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3 **Regulatory compliance of products making use of Artificial**
4 **Intelligence or other embedded digital technologies**

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18 **White Paper**

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20 **I. Preamble**

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22 Products making use of artificial intelligence (AI) or other embedded digital technologies are
23 used widely yet without universally agreed or accepted definitions and under varying
24 regulatory frameworks that are often established prior to the arrival of and hence may not be
25 able to cater for the emerging risks posed by products with embedded AI systems or other
26 digital technologies.

27 With a view of clarity on this topic, internationally agreed terms and their definitions are
28 indispensable for developing international regulatory cooperation in the field of AI. The
29 working team proposes the following definitions for the purpose of this white paper:

- 30
- 31 • **Technical regulation:** a document which lays down product characteristics or their
32 related processes and production methods, including the applicable administrative
33 provisions, with which compliance is mandatory. It may also include or deal
34 exclusively with terminology, symbols, packaging, marking or labelling requirements
35 as they apply to a product, process or production method.¹
 - 36 • **Product:** a product is an item produced and sold, often as a result of a manufacturing
37 process, that may change or be re-purposed after entering the market or following a
software update and can include software in itself.

¹ World Trade Organization Technical Barriers to Trade Agreement, Annex 1:
https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

- 38 • Product with AI system: a product with an embedded system, that operates with
39 varying levels of autonomy and can make decisions influencing real or virtual
40 environments in a way that is generally intended to further human objectives.
- 41 • Product with integrated software: a product with an embedded, upgradeable
42 (remotely, offline or by other means) system that controls the functioning of the
43 product and directs its operation.
- 44 • Product with embedded digital technologies: a product with an AI system or with
45 integrated, upgradeable software or with a combination of both.
- 46 • Product characteristic: hazardous features of products with embedded digital
47 technologies addressed by technical regulation that may concern, for example product
48 safety, cybersecurity, resilience, privacy, climate and sustainability (or a combination
49 of these).
- 50 • Safety case: a structured argument, supported by a body of evidence that provides a
51 compelling, comprehensible and valid case that a product with an embedded AI
52 system or other digital technology is safe for a given application in a given operating
53 environment.

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

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

66 Existing conformity assessment procedures might not be applicable for consumer products
67 with embedded AI systems, as many are opaque or not transparent. Developing a safety case
68 to show that the risk of a product is brought to a level that can be accepted based on a thorough
69 regulatory impact assessment involving all relevant stakeholders, including the regulated
70 entity, might be the key instrument of conformity assessment for consumer products with
71 embedded AI elements or other digital technologies. That being said, products with embedded
72 digital technologies will likely undergo many pre-market revisions which shall necessitate
73 safety case amendments in instances where the original use case fundamentally changes or
74 would trigger a product reclassification.

75 There are a wide range of regulatory uncertainties present within products with embedded
76 digital technologies due to their nascency. There is thus a need for developing and applying
77 risk management tools based on scenario analysis for proving that products with embedded
78 digital technologies have a tolerable level of risk.

79 International standards play an important role in the global economy and in facilitating
80 international trade through aligning technical regulations, conformity assessment procedures,
81 and national standards.² There are a number international standards being developed and
82 under development that are of pertinence to the regulatory compliance of products making

²https://www.wto.org/english/tratop_e/tbt_e/principles_standards_tbt_e.htm

83 use of AI or other embedded digital technologies, including those relating to risk
84 management; artificial intelligence; conformity assessments; quality management systems; as
85 well as international guides and recommendations. These need to be taken into consideration
86 in future work related to this topic.

87 It is reminded that the UNECE Working Party on Regulatory Cooperation and
88 Standardization Policies (WP.6) has already developed a number of recommendations also
89 pertinent to this topic, including:

- 90 • *Recommendation G on the Acceptance of Conformity Assessment Results.*³ This can
91 be applied to this topic with acceptance of the results of conformity assessment
92 procedures (e.g., calibration, testing, inspection, certification, and accreditation) for
93 products with embedded digital technologies, including acceptance by means of
94 multilateral mutual recognition agreements, facilitating international trade and
95 reducing duplication.
- 96 • *Recommendation K on Metrological Assurance of Conformity Assessment Training.*⁴
97 This ensures that results of measurements are the basic facts on which decisions are
98 taken in conformity assessment and testing.
- 99 • *Recommendation N on Good Market Surveillance Policies and Practices.*⁵ Effective
100 enforcement practices for products with embedded digital technologies placed on the
101 market or imported ensure that these meet legal requirements on safety, health,
102 environment, fair competition between economic operators, and any other aspects of
103 public interest.
- 104 • *Recommendation S on Applying Predictive Risk Management Tools for Targeted*
105 *Market Surveillance.*⁶ The management of non-compliance risk is of particular
106 importance for setting priorities in market surveillance, import compliance and
107 effective enforcement practices with the purpose of removing dangerous and non-
108 compliant products from the market.
- 109 • *Recommendation T on Standards and Regulations for Sustainable Development.*⁷
110 Effective risk management is a necessary component of any regulatory system and
111 building risk-based regulatory systems that would be proportionate to products with
112 embedded digital technologies' risks that are relevant to the Sustainable Development
113 Goals (SDGs) and targets is essential for sustainable development.
- 114 • *Recommendation U on Gender-Responsive Standards.*⁸ There will likely be gender
115 implications for products with embedded digital technologies that need to be taken
116 into consideration.

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

³ https://unece.org/DAM/trade/wp6/Recommendations/Rec_G_en.pdf

⁴ https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_K_en.pdf

⁵ https://unece.org/DAM/trade/wp6/Recommendations/Recommendation_N_en.pdf

⁶ http://www.unece.org/fileadmin/DAM/trade/wp6/Recommendations/Rec_S_en.pdf

⁷ https://unece.org/sites/default/files/2022-09/ECE_CTCS_WP6_2022_06_E.pdf

⁸ https://unece.org/DAM/trade/wp6/Recommendations/Rec_U_en.pdf

122 Realizing responsible products with embedded digital technologies innovation will require
123 concerted action across governmental agencies and the private sector. The principles set out
124 in this paper may accordingly be relevant to actors in all of these settings. It is advised that
125 the principles set out in this document be considered as a whole as they are all complementary.

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

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

136 II. Proposed way forward

137 Governments, when establishing regulatory objectives should consider that products with
138 embedded digital technologies deploy human-centric technology and do not substitute human
139 autonomy or assume the loss of individual freedom and should embrace best practices
140 implementing Agenda 2030 SDGs such as following of, and not limited to Recommendation
141 U.

142 Governments should also ensure – in order to achieve a consistent and high level of protection
143 of public interest with regards to health, product safety, fundamental rights and the UN values
144 enshrined in the Universal Declaration of Human Rights and the UN Global Compact – that
145 common international standards for products with embedded digital technologies be
146 established. Those standards should be non-discriminatory and in line with international trade
147 commitments.

148 Governments can prevent and mitigate regulatory concerns regarding products with
149 embedded digital technologies by ensuring that only compliant products with embedded
150 digital technologies are placed on the market, given that safety and security risks may be
151 generated by a product as a whole due to its digital components, including embedded digital
152 technologies, and consider mandating independent audits of products as appropriate with
153 embedded digital technologies upon auditable (binary compliant/non-compliant) criteria.

154 Governments can ensure that in sectors where the stakes for life and health are particularly
155 high, increasingly sophisticated diagnostics systems and products with embedded digital
156 technologies supporting human decisions should be reliable and accurate.

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

160 Governments may, considering children’s vulnerabilities and provision of protection and care
161 as necessary for their well-being with respect to products with embedded digital technologies,
162 protect children’s specific rights as enshrined in the United Nations Convention on the Rights
163 of the Child, further elaborated in the UNCRC General Comment No 25 (2021) as regards
164 the digital environment.

165 Governments should recognize the needs of emerging economies in implementing digital
166 technologies and related regulatory frameworks as part of national quality infrastructure and,

167 as consequence, the necessity for capacity building and technical assistance in
168 avoiding/minimizing a digital divide.

169 Governments should provide natural and legal persons and groups of natural or legal persons
170 with access to proportionate and effective remedies for harm caused by products with
171 embedded digital technologies. In particular, Governments should provide the right to lodge
172 a complaint against the providers of such products and receive compensation against any
173 direct damaged or loss they have with regard to their health, safety, privacy or fundamental
174 rights due to an infringement of their rights by the original producer of such products or third
175 parties which have impacted the product.

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

181 Product regulators should develop and implement procedures necessary to explicitly address
182 regulatory concerns of products with embedded digital technologies' non-compliance within
183 their scope of responsibility, including within import compliance processes at the border, as
184 described in *Recommendation V on Addressing Product Non-Compliance Risk in*
185 *International Trade*.⁹

186 Governments should implement processes required for the management of non-compliance
187 concerns of products with embedded digital technologies within processes aimed at
188 addressing customs-related and trade disruption risks.

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

192 Governments should implement mechanisms and processes, as appropriate, for bodies that
193 develop and implement their national quality infrastructure to exchange information, consult,
194 and operate in an aligned and efficient manner to promote a whole-of-system approach to
195 standards and conformance for products making use of AI or other embedded digital
196 technologies.

197 Governments should ensure that regulatory measures applied to products with embedded
198 digital technologies are consistent with the World Trade Organization (WTO) Technical
199 Barriers to Trade (TBT) Agreement.¹⁰ This includes, but is not limited to, the TBT
200 Agreement's obligations pertaining to notification, publication, non-discrimination,
201 avoidance of unnecessary barriers to trade, achievement of legitimate objectives and use of
202 international standards.

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⁹ https://unece.org/sites/default/files/2021-10/ECE_CTCS_WP.6_05_E.pdf

¹⁰ https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm