

How to target continuous compliance

Background: WP.6 project on regulatory compliance of products with embedded AI...



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The regulatory compliance of products with embedded AI or other digital technologies



- Project started initially in November 2020 within GRM
- Formal project launched in January 2023

- Project leader: Markus Krebsz
- Project team of a dozen international experts
- 30-day public review (6 June to 10 July; 81 comments, 78% accepted)

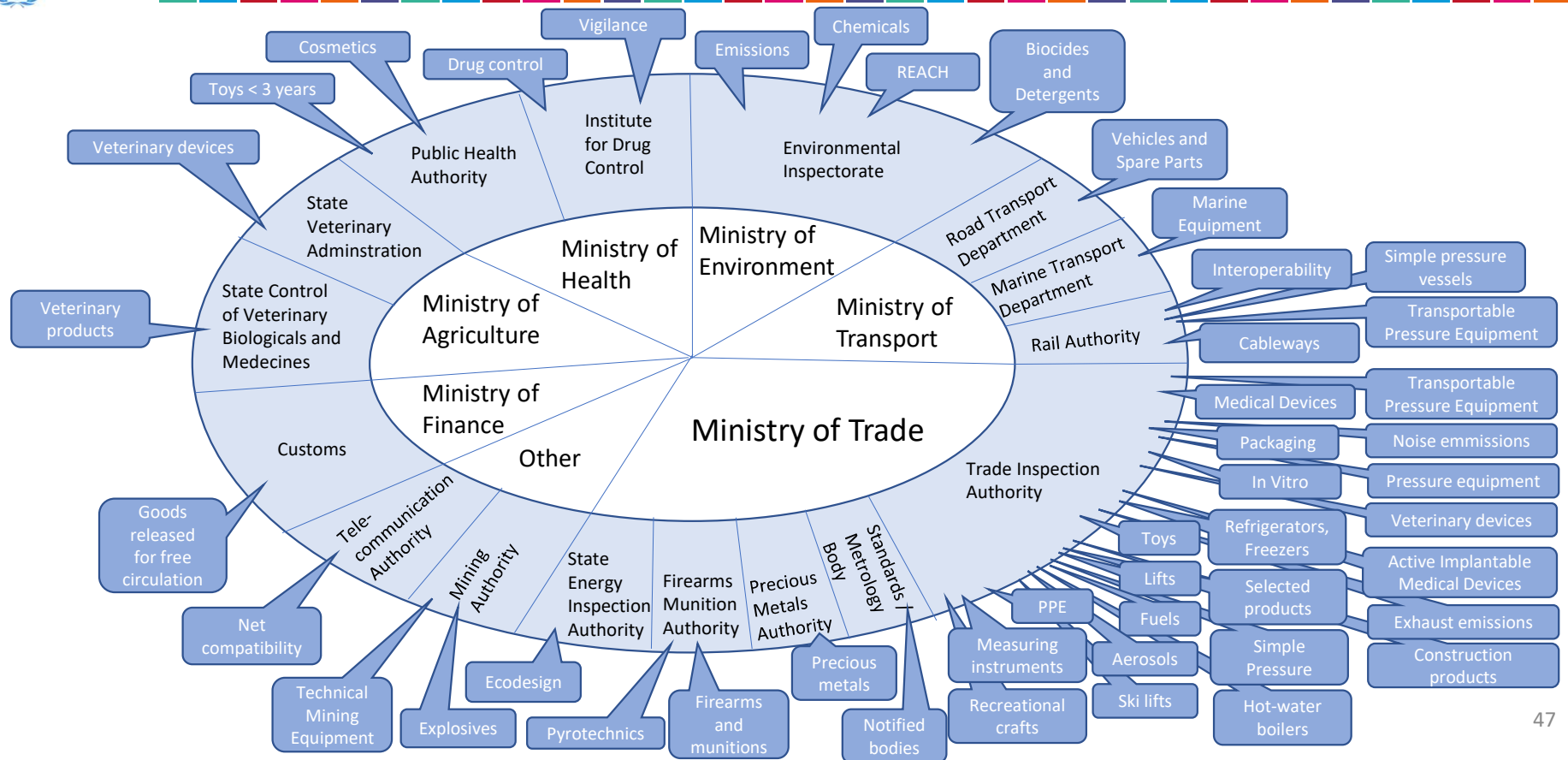
- Supports the ECE 70th Commission session theme “Digital and green transformations for sustainable development”

Definitions



- **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.

Regulatory compliance of embedded AI & digital technologies is of horizontal nature



Relevant international standards



- ISO/IEC JTC 1 / SC42 on artificial intelligence
- ITU AI for Good Global Summit 2023
- WP.6 Recommendation of relevance (G, K, N, S, T, U, V)
- WTO *Technical Barriers to Trade*
- *Universal Declaration of Human Rights*
- *United Nations Convention on the Rights of Persons with Disabilities (CRPD)*
- *United Nations Global Compact*
- *United Nations Convention on the Rights of the Child (UNCRC)*
- Other

Considerations for market surveillance of products with embedded digital technologies



- Ensure human-centric objectives
- Protect society, particularly vulnerable, children, environment
- Consider needs of emerging economies and reducing the digital divide
- Have mechanisms to report incidents & monitor non-compliance
- Embrace best practices implementing Agenda 2030 SDGs
- Consider mandating independent audits with binary criteria
- Consider product characteristics of autonomous weapons

Possible deliverables of WP.6



- Given the prevalence of the topic of artificial intelligence and the challenge that products with AI will pose to quality infrastructure
- WP.6 could potentially develop one or a combination of the following:
 - Common regulatory arrangement (CRA)
 - WP.6 recommendation
 - Declaration
 - Convention

Common regulatory arrangement



- Based on *Recommendation L on an International Model for Transnational Regulatory Cooperation Based on Good Regulatory Practice*
- Technical in nature; often adopted at the agency level
- Can evolve with the technology / standards
- Financial implications are indirect related to the cost of compliance to the CRA

WP.6 Recommendation



- Highest level policy document within WP.6
- Establishes a policy direction; may go beyond today's practices towards an envisioned best practice
- Policy in nature; usually does not contain technical aspects
- Adopted by member States or government agencies, or private-sector bodies
- Modifications would be slow; deprecation difficult
- Non-binding and voluntary
- Financial implications are indirectly related to the cost of compliance



- Declaration outlines a universal principle that the signatories engage to implement
- Political in nature – normally not technical, though could integrate some éléments which are technical in nature
- Could be signed by member State or directly by the pertinent entity that would implement
- Declaration demonstrates an intent (but may not be binding)
- Modifications difficult; would require agreement of all signatories
- Financial implications are indirect related to the cost of compliance



- Written legal agreement between Member States
- Results from negotiations between Member States who wish to advance on the same topic
- Political by nature (will normally not be technical)
- Signed by member States
- It is binding for those who have signed and ratified, after entry into force
- Withdrawal process integrated into articles of the agreement
- Modifications after entry into force defined by the agreement
- Financial implications for compliance and for creation and maintenance of a secretarial body