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Risk management in regulatory systems

Report on the activities of the Group of Experts on Risk Management in Regulatory Systems

Note by the secretariat¹

Summary

This report summarizes the main results achieved by the Group of Experts on Risk Management in Regulatory Systems as of August 2013.

In particular, it details recent activities against the project plan approved by the Working Party, and sets out current priorities. It concludes by laying out the plan of work for 2014 for discussion and approval by the Working Party, and highlights the risks that could hinder the realization of the plan.

Annex I includes the names of the individuals and organizations that have participated in the work of the Group.

Annex II includes Report on the application of the UNECE GRM Reference Model for Risk Management to a specific regulator.

¹ At its twentieth session, the Working Party established a Group of Experts on Risk Management in Regulatory Systems and adopted its terms of reference, and requested it to report on activities to the Working Party (ECE/TRADE/C/WP.6/2010/2 para.9).

I. General information on the Group, and main accomplishments

1. The main results of the activities of the Group of Experts on Risk Management in Regulatory Systems from 2011 to 2013 are as follows:

(a) The book *Risk Management in Regulatory Frameworks: Towards a Better Management of Risks* was launched at the twenty-first annual session of the Working Party. In 2013, the book was republished by the United Nations Publications Office and is available on the website: <https://unp.un.org/Details.aspx?pid=23517>;

(b) A technical project was implemented at the Brazilian National Institute of Metrology, Quality and Technology (Inmetro) to improve the country's regulatory system by using the framework developed by the GRM and laid out in Recommendation "R" and in the book *Risk Management in Regulatory Frameworks: Towards a Better Management of Risks*;

(c) The Group organized a featured event on "Disaster Risk Management Standards for Business and Citizens" as part of the Global Platform for Disaster Risk Reduction 2013, organized in cooperation with the United Nations Office for Disaster Risk Reduction. The event and the participation of the Group in the Platform brought increased recognition for the role standards can play in mitigating disaster risks (see the Global Platform's Chairman's summary: <http://www.preventionweb.net/globalplatform/2013/news/view/33306>);

(d) Nomination in the category "Partnership of the Year" at Global Risk Awards 2013;

(e) Two recommendations, approved at the twentieth annual session of the Working Party:

(i) A general recommendation on the use of risk-management tools in regulatory systems – "Managing Risk in Regulatory Frameworks" (Recommendation "R");

(ii) A specific recommendation, which describes one of the functions of the risk-management process, as defined in the general recommendation "Crisis Management within a Regulatory Framework" (Recommendation "P");

(f) An analysis of several legislative texts that regulate the electrical appliances sector in different jurisdictions based on the GRM risk management framework;

(g) Cooperation with ISO TC 262 (Risk management) on the use of the draft recommendation on improving consistency of application of risk management concepts in legislation in the work of TC 262 and possible inclusion of the draft in ISO standards;

(h) Participation in the work on the Organisation for Economic Co-operation and Development Working Party on Consumer Product Safety and participation in the Workshop on Product Risk Assessment (Tel Aviv, April 2012);

(i) Participation in the work of the ISO TC 262 Project committee: Risk management (participation in the meetings of the TC 262 in London, October 2011, and in Dublin, February 2012);

(j) Awareness-raising activities, including through social media and by participating in the First International Conference on ISO 31000 (Paris, March 2012).

2. The Group continues to function on the basis of:

- (a) Broad and diversified membership, with representation of different geographical and economic regions, as well as of different areas of competence and end-users' interest;
 - (b) An e-mail list server and an interactive website;
 - (c) Technology and rules of procedures that permit efficient organization of the work of the Group despite the limited secretariat resources;
 - (d) Ongoing webinars and face-to-face meetings.
3. It also benefits from the results of the previous activities of the Working Party related to risk management in regulatory systems. The most important milestones of the risk-management work of the Working Party are described in document ECE/TRADE/C/WP.6/2012/5.

II. Members and representation

4. In 2013, the Group welcomed one new member, one member left the Group. Twenty-seven experts participate in the Group, representing the following areas of competence:
- Planning, developing and implementing technical regulations
 - Choosing and implementing conformity-assessment procedures
 - Cooperation among business companies and regulators
 - Risk-management methodologies and standards
 - Project management.
5. The work is coordinated by Messrs. Donald Macrae and Valentin Nikonov.
6. The coordinators are responsible for:
- preparing and keeping up-to-date project plans
 - identifying project risks
 - project communication, including maintaining the website
 - consolidating information required for developing the recommendations
 - internal reporting, including reporting to the secretariat
 - other functions as required.
7. The updated list of members is attached to the present report as annex I and can also be found on the website.

III. Summary of webinars and meetings

8. Monthly webinars and electronic data exchange are the usual means of communication in the Group. The Group held three webinars between November 2012 and August 2013, seven between March 2011 and November 2011 (see ECE/TRADE/C/WP.6/2011/3), and five between November 2012 and August 2012, the reports of which are available on the website (see ECE/TRADE/C/WP.6/2012/5 and ECE/TRADE/C/WP.6/2012/3).

9. At its thirteenth webinar, held on 24 January 2013, the Group discussed decisions made at the twenty-second session of the Working Party and agreed on the promotion strategy for the publication *Risk Management in Regulatory Frameworks: Towards a Better Management of Risks*. The Group approved the draft recommendation on improving consistency of risk management legislation. It continued discussing approaches to developing a recommendation on applying risk management to evaluating equivalency of regulations.

10. At its fourteenth webinar, held on 26 March 2013, the Group discussed the horsemeat scandal, on the basis of the GRM framework. This led to publishing an expert opinion prepared by one of the Group's members on the UNECE website (www.unece.org/index.php?id=32495). The Group decided to send the draft recommendation on improving consistency of risk management legislation to the ISO TC 262 for comments. It agreed that it should coordinate the work on the recommendation with the similar work undergoing within the ISO Technical Committee 262 "Risk Management". The Group noted a brief overview of risk management work in marine planning in Canada and a brief presentation of the manual that connects ISO risk management tools (ISO 31000) with ecosystem risk management approaches.

11. At the fifteenth webinar, held on 11 June 2013, the Group analysed the results of the implementation of the GRM recommendations within the regulatory system of Brazil. Based on the feedback, the Group made a list of areas for further improvement of models and recommendations. It agreed to focus on analysing differences in regulatory approaches instead of developing a recommendation on using risk management to evaluate equivalency of regulations. It discussed the results of the GRM participation in the Global Platform for Disaster Risk Reduction and agreed to continue working in the area of crisis management, business continuity and disaster preparedness.

IV. Progress in the completion of the initial plan

12. The following table provides information on when and how each of the tasks listed in the plan of work for 2013 (contained in ECE/TRADE/C/WP.6/2012/5) was performed and what the result was. It explains why certain tasks were not accomplished, suggests moving some tasks to other periods or deleting them from the plan.

<i>Tasks and deadlines, as originally planned</i>	<i>Results/Comments</i>
Developing a draft recommendation on applying risk management to evaluating equivalency of regulations	The GRM discussed various approaches to developing such a recommendation and agreed to focus on analyzing differences in regulations within a specific economic sector in various countries.
Finalizing the recommendation aimed at improving consistency of risk-management legislation•	The draft of the recommendation was approved.
Fundraising	No funds were raised.
Performing the field work:	
• Running risk forums and trainings;	A training session was conducted in Brazil by Mr. Donald Macrae, coordinator of the GRM.
• Preparing reports on best practice and problems to be solved.	

<i>Tasks and deadlines, as originally planned</i>	<i>Results/Comments</i>
Developing specific recommendations (on how to perform risk-management functions, such as risk identification, risk analysis and evaluation).	Specific recommendations were not developed.
Running pilot implementation projects	An implementation project was conducted in Brazil by Mr. Donald Macrae, coordinator of the GRM.
Updating the recommendations and intergroup approval	The GRM didn't receive any requests for updating recommendations.
Approving recommendations	
Promoting the recommendations	The GRM developed and is currently implementing a promotion plan for the publication "Risk Management in Regulatory Systems: Towards a Better Management of Risks".
Presenting the feedback	The feedback on the GRM recommendations is presented in the Annex 2 of the Report.

V. Priorities and the plan for 2013-2014

13. Work for the remainder of 2013 and for 2014 will focus on increased cooperation with the United Nations Office for Disaster Risk Reduction (UNISDR) to evaluate how the work of the GRM could be used to mitigate disaster risks.

14. UNISDR has proposed that UNECE coordinates a new area of research on the role of voluntary standards and technical regulations in disaster risk reduction as part of the 2015 *Global Assessment Report on Disaster Risk Reduction* (GAR 15) publication.

15. GAR 15 will be published in early 2015 and will set the tone for discussions at the World Conference on Disaster Reduction to be held in March 2015 in Sendai, Japan. The conference looks poised to adopt a successor agreement to the Hyogo Framework for Action, a ten-year United Nations plan to make the world safer from hazards.

16. Resources permitting, the GRM could play an important role in this proposed new project.

VI. Main risks

15. The main risks for the successful completion of the GRM work and specifically the new project of cooperation with UNISDR include:

- Insufficient funding for the organization of the work and for field work.
- Lack of secretariat resources.
- Insufficient participation by government representatives owing to resource constraints.

Annex I [English only]

List of members (as of 30 August 2013)

Chairperson

Kevin Knight (Chair, Technical Committee 262: Risk management, International Organization for Standardization)

Coordinators

Donald Macrae (Independent consultant)

Valentin Nikonov (Project Manager, Bank24.ru)

Active members

Alberto Alemanno (Associate Professor of Law, HEC Paris, France)

Lorenzo Allio (Independent Consultant on Regulatory Reform and Risk Regulation, and representative of the European Risk Forum)

Gabriel Barta (International Electrotechnical Commission)

Florentin Blanc (The World Bank Group)

Bo Yumin (National Accreditation Service for Conformity Assessment, China)

Ronald Cormier (Fisheries and Oceans Canada, Canada)

Alex Dali (President, Global Institute for Risk Management Standards, G31000, France)

A.M. Dolan (University of Toronto, Canada)

Graeme Drake (Committee on conformity assessment, International Organization for Standardization)

Valery Hurevich, (Belarusian State Institute for Standardization and Certification (BelGISS), Belarus)

Phil Kelly (Liverpool Business School, United Kingdom)

Markus Krebsz (Risk Reward Limited, United Kingdom)

Sean MacCurtain (Secretary, Committee on conformity assessment, International Organization for Standardization (ISO))

Peter Morfee (Ministry of Economic Development, New Zealand)

Greg Paoli (Risk Sciences International, Canada)

Christophe Renard (Cotecna, Switzerland)

Mikhail Rogov (RusRisk, RusHydro, Russian Federation)

Dan Roley (Caterpillar, United States)

Marc Schaedeli (Group for Risk Management, Nestlé)

Paul Taylor (Federation of European Risk Management Associations (FERMA), United Kingdom)

Olivier Testoni (International Telecommunication Union)

Jan van Tol (Ministry of Interior and Kingdom Relations, Netherlands)

Simon Webb (The Nicholas Group, United Kingdom)

Carolyn Williams (Institute of Risk Management, United Kingdom)

Annex II

Report on the application of the UNECE GRM Reference Model for Risk Management to a specific regulator.

Prepared by Donald Macrae, Director, XDG Consulting Ltd

Joint Convenor of UNECE GRM

April 2013

Introduction

1. Inmetro is the National Institute of Metrology, Quality and Technology for Brazil. It prepares technical regulations and conformity assessment procedures on its own quadrennial plan and in response to requests from other organisations, including other Ministries. Other regulators can themselves prepare technical regulations and conformity assessment procedures for their own sector or can request Inmetro to do it. It is also Brazil's Inquiry Point for TBT Agreement and represents Brazil in many international forums.

2. In many ways it is a forward-looking regulator and was the first in Brazil to apply impact assessment to its regulatory decisions. It has never formally applied risk management to its operations but has now started to address that. It has been performing risk management for many years with some success but without any formal structures at organisation-wide level. An initiative begun in the Conformity Assessment Directorate and supported by the Inmetro President led to inviting me to work with Inmetro for three weeks in April 2013 exploring the scope for applying risk management more formally.

3. I was chosen partly for my previous work with Inmetro on Impact Assessment and my work on both regulatory reform and risk management. In particular, Inmetro was interested in the possible suitability of the GRM Reference Model, so I was also invited as a Joint Convenor of the GRM group.

4. I worked with the informal Comitê Interno de Gestão de Riscos (CIGR) and, in particular, its Executive Secretary, Mayard Zolotar in Dconf, with the management support of Director Lobo.

5. President Jornada had the foresight to set up a meeting with the Directors in the third week of my visit at which he asked them each to present to him and to me what they saw as the chief risks in their area of operations. This focused attention of their Directorates to send representatives to the training programme that was arranged by the CIGR. That training consisted of a series of workshops which applied the GRM model to Inmetro's operations and produced a collection of illustrative "risks". These brought to life a seminar held on 11 April which was well attended from across the whole organisation. That was followed by more specialised seminars on Corporate Risk, on Regulatory Risk and on Risk-based Market Surveillance.

6. The meeting with Directors on 17 April showed Inmetro at its best. The engagement was genuine, the concerns were compelling and, as usual, the level of debate was high. Very serious concerns about Inmetro's strategic risks surfaced but there was total consensus across very different areas. It demonstrated a good grasp of risk management in various parts of Inmetro but a lack of joining up across the organisation. But, at the same time, it demonstrated the need for and value of that joining up. I was already persuaded that Inmetro was more than ready to adopt a greater degree of formalisation of risk management but this session also reinforced the need for it.

7. The conclusion was that the GRM model suited Inmetro very well and should form the basis of the application of risk management in the organisation.

Analysis of the strengths and weaknesses of the GRM model

8. A distinction needs to be drawn between the actual reference model and the book. Few people had read the book as a downloaded .pdf but I brought seven copies which they welcomed. The book was well received as an easy guide to the subject, at least for the first three chapters. What was mainly commented on was the actual model.

The additional first stage

9. It worked well. Adding the stage on assets and objectives was fully supported as useful. To some extent it covers the same ground as the consideration of the context in ISO 31000 but it is much clearer in identifying what is of value to the organisation and therefore what needs to be protected. This was the way in to the subject. ISO 31000's first Principle is about risk management protecting value. These first questions about identifying the hazards and then risks to be managed are vital but also extremely difficult without a method. If the right risks are not identified, the rest of the management system is pointless. But people find it very difficult to identify major risks in the abstract. Starting with what needs to be protected and considering what might threaten that is the way to do it. Also, considering the objectives of the organisation and thinking of factors that will influence success and failure also follows the same overall approach of identifying value and protecting it.

10. The workshops started with a SWOT analysis, which is always a good way to develop energy in groups and focus on the main issues. From this we drew major concerns or hazards and developed them into risks and opportunities. What did not work so well was the description of "assets" and we found that "value" worked better. It was also difficult to apply the arguments about traceability but that was not found to be necessary.

11. There was confusion between "hazard" and "risk". It is very common for people to refer to hazards as risks but we had to take it step by step and identifying risks comes from risk analysis of the hazard. Simply stating the potential damage – loss of capacity of the organisation to deliver – is not describing a risk but a hazard. Identifying factors or events that may happen and will lead to loss of that capacity is identifying the risks. So, having identified hazards they had to then consider what might increase or decrease the likelihood of that hazard materialising. At this early stage in the process, terminology is confusing.

The additional GRM stage at the end

12. There was also strong support for the additional stage at the end – Contingency Planning. What generated most interest and discussion was the risk strategies stage and that included serious consideration of risk tolerance. They understood that this not a "do nothing" option but that it can be a delaying of mitigation measures until the event occurs. I took time at the start to draw out a key distinction about risk as "managing uncertainty":

- one option is to try to change what will happen in the future, usually through risk avoidance measures or risk mitigation measures;
- the other option is to allow events to take their course and deal with the consequences if the unwelcome event actually occurs.

13. The former approach tended to be favoured in earlier approaches to risk, where it was seen as "managing the future", but this can be a waste of resource. If the event never occurs, the costs applied would be wasted (unless the reason it didn't occur was because of

the efforts made) whereas it may be more cost effective to deal with the consequences later. Of course some threats are too radical to be left to be dealt with later, e.g. threats to the survival of the organisation.

14. Risk acceptance can apply to both minor and major hazards. It applies to minor hazards because they are not worth trying to manage in advance but it also applies to the major ones that are too big to influence. They cannot be wholly avoided and mitigation measures are deemed to be unlikely to have much effect. I used animal disease outbreaks as an example of the latter and my experience in Defra in applying contingency planning.

15. Put simply, the emphasis on this additional stage of contingency planning opened up the debate and the thinking on the four strategies. The common ones of avoidance and mitigation were put into a more useful perspective.

Other successes

16. In these ways, the additional steps in the GRM model succeeded well. The overall model worked when split into stages in PowerPoint slides. The overall model as a whole was regarded as too complicated but it became clear when taken in small bits.

17. President Jornada was pleased with the model and endorsed it for Inmetro. The two main things that appealed to him were that it had been designed for regulatory systems and that it was relatively simple compared to other models. Although he is an eminent scientist, he felt strongly that risk management should be kept simple. That also coincided with my approach, which was very fortunate. We both saw it as essentially an intellectual checklist of questions in an ordered sequence that can be applied with great flexibility. The answers can be very difficult but the questions are simple.

18. My recommendation for applying it was to base the application on ISO 31000, figure 2, but adopt the GRM model as the central discipline, i.e. add the two extra stages. (This would be 4.4.2 in the ISO model.) I also recommended a minimalist approach to the framework, so that the use of risk management would be distributed throughout the organisation with the management layer being in support of what was needed centrally rather than a top down structure. Management needs to give clarity on risk culture and define various risk criteria and risk indicators for the organisation but should leave as much as possible to local level.

Weaknesses

19. The book was less useful when talking about regulatory systems. It is a very good introduction to regulatory systems but does not really deal with the application of risk management. For the specialised seminars on Regulation and on Market Surveillance, I found it difficult to take much from the book to help focus a discussion on risk.

20. For the Regulation seminar, the key risk issue is the decision on what to regulate and how. Inmetro already apply high quality impact assessment once they begin their regulatory process so risk management is built in at that stage. The criteria for accepting a request and how to establish priority must be developed first but could be enhanced by applying a risk approach. That is the nature of their key challenge and not really foreseen in the book. Discussion showed that their criteria for these decisions are primarily around safety, but their objectives also take into account economic impact as well as public protection. However, there is room for improvement concerning the use of their core business to take forward their key objectives, The latter was one of the key benefits of having embarked on the exercise: they are supposed to balance safety issues with promotion of fair competition, support for innovation and support for Brazilian business generally. They are part of the Ministry for Development, Industry and Foreign

Commerce. Risk management took them back to their objectives – and it was the GRM initial stage that emphasised this, so this was seen as further endorsement of the model.

21. For Market Surveillance, the challenge was applying a risk-based approach. Inmetro inspect only products regulated by Inmetro rather than broad market surveillance. So decisions about risk profiles and severity are already dealt with upstream. Again, the key decision is what products to focus on. Again, the organisation's objectives come into focus. But I added the perspective of the UK's "business-based" approach. Products do not get onto the market on their own. All products will have businesses connected with them, with different businesses at different stages. These businesses themselves may add hazard to the product, e.g. dividing bulk supplies, measuring, packaging and distributing, as opposed to simply handing over a pre-packaged product to an end-user. The UK has worked out a set of criteria for assessing business-based risks which can be added to Inmetro's current criteria to make a richer mix.

Risk Transfer / Sharing

22. The majority of discussions focused on risk criteria and on risk strategies. The book was very helpful on risk strategies. In addition to earlier comments on how the final stage of Contingency Planning raised the importance of Risk Tolerance / Acceptance, there was considerable interest in Risk Transfer / Sharing. At first, this was seen as other government bodies transferring their risks to Inmetro. But it grew into a more crucial issue of managing relationships with partners, especially Inmetro's delivery chain. Risks in the delivery chain emerged as one of Inmetro's biggest risks. Even if they speed up their regulatory processes, they are dependent on third party certification, on there being enough labs (and, of these, enough accredited labs), on the businesses having the skills to gain certification, etc. Ultimately, as a developing economy, they risk hitting the limits of the capacity of the private sector to deliver.

23. As an illustration of how forward-looking Inmetro is, they already have a compliance assistance programme which looks at support issues in the delivery chain. They think through the capacity issues and can give some funding assistance to businesses, as well as education. What they cannot do, however, is persuade labs to apply for accreditation for new conformity assessment procedures (which are mandatory on the business but not on the certifier). So a small team is already engaging on this issue but it needs to be tackled more strategically, which the seminar with Directors brought out very forcibly.

24. They also need to explore alternatives to regulation as a risk transfer strategy (as opposed to risk avoidance). They have astonishing influence over consumers and can shape markets through influencing buying choices so consumer education may in some cases be more effective than a regulatory approach. This still has to deliver the levels of protection of regulation but could do so. It also removes the risks of the current delivery chain. Again, this is something that part of the organisation is already working on and it needs to be developed further.

Risk Criteria

25. Risk Criteria emerged as the heart of the exercise. After asking the right questions in the right order, the next step is to evaluate and that requires criteria. The organisation has few criteria already articulated but the organisation's objectives, Mission and Vision have to be the source of them all. The risk management exercise therefore kept taking us back to looking at the organisation's objectives which was a huge benefit. An organisation's objectives are often ignored and forgotten at daily operation level. When we did refer back to the objectives, it was often challenging making them apply.

These criteria then need to be scored, which is where risk culture and risk appetite come in. On a scale of 1 – 5, everything was 4 or (more usually) 5. It took a lot of discussion to gain perspective and to work out a series of descriptions of 1 – 5. Where possible, numbers helped a lot but the evaluation tended more to qualitative factors. A relatively simple one that we constructed in a workshop was for loss of institutional capacity. Loss of an entire function, such as conformity assessment or market surveillance, scored 5. A loss of 75% capacity in a key function would score 4, etc. But we then got into arguments over whether it was loss of capacity or loss of quality (i.e. we have the people to do it but they are producing rubbish). But at least they had got the point.

26. Some risk criteria need to be established at enterprise level and I assume that in ISO 31000 these are the risk indicators referred to in 4.2. The organisation cannot be applying different criteria or the same criteria with different scoring values in different parts of the organisation.

Lessons Learned and Next Steps

Implications for the model

27. The reason for mentioning these other aspects is to see what learning there may be for GRM. In testing out the model against a functioning regulator, some things worked well but there are also various needs that the regulator had in applying risk management that the model and the book did not really cover. Some of this will be peculiar to Inmetro or to a technical regulator but the GRM model is aimed specifically at technical regulators (as opposed to economic regulators or quality regulators).

28. More on risk criteria would definitely help. Applying risk sharing with partners is also likely to be fairly universal.

29. Consideration could be given to a Second Edition to apply the learning from the Inmetro experience. This report is fairly superficial but there is a wealth of material from the workshops and my final Report that has more detail. Alternatively, we may want to find another regulator to test against.
