UNECE

The regulatory compliance of products with embedded artificial intelligence or other digital technologies

WP.6 Working Party on Regulatory Cooperation and Standardization Policies

Note

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Acknowledgement

About WP.6

The Working Party on Regulatory Cooperation and Standardization Policies (WP.6) was founded in the 1970s as a forum for exchange on the harmonization of non-agricultural product regulations. WP.6 aims to promote regulatory cooperation, standardization policies and activities which contribute towards reducing technical barriers to trade, promoting sustainable development in all its dimensions including, for example, gender equality, climate and environmental protection, circular economy and the adaptation to new technologies.

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I.   Introduction

Products making use of artificial intelligence (AI) or other embedded digital technologies are used widely yet without universally agreed or accepted definitions and under varying regulatory frameworks. Regulatory frameworks are often established prior to the arrival and implementation of new technologies and fast developing new use cases. Hence, they may not be able to cater to the emerging risks posed by these products with embedded AI systems or other digital technologies.

Ethical and other societal concerns and negative impacts related to the use of products with embedded AI or other digital technologies continue to be addressed by United Nations Educational, Scientific and Cultural Organization (UNESCO) and other global initiatives. Such recommendations represent important complementary factors to consider in conjunction with the recommendations in this document as those concerns are closely related to technical regulation.

While this document generally covers products that make use of AI or other embedded digital technologies, products subject to domain-specific regulation may fall out of scope, e.g., specifically the following:

- Self-driving cars and autonomous wheeled vehicles

- Autonomous weapons and other military applications

- Standalone AI software platforms and generative AI not embedded in products

Self-driving cars and autonomous wheeled vehicles are covered under separate United Nations regulations. In contrast, aerial and submarine vehicles as well as robots are within the scope of this document.

The deployment of autonomous weapons and defence products with embedded AI system and other digital technologies falls within national defence and national security strategies and hence are out of scope. Despite not applying from a pure scoping perspective, the recommendations of this document may provide useful content within a defence context.

In contrast to out-of-scope standalone AI software platform and generative AI, products embedded with such AI systems or other digital technologies fall within the scope of this document.

To address emerging risks that arise from products with embedded AI systems or other digital technologies, internationally agreed terms, definitions, and developing an international regulatory cooperation in the field of AI are indispensable. The working team proposes the following definitions for the purpose of this document:

- **Technical regulation**: a document which lays out product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

- **Product**: a product is an item produced and given or sold, often as a result of a manufacturing process, that may change or be re-purposed after entering the market or following a software update (and can include software in itself).

- **Product with AI system**: a product with an embedded system, that operates with varying levels of autonomy and can make decisions influencing real or virtual environments in a way that is generally intended to further human objectives.

- **Product with integrated software**: a product with an embedded, upgradeable (remotely, offline or by other means) system that controls the functioning of the product and directs its operation.

- **Product with embedded digital technologies**: a product with an AI system or with integrated, upgradeable software or with a combination of both.

- **Product characteristic**: features of products with embedded digital technologies that may cause hazards addressed by technical regulation, for example product safety, cybersecurity, operational resilience, privacy, socioeconomic inequality, discrimination, exploitation, climate and sustainability (or a combination of these).

- **Safety case**: a structured argument, supported by a body of evidence that provides a compelling, comprehensible and valid case that a product with an embedded AI system or other digital technology is safe for a given application in a given operating environment.

Products with embedded digital technologies, such as software and/or AI, may also be connected to central or decentralized systems monitoring and/or controlling real or virtual environments that these products operate in. This may result that products with embedded digital technologies may have been changed since their original production, including having been changed by updating instructions to the embedded digital technologies.

Current regulatory practices follow sector-specific mandates while compliance of products with embedded digital technologies is of horizonal nature, requiring new expertise, horizontal regulatory collaboration as a multi-disciplinary approach to both identify and address risks, vulnerabilities, cyberthreats and increase operational resilience. This necessitates the development of regulatory capabilities beyond sectoral mandates, that are cutting across mandated procedural silos and are both supportive of the dynamic nature of digital innovation and conducive of enforcement strategies demanded by a digital market.

Existing conformity assessment procedures might not be applicable to consumer products with embedded AI systems, as many of these products have limited transparency or are opaque. Developing a safety case to show that the risk of a product is brought to a level that can be accepted based on a thorough regulatory impact assessment involving all relevant stakeholders, including the legal entity/ies subject to regulation, might be the key instrument of conformity assessment for consumer products with embedded AI elements or other digital technologies. That being said, products with embedded digital technologies will likely undergo many pre-market revisions which shall necessitate safety case amendments in instances where the original use case fundamentally changes or would trigger a product reclassification.

There are a wide range of regulatory uncertainties present with regards to products with embedded digital technologies due to their nascency. There is thus a need for developing and applying risk management tools based on scenario analysis for proving that products with embedded digital technologies have a tolerable level of risk, deemed acceptable by society in exchange for the benefits and functionality of such products.

International standards play an important role in the global economy and in facilitating international trade through aligning technical regulations, conformity assessment procedures, and national standards. There are a number of international standards being developed and under development that are of pertinence to the regulatory compliance of products making use of AI or other embedded digital technologies, including those relating to risk management, conformity assessments, quality management systems, as well as international guides and recommendations. These need to be taken into consideration in future work related to this topic.

It is reminded that the ECE WP.6 has already developed a number of recommendations also pertinent to this topic, including:

- *Recommendation G on the Acceptance of Conformity Assessment Results*. This can be applied to this topic with acceptance of the results of conformity assessment procedures (e.g., calibration, testing, inspection, certification, and accreditation) for products with embedded digital technologies, including acceptance by means of multilateral mutual recognition agreements, facilitating international trade and reducing duplication.

- *Recommendation K on Metrological Assurance of Conformity Assessment Training*. This ensures that results of measurements by products with embedded digital technologies are the basic facts on which decisions are taken in conformity assessment and testing.

- *Recommendation N on Good Market Surveillance Policies and Practices*. Effective enforcement practices for products with embedded digital technologies placed on the market or imported ensure that these meet legal requirements on safety, health, environment, fair competition between economic operators, and any other aspects of public interest.

- *Recommendation S on Applying Predictive Risk Management Tools for Targeted Market Surveillance*. The management of non-compliance risk of products with embedded digital technologies is of particular importance for setting priorities in market surveillance, import compliance and effective enforcement practices with the purpose of removing dangerous and non-compliant products from the market.

- ***Recommendation T on Standards and Regulations for Sustainable Development***. Effective risk management is a necessary component of any regulatory system and building risk-based regulatory systems that would be proportionate to products with embedded digital technologies' risks that are relevant to the Sustainable Development Goals (SDGs) and their targets is essential for sustainable development and a sustainable planet.

- ***Recommendation U on Gender-Responsive Standards***. There will likely be gender implications for products with embedded digital technologies that need to be taken into consideration.

There are fast-moving, dynamic and sometimes uncertain regulatory pathways affecting the properties of products with embedded digital technologies, like any other emerging technologies. Consequently, regulation of products with embedded digital technologies might require agile forms of governance and flexible regulatory approaches following the individual AI use cases rather than an overarching policy on AI technology itself in order to address concerns that require regulatory action.

Realizing responsible distribution and sale of products with embedded digital technologies, innovation will require concerted action across governmental agencies and the private sector. The principles set out in this document may accordingly be relevant to actors in all of these settings. It is advised that the principles set out in this document be considered complementary and should be considered together.

An important element of market surveillance and product compliance enforcement strategies of products with embedded digital technologies (as non-connected and non-digital products) is to provide safety of consumers by addressing the need of suitable and renewed enforcement methodologies resulting in traceability, verification and auditability covering the life-cycle perspective of the compliance of these products.

Functional features and characteristics of products with embedded digital technologies pose a greater challenge with additional demands on traceability and validation in regulatory compliance. The need for cross-sectoral regulatory impact assessment for products with embedded digital technologies should consider horizontal digital frameworks coinciding with sector-specific technical regulation.

II.   Proposed way forward

1) Governments, when establishing regulatory objectives, should ensure that products with embedded digital technologies deploy human-centric objectives/goal-setting/outcomes, and do not substitute human autonomy or lead to the loss of individual freedom. Governments should embrace best practices implementing Agenda 2030 SDGs such as following of, and not limited to *Recommendation U*.

2) Governments should mandate – in order to achieve a consistent and high level of protection of public interest with regards to health, product safety, fundamental rights and the United Nations values enshrined in the *Universal Declaration of Human Rights*, the *United Nations Convention on the Rights of Persons with Disabilities* (CRPD) and the *United Nations Global Compact* – that common international standards for products with embedded digital technologies be established. Those standards should be non-discriminatory and in line with international trade commitments.

3) Governments should prevent and mitigate concerns that require regulatory action regarding products with embedded digital technologies by ensuring that only compliant products with embedded digital technologies are placed on the market, given that safety and security risks may be generated by a product as a whole due to its digital components, including embedded digital technologies, and consider mandatory independent audits of products to assure compliance to binary (compliant/non-compliant) government-approved criteria as appropriate.

4) Governments should mandate that in sectors where the stakes for life and health are particularly high with an intrinsically higher severity, increasingly sophisticated diagnostics systems and products with embedded digital technologies supporting human decisions are reliable and accurate and wherever possible, include the use of human decision-making alongside algorithmic decision-making.

5) Governments should consider the fundamental right to a level of protection of citizens, environment and sustainability when assessing the severity of the harm that products with embedded digital technologies might cause.

6) Governments should consider children's vulnerabilities and provision of protection and care as necessary for their well-being with respect to products with embedded digital technologies and should protect children's specific rights as enshrined in the *United Nations Convention on the Rights of the Child* (UNCRC), further elaborated in the *Convention*'s General Comment No 25 (2021) as regards the digital environment, which can include (but is not exclusive to) education, home, media and gamification/play.

7) Governments should recognize the needs of emerging economies in implementing digital technologies and related regulatory frameworks as part of national quality infrastructure and, as consequence, the necessity for capacity building and technical assistance in avoiding/minimizing a digital divide.

8) Governments should provide natural and legal persons and groups of natural or legal persons with access to proportionate and effective legal rights and remedies (such as the right to correct, the right to object, and where appropriate, the right for human intervention) for harm caused by products with embedded digital technologies. In particular, Governments should provide the right to lodge a complaint against the providers of such products and receive compensation against any direct damage or loss they have with regard to their health, safety, privacy or fundamental rights due to an infringement of their rights by the original producer of such products or third parties which have impacted the product.

9) Governments should reaffirm sustainable development as a United Nations cornerstone and consequently develop harmonized, cross-agency criteria for the evaluation of the non-compliance risk of products with embedded digital technologies. These risk criteria for evaluation of non-compliance risks should endorse regulatory objectives, which take relevant SDGs into account, as described in *Recommendation T*.

10) Product regulators should develop and implement procedures necessary to explicitly address concerns that require regulatory action regarding products with embedded digital technologies' non-compliance within their scope of responsibility, including within import compliance processes at the border, as described in *Recommendation V on Addressing Product Non-Compliance Risk in International Trade*.

11) Governments should add processes that manage non-compliance concerns of products with embedded digital technologies within processes that address customs-related and trade disruption risks.

12) Governments should encourage and provide resources for the participation of citizens in the development of international standards, guides, and recommendations on AI and other embedded digital technologies.

13) Governments should implement accessible mechanisms and clear processes including a process for submitting adverse incidents reports, and consider diverse input and multi-stakeholder feedback from human risk assessors trained in AI systems risk assessment as appropriate, for bodies that develop and implement their national quality infrastructure to exchange information, consult, and operate in an aligned and efficient manner to promote a whole-of-system approach to standards and conformance for products making use of AI or other embedded digital technologies.

14) Governments should ensure that regulatory measures applied to products with embedded digital technologies are consistent with the World Trade Organization (WTO) *Technical Barriers to Trade (TBT) Agreement*. This includes, but is not limited to, the *TBT Agreement's* obligations pertaining to notification, publication, non-discrimination, avoidance of unnecessary barriers to trade, achievement of legitimate objectives and use of international standards.