Report of the webinar of the GRM held on April 7, 2011

Introduction

The second webinar of the Group of Experts on Risk Management in Regulatory System (GRM) was held on the 7th of April, 2011, at 11:00 (Geneva time). The goals of the webinar were to:

1. Update the Members on the decisions taken at the previous meetings of the Group and to share the results of the Group's participation in the International Regulatory Reform Conference;
2. Initiate the development of a general recommendation on application of risk management tools in regulatory systems, based on the UNECE background document ECE/TRADE/C/WP.6/2010/3;
3. Approve the list of priorities for the Group;
4. Approve the project concepts (trainings and a forum) to be further developed into proposals for sponsors.

The agenda and a recording of the webinar are available on the GRM wiki website.

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

Participants: Mr. Donald Macrae, Mr. Valentin Nikonov (Coordinators of the GRM)

Lorenzo Allio (Independent Consultant on Regulatory Reform and Risk Regulation, Switzerland), Mr. Gabriel Barta (IEC), representative of Mrs. Bo Yumin (National Accreditation Service for Conformity Assessment (CNAS), China), Mr. Phil Kelly (Liverpool Business School, UK), Mr. Kevin Knight (Chair of the ISO TC responsible for ISO 31000, Australia), Mr. Sean MacCurtain (ISO/CASCO), Mr. Peter Morfee (Ministry of Economic Development, New Zealand), Mr. Massimo Polignano (Esaote, Italy), Mr. Christophe Renard (Cotecna, Switzerland), representatives of BelGISS (Belarus), Mr. Paul Taylor (FERMA, UK), Mr. Olivier Testoni (ITU), Mr. Jan van Tol (Ministry of Interior and Kingdom Relations, the Netherlands), Mr. Simon Webb (The Nicholas Group, UK), Ms. Carolyn Williams (Institute of Risk Management, UK).

Brief summary of presentations and discussions

The Secretary of the UNECE WP.6 opened the second webinar of the GRM by welcoming participants and by remarking that the month of March was an exciting month for the Group. GRM had its first webinar on March 8, followed by the Group's participation in the International Regulatory Reform Conference in Amsterdam and its first face-to-face meeting there.

Ms. Jachia shared the main results of the previous meetings of the Group: decisions taken at the webinar and at the meeting in Amsterdam (reports of the meetings are available at: http://www.unece.org/trade/wp6/OtherEvents/OtherEvents.html) and the Group's input into the Outcome of the International Regulatory Reform Conference. This was followed by a brief outline of how results of the previous meetings were reflected in the current webinar's agenda (see the presentation: http://www1.unece.org/reg_coop/platform/download/attachments/327946/Webinar+07.04+Previous+Meetings+and+Agenda.pdf).

Developing a general recommendation

Mr. Nikonov initiated the discussion under the agenda item 'Developing a recommendation based on the UNECE background paper "Risk Management in Regulatory Systems: A Proposed Reference Model" by recalling that the main objective of the Group was to develop recommendations for regulatory stakeholders on the application of risk management tools. These recommendations can be of three types (see the report from the previous webinar http://www.unece.org/trade/wp6/AreasOfWork/RiskManagement/WebinarReportGRM_March2011.pdf). Mr. Nikonov noted that it would be logical to start the work on developing recommendations with a general recommendation that would 'establish the common system of coordinates' for all regulatory stakeholders in managing risks'. This general recommendation would aim at 'showing roles of various regulatory stakeholders and 'uniting' them in managing risks' and at 'providing regulatory stakeholders with a check-list' to make sure that all relevant risk management functions are performed within a regulatory system. The recommendation would also promote the application of International Standards on Risk Management by regulatory stakeholders. The objective of the presentation was to get a general approval which would allow preparing the first draft of the document to be presented at the next webinar. The draft of the recommendation as it was presented can be found at http://www1.unece.org/reg_coop/platform/download/attachments/327946/Webinar+07.04+Developing+a+recommendation.pdf.

Discussion

Mr. van Tol recommended that the proposed recommendation strongly makes the point that **absolute safety cannot be a regulatory goal**. The GRM should find ways to promote this point to public administrators and the public. Mr. van Tol also advised referring to existing ISO standards that cover various subjects mentioned in the reference model.

Mr. Knight also emphasized the "danger that regulators would try to make life and the world in general totally risk-free". The regulator's goal should be to manage, and not to eliminate, risks..

Mr. Polignano suggested a discussion on the definitions of terms related to risk. The Group has representatives of different fields; in which risk management concepts can be applied differently. Mr. Polignano proposed that at the next webinars the Group members present how risk management concepts are applied in different fields and the standards that they make reference to..

Mr. Morfee supported that point by saying that medical equipment was particularly difficult to deal with since risks included those related to functionality and to safety of the product itself. Mr. Morfee noticed that 'tolerance' and 'acceptability' were different terms, and that if the public were asked about the risks that they would tolerate, the answer would be very different than if the public were asked about the risks that they would accept. This difference should be considered in the work of the Group.

Ms. Williams supported the point about the absolute safety, which should not be a regulatory objective and suggested that the documents developed by the Group should reference ISO 31000. This series of standards reflect a lot of work that was done in risk management standardization, e.g. in terms of terminology. Its application would help understanding each other, and would provide common ground for understanding risk management concepts.

Mr. Renard also supported reference to ISO 31000 and encouraged the Group to also apply standards developed by ISO/CASCO.

Mr. Renard also suggested that in its work, the Group considers risks of three types:

- Risks to products and goods,
- Risks related to infrastructure and
- Risks related to systems.

Mr. Allio raised a question on how to differentiate between three categories of recommendations that were mentioned in the presentation. To answer this question, **Mr. Nikonov** provided an analogy between a regulatory system and a management system. A general recommendation could be compared to a management system standard: it is a recommendation for the system as a whole, specifying processes and the structure it should have, like, e.g. a standard for an information security management system. The next level of decomposition could be presented as follows: an information security management system includes a number of processes, as the regulatory system does, so the next layer of recommendations covers specific regulatory processes, like, say, crisis management in regulatory systems. And the third layer of recommendations covers specific functions or events, like 'involving stakeholders in risk identification'.

List of decisions is presented at the end of the document.

List of priorities

Mr. Macrae presented the results of the previous discussion on the list of priorities and observed that priorities of the Group can be discussed in terms of regulatory areas, regulatory processes, and countries (see the presentation of priorities

http://www1.unece.org/reg_coop/platform/download/attachments/327946/Webinar+07.04+List+of+Priorities.pdf).

Mr. Knight proposed the area of nursery equipment or other products for pre-school age children as a priority area for the Group to study. Behind this is the Australian experience of trying to permit self-regulation in this area. Given the extreme sensitivity of the group of vulnerable people which the regulatory system is intended to protect, this is a remarkable initiative. If self-regulation can work effectively in this area, that could form an important test case for other jurisdictions and for other product areas.

Mr. Renard was also concerned with processes rather than areas and focused on traceability as a key process in the end-to-end regulatory system. For example, areas he mentioned included toys from China and fake medicines in Cameroon. This illustrated a broader conclusion from this discussion that of our three categories of areas, processes and countries, the main priority is likely to be in processes, with areas being used as examples of these processes and perhaps areas within specific countries for even more detailed examples.

Mr. Morfee raised another process issue - the role of risk management in the contrasting approaches of performance-based regulation and prescriptive regulation. The debate between these approaches is a staple of the regulatory world, with no clear winner and politicians capable of campaigning for the merits of either. How these approaches manage risk is a key part of that debate since risk management is always an underpinning reason for regulation. Prescriptive regulation builds in a risk assessment as part of its justification for the prescriptive rule and

it is usually inflexible and will in many cases be totally inappropriate. It will set a higher level of risk protection than is often needed and may even be set to a maximum level that is rarely necessary at all. The current debate on the safety levels of radiation is a good example of where prescriptive regulation and standards aims for a very pessimistic possibility and perhaps also influences the public's perception of the level of danger, insofar as the public will assess a level of danger from the seriousness with which it is treated by the authorities. Performance-based regulation will tend to build in a risk assessment process so that the risk can be assessed in each case, giving greater flexibility but, for some businesses, greater confusion and, for the public, sometimes a feeling of less safety. It may be that some risks are better suited to one than the other, which is something we could explore. That can take us back to the other level of Area and even Country. The UK at present has a big political push towards performance-based regulation. **Ms. Williams** offered IRM assistance in looking at the Group's priorities and taking forward this debate in the UK might suit IRM.

Mr. Taylor argued for pushing back more responsibility to the citizen. This is against the trend but there are instances where it is being tried. Again, it fits with some UK thinking and it is also very much tied in with Mr. van Tol's current programme in The Netherlands. It would give the Group a fresh voice in our regulatory world if we were to take that sort of line.

Mr. Webb reinforced this point by referring to a recent example from Scotland where policymakers are exploring developing a rapid response facility in the event of a risk materializing as an alternative to regulation to prevent the risk materializing. That is also a radical and innovative approach. Insofar as regulation is about managing risks, this is an alternative model. It would not suit all risks but it would be interesting to study which ones would be appropriate.

Mr. Knight also came back in support of making more effort to avoid unnecessary regulation, giving Queensland as an example of a process which requires a risk management assessment before a regulation can be adopted. Mr. Knight also proposed that the GRM adopts ISO Guide 73, recently amended in ISO 31000) terminology.

Mr. Taylor suggested that the reference model may need some adjustment to take account of these decision points (especially as regards the decision of whether or not to regulate)

Conclusions on the list of priorities

The discussion focused on the use of risk management in regulatory systems at a fundamental level, dealing with the issue of whether regulation is justified. It ranged from looking at alternatives to regulating at all, such as a rapid response facility in the event that the threat materialised, to looking at the relationship between regulator / government and the citizen, particularly on the issue of whether the risk ought to be managed by the citizen or other non-governmental bodies. That discussion also accommodated in the middle the ongoing debate - where it is decided that regulation is needed - as to whether the regulation should be prescriptive or performance-based.

That gives the Group some innovative and radical thinking, with examples that can be followed through and developed. That further consideration and research could give the Group a new direction to provide to the technical regulation community. The immediate actions suggested would be to reconsider whether the reference

model needs to be adapted to bring out any of these issues and to have further discussions with the contributors to assess where next to take the work.

Project proposals

As it was agreed at the previous meeting, **Mr. Nikonov** presented two project concepts, as follows:

1) Organizing a forum to discuss a risk events that occurred. The objective of the forum would be to develop recommendations aimed at enhancing the stability of a specific regulatory system.. Recommendations would be developed by bringing together the involved regulatory stakeholders and by analyzing the situation using the methodologies developed by the Group.

2) Organizing trainings on one or more specific regulatory systems. The training would aim at bringing together all the regulatory stakeholders for one specific sector and applying the reference to that sector step-by-step. This would provide common language and common understanding of risk management processes by all parties involved and would raise the effectiveness of regulatory systems (see the presentation of the project proposals http://www1.unece.org/reg_coop/platform/download/attachments/327946/Webinar+07.04+Project+proposals.pdf).

The projects would promote the Group and provide resources to support its work, meetings and members' participation in its work.

Mr. Taylor agreed with the concept of trainings and suggested that the reference model should be first stress-tested. The form of the training session, in turn, can take two different directions. One could be devoted to new regulations coming in, and another – to changing or reviewing regulations. Tobacco regulations could be used as an example of evolving regulations. The Group could try to apply the model to both proposed and existing legislation.

Ms. Williams noted that the Institute of Risk Management would be happy to help in providing materials for trainings and asked about how these trainings would be organized. The Secretariat replied that the format of the trainings would be highly dependent on the sort of fundraising that the project will get. Providing materials could be a kind of contribution which would be very welcomed by the Secretariat.

Other issues

The Group agreed to have a discussion on Crisis management in Regulatory System on the next Webinar. The objective of the discussion will be to develop a proposal for a recommendation that would suggest crisis management be a part of the toolbox that authorities use in advance of the regulating.

Decisions

1. To hold the next Webinar of the GRM on 5 May 2011 at 11:00 Geneva time.
2. To organize a discussion on Crisis Management in Regulatory Systems at the next Webinar.

3. To request the Secretariat to prepare a draft of the general recommendation based on the UNECE background document “Risk Management in Regulatory Systems: A Proposed Reference Model”, taking into account all the comments made at the webinar, in particular:
    a. To stress the point that absolute safety cannot be a regulatory objective, to emphasize that regulators should identify risks to manage them other than to try to make the world and life risk-free;
    b. To consider applying both the concept of ‘tolerance’ and the concept of ‘acceptability’;
    c. To refer to ISO 31000 standards and other standards available in the documents developed by the Group; to use ISO Guide 73 as a Dictionary.
    d. To include into the model a function related to identifying if there is a need for a regulation.
4. To stress test the model

5. To plan presentations on how risk management concepts and standards are applied in different sectors;
6. To include the following items in the list of priorities:
    a. Sectors:
        i. Cosmetics;
        ii. Nursery equipment;
    b. Processes:
        i. Dialogue with the public over the issue of tolerability of risk;
        ii. Connecting ISO and EU standards;
        iii. Traceability in regulatory systems;
        iv. Contingency planning;
        v. The role of risk management in the contrasting approaches of performance-based regulation and prescriptive regulation;
        vi. Self-regulation;
        vii. Pushing back more responsibility to the citizen in managing risks;
7. Contingency planning and crisis management. To approve the proposed project concepts (training and forum) and to request the Coordinators to prepare project proposals (to be presented at the next Webinar).