Risk Management in Regulatory Systems: A proposed survey

Note by the secretariat

I. Introduction

At its nineteenth session, the Working Party agreed to “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” (ECE/TRADE/C/WP.6/2010/19, para. 10). This document contains a proposed survey to document actual use and outstanding needs in all the areas of activity of the Working Party: technical regulations, standardization conformity assessment, market surveillance and business operations. The background information regarding methodology is set out in document ECE/TRADE/C/WP.6/2010/3.

2. This document is presented for information to the Working Group.
II. Questionnaire on risk management in technical regulations

1. Does your organization apply risk management tools in regulatory processes, like, for example in 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 the question 4

3. We would like to better understand the obstacles you experience when using risk management tools. Would you be willing to participate in a 30-40 minutes internet survey with an assistance of an interviewer so that we could through the process in detail?
   a. Yes – go to the questions in the table and don’t forget to return to question 5 after it
   b. No – go to the question 5

4. We would like to better understand your experience in using risk management tools. Would you be willing to participate in a 30-40 minutes internet survey with an assistance of an interviewer?
   a. Yes – go to the questions in the table and don’t forget to return to question 5 after it
   b. No – go to the 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. ________________________________

9. **Please provide your view on how comprehensive risk identification usually is (approximately, just to give us an idea):**
   a. More than 10% of risks are timely identified
   b. More than 50% of risks are timely identified
   c. 100% of risks are timely identified

10. **How regularly do you perform risk identification?**
    a. Daily
    b. Monthly
    c. Quarterly
    d. Yearly
    e. Other ________________________________

11. **Do you have agreed criteria for “accepting” the risks (i.e. take up no action to mitigate them)?**
    a. Yes
       i. If “Yes” – please provide an example _____________________
    b. No

12. **On average, what is the percentage of risks that 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 feel as if regulatory intervention is required?

_____________________________________________________________________________________

15. Please mark the stakeholders that participate 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/CAB/MSA 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 on risks do you receive per year from them?
   a. More than a hundred;
   b. 50-100
   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
      i. Who approves the list of risks ranked 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, examples:

21. Which risk parameters do you analyze to choose a risk management strategy?
   a. Impact and Probability  c. Probability only
   b. Impact only  d. Other

22. Is there an approved methodology for determination of a risk management strategy?
   a. Yes  b. No

23. How many risks are currently 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. Benefit-cost analysis
   b. Efficiency cost 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, it is not doable

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. Text ______________________________________________________________________

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 MS 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
30. How do you assess the risk of the regulatory failure?

31. Do you have approved risk management tools in place for choosing conformity assessment procedures?
   a. Yes  b. No

32. Please list the main obstacles you face in application of risk management tools in the regulatory process:
   a. In risk identification: _________________________________________________
   b. In risk quantification: _________________________________________________
   c. In determination of a risk management strategy: ____________________________
   d. _________________________________________________________________
   e. _________________________________________________________________
   f. _________________________________________________________________

33. Please list your “Risk Management Needs”:

Add question on regulations and standards - relationship

III. Questionnaire on risk management in technical regulations

1. Does your organization apply risk management tools in regulatory processes, like, for example in 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 – go to the question 3
   b. No – go to the question 4
3. We would like to better understand the obstacles you experience when using risk management tools. Would you be willing to participate in a 30-40 minutes internet survey with an assistance of an interviewer so that we could through the process in detail?
   a. Yes – go to the questions in the table and don’t forget to return to question 5 after it
   b. No – go to the question 5

4. We would like to better understand your experience in using risk management tools. Would you be willing to participate in a 30-40 minutes internet survey with an assistance of an interviewer?
   a. Yes – go to the questions in the table and don’t forget to return to question 5 after it
   b. No – go to the question 5

5. What are the areas that you would be most interested in receiving information on risk management application in standards development process?
   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 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 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. More than 10% of risks are timely identified
   b. More than 50% of risks are timely identified
   c. 100% of risks are timely identified

10. How regularly do you perform risk identification?
    a. Daily
    b. Monthly
    c. Quarterly
    d. Yearly
    e. Other _____________________________

11. Please mark the stakeholders that participate 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/CAB/MSA 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. More than a hundred;
   b. 50-100
   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? ______
   c. 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 request 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 determination of risk management strategies?**
   a. Yes  
   b. No

21. **Do you perform risk assessment when performing five year review of a standard? In what form?**
   a. Yes  
   b. No

22. **How many risks are currently in the list of risks that need to be mitigated?**
   a. More than 10  
   b. Less than 10

23. **What other tools do you use to assess standard implementation?**
   a. Benefit-cost analysis  
   b. Efficiency cost analysis  
   c. Other _______________________________

24. **Could you link standards available of the market with risks they are mitigating?**
   a. Yes, we have a map  
   b. We don’t have a map, but it is not doable  
   c. _______________________________

25. **Do you have a methodology in place that helps managing the risks that may occur when business companies start using the standard?**
   a. No  
   b. 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.?**
   a. Text

27. **Please list the main obstacles you face in application of risk management tools in the standards development process:**
   a. In mapping out the risks _________________________________
   b. In risk prioritization _________________________________
   c. In determination of a risk management strategy _________________________________
   d. _________________________________
28. Please list your “Risk Management Needs”:

____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

IV. Questionnaire on risk management in 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 developing and implementing of technical regulations?
   a. Yes – go to the question 3
   b. No – go to the question 4

3. We would like to better understand the obstacles you experience when using risk management tools. Would you be willing to participate in a 30-40 minutes internet survey with an assistance of an interviewer so that we could through the process in detail?
   a. Yes – go to the questions in the table and don’t forget to return to question 5 after it
   b. No – go to the question 5

4. We would like to better understand your experience in using risk management tools. Would you be willing to participate in a 30-40 minutes internet survey with an assistance of an interviewer?
   a. Yes – go to the questions in the table and don’t forget to return to question 5 after it
   b. No – go to the 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 application of 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, just to give us an idea):
   a. 10% of risks are timely identified
   b. 50% of risks are timely identified
   c. 100% of risks are timely identified

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
   c. 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 analyze 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 identification of 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 the methodology for dealing with such risks is 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 application of 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. _________________________________
V. Questionnaire on risk management in market surveillance processes

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 developing and implementing of technical regulations?
   a. Yes – go to the question 3A
   b. No – go to the question 4

3. We would like to better understand the obstacles you experience when using risk management tools. Would you be willing to participate in a 30-40 minutes internet survey with an assistance of an interviewer so that we could through the process in detail?
   a. Yes – go to the questions in the table and don’t forget to return to question 5 after it
   b. No – go to the question 5

4. We would like to better understand your experience in using risk management tools. Would you be willing to participate in a 30-40 minutes internet survey with an assistance of an interviewer?
   a. Yes – go to the questions in the table and don’t forget to return to question 5 after it
   b. No – go to the 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

7.a When performing risk identification, how do you take into account the results of the previous risk mitigation activities (controls that were implemented earlier)?

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, just to give us an idea):**
    a. 10% of risks are timely identified
    b. 50% of risks are timely identified
    c. 100% of risks are timely identified

11. **In which form the products and respective risks are recorded?**
    a. ____________________

12. **How many products that were in the list didn’t cause any damage?**
    a. ____________________

12.a **How do you check the adequacy of previous risk assessment?**

13. **How regularly do you perform risk identification (products that present a risk)?**
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 is the percentage of risks that are “accepted” annually? Could you provide examples on accepted risks?
   a. We don’t accept risks
   b. ______________________
      i. Examples:
         1. ______________________________
         2. ______________________________
         3. ______________________________
18. Which risk parameters do you analyze 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. Please mark the stakeholders that participate 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 (understanding the concepts, different perceptions, etc)?
   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 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 importer, distributor or manufacturer informs you on 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 with regard to 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 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 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 process:
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. ________________________________________________________________

VI. Questionnaire on risk management in business

1. Is your Company involved in any kind of cooperation with authorities with regard to 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 in developing and implementing of technical regulations?

a. Yes  b. No – go to the question 4

3. We would like to better understand the obstacles you experience when using risk management tools in your cooperation with authorities. Would you be willing to participate in a 30-40 minutes internet survey with an assistance of an interviewer so that we could through the process in detail?

a. Yes – go to the questions in the table and don’t forget to return to question 5 after it  
b. No – go to the question 5

4. We would like to better understand your experience in using risk management tools within the regulatory system. Would you be willing to participate in a 30-40 minutes internet survey with an assistance of an interviewer?
a. Yes – go to the questions in the table and don’t forget to return to question 5 after it
b. No – go to the 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 regulatory intervention with the purpose of risk mitigation 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 yours and 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 process? _________________________________
   b. No

13. On which stages could 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 _________________________
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 is the main way 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 with complying to 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 different
   
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 with complying to 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
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 determination of risk presented by a product?

a. Yes  b. No

22. How do you consider this risk when:

a. Determining the period 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 experienced problems with conformity assessment bodies or market surveillance authorities caused by different
approaches/perceptions of these risks, when, for example, CAB or MSA 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/conformity assessment body?

a. Yes
   i. By whom? ___________________________________________

b. No

29. Did you ever experienced 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 perform 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 situation when your perception of risks and the results of risk analysis were substantially different from one 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. ____________________________
34. Please list your “Risk Management Needs”:

a. ________________________________________________________________

b. ________________________________________________________________

c. ________________________________________________________________