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Risk management in regulatory systems

Risk management in regulatory systems: a proposed survey

Note by the secretariat* **

Summary

The questionnaires presented in the document can be used to conduct a survey for assessing the use of risk-management tools in regulatory systems.

Background information on the survey and the reference model used in drawing up the questionnaires are reproduced in ECE/TRADE/C/WP.6/2010/3.

The document is presented for information to the Working Party.

* This document was submitted late for processing since clearance in finalizing this document took longer than anticipated.

** At its nineteenth session, the Working Party agreed to consider establishing a Group of Experts on Risk Assessment and Management and requested the secretariat to report on activities on risk management systems (ECE/TRADE/C/WP.6/2009/19, para. 10).

Introduction

1. On the basis of the reference model presented in document ECE/TRADE/C/WP.6/2010/3, the secretariat prepared a set of five online questionnaires tailored to the specific functions of the different stakeholders in the regulatory system.
2. The questionnaires are addressed to the following stakeholders:
 1. Technical regulators
 2. Standardization bodies
 3. Conformity-assessment bodies,
 4. Market-surveillance authorities
 5. Economic operators
3. These questionnaires can be used as the basis for conducting a survey to evaluate the risk-management needs of the different stakeholders of regulatory systems.
4. The secretariat conducted a preliminary survey between March and August 2010, and the results will be presented during the panel session “Risk Management in Regulatory Systems”.
5. For further information about the survey, or if you would like to participate, please contact regulatory.cooperation@unece.org or telephone Lorenza Jachia at. 004122 9175593

1. Questionnaire for technical regulators

1. **Does your organization apply risk-management tools in regulatory processes, like for example in technical-regulation development and implementation?**
 - a. Yes
 - b. No
2. **Do you encounter obstacles (inefficient procedures or processes, insufficient know-how or IT infrastructure) in applying risk management tools in developing and implementing of technical regulations?**
 - a.. Yes
 - b. No – go to question 4
3. **We would like to better understand the obstacles you experience when using risk management tools. To help us do this, would you be willing to answer a few additional questions on this topic? (this should take approximately 15 minutes)**
 - a. Yes – go to questions 6 to 33, and then to question 5
 - b. No – go to question 5
4. **We would like to better understand your experience in using risk management tools. To help us do this, would you be willing to answer a few additional questions on this topic? (this should take approximately 15 minutes)**
 - a. Yes – go to questions 6 to 33, and then to question 5
 - b. No – go to question 5

5. What are the areas that you would be most interested in receiving information and implementation assistance in?

- a. Risk identification (mapping out the risk, development of risk profiles)
- b. Risk quantification and prioritization in development of technical regulations
- c. Determination of the criteria for acceptable risk;
- d. Management of implementation risk;
- e. Management of the regulatory failure risk
- f. Choosing conformity assessment procedures
- g. _____
- h. Other

6. Does your organization have an approved methodology for risk management: for example, do you have an established process for mapping out the risks that should be mitigated by new regulations?

- a. Yes and we use it
- b. Yes but we don't use it
- c. No but we perform risk identification
- d. There is no methodology and we don't do risk identification

7. How do you call the document where the risks are listed?

- a. Risk map
- b. Risk profile
- c. We write down risks on the yellow stickers
- d. Risk inventory
- e. We don't have any document of this type
- f. Other, please specify _____ (text field)

8. Which software tools do you use for risk identification?

- a. We don't use any tools
- b. _____ (text field)

9. Please provide your view on how comprehensive risk identification usually is (approximately, just to give us an idea):

- a. Over 10% of risks are identified on time
- b. Over 50% of risks are identified on time
- c. All risks are identified in time

10. How regularly do you perform risk identification?

- a. Daily
- b. Monthly
- c. Quarterly
- d. Yearly
- e. Other _____ (text field)

11. Do you have agreed criteria for “accepting” the risks (i.e. take up no action to mitigate them)?

- a. Yes. If “Yes” – please provide an example _____
- b. No

12. On average, what percentage of risks are accepted annually? Could you provide examples on accepted risks?

- a. We don't accept risks
- b. _____
- c. Examples: _____

13. Which risk management tools do you use to create a list of products that may present risk?

14. How do you resolve a situation when business informs of a risk but you don't believe that regulatory intervention is required?

15. Who participates in risk identification?

- a. Business organizations
- b. Market-surveillance authorities
- c. Conformity-assessment bodies
- d. Standard-setting organizations
- e. Consumer associations
- f. Other _____

16. How can business companies/consumers/conformity-assessment bodies/market-surveillance authorities inform you about a risk they perceive in their area of work?

- a. There is a database that business companies can access;
- b. Business companies write to us;
- c. Other _____

17. How many notifications of risks do you receive per year from them?

- a. Over 100
- b. Between 50 and 100
- c. Less than 50

18. Who in your organization is responsible for a methodology of risk quantification?

- a. Risk officer
- b. We don't have a special person for that
- c. Other _____

19. Is there an approved methodology/procedure for prioritizing the risks?

- a. Yes. If Yes, who approves the list of risks ranged by criticality? _____
- b. No

20. Could you provide examples of a situation when imposing a regulation only led to additional costs?

- a. No
- b. Yes. Give examples: _____

21. Which risk parameters do you analyse to choose a risk-management strategy?

- a. Impact and probability
- b. Impact only
- c. Probability only
- d. Other

22. Is there an approved methodology for determining a risk-management strategy?

- a. Yes
- b. No

23. How many risks are in the list of risks that need to be mitigated?

- a. More than 10
- b. Less than 10

24. What other tools do you use to assess regulations?

- a. Cost-benefit analysis
- b. Cost-efficiency analysis
- c. Other _____

25. Could you link regulations in force with risks they are mitigating?

- a. Yes, we have a map
- b. We don't have a map, but it is not feasible

26. Do you have a methodology in place that helps managing the risks that may occur when implementing a new technical regulation?

- a. No
- b. Yes, it is called: _____

27. How and when do you assess the risks the envisaged technical regulation may have on trade, what the costs would be, whether all of society will benefit or just a small part, how the market structure will be changed, etc.?

- a. _____

28. Who is responsible for identifying the risks that may appear when imposing a regulation?

- a.
- b. There is no person responsible assigned

29. What is the role of business companies, regulators, conformity-assessment bodies and market-surveillance authorities in the management of these risks?

- a. Business companies _____
- b. Conformity-assessment bodies _____
- c. Market-surveillance authorities _____
- d. It is hard to assign a role

4. We would like to better understand your experience in using risk management tools. To help us do this, would you be willing to answer a few additional questions on this topic? (this should take approximately 15 minutes)

- a. Yes – go to questions 6 to 28, and then to question 5
- b. No – go to question 5

5. What are the areas that you would be most interested in receiving information on risk-management application in standards development processes?

- a. Risk identification (mapping out the risk, development of risk profiles), considering risks during standard development process planning
- b. Risk quantification and prioritization for planning of standards development process
- c. Management of standards implementation risk
- d. Determination of risk management strategies
- e. Other

6. Does your organization have an approved methodology for risk management: for example, do you have an established process for mapping out the risks that should be mitigated by new standards?

- a. Yes and we use it
- b. Yes but we don't use it
- c. No, but we perform risk identification with a methodology
- d. There is no methodology and we don't do risk identification (please provide more information on how to do it)

7. How do you call the document where the risks are listed?

- a. Risk map
- b. Risk profile
- c. We write down risks on the yellow stickers
- d. Risk inventory
- e. We don't have any document of this type
- f. Other, please specify _____ (text field)

8. Which software tools do you use for risk identification?

- a. We don't use any tools
- b. _____

9. Please provide your view on how comprehensive risk identification usually is (approximately, just to give us an idea):

- a. Over 10% of risks are identified on time
- b. Over 50% of risks are identified on time
- c. All risks are identified on time

10. How regularly do you perform risk identification?

- a. Daily
- b. Monthly
- c. Quarterly
- d. Yearly
- e. Other _____

11. Who participates in risk identification?

- a. Business organizations
- b. Market-surveillance authorities
- c. Conformity-assessment bodies
- d. Regulatory authorities
- e. Consumer organizations
- f. Other _____

12. How can business companies/consumers/conformity assessment bodies/market surveillance authorities inform you about a risk?

- a. There is a database that business companies can access;
- b. Business companies write to us;
- c. Other _____

13. How many notifications on risks do you receive per year from them?

- a. Over 100
- b. Between 50 and 100
- c. Less than 50
- d. Other _____

14. Do you have an approved methodology for managing risks that appear during standard development process (operational risks), for example conflicts of interest, proprietary information, etc?

15. Who in your organization is responsible for a methodology of risk quantification?

- a. Risk officer
- b. We don't have a special person for that
- c. Other _____

16. Is there an approved methodology/procedure for prioritizing the risks?

- a. Yes
 - i. Who approves the list of risks ranged by criticality? _____
- b. No

17. Are risks that the standards could mitigate considered during the standard development planning process?

- a. Yes
- b. No

18. When planning the standard development process, do you assess the risks that the implementation of the standards may cause (impact on trade, market structure, etc)?

- a. No
- b. Yes
 - i. In which form? _____
 - ii. Do you have a methodology for that? _____

19. When sending out the standard for comments, do you ask stakeholders to identify the risks related to the implementation of this standard?

- a. Yes
 - i. Do you provide methodology for risk identification? _____
- b. No

20. Do you have an agreed methodology for determining risk-management strategies?

- a. Yes
- b. No

21. Do you perform risk assessment when conducting a five-year review of a standard? In what form?

- a. Yes
- b. No

- 22. How many risks are in the list of risks that need to be mitigated?**
- More than 10
 - Less than 10
- 23. What other tools do you use to assess standard implementation?**
- Cost-benefit analysis
 - Cost-efficiency analysis
 - Other _____
- 24. Could you link standards available on the market with risks they are mitigating?**
- Yes, we have a map
 - We don't have a map, but it is not feasible
 - _____
- 25. Do you have a methodology in place that helps manage the risks that may occur when business companies start using the standard?**
- No
 - Yes, it is called: _____
- 26. How and when do you assess the risks the envisaged the new standard may have on trade, what the costs would be, whether all of society will benefit or just a small part, how the market structure will be changed, etc.?**
- _____ (text field)
- 27. Please list the main obstacles you face in applying risk-management tools in the standards development process:**
- In mapping out the risks _____
 - In risk prioritization _____
 - In determination of a risk management strategy _____
 - _____
 - _____
 - _____
- 28. Please list your "Risk-management needs":**
- _____
- _____

3. Questionnaire for conformity assessment bodies

1. Does your organization apply risk-management tools in conformity-assessment processes?

- a. Yes
- b. No

2. Do you encounter obstacles (inefficient procedures or processes, insufficient know-how or IT infrastructure) in applying risk-management tools in conformity assessment?

- a. Yes – go to question 3
- b. No – go to question 4

3. We would like to better understand the obstacles you experience when using risk-management tools in conformity assessment procedures. To help us do this, would you be willing to answer a few additional questions on this topic? (this should take approximately 15 minutes)

- a. Yes – go to questions 6 to 20, and then to question 5
- b. No – go to question 5

4. We would like to better understand your experience of using risk-management tools in conformity assessment. To help us do this, would you be willing to answer a few additional questions on this topic? (this should take approximately 15 minutes)

- a. Yes – go to questions 6 to 20, and then to question 5
- b. No – go to question 5

5. What are the areas that you would be most interested in receiving information and implementation assistance in?

- a. Risk-management application when devising a sample plan for product certification
- b. Risk identification when issuing a non-conformity in management system certification
- c. Identification of special risks during CE marking process
- d. Checking the correctness of risk identification in conformity assessment procedures (in technical documentation)

6. In certification processes - what are the main problems in applying the risk-management tools, for example, when considering risk associated with a possible failure of the product when devising a sample plan, or when identifying special risk in CE marking?

7. Does your organization have an approved methodology for risk identification: do you have an established process for mapping out the risks of a product/system failure?

- a. Yes and we use it
- b. Yes but we don't use it
- c. No but we perform risk identification
- d. No and we don't perform risk identification

8. Please provide your view on how comprehensive risk identification usually is (approximately):

- a. 10% of risks are identified on time
- b. 50% of risks are identified on time
- c. 100% of risks are identified on time

9. Who in your organization is responsible for methodologies of risk quantification?

- a. Risk manager
- b. We don't have a special person for that

Other _____

10. Do you have agreed criteria for risks that could be considered to be acceptable?

- a. Yes
- b. No
- c. If "Yes", please provide an example _____

11. Which risk parameters do you analyse when deciding on a risk-management strategy?

- a. Impact and probability
- b. Impact only
- c. Probability only
- d. Other _____

12. Is there an approved methodology?

- a. Yes
 - i. Where is it described? _____
- b. No

13. In management-system certification, did you ever have any disputes with clients about the parameters of the risk corresponding to nonconformity to a management-system standard?

- a. Yes
- b. No

14. Is there an approved methodology for identifying such risks?

- a. Yes
 - i. Where is it described? _____
- b. No

15. What are the most common problems in risk assessment when indicating a special risk in CE marking certification?

- a. _____

16. Where is the methodology for dealing with such risks described?

- a. _____

17. When checking the correctness of technical documentation, were there any disputes on the methodologies for the risk assessment with clients?

- a. _____

18. What is the reference model for checking the correctness of risk assessments?

- a. _____

19. Please list the main obstacles you face in applying risk-management tools in the conformity-assessment procedures:

- a. In mapping out the risks _____
- b. In risk prioritization _____
- c. In determination of a risk-management strategy _____
- d. _____
- e. _____
- f. _____

20. Please list your “Risk-management needs”:

- _____
- _____
- _____

4. Questionnaire for market surveillance authorities

1. Does your organization apply risk-management tools in market-surveillance processes?

- a. Yes b. No

2. Do you encounter obstacles (inefficient procedures or processes, insufficient know-how or IT infrastructure) in applying risk-management tools in market-surveillance processes?

- a. Yes – go to question 3
b. No – go to question 4

3. We would like to better understand the obstacles you experience in using risk-management tools. To help us do this, would you be willing to answer a few additional questions on this topic? (this should take approximately 15 minutes)

- a. Yes – go to questions 6 to 35, and then to question 5
b. No – go to question 5

4. We would like to better understand your experience in using risk-management tools. To help us do this, would you be willing to answer a few additional questions on this topic? (this should take approximately 15 minutes)

- a. Yes – go to questions 6 to 35, and then to question 5
b. No – go to question 5

5. What are the areas that you would be most interested in receiving information and implementation assistance in?

- a. Identification of risks of the product
b. Quantitative analysis of risks
c. Communication with business companies on risks
d. Verification of risk assessments made by business companies
e. Software tools for risk management
f. Other

6. Do you have an approved methodology for performing the assessment of risks of the product?

- a. Yes
 i. Where is it described? _____
b. No

7. Is there an approved methodology for determination of products that present a risk?

- a. Yes
- b. No

8. Does the methodology provide consistent results?

- a. Yes
- b. No

9. Which software tools do you use for risk identification?

- a. _____
- b. _____

10. Please provide your view on how comprehensive risk identification usually is (approximately):

- a. 10% of risks are identified on time
- b. 50% of risks are identified on time
- c. All risks are identified on time

11. In which form are the products and risks recorded?

- a. _____

12. How many products that were in the list didn't cause any damage?

- a. _____

13. How regularly do you perform risk identification (products that present a risk)?

- a. Daily
- b. Monthly
- c. Quarterly
- d. Yearly
- e. Other

14. Who in your organization is responsible for the methodology of risk quantification and product ranging?

- a. Risk manager
- b. We don't have a special person for that
- c. _____

- 15. Is there an approved methodology for quantifying and prioritizing the risks?**
- a. Yes
 - i. Where is it described? _____
 - b. No
- 16. Do you have agreed criteria for “accepting” the risks (i.e. undertaking no further action to mitigate them)?**
- a. Yes,
 - i. If “Yes”, please provide an example _____
 - b. No
- 17. On average, what percentage of risks are “accepted” annually? Could you provide examples of accepted risks?**
- a. We don't accept risks
 - b. _____
 - i. Examples:
 - 1. _____
 - 2. _____
 - 3. _____
- 18. Which risk parameters do you analyse when making a decision on a risk-management strategy?**
- a. Impact and probability
 - b. Impact only
 - c. Probability only
 - d. Other
- 19. Is there an approved methodology?**
- a. Yes
 - i. Where is it described _____?
 - b. No
- 20. What is the process in your organization for risk evaluation?**
- a. _____

21. Who participates in risk identification?

- a. Business organizations
- b. Technical-regulation authorities
- c. Conformity-assessment bodies
- d. Consumer associations
- e. Regulatory authorities
- f. Other organizations

22. How can business companies/consumers inform you about a risk?

- a. There is a database that business companies can access
- b. Business companies write to us
- c. Other ways _____

23. How often does your organization evaluate risks differently from other stakeholders?

- a. Almost always
- b. Seldom
- c. Sometimes
- d. Could you provide examples? _____

24. Are there any problems in cooperation with economic operators with regard to risk (e.g. understanding the concepts, different perceptions)?

- a. _____

25. Do you have an approved methodology for determination whether the risk mitigating measure chosen by economic operator was appropriate?

- a. Yes
 - i. Where is it described _____?
- b. No

26. How often are these measures (chosen by economic operators) are inappropriate?

- a. Almost always
- b. Seldom
- c. Sometimes
- d. Could you provide examples when not? _____

27. When distributors and importers provide you with the information related to the product, does it contain the assessment of risks?

- a. Yes b. No

28. Do you have an approved methodology to verify results of risk assessments?

- a. _____

29. When an importer, distributor or manufacturer informs you about a product that presents a risk, do you check the correctness of the information?

- a. Yes

- b. No

- i. What tools do you use to check the correctness of the risk assessment?

- ii. Do you perform an independent risk assessment? Is there a methodology in place?

30. How often do you have disputes with economic operators over the results of risk assessment?

- a. Almost always

- b. Seldom

- c. Sometimes

- d. Could you provide examples of such disputes? _____

31. When sending a request to provide information on risks, do you refer to any recognized methodology?

- a. Yes

- i. Could you provide an example? _____

- b. No

32. How often do you see errors in risk assessments of the distributors?

- a. Almost always

- b. Seldom

- c. Sometimes

- d. Could you provide examples of such disputes? _____

33. What is the threshold level of risk which leads to requesting the economic operator to present information on its suppliers/buyers?

a. _____

34. Please list the main obstacles you face in application of risk-management tools in the market-surveillance processes:

a. In mapping out the risks _____

b. In risk prioritization _____

c. In determination of a risk management strategy _____

d. _____

e. _____

f. _____

35. Please list your “Risk-management needs”:

a. _____

b. _____

5. Questionnaire for economic operators

1. Does your company cooperate with authorities concerning risk management?

a. Yes b. No

2. Do you encounter obstacles (inefficient procedures or processes, insufficient know-how or IT infrastructure) in applying risk-management tools?

a. Yes

b. No – go to question 4

3. We would like to better understand the obstacles you experience when using risk-management tools. To help us do this, would you be willing to answer a few additional questions on this topic? (this should take approximately 15 minutes)

a. Yes – go to questions 6 to 34, and then to question 5

b. No – go to question 5

4. We would like to better understand your experience in using risk-management tools. To help us do this, would you be willing to answer a few additional questions on this topic? (this should take approximately 15 minutes)

a. Yes – go to questions 6 to 34, and then to question 5

b. No – go to question 5

5. What are the areas that you would be most interested in receiving information and implementation assistance in?

- a. Risk identification and communication with a regulatory system
- b. Risk assessment tools for determination of risks related to the product
- c. Implementation of systemic risk management within a company
- d. _____
- e. _____
- f. _____

6. What is your perception of the regulatory balance within the industry?

- a. Industry is overregulated
 - i. Please provide examples _____
- b. Industry is under regulated
 - i. Please provide examples _____
- c. Regulatory intervention is balanced
 - i. Please provide some evidence _____

7. If you were shown a map “Regulations – Risks”:

- a. How many risks would be missing regulations? Approximately _____
- b. How many regulations would be missing risks? Approximately _____

8. Could you provide examples of regulatory intervention for risk mitigation which instead caused even bigger risks?

- a. Yes
- b. No, this is something that never happened

9. Usually, your perception of risks is that

- a. Risks are indeed higher than perceived by a regulator
- b. Risks are lower than perceived by a regulator
- c. We have similar risk perceptions

10. How often do you experience situations when your and the regulator’s perceptions of a risk are substantially different?

- a. Almost always
- b. Seldom

- c. Sometimes
- d. Never
- e. Could you provide examples? _____

11. Do you participate in the risk-identification processes performed by your regulator?

- a. Yes
 - i. Could you provide examples? _____
- b. No this possible
- c. No, we don't have such an option

12. Is there an established process to inform regulator about a risk?

- a. Yes
 - i. How many times per year do you inform the regulator about a risk? ____
 - ii. What is the process? _____
- b. No

13. At which stages do you participate in risk-management processes performed by the regulator? How is this organized?

- a. Risk identification _____
- b. Risk assessment _____
- c. Development of a regulation to address a risk _____
- d. Implementation of a regulation _____

14. Were there any changes in regulatory intervention caused by risk identification performed by business companies?

- a. Yes
 - i. Please provide examples
- b. No

15. In your sector of activity, what are the principal means of regulatory intervention?

- a. Goal-setting regulations, please indicate percentage
- b. Risk-based regulations, please indicate percentage
- c. Deterministic regulations, please indicate percentage

16. What are the most common risk-management-related problems that you face in complying with goal-setting regulations?

- a. The most common problems:
 - i. We don't have enough tools and guidance
 - ii. Our perceptions of risks and risk-management tools are difference
 - iii. _____
 - iv. _____
- b. We don't have to apply risk-management tools for compliance
- c. We don't face any problems

17. What are the most common risk-management-related problems that you face in complying with risk-based regulations?

- a. There are some problems:
 - i. We don't have enough tools and guidance
 - ii. Our perceptions of risks and risk management tools are different
 - iii. _____
 - iv. _____
- b. We don't have to apply risk management tools for compliance
- c. We don't face any problems

18. Could you provide some cases when a shift from deterministic regulations to risk-based or goal-setting regulations would be appropriate?

- a. _____
- b. _____

19. Which risk-management standards, voluntary standards, methodologies and frameworks do you use to implement risk-management techniques?

- a. _____
- b. _____
- c. _____

20. Do you have systemic processes implemented for corporate-wide risk management?

- a. Yes, we have a risk-management system
- b. No, we have risk management but it is not systemic
- c. We don't have risk management at all

21. Do you have an approved methodology for determining a risk presented by a product?

- a. Yes
- b. No

22. How do you consider this risk when:

- a. Determining how long the technical documentation and Declaration of Conformity shall be kept _____
- b. Planning sample testing _____
- c. Designing/Keeping a register of complaints _____

23. Did you ever experience problems with conformity-assessment bodies or market-surveillance authorities caused by different approaches/perceptions of these risks, when, for example, they didn't accept the results of your risk assessment?

- a. There are some problems:
 - i. Could you provide an example? _____
- b. No

24. Do you perform risk assessment along with the Declaration of Conformity?

- a. Yes
- b. No

25. Are the results of risk assessment checked by any authority?

- a. There are some problems:
 - i. By whom? _____
- b. No

26. Did you ever experience situations when authorities didn't accept the results of the risk assessment?

- a. There are some problems:
 - i. Could you please explain why? _____
- b. No

27. Do you perform risk assessment along with developing technical documentation?

- a. Yes
- b. No

28. Are the results of risk assessment checked by any authority or conformity-assessment body?

- a. Yes
 - i. By whom? _____
- b. No

29. Did you ever experience situations when authorities/conformity assessment bodies didn't accept the results of the risk assessment?

- a. Yes
 - i. Could you please explain why? _____
- b. No

30. How often do you inform market-surveillance authorities about the products that present a risk?

- a. Very often
- b. Sometimes
- c. Never
- d. Could you provide examples? _____

31. Did you ever experience a situation when your perception of risks and the results of risk analysis were substantially different from those of the market surveillance authority?

- a. Yes
 - i. Could you provide an example? _____
- b. No

32. Could you give examples of the situation when blurriness of the risk-management methodology changed the market structure (when the argument for banning a product was that it presented a big risk but it didn't?)

- a. Yes
 - i. Could you provide an example? _____
- b. No

33. Please list the main obstacles you face in application of risk-management tools in cooperation with other stakeholders within a regulatory system:

- a. In communicating risks to the technical regulation authority _____
- b. In analysis of risks related to the product _____
- c. In risk assessment for technical documentation _____

- d. _____
- e. _____
- f. _____

34. Please list your “Risk-management needs”:

- a. _____
- b. _____
- c. _____
