act (DGA Regulation), (EU) 2022/868	Standard essential patents, 2023/0133(COD)	Cyber Solidarity Act (Regulation), 2023/0109(COD)	Digitalisation of cross-border judicial cooperation, (EU) 2023/2844	General Product Safety Regulation, (EU) 2023/988	Regulation on cooperation for the enforcement of consumer protection laws, (EU) 2017/2384	Vertical Block Exemption Regulation (VBER), (EU) 2022/720	European Media Freedom Act, (EU) 2024/1063	Payment Services Regulation, 2023/0210(COD)
	Establishing the Strategic Technologies for Europe Platform (STEP), (EU) 2024/795	Gigabit Infrastructure Act, (EU) 2024/1309	European Data Act (Regulation), (EU) 2023/2854			Directive on combating violence against women, 2022/0066(COD)	Machinery Regulation, (EU) 2018/2002	Geo-Blocking Regulation, (EU) 2018/2002	Digital Market Act (DMA Regulation), (EU) 2022/1924	Remuneration of musicians from third countries for recorded music played in the EU	Digital euro, 2023/0212(COD)
	European critical raw materials act (Regulation), (EU) 2024/1252	New radio spectrum policy programme (RSPP 2.0)	Interoperable Europe Act, (EU) 2024/903			Directive for combating sexual abuse and child sexual abuse material, 2024/0035(COD)	AI Act (Regulation), 2021/0168(COD)	Digital content Directive, (EU) 2019/770	Regulation on distortive foreign subsidies, (EU) 2022/2560		Regulation on combating late payment, 2023/0323(COD)
	Net Zero Industry Act, 2023/0081(COD)	Digital Networks Act	Regulation on data collection for short-term rental, (EU) 2024/1028			Digitalization of travel documents	Eco-design Regulation, 2022/0095(COD)	Directive on certain aspects concerning contracts for the sale of goods, (EU) 2018/771	Horizontal Block Exemption Regulations (HBER), (EU) 2023/1066		
	EU Space Law		European Health Data Space (Regulation), 2022/0148(COD)				AI Liability Directive, 2022/0303(COD)	Digital Services Act (DSA Regulation), (EU) 2022/2585	Platform Work Directive, 2021/0414(COD)		
			Harmonisation of GDPR enforcement procedures, 2023/0202(COD)					Political Advertising Regulation, (EU) 2024/900	Single Market Emergency Instrument (SMELI), 2022/0278(COD)		
			Access to vehicle data, functions and resources					Right to repair Directive, 2023/0083(COD)			
			GreenDatafall					Consumer protection: strengthened, enforcement, cooperation			

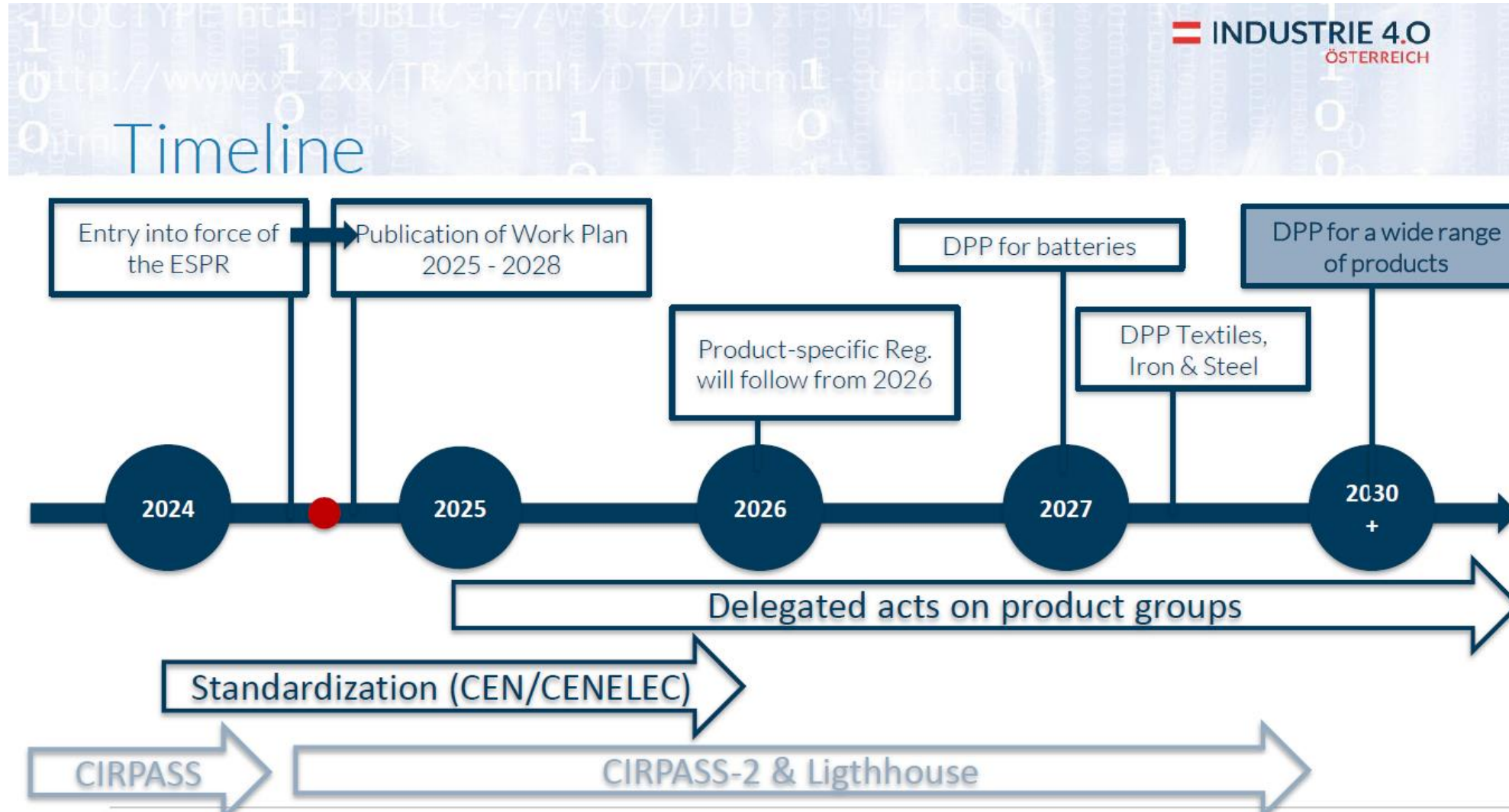
Applicable law	Published in the Official Journal of the European Union.
In negotiation	Proposal by the European Commission entered the legislative process.
Planned initiative	Mentioned by the European Commission as potential legislative initiative.

1. What is the Digital Product Passport?

- DPP is an integral part of Ecodesign for Sustainable Products Regulation; it shares:
 - The adoption timeline
 - The (future) work programme for priority products
 - The entry into force timeline for product requirements (except for batteries)
- A (growing) number of other EU policies will rely on DPP (or elements of it) to make product-related information digitally available :
 - Batteries Regulation
 - Toys regulation
 - Detergents regulation
 - Construction Products Regulation
 - Critical Raw Materials Act

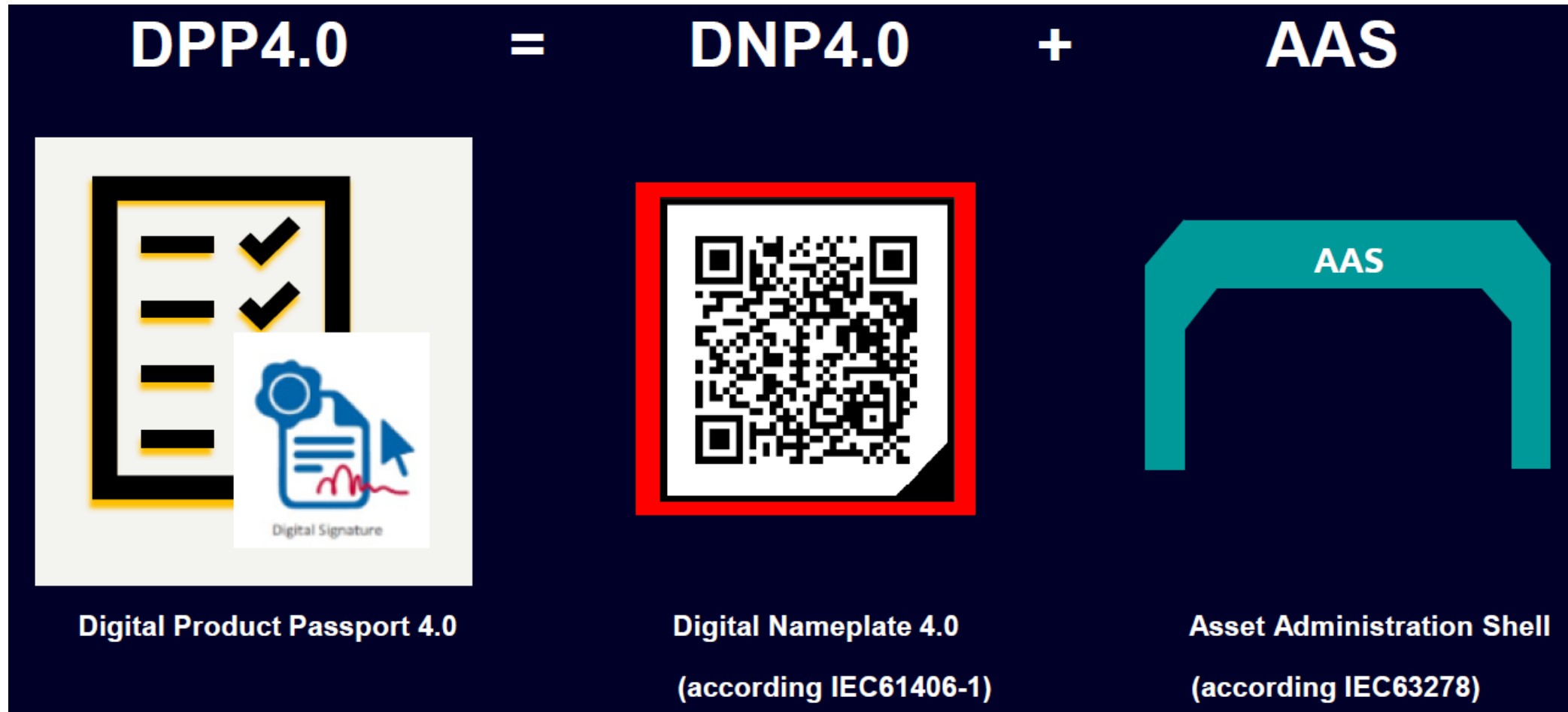
DPP

Digital Product Passport



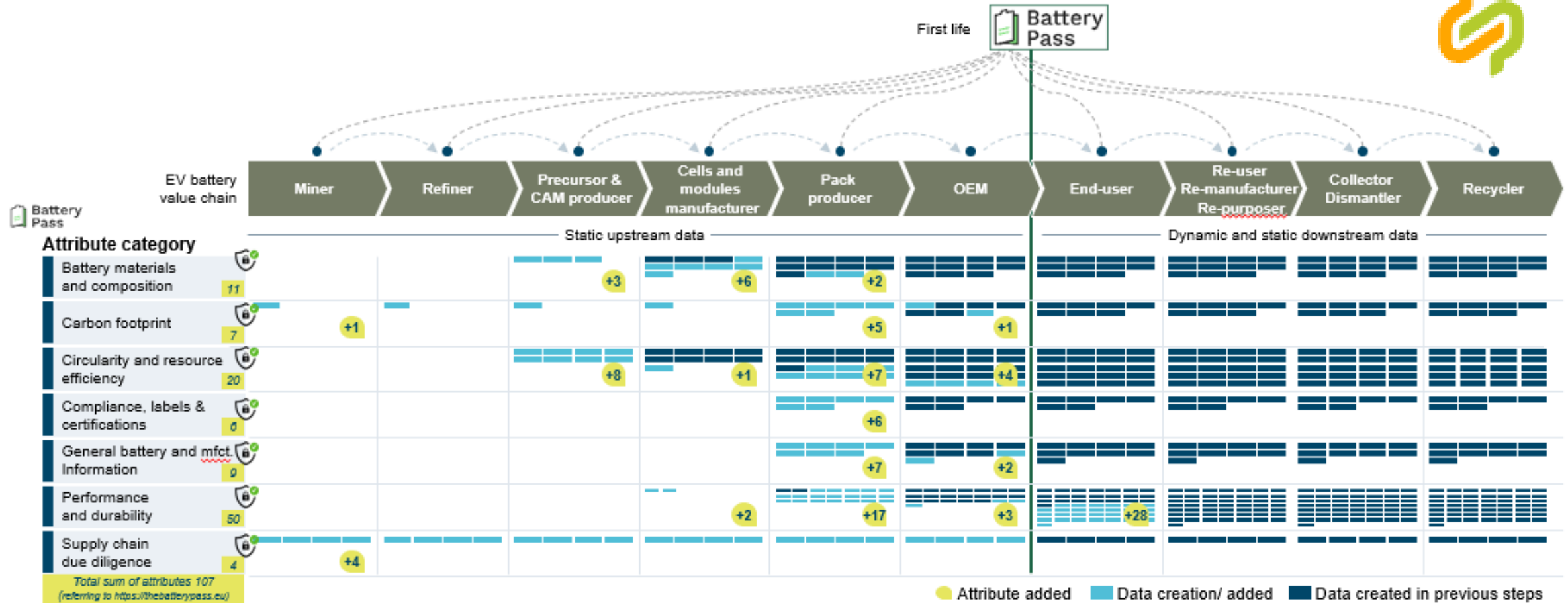
DPP4.0

Digital Product Passport for Industry



DPP Example

Battery Passport



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Headlines

EU Data Act

Access to user-generated IoT data (B2B and B2C) or transfer to third parties

Chapter
2 & 3

General terms and conditions & unfairness test for data sharing contracts

Chapter
4

Non-personal data for the public sector (B2G) for “exceptional needs”

Chapter
5

Simplified switching between cloud service providers

Chapter
6

Protection regulations for the international transfer of non-personal data

Chapter
7

Technical standards and interoperability for data and cloud service providers

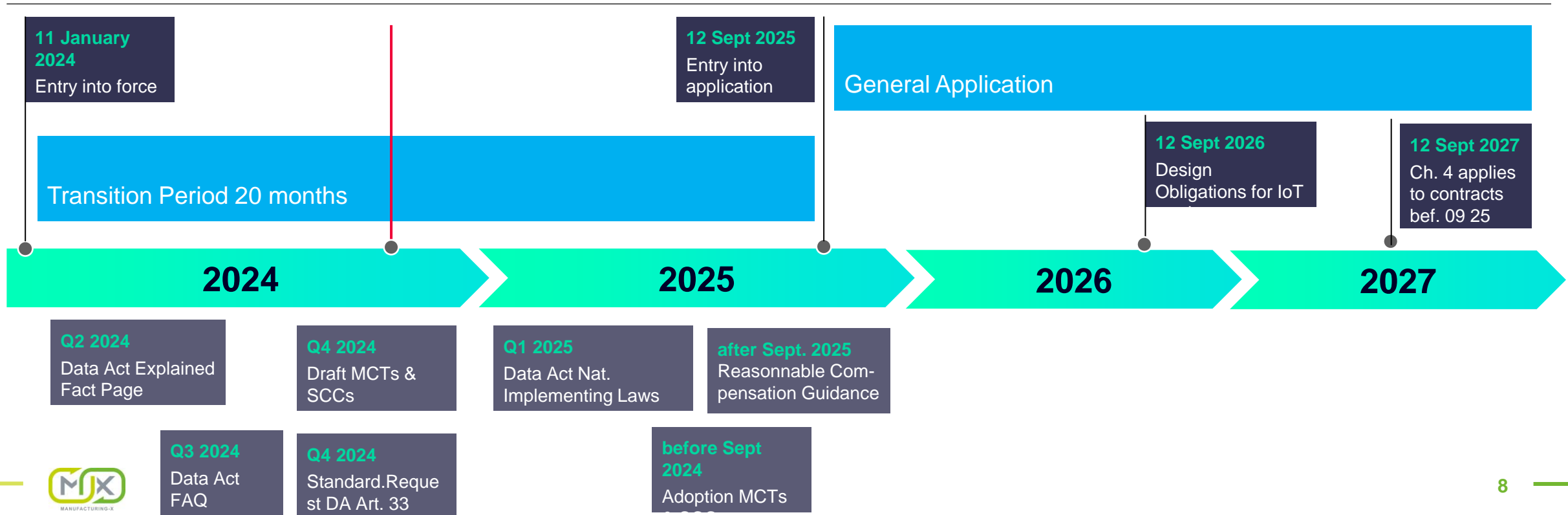
Chapter
8

Importance and timeline

EU Data Act

Affecting industry (B2B and B2C)

- Manufacturers and providers of connected products and related services are affected [Art. 4]
- By default, products and related services must be designed and manufactured in such a way that the data generated by their use is made directly accessible to the user in a simple and secure manner [Art. 3].



Timeline and key information

Cyber Resilience Act



Cybersecurity requirements for products

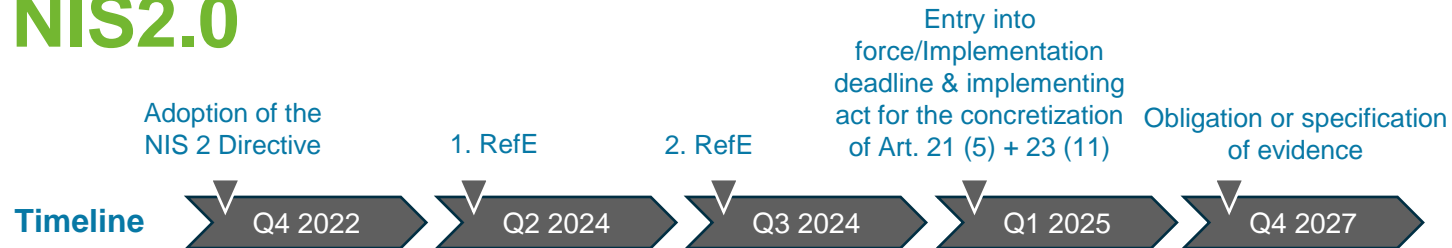
- Cybersecurity risk assessment and consideration of the result during the entire life cycle
- Protection requirements (implementation of authentication, identity or access management systems)
- Data protection requirements (confidentiality, integrity & “minimization”)
- Design specifications (minimization of attack surfaces, opt-out mechanism)
- Action and reporting requirements (reporting obligations, vulnerability management, security updates)
- Cyber security throughout the entire supply chain, as well as integrated remote data processing solutions and, in some cases, cloud solutions (incl. SBOM)

Affected products

- All products made available on the market with **digital elements (hardware & software)** whose intended purpose or reasonably foreseeable use involves a direct or indirect logical or physical data connection to a device or network.
- **Categorization** into basic category, important products (I&II), and critical products
- **Not in scope:** Identical spare parts with the same specifications, vehicles or their systems & components, aircraft or components & equipment, equipment of EU ships, products for national security & defense purposes, medical devices & in-vitro diagnostics
- Commission can make changes to Annex III & IV (important & critical products) by delegated act

Timeline and key information

NIS2.0



Cybersecurity requirements for organizations

- Cyber security concept following risk analysis (backup management, supply chain security, business continuity management)
- Vulnerability management and security measures for the acquisition, development and maintenance of IT systems, components and processes
- Cryptography & encryption, access control and management of systems, multi-factor authentication
- Awareness, training & cyber hygiene measures
- Reporting, registration, verification and information obligations

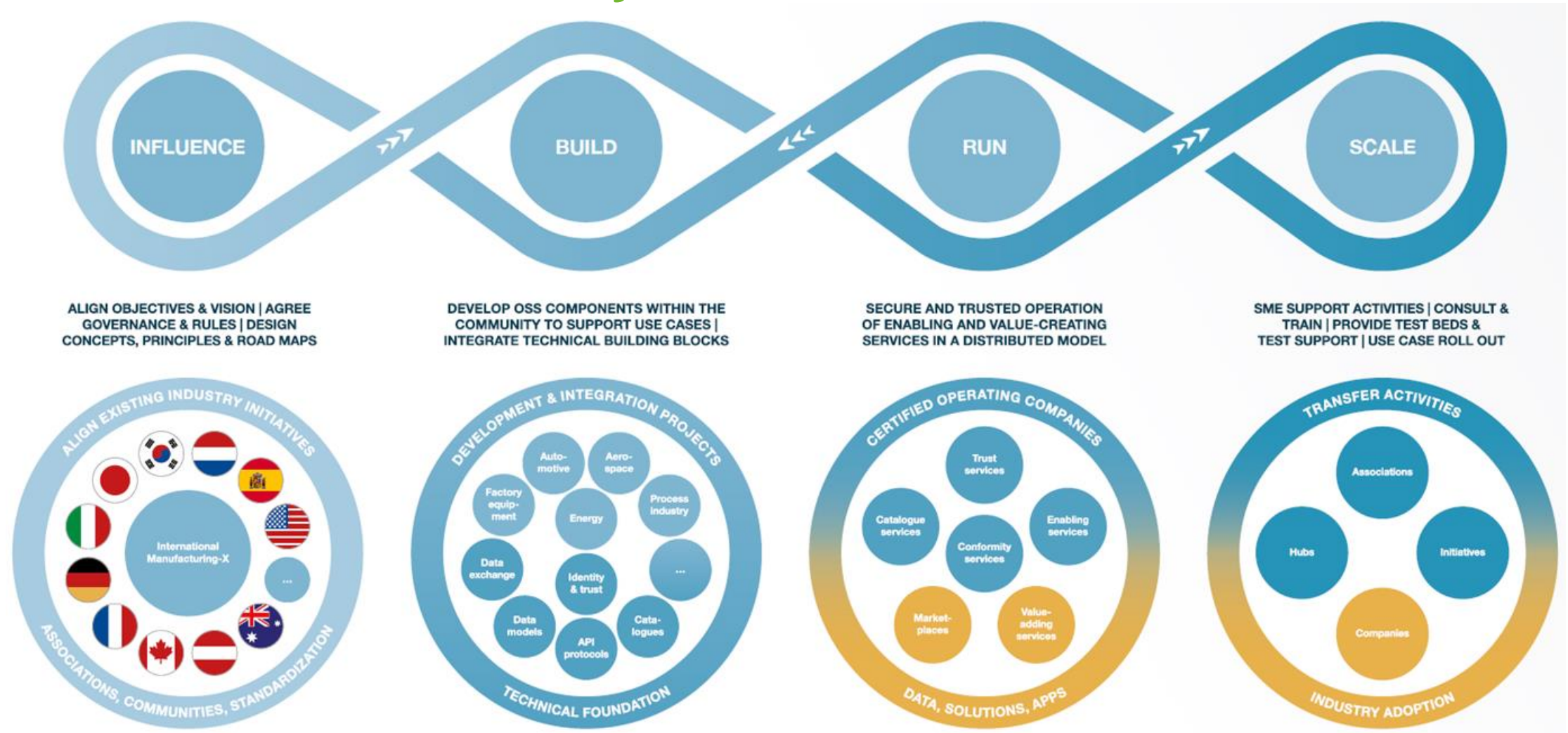
Affected

- | | | |
|---|--|---|
| <ul style="list-style-type: none">• Important facilities Type of establishment in Annex I & II• at least 50 employees, or annual turnover over € 10 million & annual balance sheet total over € 10 million | <ul style="list-style-type: none">• Particularly important facilities Type of establishment in Annex I• at least 250 employees, or annual turnover over € 50 million & annual balance sheet total over € 43 million | <ul style="list-style-type: none">• Operators of critical systems Critical system = systems whose failure or impairment would result in significant supply bottlenecks or threats to public safety Is defined in more detail by RVO pursuant to NIS2UmsuCG § 58 (4). |
|---|--|---|

Potential conformity assessment procedures

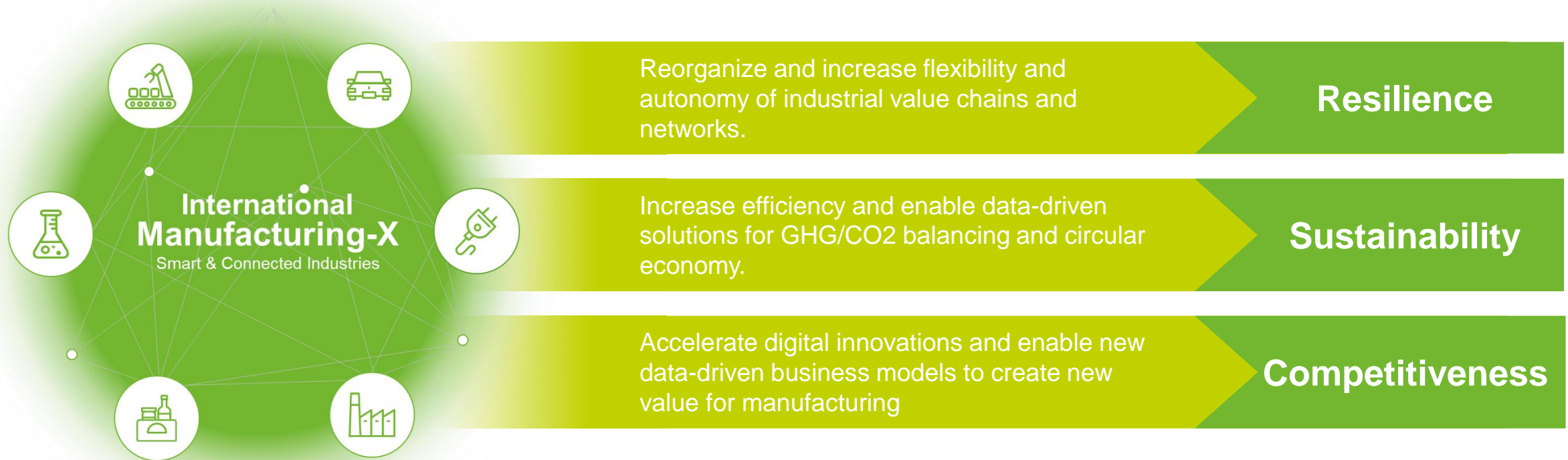
- **Future designation of ICT products, services or processes that require cyber security certification** in accordance with the Cyber Security Act by statutory order by the BMI
- Obligation for operators of critical systems to apply for the use of critical components Obligation to issue a guarantee declaration for manufacturers of critical components
- Voluntary declaration of conformity with technical guidelines or IT security mark of the BSI

How Industrial Data Ecosystems work



International Manufacturing-X (IM-X): Make Data Work

IM-X will implement a federated, decentralized and collaborative data ecosystem for smart manufacturing. Open, global and cross-industry, following FAIR Data Principles.



Why

Challenges and Opportunities for Global Manufacturing Industries



Deployment needs customization across an **infrastructure continuum from cloud to edge**, depending on the applications.



Information sharing and data-driven collaboration among manufacturing initiatives across the supply network are becoming more relevant for impactful manufacturing data networks.



Harmonized standards facilitate business scale-up of data ecosystems, which are becoming essential.



No country, no initiative, no company can achieve this on its own!

Landscape of Initiatives in the Context of global manufacturing

Manufacturing-X is international. Our intention is to trigger international R&D, partnerships, cooperation, standardization and deployment with and for customers globally.



Who?

Initiatives Involved in Establishing the IMX Council



What has happened so far:



**2023
July**

Initiation
Brussels,
Belgium



**2023
October**

Inauguration
Tokio,
Japan



**2024
February**

Kick-off
Paris,
France



**2024
Novem.**

November 5th
in USA/CESMII

OAK RIDGE
National Laboratory
MANUFACTURING
DEMONSTRATION
FACILITY

Quick Facts
2011, ORNL is established
2/3 of the U.S. population is within a
day's drive of ORNL
60,000 sq ft of R&D floor space

Impact
\$1B+ of follow-on private industry
investment

Contact

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