

Working Party on Regulatory Cooperation and Standardization Policies (WP.6)
Group of Experts on Risk Management in Regulatory Systems meeting discussion notes and actions
13 June 2024, 11:00 CET

| Item | Subject | Discussion / Action |
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| 1a | Roll call | <p>Leadership: <u>Alexia Davison</u> (Chair), Donald Macrae (Vice-Chair), Valentin Nikonov (Vice-Chair) Secretariat: Lance Thompson Members: <u>Fatmanur Tülümen</u>, Ian Gardner, Leonid Dvorkin, <u>Lucy Salt</u>, Markus Krebsz, Paul Taylor, Simon Webb, <u>Victoria Vlasova</u> Experts: Andrei Batagen, Andrea Gratz, <u>Caro Robson</u>, David Anikoh, Warren Merkel 17 participants (5 <u>women</u>)</p> |
| 2 | Update from the secretariat | <p>The secretariat provided an update on the publication “Basics of Risk Management in Regulatory Systems”. The content has been finalized and it is now being cleared internally and prepared for publication. It is hoped that the publication will be ready for launch at the 34th annual session end of August 2024.</p> <p>The secretariat also updated on the annual session of the Steering Committee on Trade Capacity and Standardization (SCTCS) which will take place 26(pm) to 28 June 2024. It reminded that GRM reports to WP.6 and WP.6 reports to the SCTCS. During this meeting, the WP.6 Vice Chair Marco Pangallo will present the work of WP.6 (and of the GRM) to the SCTCS. There are no documents for approval directly concerning the GRM. The WP.6 segment of the agenda will also include a 90-minute presentation of the Basics of quality infrastructure publication. It is planned that one of the additional editors of the Basics of Risk Mgmt will make a short presentation which will announce the imminent release of this publication.</p> |
| 3 | Prep for WP.6 24 th Session | <p>The secretariat reminded of the WP.6 34th Annual Session which will take place 26(pm) to 28 August 2024 in Geneva. Each subgroup will have 60 minutes for their reporting. This must include at least 10 minutes for the formal reporting of activities of the GRM by the GRM Chair. And there should be at least 10 minutes for discussion. This leaves 40 minutes for topics which the GRM would like to bring to the attention of member States. The secretariat underlined that this is an in-person only meeting, so speakers will need to be physically present. Efforts will be made to allow experts to listen-in with a live feed, but no distant participation is planned.</p> <p>A few suggestions were discussed. It was agreed to gather any comments until Wednesday 26 June 2024 at which time, the GRM Chair will define the speakers during the 40 minute part of the segment.</p> |
| 4 | Project IRM+SW | <p>Project leader provided an overview of the project objectives and methodology and presented the initial report of 10 pages which will be further discussed on the dedicated project meeting. Among the initial findings, it was noted that there is currently no integrated risk management system as described in WP.6 Rec. V; there do exist elements though. It was generally recognized the key roles of single window in integrated risk management. Methodology is one of the areas</p> |
| 5 | Risk mgmt. in context of CRA on AI | <p>A review of the Overarching CRA on AI underlined that there are opportunities for new work concerning risk management to supplement this work. For example, risk criteria or risk tolerance can fill the gap where standards don't yet exist. GRM could also further expand on the risk criteria in paragraph 12.</p> |
| 6 | Competence mgmt. | <p>Information collection has continued – there are four additional responses. The overall responses is mixing observers and members. The matrix could be used for future projects to see what skills are available. Perhaps reviewing the matrix could be used when looking to launch new projects to see who could participate.</p> |

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| 7 | Potential new projects | <p>One topic for new, potential projects include residual risk.</p> <p>There is potential future work on risk management and targeting non-compliance on on-line markets. This could potentially be cross-cutting, involving multiple subgroups of WP.6 (notably with MARS). There could be a joint meeting to brainstorm on this with MARS. It was suggested either the September or November meetings could be used for this.</p> <p>On the latter, there is already a basis: application of Recommendation S and V on targeted market surveillance of online markets. Rec. S main objective is to outline probability of non-compliance and the consequences. This methodological basis could be used; will need to define how this would be applied to online markets.</p> <p>Another idea future work could use generative AI in the pharmaceutical industry, for example, used as a means to detect the use of the drugs for areas of potential abuse/misuse. The secretariat asked to please ensure the work is within the scope of WP.6 and its PoW.</p> <p>The change of distant updates in products with embedded technologies could result in non-compliance; perhaps a project on the need to have a regulatory clearance of updates before they are implemented.</p> |
| 8 | ISO TC262 | <p>There is a call for experts, convenors and project leads for the 31000 series.</p> <p>There was a workshop on management system standard (MSS) on the proliferation of MSS. Another document outlines that certified organizations should take into account climate change aspects and risks.</p> |
| 9 | Risk mgmt. related events | None to report |
| 10 | AOB | None |
| | | Next GRM meeting: 12 September 2024 (11:00 Geneva-time) |