



**Economic and Social
Council**

Distr.
GENERAL

ECE/TRADE/C/WP.6/2010/2
7 April 2010

Original: ENGLISH

ECONOMIC COMMISSION FOR EUROPE

COMMITTEE ON TRADE

Working Party on Regulatory Cooperation and
Standardization Policies

Twentieth session
Geneva, 1 to 3 November 2010
Item 12 of the provisional agenda

**RISK ASSESSMENT AND MANAGEMENT
IN THE ACTIVITIES OF THE WORKING PARTY***

Note by the secretariat

1. At its nineteenth session, the Working Party requested the secretariat to follow up on the conference on risk and management and to report on activities at its next session (ECE/TRADE/C/WP.6/2009/19, para. 10).
2. This document is presented for information to the Working Party.

Introduction

3. The Working Party on Regulatory Cooperation and Standardization Policies held an “International Conference on Risk Assessment and Management” on 24 and 25 November 2009, and a Workshop on “Practical Application of Risk Assessment and Management Tools” on 23 November 2009.

* All the presentations made are available on the WP.6 website:
http://www.unece.org/trade/wp6/documents/2009/2009_ConferenceRisk.htm

4. The present document is the basis for follow-up work to these events for the Working Party. It is structured as follows:

Chapter I contains the outcome of the Conference, discussed and agreed to by the participants, and recommendations to the Working Party;

Chapter II contains a summary of the presentations and discussions that were held during the three sessions of the Conference;

Chapter III contains a summary of the presentations and discussions held during the Workshop;

The annex contains the Draft Terms of Reference (ToR) for the Group of Experts on Risk Management in regulatory and standardization policies (GOERM).

I. Conference outcome

5. The conference addressed the principal components of risk management:

- Risk identification
- Risk assessment
- Determination and implementation of risk management strategies
- Risk communication.

6. It discussed these issues within the context of the activities of policymakers, intergovernmental organizations, standardization bodies, technical regulation authorities, conformity assessment bodies and business companies.

A. Policymakers, standardization bodies and technical regulation authorities

7. Policymakers and technical regulation authorities are responsible for identifying and addressing public risks – i.e. risks that may have an undesirable impact on society - in a systemic way. This includes taking decisions on the following:

(a) Acceptable level of risks, with due consideration of the costs and benefits of risk mitigation for different societal groups. Additional costs should not be imposed simply because an increased level of security is technically possible;

(b) Responsibility of different stakeholders for the management of risks.

8. Standards developed and maintained by standardization bodies play a key role in mitigating risks of all types. They also assist in addressing global challenges and core policy interests, and enable organizations to systematically integrate the management of risks into their overall strategies, policies, values and culture.

9. Regulatory goals for appropriately addressing and mitigating risks cannot be met unless all stakeholders are actively involved. These include business operators, conformity assessment

bodies, market surveillance authorities and consumers.

B. Risk management in the activities of intergovernmental organizations

10. The World Trade Organization Agreements on Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement) provide, for all WTO members, a framework and policy principles within which national technical regulations are developed. Risk assessment has a well-defined role in the SPS agreement and its importance in the context of “good regulatory practice” is also recognized.

11. Work under way in the Organisation for Economic Co-operation and Development shows that risk assessment is one essential element in the policy frameworks of the Organisation’s members, specifically in regulatory impact assessment.

12. Various regional organizations have developed approaches that ensure proportionality between risks and regulatory response. In the European Union, for instance, risk assessment forms part of the impact assessment that precedes new legislation.

13. Intergovernmental organizations consider risk management to be an important methodology. A number of issues need to be addressed to make it more effective, including how to establish common methods for risk identification, determination of the level of criticality, and risk communication.

C. Risk management in legislative and regulatory activities

14. Technical regulations, together with voluntary standards, contribute to ensuring the safety of products and services and the stability of processes within organizations.

15. A basic distinction was drawn between two different types of regulatory frameworks:

(a) Goal-setting regulations set a goal – while leaving economic operators to select their preferred means of attaining it;

(b) Prescriptive regulations that instead set specific requirements, which can be:

(i) **Risk-based:** requiring the operator to analyse unintended events that might occur and take appropriate measures to prevent their occurrence and minimize their consequences;

(ii) **Deterministic:** setting precise and mandatory safety measures.

16. In many countries, regulators are moving towards goal-setting regulations. Risk-based regulations may be perceived as shifting the responsibility of a decision on what is an “acceptable risk” to operators, and away from legislators. National authorities are increasingly aware of the need for proportionate management of risks in the development of technical regulations to achieving a balance between core policy concerns and business efficiency. They perceive a need for further assistance in the following:

- (a) Identifying risk factors linked to consumer product safety;
- (b) Estimating the frequency and seriousness of exposure;
- (c) Developing risk profiles;
- (d) Systematic collection, registration and analysis of data;
- (e) Allocation of responsibilities for risk management among competent authorities.

17. The predictable and consistent implementation of regulations requires close collaboration among all stakeholders. A common understanding of risks and risk management tools is therefore essential.

D. Risk management in business

18. Business operators play a key role in preventing events that could compromise business efficiency and at the same time have undesirable consequences on workers, on communities living close by, on the natural environment and on society. They have longstanding expertise in implementing consistent and professional risk management.

19. This expertise is embodied in standards (ISO 31000, ISO 14000 series, ISO 9000 series, ISO/IEC 27000) that come from different spheres and address different components of business risks, including operational, environmental, occupational health and safety, information security and financial risks.

20. Standards help improve the managerial control of risks within all organizations. However, they are not yet being implemented either generally or systematically and are not perceived as one of the tools to achieve an organization's objectives and mission, although this is clearly the case.

21. Wider implementation of professional risk management in companies and organizations of all types will require actions by all societal stakeholders and can be promoted by fostering:

- (a) Exchange of best practice;
- (b) Better managerial and professional education on all aspects of risk management, including standards;
- (c) More extensive implementation of specific processes and tools for addressing different types of risks;
- (d) A cultural shift in the attitude of management, by consumers and civil society, towards risks.

E. Risk management in conformity assessment and market surveillance

22. Conformity assessment contributes to managing risks while facilitating trade, and helps in managing supply chains effectively. Risk assessment is therefore an integral part of conformity assessment of products and of certification of firms according to risk management standards. However, the certification of a product or process is no guarantee of its safety, also due to the pervasiveness of fraud.

23. Effective use of risk management tools helps market surveillance authorities and conformity assessment bodies attain desired objectives such as the protection of health, safety, and the natural environment as well as other core policy interests, while minimizing the costs and disruptions of tests and controls to business.

24. Risk assessment is of particular importance to market surveillance authorities when they cannot rely on existing standards. It also helps them assess whether non-compliant products pose a threat. International data banks on accidents and other undesirable consequences should be further developed.

F. Risk communication

25. Risk communication ensures an effective relay of responsibilities between authorities and economic operators, as well as among the different market surveillance authorities responsible for different economic sectors, or different regions within one country, and at the international level.

26. EU Member States, for instance, cooperate within the Product Safety Enforcement Forum of Europe (PROSAFE) to draw up best practice in risk assessment and management. And countries in the Commonwealth of Independent States are developing joint action to counter the proliferation of hazardous goods. A key challenge is how to make information from the data banks accessible to external users with due consideration to confidentiality.

27. Countries need to develop effective national strategies for communication, targeted at different groups of people and making use of the most efficient communication channels. Communication should proceed in a stepwise manner: a communications strategy may not reach everyone simultaneously, but it should deliver the messages in an optimal sequence and language.

Recommendations to the Working Party on Regulatory Cooperation and Standardization Policies

28. The Working Party should support already established cooperation in the area of risk assessment and management between authorities and stakeholders concerned and encourage further cooperation to achieve a shared regulatory framework, i.e. one that meets societal demand without stifling innovation or creating technical barriers to trade.

29. The Working Party should continue the dialogue among stakeholders to build an effective regulatory framework – including a common language– to address risks related to products, process and production methods, and to develop best practices in the management of hazards that could cause harm or damage to people, the environment, property and immaterial assets.

30. To this end, the Working Party should consider establishing a Group of Experts on Risk Assessment and Management, and identify the mandate to be given to such a group, including the priorities related to WP.6 work areas.

II. Summary of presentations and discussions made at the International Conference on Risk Assessment and Management

A. Opening session

31. The Conference was opened by the UNECE Executive Secretary, the Secretary-General of the International Organization for Standardization (ISO), the Deputy Minister of Architecture and Construction of Belarus and the Chair of WP.6.

32. The United Nations works in many ways to protect people and the environment from hazards. The normative and technical work of UNECE helps Governments set up a well-balanced regulatory “toolbox”, one that meets societal demands, adequately safeguards consumers and workers, and preserves our natural resources without stifling innovation and entrepreneurship. UNECE intends to use risk assessment as a tool to enhance the stability of its own activities, an exercise that several governmental organizations in the audience had already undertaken.

33. Voluntary standards define the safety features of products that consumers and workers use every day, and that shape our everyday lives. ISO published in November 2009 a “Risk Management Standard” (ISO 31000:2009). Together with existing management system standards (including ISO 9001:2008) it provides principles and guidelines for managing any form of risk in a systematic, transparent and credible manner. These tools can be used to systematically integrate the management of risks into the overall strategies, policies, values and culture of any organization. This implies establishing the context, performing the risk assessment (including risk identification, analysis and evaluation) and making decisions on risk treatment, with ongoing monitoring and review and in consultation with stakeholders. Over 1 million organizations all over the world (including central and local government organizations) use ISO 9001 standards.

34. Belarus is one of the many countries, in Eastern Europe, the Caucasus and Central Asia (EECCA), that are revising their regulatory framework to approximate it to international and European best practice, which implies application of advance risk management tools and methods.

35. Risk assessment and management tools are integral to all the areas of activity of UNECE WP.6. In particular, they can be used to make informed choices on: sectors and/or productive activities that deserve regulatory intervention, alternative regulatory options, alternative

conformity assessment tools (supplier's declaration of conformity, third party assessment of conformity). They can also be used in the planning and execution of market surveillance activities.

B. Session 1: Risk-based regulations: minimizing the cost of safety

36. Speakers from intergovernmental organizations (WTO, OECD), from regional organizations (European Commission), national governmental institutions (the Belarusian State Institute for Standardization and Certification, the Risk and Regulation Advisory Council (United Kingdom), VNIINMASH) and a business association (Technical Association of the European Natural Gas Industry, Marcogaz) discussed how regulators can achieve proportionality between risk and regulatory responses and how a socially acceptable level of risks can be defined.

37. In the context of the WTO SPS and TBT agreements, the proportionality principle is reflected in the provision that measures taken by members should be "no more trade restrictive than necessary". Differences between the SPS and the TBT frameworks are, however, substantial. Under the SPS agreement, every trade restriction needs to be based on scientific evidence of a risk to the life or the health of humans, animals or plants. Under the TBT agreement, measures can be justified more broadly on the basis of "legitimate government objectives". In addition, under the SPS agreement, all measures must be based on Codex Alimentarius, International Plant Protection Convention (IPPC) or the World Organisation for Animal Health (OIE) standards. In case of deviation from these international standards, appropriate risk assessment is required. Under the TBT agreement, the link between scientific evidence, international standards, risk assessment and the measures applied is defined more loosely. Whether this link could and should be reinforced in the context of the TBT agreement, so as to better guarantee proportionality between risks and regulatory responses has been the subject of discussion for many years.

38. In OECD countries regulatory impact assessment (RIA) is widely used to minimize the costs associated with failing to regulate when there is a need, or regulating when there is no need. RIA includes several stages, namely defining the problem, determining the objectives of the government action, considering alternative options and related impacts, consulting with relevant stakeholders, making, implementing and reviewing recommendations. The main difficulties in completing the RIAs were obtaining the relevant data, developing in house risks, building the capacity for risk assessment over time and recognizing and managing risks inherent in regulatory policies. RIAs enable regulators to make optimal choices, which include a continuum of measures ranging from information campaigns, to regulations, to outright product bans.

39. Under the European Community framework, any relevant common regulatory intervention must be accompanied by an impact assessment (IA). IAs are conducted in consultation with scientific committees, specialized agencies or other relevant scientific experts, and includes an analysis of problems, policy objectives and options, as well as of the potential economic, social and environmental impact. IA has two main phases: risk assessment, defined as "the process of assessing, quantitatively or qualitatively, an adverse effect related to an activity, product or event and its probability" and risk management: "the legislative (non-)response to the

identified risk: appropriate, proportionate and effective". The second phase goes beyond scientific and economic considerations, and implies a political decision on the level of acceptable risk, in consultation with all stakeholders, including international trade partners.

40. The Risk and Regulation Advisory Council (United Kingdom) promoted a wide political debate on acceptable risk levels. Regulatory and standardization activities should not be based on the technical feasibility of achieving a greater level of safety, but instead on a form of risk-benefit analysis. The general public is – however – perceived as becoming more and more risk averse and Governments are pressured to increase the stringency of regulations. This analysis is culture-specific and critically depends on how a society defines “public risks” – risks to which the government is expected to respond – and on its “risk landscape”. This is a complex web including regulators, standards setters, the judiciary, public authorities, the public as well as professional risk managers and insurers, which contribute to determine the socially acceptable level of safety.

41. This acceptable level of safety is de facto embodied in standards and regulations: these tools help define the desired characteristics of products and processes, and hence the residual risks that a specific activity will entail. Standards and regulations emerge from consensus among all stakeholders involved in normative and standardization activities. The Belarusian State Institute for Standardization and Certification and the Belarusian National Technical University have developed a systemic model describing the process of consensus-building. This complex process works in markedly different ways at different levels (e.g. national, European and international level), and in different contexts (e.g. public authorities vs. the business community).

42. In the gas industry, safety is defined in national laws, regulations, and standards, constantly updated to keep abreast of the industry’s technical innovation. Innovation is itself a response to the tremendous geopolitical and economic challenges the industry faces. The European gas industry has a proven safety record which is also recorded in the European Gas pipeline Incident data Group (EGIG). The number of system failures has been constantly reduced over the last thirty years. This is the result of safety measures introduced by the industry to reduce probability of hazards, mitigation measures to reduce exposure, and technical and organisational safety measures to minimize any threat to pipelines gas transport. These efforts are well integrated with the regulations in force, based on a balanced use of both the deterministic and the probabilistic approach.

43. Risk management is becoming more important in the Russian Federation regulatory system. The development of technical regulations and standards starts with the identification of risk factors that might influence the product. Risk assessment is the basis for setting safety requirements. A number of technical regulations explicitly reference methods for performing assessment of risks in practice.

44. During the Q&A session, the audience discussed a number of issues, including:

- Mapping out all the risks that have a potentially significant impact on societies would be a complex but useful undertaking;

- Publicly available databases on risks are an important tool for policy-makers, business, and the civil society, however, it posed concerns for intellectual property protection;
- Risks may affect more than one sector and challenge authorities to attribute responsibility for them to the institutions that are most appropriate for managing them;
- Compliance with standards or regulations does not guarantee safety: in particular in cases of third-party interference.

C. Session 2: Markets for consumer products: what role for risk management standards

45. In this session, professional risk management associations (PRMIA, FERMA), consulting companies (Growth Trajectory Consulting Company) and organizations that are professionally involved in risk management development, training and implementation (Non Profit Risk Management Centre, Test-St.-Petersburg, Institute of Risk Management) discussed how risk management can be integrated into everyday business practice.

46. Speakers agreed that success and mission achievement in organizations of all kinds critically depend on how risk governance is built into corporate governance and emphasized role of standards in developing and implementing a risk management system.

47. Management System Standards provide the basis for an enterprise-wide process management system, which is the key to an effective and consistent management of risks. Process management and operational risk management are necessary conditions for building an effective risk management system.

48. Risk management is an integral part of a number of standards such as ISO 14001 and ISO/IEC 27001. In contrast, ISO 9001 contains no explicit reference to risk management, but indirectly refers to a number of its attributes. As some users do not recognize the already existing elements of risk management in ISO 9001, there is a need to address the topic of risk clearly and to decide whether this is related to risk affecting, for example, product, market or organization. These might be included in the revised version of ISO 9001. Other methodologies and standards also help manage risks for future generations: for example, AFAQ 100NR scheme promotes sustainable development by subsuming social, economical and environmental factors.

49. A number of specific risk management standards are available to companies and organizations, including ISO 31000:2009, COSO Enterprise Risk Management Integrated Framework 2004, plus some standards developed by professional organizations. Their implementation poses several practical problems: guidance on their implementation is lacking, and users do not have enough knowledge of how to apply them and effectively explain them to all the partners involved.

50. In a business environment, risk management standards won't work unless the following conditions are met: (a) the risk management system is integrated with other management systems; (b) risk management 'starts at the board' and permeates all business operations (risks are controlled, accurate risk information is collected, managers understand risk and allow for it in their day-to-day activities; (c) compliance with risk standards does not stifle creativity and entrepreneurship.

51. Since firms are an integral and functional part of society, successful risk management in enterprises also depends on the society's risk management culture. Effective communication with all societal stakeholders can help the public to better understand risk. Academic institutions also have a role to play in teaching how to manage – rather than avoid – risks. These tasks were especially difficult in multicultural societies, because the same risks are perceived differently by different people.

52. Firms often adopt a risk management framework or standard because of a perception that this is required by authorities. However, when the management fails to see risk management as a critical part of its operations, and the organization simply seeks to show compliance with the risk management standards, it will likely see overall performance fail. An improved management of risks in enterprises could instead result from: enforcement – using market self-regulating processes – and the recognition of risk management as a professional status similar to law, accountancy, for instance. This would be based on: global standards, a strong educational foundation, qualification requirements, continuous education, and a code of conduct.

53. Increasing cooperation with risk management professionals might be beneficial for authorities for a number of reasons. For example, it could assist in developing guidelines for applying current risk management standards, promoting awareness of risk management and educating the media in communicating risks appropriately.

D. Session 3: Implementing technical regulations: risk management for conformity assessment, certification, and market surveillance

54. In this session, speakers from governmental organizations (the German Federal Institute for risk assessment, the Danish Safety Technology Authority), conformity assessment bodies (AFNOR Rus), civil society (ORGALIME) and the private sector (Nestlé and Cotecna Inspection SA) discussed how risk management tools can be used to reinforce compliance with standards in the pre- and post-market phases, and highlighted the role of risk communication in risk management.

55. Each person has a different perception of risks and of critical risk levels, depending on a number of factors including culture, education levels, and life-style. For this reason, sending out messages without validating the public response is not effective. Instead, communication should be a two-way process and should make use of different communicators, such as NGOs, politicians, business people, scientists, journalists, TV. This will ensure a better outreach because different target groups place their confidence in very diverse sources of information. Ideally, information about risks should start from scientific experts through symposia, then, reach out to economic and technical experts (through workshops), and then politicians and NGOs (stakeholder conferences), consumers and the media (round tables, open door events).

56. Risk management is an important tool in conformity assessment. For example in management system certification process an auditor cannot issue a nonconformity to a management system standard unless a “proven risk” related to this nonconformity is identified. This increases the objectivity of the results of the audits; also, management system audits can be treated as an important part of corporate risk management.

57. In many cases, market surveillance authorities (MSAs) do not need to conduct an independent risk assessment but may refer to applicable product standards. Standards are especially relevant because in EU legislation, they are widely used for presumption of conformity with the safety requirements. However, risk assessment by MSAs may be called for, especially when there is a lack of applicable standards, and to determine whether or not a product that is found to be non-compliant with the standard is indeed dangerous. In these cases, risk assessment tools will be used to estimate the degree of danger and the appropriate action for the MSAs. This will be based on the estimated probability and the severity of health/safety consequences, which help authorities to grade risks. In the EU, risks are graded under the Rapid Alert System for Non Food Products (RAPEX) as “serious”, requiring rapid action, “moderate”, requiring some form of action, and “low”, for which an EU-wide notification of the risk is not required.

58. Trade facilitation and trade security services provided by inspection and conformity assessment companies also play a critical role in both the pre- and post-market phases. The companies typically screen goods that are traded internationally, using a number of control methods. These include: documentary checks and inspections. Inspections can be visual (to probe quality and quantity) and/or involve scanning and other non-intrusive methods. Certain goods receive specific treatment, in order to tackle risks for supply chain stakeholders (chemicals, radioactive, explosives, narcotics, counterfeit goods, etc.) and consumers (biological, chemical and physical checks). For further mitigation of risks, a number of international standards are followed at different stages of the production and transportation processes. Activities of conformity assessment bodies play a key role at origin and at destination to identify and report on illicit trade practices. They help prevent markets of developing countries and countries with economies in transition from becoming end-destinations for waste, illegal, dangerous or counterfeit goods.

59. The EU single market allows for free circulation to products that meet a minimum set of common “essential requirements”. But since legitimate business, however, needs clear rules and legal stability in order to prosper, key concepts of risk/hazard/safety should be harmonized. Industry needs legal certainty, and therefore it expects the enforcement of the law not to give rise to varying interpretation from one administration to another. Business expects authorities to make a wider use of standards to set measurement methods and assess risks. Efficient market surveillance is also about proportionate risk management which would entrust all stakeholders with managing risks at their respective levels, leaving it up to them to evaluate risks according to their size, risk perception, culture and individual behaviour.

60. In private companies, risk management helps ensure that all products and processes are continuously monitored for compliance with regulations. Typically, the risk management process starts by highlighting the most relevant (cross)-business risks, then evaluates the potential for cross-fertilization between different businesses and finally provides relevant information for management change. This assessment helps companies focus only on relevant risks. Large companies typically have databases on product safety with data from the manufacturing process and consumers' complaints. These records also help estimating risks on the basis of risk events.

III. Summary of presentations and discussions held at the Workshop on “Practical Application of Risk Assessment and Management Tools”

A. Introduction

61. The Workshop was organized by WP6, in cooperation with the Euro-Asian Council for Standardization, Metrology and Certification (EASC).

62. It was attended by delegates from the following countries: Armenia, Azerbaijan, Belarus, Georgia, Kyrgyzstan, Republic of Moldova, Russian Federation, Slovakia, Tajikistan, Trinidad and Tobago, Ukraine, Uzbekistan, as well as representatives of the International Federation of Standard Users (IFAN) and the UNECE Secretariat.

B. Opening session

63. Risk management is a key tool for improving the quality of regulations, and effectively monitoring compliance with regulations in force, which are among the Working Party's main goals.

64. Safety is a key priority for EASC. Two regulatory documents have been adopted on rules of cooperation among oversight bodies and common guidelines for checks and inspections. Members have also agreed on priorities for oversight bodies and have established a model programme for training State inspectors. Current activities focus on how risk assessment and management tools can guide the work of inspectorates, to better monitor the safety of products on the markets. Finally, the organization runs an interstate system for the exchange of information on product safety, based on the example of the EU RAPEX system. Unfortunately, exchange of information on dangerous goods between the two systems was not as yet possible.

65. EASC, which aims at formulating and implementing a coordinated policy for the countries of the Commonwealth of Independent States, actively partners with the WP.6 in many ways. The Coordinator for Liaison with Market Surveillance Bodies of the Commonwealth of Independent States (CIS) keeps information flowing between the two organizations on a regular basis. At the last Council meeting, members had reiterated their commitment to UNECE Recommendation L, as a basis for developing a common regulatory framework. Another area where the member states aim at increased cooperation is the exchange of experience in the implementation of the REACH regulation of the European Union.

C. Core principles of risk management

66. Risk management helps achieving an optimal level of safety. While different organizations face different risks, any risk can be characterized by four attributes: the possible hazard, its probability, impact and associated vulnerabilities. These were defined as circumstances that alone or in combination may contribute to the event.

67. Manage risks means: (a) identifying, (b) quantifying and (c) treating risks. Identification: Looking at an organization's main building blocks, categorize hazards that may affect each of them. Quantification: Using statistical methods, as well as expert judgment, assign a quantitative value to the two attributes of each risk (probability and impact). Treatment: Decide what actions to take.

68. Possible actions include: retention, avoidance, mitigation, and transfer. Retention: Accepting the risk, and developing a strategy to cope with it in case it occurs. Avoidance: Eliminating the activity that leads to a risk. Mitigation: Taking action to reduce the probability or the impact of risks, including through diversification and hedging. Transfer: to another economic operator (for example, through insurance coverage or outsourcing). To choose among possible strategies, organizations need to quantify and compare the costs and benefits of each of them.

69. While these general principles were developed in the context of business management, they could be easily applied to the development and implementation of regulations. For example, in choosing whether to adopt a new regulation, authorities compare the cost of compliance with the economic value of the increased safety it affords. In the face of critical risks to consumers, market surveillance authorities set out to avoid risks by removing dangerous products from the market.

70. Belarus applies risk assessment tools in deciding whether or not to regulate, and in developing and implementing technical regulations. Essential requirements in technical regulations are defined on the basis of: (a) an estimate of the risks inherent to the targeted products; (b) the degree of state intervention necessary to manage these risks effectively; (c) the level of tolerable non-conformity and (d) relevant international standards. These elements will jointly determine how a technical regulation can optimally reference the related voluntary standards.

71. Technical regulations should explicitly set the level of safety required of producers. For this reason, a risk analysis should be performed to determine the sphere of usage of a product and the hazards associated with the product's use. Then, the magnitude of risk in the case the hazard takes place should be determined and compared to its tolerable level. In turn, the tolerable risk level represents an optimal balance between safety, the other requirements that the production process, the products or services need to match and other factors (such as profitability, cost efficiency or traditions). Essential requirements can be specific, essential or presented as references to specific standards, and either be prescriptive, or contain operation safety requirements.

72. In Belarus, producers may either implement the national standard, or if they wish to deviate from it, have the right to do so if they are able to prove, based on risk analysis, that their goods meet substantial safety requirements.

73. In the framework of conformity assessment, different rules and procedures apply depending on a product's complexity, degree of potential hazard, sensitiveness, riskiness and also the applicant's status. Through the declaration of conformity, the producer takes responsibility for meeting all technical regulation requirements and having performed sufficient testing for ensuring compliance.

D. Experience in implementing Risk Management in Market Surveillance

74. The Chair of the MARS group provided a review of terminology including concepts such as risk, harm, event, hazard, hazard situation. RAPEX guidelines provide a classification for risks, according to their severity, probability of occurrence, source and other attributes. The main purpose of RAPEX is to eliminate diverging risk assessment. Eight meetings of experts were held in the years 2006-2007 in order to review the previous guidelines. Aspects positively affected by the development of a risk assessment system include cost (both in temporal and monetary terms), competition, international influence, quality, capturing knowledge, schedule control, customer requirements. An important result of the review is the fact that the new edition encourages not only risk detection but also risk management. As illustrated by an example, risk scenarios should be clearly specific and the probability of their occurrence should be tested.

75. The Slovak Trade Inspection (SOI) runs a national system for the exchange of information on product safety. SOI experienced some problems in risk assessment and labelling as the estimates of different expert groups tend to diverge. The delegate provided information and statistics on risky products, as well as on national market surveillance programme. SOI cooperates mostly with customs authorities, public health authority and notified bodies. Enhancing the cooperation and increasing the information level should be the main directions of the improvement of SOI work.

76. Ukraine, which acceded to the WTO in 2008, is overhauling its system of technical regulations, with the goal of minimizing mandatory certification to technical regulations. Risk assessment is at the very core of market surveillance activities. The Law "On Basic Principles of State Control in the Sphere of Economical Activity", which was passed in December 2007, classifies market agents and goods into three risk categories. Based on 2009 state monitoring, some high-risk goods were moved to the medium-risk category. A law in draft aimed at setting up a modern market surveillance system states that it would be the producer who hires and pays specialists to estimate the degree of risk that goods expose consumers to. Information and opinion exchange session are supposed to be conducted as well.

77. In Belarus, a presidential decree sets out the general framework for market surveillance, including the respective responsibilities of market surveillance bodies, the criteria for assigning market agents into different groups of risk, and the procedures for monitoring and inspections. The frequency of regular checks depends on the risk group of the producer. Extraordinary checks may be conducted at any time under the authorization of the officials specified by the decree, in response to an incompliance report or producer's request. The same applies to spot-checks.

78. Developing a unified system analogous to RAPEX in Belarus requires further developing the law on "Product Safety" and creating the necessary institutional infrastructure. Such a system should contain information on dangerous products (titles, manufacturers, cases when they caused harm) and be based on information obtained not only from the state control system, manufacturers, importers and distributors.

79. In Tajikistan, the ISO Standard 22000 should be a reference for companies producing food and feed. ISO 22000 specifies requirements for a food safety management system where an organization in the food chain needs to demonstrate its ability to control food safety hazards and ensure that food is safe at the time of human consumption. It is applicable to all organizations, regardless of size, which are involved in any aspect of the food chain and want to implement systems that consistently provide safe products. Several companies in Tajikistan have already adopted this standard.

80. The representative of the Republic of Moldova focused on the practice of reforming the national legislation with reference to EU practice and international standards. To overcome difficulties in the Moldovan law on product safety (which is a transposition of the EU directive), a practical guide with detailed explanations and specific examples has been issued. It includes criteria on classifying products among risk groups. However, the application of the legal acts poses challenges due to the limited institutional capacity. Certain problems stem from the fact that risk is a theoretical concept based on the core legal act, whereas risk assessment is a practical activity that has to be based on specific circumstances. There is a need for unifying risk assessment legislation and standards, as well as for introducing a RAPEX-type system for CIS countries.

81. The Chief of the UNECE Trade Facilitation Unit, and the former Secretary of WP.6 outlined possible areas of cooperation among the two units in the area of risk assessment and management, including product traceability and development of regional or international databases.

* * * *

ANNEX

Draft terms of reference of the Group of Experts on Risk Management in regulatory and standardization policies (GOERM)

Introduction

1. At its nineteenth session, the Working Party on Regulatory Cooperation and Standardization Policies recommended the establishment of a Group of Experts on Risk Management in regulatory and standardization policies (GOERM), to consider how risk management can contribute to an efficient regulatory framework.

2. The Group is open to participation from any individual or organization from all United Nations Member States. Participation from governmental authorities, intergovernmental organizations, business associations and private firms, standards-setting organizations, certification bodies, test houses, international schemes for conformity assessment, civil society and consumer organizations is particularly welcome.

Goal

3. The Group of Experts aims at an improved management of hazards that have the potential to affect the quality of products and services, and/or cause harm or damage to people, the environment, property and immaterial assets.

4. To achieve this goal, the Group of Experts will:

(a) Collect and share information about hazards resulting from use of products and from production processes;

(b) Develop and share best practice on how to address these hazards through regulatory and managerial best practice.

Work programme

4. The Group of Experts will develop and share best practice - including if relevant in the form of recommendations - as regards the use of risk management tools to:

(a) Achieve proportionality between technical regulations and the risks they set out to address, including through regulatory impact assessment and good regulatory practices;

(b) Choose among alternative regulatory instruments;

(c) Assess the respective merits of risk-based regulations and deterministic regulations in different contexts and sectors;

(d) Increase effectiveness of the implementation of regulations and standards as regards pre-market activities (certification, registration, conformity assessment) and post market ones (inspections and market surveillance);

(e) Improve managerial control of processes and operations as a contribution to a consistent and predictable implementation of standards and regulations;

(f) Analyse legal and supply chain requirements on traceability of goods as a means of meeting legitimate security and consumer safety concerns;

(g) Promote measures to build mutual confidence through better access and wider sharing of relevant information among regulatory agencies, both at a national and at a regional level (data banks on dangerous goods).

* * * *