

Report of the webinar of the GRM held on 6 February 2012, 11:00 (Geneva time)

Executive summary

The ninth webinar of the UNECE Group of Experts on Risk Management in Regulatory Systems (GRM) was held on Monday 6 February 2012, at 11:00 (Geneva time). The [agenda](#) and a [recording](#) of the webinar are available on the UNECE Wiki website.

Chairperson: Mr. Kevin Knight, Chair of the GRM

Moderator: Ms. Lorenza Jachia, Secretary of the UNECE WP.6

Participants: Mr. Alberto Alemanno (HEC Paris), Mr. Valentin Nikonov (GRM Coordinator), Mr. Gabriel Barta (IEC, Switzerland), Mr. Peter Morfee (Ministry of Economic Development, New Zealand), Mr. Olivier Testoni (ITU, Switzerland), Mr. Graeme Drake (ISO/CASCO), Mr. Paul Taylor (UK), Mr. Simon Webb (The Nicholas Group, UK), Mr. Fabrizio Meliadó (UNECE).

Main points:

- Discussion on electrical appliances as an area of priority for the GRM: the GRM agreed on working on the application of existing recommendations to the sector of electrical and electronic appliances. (**[ACTION](#)** : Valentin Nikonov and Peter Morfee);
- Presentation by Alberto Alemanno on an a recently published opinion by the EU scientific committees on how to make risk assessment more relevant to the risk managers: the GRM suggested providing comments as relevant (**[ACTION](#)** : UNECE Secretariat);
- Participation of the GRM in the work of the ISO Project Committee 262 currently developing the first draft of the ISO 31004 standard on the implementation of ISO 31000 (**[ACTION](#)** : UNECE secretariat);
- Finalization of the Recommendation on Risk Management in Regulatory Frameworks: the GRM agreed on adding a clause to the Recommendation (**[ACTION](#)** : UNECE Secretariat);
- Approval of the plan of work for 2012: the GRM decided to start working on a recommendation on applying risk management tools to establishing equivalency of regulations (**[ACTION](#)**: GRM).

Detailed proceedings

Decisions Taken at the Latest Webinar and “Today’s Agenda”

Lorenza Jachia presented the decisions taken at the latest GRM webinar and the agenda for the current webinar. It was recalled that at the previous webinar participants had discussed the [Recommendation on Risk Management in Regulatory Frameworks](#) (Recommendation R), and had entrusted the Secretariat to ensure that comments were duly reflected in the final draft. The UNECE Secretariat had accordingly circulated a new version of the draft Recommendation R, in advance of the present meeting. Secondly, at the previous webinar it was decided to apply the approach of Recommendation R to the analysis of legislation in the field of electrical and electronic appliances, taking into account the experience of New Zealand as introduced by Peter Morfee. The webinar would discuss how to proceed.

Discussion on Electrical Appliances as an Area of Priority for the GRM

Valentin Nikonov and Peter Morfee jointly presented the topic:

Following the approval of the two recommendations on Recommendation P on “[Crisis Management within a Regulatory Framework](#)” and Recommendation R, the GRM should start to discuss areas where those recommendations could be applied.

The speakers, referring back to discussions held in the previous GRM webinar, said that the experience of New Zealand in regulating electrical appliances provided good grounds to start a discussion on the application of the Recommendation R. For example, it was recalled, elements that could be taken into account were the application of risk management tools to regulatory design; the grouping of electrical and electronic products in accordance with the high/medium/low level of risk to which they can be associated; determining the applicable level of regulatory intervention; establishing equivalency of regulation on the basis of risk analysis; and tools, methods and processes applied to assess the level of risk.

Peter Morfee noted that New Zealand and Australia, as well as many other countries in the region, favor a risk-based regulatory system focusing on pre-market controls for electrical products. In the EU instead, given the importance of the electrical products sector, the post-market approach works smoothly. In terms of performance-based regulation, meanwhile, both the EU and New Zealand have an almost identical set of performance-based criteria, but New Zealand uses a slightly different model for implementation. This scenario would therefore provide an opportunity to analyze how the pre- and post-market approaches work alongside each other, so as to make a comparison.

(ACTION) Kevin Knight then proposed that Peter Morfee and Valentin Nikonov start working on a comparative analysis of the legislation of New Zealand and the EU through the lens of the reference model developed with the recommendations of 2011. Peter Morfee and Valentin Nikonov agreed to jointly work on this issue.

Presentation of a Recent Opinion by the EU Scientific Committees

Reference: “[Improvement of Risk Assessment in View of the Needs of Risk Managers](#)”

Alberto Alemanno presented the topic.

Science-based decision making is broadly supported in the EU policymaking. One of the main problems in further applying this approach is that risk assessment in the EU is highly fragmented and different bodies provide scientific advice in different ways.

The three non-food committees involved in risk analysis (the [Scientific Committee on Health and Environmental Risks](#), the [Scientific Committee on Emerging and Newly Identified Health Risks](#) and the [Scientific Committee on Consumer Safety](#)) have recently issued the joint opinion: “[Improvement of Risk Assessment in View of the Needs of Risk Managers and Policy Makers](#)”.

The joint opinion acknowledges the need for more cooperation among the Scientific Committees and more generally calls for increased coherence between risk assessment and risk management. The document highlighted ways in which the risk assessment process could be made more management-relevant, inter alia by facilitating cost/benefit analyses. The document also suggests changing the form of risk characterization in order to better express potential impact on human health and natural environments.

An open question is now whether the recommendations could be extended to the food-related authorities (as the EU document currently refers only to the non-food bodies).

(ACTION) To conclude his presentation, the speaker suggested that given that the EU document has currently reached the public-consultations phase, it could be appropriate for the GRM to prepare comments and send a note on the EU document to the EU Commission. The GRM, during the “[any other business session](#)”, endorsed the idea of preparing a note to be sent to the EU and entrusted the secretariat with the task of preparing the draft-note. The **deadline for sending the note would be Feb. 21, 2012.**

Questions & Answers

Kevin Knight opened the discussion by referring to the international standard [ISO/IEC 31010:2009](#) on Risk Assessment Techniques, and said that there seems to be a disconnect between RA *per se* and the objectives pursued by a new regulation, which ultimately justify and motivate RA and are normally provided by the mandating organization.

Valentin Nikonov recalled that one of the original ideas behind the Recommendation R was to help align RM to rules as they are applied in regulatory frameworks; another point made in the recommendation R, he added, is that, in spite of the various technical features characterizing RA, it would still be beneficial if RA were presented within the overall RM framework. These elements appear to be complementary to the findings of the EU document, he concluded.

Paul Taylor enquired about the identity of the persons or bodies conducting RA and RM. Alberto Alemanno answered that in general the non-food committees are composed of independent scientists selected by the EU Commission to provide scientific advice on an individual basis. They also put together “meta-analyses” by looking at scientific literature and studies also from other parts of the world, and then construct a scientific opinion on that basis. The risk manager, in the vast majority of instances, is represented by the EU Commission, as experts representing the EU Member States meet in committees under the chairmanship of the Commission. These Committees take decisions on safety thresholds and similar matters, and prepare legislative proposals that would become law at a later stage, following the relevant EU legislative procedure for this type of acts. Paul Taylor commented that risk assessors could easily present information on RA in a format more easily understandable for non scientists. Alberto Alemanno said that - because of the need to grant independence of assessment - risk assessors and managers have little opportunities to engage in debates. Paul Taylor and Alberto Alemanno added that this would seem to be a good reason to have a common language between the two areas. The conventional wisdom on the need for a rigid separation between RA and RM was also, itself, under discussion.

Simon Webb proposed a link to other forms of analysis: cost-benefit analyses and regulatory impact assessments (RIA). He introduced the experience of the transports sector, where there was a tension between scientists who were good at conducting risk analyses, and economists who valued the socio-economic perspective of those analyses. Currently, he said, the EU too endorses impact assessment in its regulatory process, but it seems that impact assessment is carried out too late in the EU process. So the issues are, first, to study the link between RA and cost-benefit analyses, and second, to streamline the impact assessment part of the EU decision-making process.

Alberto Alemanno noted that RIAs do not apply to administrative acts, which represent a large part of the EU regulatory activity. One challenge is now to extend RIAs to these non-legislative regulatory acts; there are signs suggesting that we are slowly moving towards a cost-benefit approach also at lower levels of decision-making and administration. Simon Webb added that a quick form of impact assessment could be developed also in the EU context in order to benefit the whole process. An example would be analyses that are proportionate to the subject matter being evaluated. Alberto Alemanno highlighted the fact that the EU Commission is not bound to conducting solely cost-benefit analyses, but rather relies on a broader set of techniques, such as cost-effectiveness, where you simply and quickly compare various policy options.

Lorenza Jachia asked a question on how the opinion published by the Scientific Committees could impact the EU legislative process in practice. Alberto Alemanno answered that the opinion could help move towards a common language for risk assessment and risk management.

Kevin Knight shared the Australian experience which is similar to that of the EU, as in Australia many agencies work independently without any formalized cooperative framework, unless a key governmental program were under discussion. Peter Morfee added that scientists use to deal with consequences and rarely with probability, so the two elements appear to be separate most of the times; also, he said, by looking at computer-based RA models, one realizes that most of the elements that form part of the overall scientific analysis do not reach the analytical stage at which effects are discussed. From a management point of view, he said, it is important to separate probability and consequence to have a better understanding of the combination of the two. At the EU level, added Alberto Alemanno, the level of uncertainty that will be communicated from assessors to managers has always been an issue; there is a tendency to avoid as much as possible uncertainty when communicating RA results to risk managers, of course, and this point is also addressed in the EU document.

Discussion on ISO 31004

Background note: The ISO is in the process of developing a new standard providing guidelines on the implementation of ISO-IEC 31000. This new standard ISO 31004. In this connection, the GRM has developed a draft-Annex to ISO 31004 proposing guidelines for applying the principles of ISO/IEC 31000:2009 to the development of RM-related legislation.

The UNECE secretariat briefly introduced the comments they had prepared on the “Regulatory Annex”, of the draft ISO/IEC 31004 standard. They also stressed the fact that the Regulatory Annex needed further work before finalization.

Kevin Knight said that the current ISO/IEC draft is a “working draft”, which means that substantive changes can still be made on the text of the standard and on its substance. The session of the Technical Committee in Dublin should be able to craft a “committee draft”, which would be a more consolidated version allowing for specific comments on the words that should appear in the final version. At that point, “column 6” of the ISO/IEC template for comments will become the focus of the revision process.

Discussion on the draft Recommendation R

Valentin Nikonov reminded participants that the latest version of the Recommendation was in an annex to the previous webinar’s report. If the GRM approved it, than the WP.6 would have 30 days for comments; and if no comments were received, the Recommendation would then be published.

Graeme Drake said that he represents in the GRM the ISO and in particular the work of ISO on conformity assessment. He suggested that the **sixth recital of the draft Recommendation**, at page 15 of the previous webinar's report, which reads as follows:

“Taking into account international standards related to the management of risk, such as ISO/IEC 31000:2009, ISO 9001:2008, ISO/IEC 27001:2005, and other standards, including sector-specific standards”

Could include a mention to ISO/IEC 17000:2004 on conformity assessment at the end of the list, considering that in the latter standard originate other ISO/IEC product-specific standards on conformity assessment.

There was general agreement from the participants in the webinar about the proposal. Gabriel Barta also stressed the need to correct the mistake in the draft about ISO 27001, which is rather ISO/IEC 27001. Accordingly, the revised recital should read as follows:

“Taking into account international standards related to the management of risk and other standards, such as ISO 31000:2009, ISO 9001:2008, ISO/IEC 17000:2004, including sector-specific standards, **such as** ISO/IEC 27001:2005”

(ACTION). The GRM decided to send the draft Recommendation for comments to WP.6. In case no comments were received, the draft would be approved without further revision.

Priorities and Work Plan for the Year 2012

Valentin Nikonov wrapped up the discussions; the following actions need to be taken:

- Finalizing the Recommendation R;
- Applying Recommendations P and R to the sector of electrical appliances and products;
- **(ACTION)** Start working on new recommendations: e.g. on equivalency of regulations based on the level of risk;
- Gabriel Barta expressed a reservation on this point: he said that perhaps the GRM will need to see some of the results of the application of the RMRF to the electrical sector before a sensible recommendation on “equivalency” can actually be prepared. Kevin Knight suggested to start gathering information and data on equivalency in other sectors, and use the electrical sector as a model.

Any other business

Paul Taylor proposed to revert to the discussion on “impact”, or “consequence”, and “probability” in RA. He said that it is not really possible to separate impact and probability when conducting RA. As impact varies, there are various impacts which are related to probability. Looking e.g. at food-related issues, there is a kind of a scale where you can look at small risk situations and disaster situation where the probability, meaning the likelihood of the event, is inversely proportional to the impact or consequence of the said event. Peter Morfee said that in cases where there is wideness of both probability and consequence, the RA should show that information; it is still important, he added, that managers take into account how the combination is made. He said that disasters in the mining sector show that, psychologically, low probability many times corresponds to high impact.

Re-opening the discussion on the opinion published by the Scientific Committees, Gabriel Barta said that IEC/ISO 31010:2009 could provide some additional techniques on RM/RA. Kevin Knight added that IEC/ISO 31010:2009 should be brought to the attention of EU stakeholders: in particular, what may be relevant is the analysis of the phases that precede RA. For example: clearly understanding why RA needs be done, what is the underlying issue, what are the methods and techniques to be used, how does it contribute to the process, who is responsible, who is accountable, who has ownership, etc. (**ACTION**) The GRM then asked the UNECE secretariat to follow up as appropriate.

Graeme Drake suggested that ISO/CASCO could support the work of the GRM on electrical appliances and provide useful comments.