

Unclassified

DSTI/CP/CPS(2012)16/FINAL

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

31-Jan-2013

English - Or. English

**DIRECTORATE FOR SCIENCE, TECHNOLOGY AND INDUSTRY
COMMITTEE ON CONSUMER POLICY**

Working Party on Consumer Product Safety

SUMMARY OF THE WORKSHOP ON PRODUCT RISK ASSESSMENT

JT03333897

Complete document available on OLIS in its original format

This document and any map included herein are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.



**DSTI/CP/CPS(2012)16/FINAL
Unclassified**

English - Or. English

FOREWORD

On 20 April 2012, the OECD's Working Party on Consumer Product Safety organised a *Workshop on Product Risk Assessment*, the purpose of which was to critically evaluate the different risk assessment practices being used in jurisdictions. The discussion was aimed at: *i)* discussing the context and vision of effective product risk assessment; *ii)* identifying its key attributes; and *iii)* gathering views from government stakeholders, businesses, consumers and academia. This report provides a summary of the discussion. It was declassified by the OECD's Committee on Consumer Policy and its working party under a written procedure on 7 January 2013.

SUMMARY OF THE OECD WORKSHOP ON PRODUCT RISK ASSESSMENT

Held on 20 April 2012, Tel-Aviv, Israel

Background

Development of sound risk assessment methods is crucial in tackling product safety issues. At the same time, it is a complex task which varies from one product to another and across countries. The OECD workshop on product risk assessment,¹ which was hosted by Israel's Ministry of Industry, Trade and Labor and the Standards Institution of Israel, on 20 April 2012, in Tel-Aviv, Israel, provided participants with an opportunity to critically evaluate their own risk assessment practices in light of methods used by other consumer product regulators. It was aimed at: *i)* discussing the context and vision of an effective product risk assessment; *ii)* identifying its key attributes; and *iii)* gathering views from Government stakeholders, businesses, consumers and academia. In addition to panel discussions, participants were invited to assess product risks of two consumer products, liquid ethanol burners for mood lighting and sky lanterns, using the Benis Nomograph and EU RAPEX approaches, and the techniques used in other jurisdictions.

Risk assessment context and vision

The workshop was seen as an important way to learn about and better understand the challenges in the risk assessment area. With cross-border trade increasing, it was noted that developing more consistent approaches to product risk assessment would simplify the work of regulators while lowering the barriers to trade for manufacturers worldwide. Currently, countries use different methods, with varying key attributes to evaluate safety of the same product. Exploring more holistic product risk assessment methods and understanding existing differences were key themes examined in the workshop.

Despite differences across countries, speakers identified a number of attributes which in their view should be included in risk assessment methodologies. It was noted that the methodologies should support assessors in reaching consistent conclusions and be transparent for all market actors, with whom an ongoing dialog should be kept, and that risk tolerance should be taken into account in the analysis. Speakers also noted that methodologies should identify all elements that contribute to the risk, including when a product is used in a foreseeable manner or is misused. It was suggested that the level of risk is crucial in estimating the safety of a product, as it would help to identify and communicate uncertainties. Approaches should therefore be based on scientific evidence and sound judgments. In this regard, the importance of tools to assist with risk assessment, such as reference tables and guidance documents, were noted. Finally, the need for risk assessment techniques to be continuously reviewed and refined was highlighted.

Expert views on risk assessment

The next session provided participants with an overview of risk assessment methods in three fields: biosecurity, chemicals and electric cars. Speakers provided an overview of methodologies used in their fields of expertise, highlighting their strengths and weaknesses.

¹ Information and material relevant to this workshop is available at:
www.oecd.org/document/57/0,3746,en_2649_34267_41625273_1_1_1_1,00.html#upcoming.

Biosecurity

Issues related to foodstuff risk assessment in Australia, which exports about 70% of its agricultural production, were presented. Australia, it was noted, is the only country in the world which has defined an Appropriate Level Of Protection (ALOP). The ALOP calls for “...a high level of sanitary and phytosanitary protection aimed at reducing risk to a very low level, but not to zero.” It was noted that the principles underlying the risk assessment are consistent with WTO SPS Agreement and international standards (IPPC/OIE/CODEX) and are transparent, flexible, science-and evidence-based and aimed at being as least trade restrictive as possible. The assessments are carried out with stakeholder engagement, *via* pre-, post- and border controls, residue testing, policy reviews and technical policy advice. The importance of capacity building, within the country and with trading partners, was discussed. The assessments are, as appropriate, open for public comment. With respect to new products coming into the country, a risk assessment is carried out by an expert group. About 300 tests are conducted annually; results are then published in a biosecurity import conditions data base (BICON).

At its borders, Australia conducts audits/verifications and inspections, phytosanitary certification and post-entry quarantine; domestically, it established a number of federal partnerships as well as emergency agreements and plans. Ongoing efforts are being made to improve the system. They have resulted in a shift in focus from “quarantines” to a proactive approach at the borders. In a pre-border phase, emphasis is placed on close collaboration with importing countries.

With a view towards enhancing biosecurity, the Australian Centre of Excellence for Risk Analysis (ACERA) was established. Three main examples of its work were presented. The first concerned inspection systems for risk return. Research revealed that most inspection efforts were triggered by public concerns, not by scientific expertise. A multi-criteria system was established that is evidence-based and supports processes aimed at improving interception, learning and deterrence. The second example concerned improving biosecurity intelligence by gathering timely, critical information on emerging threats from social media. Special software was developed for that purpose. The last case study was aimed at enhancing information sharing among experts *via* structured questions and group interactions.

Chemical risk assessment: Implications for product safety

An assessment of the risk of chromium VI use in leather textiles (*i.e.* gloves and shoes) in Germany was presented. In this case, the risk assessment process encompassed seven steps:

- Identification of the problem.
- Discussion in expert groups.
- Data collection.
- Risk assessment.
- Risk communication.
- Consideration of the amendment of regulation.
- Discussion at EU level.

The problem concerned skin allergies to chromium VI, which can be created in the tanning process when the chromium III salts are transformed into chromium VI. The issue was discussed by expert groups

and research was undertaken. Its results were submitted to the federal government with a request to develop specific legislation to ban the chemical in leather textiles. The request resulted in amendment of the German ordinance on commodities. The problem is currently being discussed at European level; the European Chemicals Agency (ECHA) has launched a six-month public consultation.

In addition, the Federal Institute for Risk Assessment (*i.e. Bundesinstitut fuer Risikobewertung*) also carries out risk assessment work on chemicals and products. A recent research project was conducted on the sensitising potential of disperse dyes, which should not migrate to the skin of consumers due to allergy hazards. It was noted that genotoxicity and sensitisation potential research were not the primary concern in this example; rather, the decisive criterion was exposure, which is difficult to measure due to lack of generally accepted models and data.

Another example concerned cosmetics, where safety assessments are based on the safety of ingredients. This work is carried out at the EU level by the Scientific Committee on Consumer Safety (SCCS). The elements of this risk assessment are as follows: *i*) hazard assessment; *ii*) dose-response relationship; *iii*) exposure assessment; and *iv*) risk characterisation. The assessments are based on a dossier provided by industry containing information on contamination and stability, toxicological data and human experience. The studies follow the OECD Guidelines for the Testing of Chemicals and its Good Laboratory Practices, as well as SCCS Notes of Guidance and its opinions.

A number of other issues arising from chemicals testing were mentioned. The current ban on testing on animals is difficult as in some cases alternative methodologies are not available, *e.g.*, against eye irritation or carcinogenicity. Further issues in the field of cosmetics risk assessment are: *i*) how to deal with extremely potent sensitizers in hair dyes; *ii*) evaluation of natural ingredients and cosmeceuticals; and *iii*) assessment of nano-materials.

The challenges facing those carrying out risk assessment were mentioned. These included scarce assessment methods, for instance, for toys and textiles, insufficient toxicological data for many chemicals used in products, and the need to enhance the involvement of manufactures from developing countries.

Assessing risks in a new market: electric cars

Product risk assessment is important for new products, where there may be many unknowns and where there may be implications for innovation. In the pre-market stage, the *Better Place* company, which produces electric cars, carried out R&D experiments, gathered feedback from its employees who were driving electric cars, reviewed case studies on similar products and participated in standards development. In addition, in assessing risks the company considered trends which could impact the characteristics and use of the cars. The factors assessed included population growth and aging, urbanisation and industrialisation, as well as a need to meet mobility and environmental challenges. The company concluded that the vehicle industry faces challenges regarding how to ensure: *i*) energy and fuel diversification; *ii*) CO₂ reduction; *iii*) lower urban congestion; and *iv*) improved air quality.

Internally, the *Better Place* has implemented an enterprise risk management (ERM) framework, which is a systemic process of identifying and amending company risks to ensure it achieves its objectives. It is composed of three layers: *i*) risk fundamentals; *ii*) ongoing process; and *iii*) risk management. Risk fundamentals can be further divided into: risk criteria, risk categorisation and risk governance. The company's risks can be classified as follows: *i*) solution (*e.g.* for product/service failure or liability), *ii*) operations (*e.g.* for safety and security); *iii*) customer (*e.g.* for reputation/ brand perception and customer satisfaction); *iv*) finance (*e.g.* for currency risks, insurance and funding), *v*) strategy (*e.g.* for information security and global policy); and *vi*) legal (*e.g.* for regulatory policy compliance and global liability risks).

The ongoing process of product risk assessment encompasses four phases: *i)* identify, in which the risk identifier reports to the ERM team; *ii)* assign, in which the ERM team assigns risk to the relevant executive risk owner based on predefined categorisation; *iii)* assess, in which the risk owner quantitatively assesses risk, using pre-defined scales for impact and probability; and *iv)* respond, in which the risk owner develops a response strategy and a treatment plan based on type and level of risk to reduce exposure. The risk response depends on the level of risk. The critical risks need to be terminated (*e.g.* not holding sensitive customer data), less critical risks are mitigated by taking an action (*e.g.* hiring a second-in-command to buffer against potential loss of a key employee). In some cases, a risk can be financially or contractually transferred to other parties by means of insurance, capital markets or contracts. Lower risks are tolerated as many risks fall below a threshold of tolerance and their financial impact and frequency do not render them a material threat to the business.

Panel discussion

Jurisdictions' approaches to product risk assessment

The discussion that followed revealed that different approaches to product risk assessment result from a number of factors such as differences in regime, culture and risk tolerance. The issue of product safety is often driven by political issues and expectations from the general public within and across jurisdictions. Therefore, some decisions on whether a product is unsafe may be taken due to political or cultural pressures in a jurisdiction. As a result, some products which are recalled in one jurisdiction may still be sold in another. As some speakers noted, different risk assessment approaches may thus indirectly become a non-tariff barrier for globally traded goods and a lack of coherence between product safety standards and/or regulations may disadvantage imported and/or exported goods in a market. Different jurisdictions' philosophies have led to the development of different product risk assessment approaches across jurisdictions.

In addition, jurisdictions maintain different levels of risk tolerance, which affects outcomes. Some jurisdictions may for instance tolerate low levels of risks while others may seek to achieve no-risk level. In the case of biosecurity in Australia, for instance, as it is difficult to quantify the risk, a commonly-accepted definition assumes that *consumer protection is aimed at reducing risk to a very low level, but not to zero*.² The question of risk tolerance also depends on how widely a product is used and by what group of consumers; children and the elderly, for example, are often characterised as vulnerable groups which are more susceptible to injuries from unsafe products.

Role of a science-based approach

One of the main issues noted in product risk assessment approaches is that they are mainly based on qualitative measures and thus outcomes of an analysis may lead to different conclusions and subjective judgments. Currently, many jurisdictions are addressing this by seeking to develop more coherent and robust risk assessment methods. Canadian authorities, for instance, are in the process of developing a formalised risk assessment framework and methodology, including a prioritisation tool for preliminary screening. Efforts are also being taken by Australia which is seeking to develop a model which will specify what can be assumed as an unsafe product and what can be done to avoid use of product safety measures for political purposes.

² Please note that in some jurisdictions the lowest possible level of risk may be called an unreasonable or tolerable risk.

The modified ways of assessing product safety are thus focusing on the use of scientific evidence. Businesses are supporting the efforts as scientific-based approaches can be more reliable and credible. This is important as businesses bear a significant burden for product safety; they need to assess product risks in pre- and post-market phases. It was noted that it would be more effective for governments to carry out pre-market risk assessment analysis; budgetary constraints, however, are preventing this. The role of third-party testing was also mentioned as a more credible and effective science-based alternative to business self-assessment. In addition, some speakers suggested that scientific advice should not only be sought from experts in the field of product risk assessment but also from psychologists and sociologists who have knowledge of consumers attitudes towards risks, and of how people perceive risk.

Stakeholder involvement

Given the responsibilities of both governments and businesses for product safety, the importance of enhancing collaboration between governments and businesses was underscored, given their joint responsibilities. It was noted that it is important to engage stakeholders in the early stages of product risk assessment, including the drafting of legislation. Such involvement can be done, for instance, through public consultation. For instance, the European Chemicals Agency carries out public consultations on an ongoing basis prior to introducing changes in EU regulations. The value of collaboration with stakeholders, notably businesses is very important as it promotes consistency in pre- and post-market risk assessment. Furthermore, once a regulation is drafted, some jurisdictions add a bibliography of guidance documents to a regulation to support businesses in its implementation. This was done for instance for cosmetics in the European Union.

Key attributes of risk assessment methodologies used for product safety: Groups' work

Prior to the workshop, participants were provided with *i*) case studies on liquid ethanol burners for mood lighting and on sky lanterns; and *ii*) information on two risk assessment methods, provided by Australia and the European Commission. They were asked to evaluate risk, using the two approaches and share their views in group work during the workshop. Principal areas examined included:

- The key attributes of an effective risk assessment methodology in priority order.
- How these contribute to achieving the vision of an effective risk assessment.
- Any tools, tables or frameworks that can assist with each attribute.

The results of their discussions were then presented in templates, extracts of which are contained in Annex I. A summary is provided in Table 1.

Table 1. Summary of groups' discussions

Key attributes of risk assessment	Future actions
<ul style="list-style-type: none"> Should result in clear and consistent outcomes. 	<ul style="list-style-type: none"> Tables, definitions and criteria should be developed in the following areas: <ul style="list-style-type: none"> Severity of injury, Probability of harm, Recognition of harm (e.g. we would need definition and criteria from the RAPEX table for harm).
<ul style="list-style-type: none"> Should have tools that allow for taking into account all the risks related to a product, such as foreseeable use and misuse. 	<ul style="list-style-type: none"> Risk classification tables which clearly define degrees of risk (e.g. "1", "2", etc). Injury databases for similar product types. Scenario tables.
<ul style="list-style-type: none"> Should be verifiable. 	<ul style="list-style-type: none"> Undertake verification. Documentation of validation/verification. Should have tools for: <ul style="list-style-type: none"> Comparing what was predicted to what actually happened, (verification, back-testing, etc.). Adjusting methodologies.
<ul style="list-style-type: none"> Should be transparent and publicly available. 	<ul style="list-style-type: none"> Publishing methods. Documentation.
<ul style="list-style-type: none"> Should allow for reliable and well-defined estimation of probabilities and capture uncertainties such as ranges for probabilities. 	<ul style="list-style-type: none"> Sensitivity analysis. Develop an agreed database of probabilities.
<ul style="list-style-type: none"> Should facilitate identification of a product. 	<ul style="list-style-type: none"> Photograph. Samples (multiple samples if necessary). Detailed description. Use of standards. Use of object identifiers (UPC codes, HTC codes, customs codes). Results from previous assessments; databases of previous assessments of similar products (e.g. Denmark product registry; cosmetics registry). Reference to relevant legislation.
<ul style="list-style-type: none"> Should facilitate identification of intended user groups of a product (e.g., children under 3). 	<ul style="list-style-type: none"> Manufacturer's information. Information on the chemical composition of the product.
<ul style="list-style-type: none"> Should facilitate identification of foreseeable use and misuse. 	<ul style="list-style-type: none"> Standards. Best practices. Manufacturers' information.
<ul style="list-style-type: none"> Should be based on sound scientific evidence and consistent with rules of probability and logic. 	<ul style="list-style-type: none"> Historical assessments of similar products – has this been done before. Knowledge of the form, fit and function of a product. Knowledge of the composition of a product, and materials. To preserve scientific integrity and independence of the process, consider changing the risk assessor on a rotational basis (e.g. so that the same person isn't assessing the same things/companies all the time).
<ul style="list-style-type: none"> Should ensure clear difference between risk assessment and risk management (this may seem obvious, but in practice, it can be very difficult to separate). 	<ul style="list-style-type: none"> It was noted that "estimate how widely available the product is" and "take into account the risk tolerance of stakeholders" are both risk management items – not risk assessment issues. It is important for there to be a linkage – risk assessors can provide options to risk managers for them to choose from.

Conclusions

The workshop contributed to developing an international and more consistent vision for sound consumer product safety risk assessment. It identified key attributes of effective risk assessment methodologies, which *inter alia* should be science and evidence based and should be developed in collaboration with stakeholders. It was noted that the workshop has helped to improve understanding of the various approaches being used and their drivers. It provided an overview of certain methodologies in different countries, highlighting their main strengths and weaknesses.

Thanks to the practical exercises carried out during the analysis of case studies, participants identified a number of steps which could be taken to improve the domestic risk assessment methodologies with a view towards developing a more robust and holistic approach at international level. It was noted that robust methodologies would be appreciated by various stakeholders to avoid creation of barriers to trade and support manufacturing, design and distribution of products around the globe. As improvement of product risk assessment is a long term and complex process, this workshop was seen as one of the milestones in achieving this aim.

A number of more specific points were noted by the work groups. These are recorded in Annex I; the most common ones were:

- Product risk assessment is important for effective risk management and should not be bypassed.
- The process of improving risk assessment methodologies has taken a long time, for instance, in the area of food safety. Thus, stakeholders, including experts performing risk assessments, should not be discouraged and seek to collaborate internationally to develop common tools and to ensure capacity building programmes in other product areas.
- The challenge of refining the concept of probability is a long term issue and requires collaboration. At the same time, risk tolerance should be a factor influencing risk treatment and need not influence risk assessment.
- Transparency in risk assessment methodologies is crucial. Publication of risk assessment methods is important in this regard.
- Events like risk assessment workshops are helpful and lead to better understanding, transparency and identification of similarities of different approaches.

ANNEX I

This annex presents summaries of group discussions on key attributes of an effective product risk assessment and provides suggestions for future actions to enhance it.

Group 1

Key attributes of an effective product risk assessment:

- Should result in clear and consistent outcomes: results in common understanding of the elements that were taken into account in risk assessment.
 - The following tables and frameworks could assist with this attribute:
 - Severity of injury.
 - Probability of harm.
 - Recognition of harm (*e.g.* we would need definition and criteria from the RAPEX table for harm).
- Should have tools that allow for taking into account all the risks related to the product, *i.e.*, foreseeable product use and misuse: *i)* helps managing risks at the design phase, *ii)* is more comprehensive; *iii)* allows for proportionate response to risks, *iv)* provides greater confidence in conclusions.
 - The following tables and frameworks could assist with this attribute:
 - Risk classification tables which clearly define degrees of risk (*e.g.* “1”, “2”, etc).
 - Injury databases for similar product types.
 - Scenario tables.
- Should be verifiable: *i)* enhances confidence and *ii)* allows refinement of methodology over time.
 - The following tables and frameworks could assist with this attribute:
 - Undertake verification.
 - Documentation of validation/verification.
 - Comparing what was predicted to what actually happened (verification, back-testing, etc.).
 - Adjusting methodologies.
- Should be transparent and publicly available: *i)* makes risk assessment more trustworthy, *ii)* improves predictability, *iii)* inspires confidence, *iv)* can influence design and *v)* assists standards making.
 - The following tables and frameworks could assist with this attribute:
 - Publishing methods, etc.
- Should ensure reliable estimation of probability: increases confidence.
 - The following tables and frameworks could assist with this attribute:
 - Sensitivity analysis.
 - Develop an agreed database of probabilities.

Suggestions for future actions to achieve the risk vision presented in session I

Action	Why is it important?	Who should do it?
Training and education	Consistency, predictability, competence, replicability.	
Publication of risk assessment methods	Transparency. Helps manage risks at the design phase because method is known.	Jurisdictions
Validation techniques to assess the risk assessment methods	Enhances confidence, allows refinement of methodology over time, and increases confidence.	
Development of tables for severity of injury and probabilities	Helps manage risks at the design phase. More comprehensive; supports proportionate response to risks. Provides for greater confidence in conclusions.	
Collection of reference cases Injury database	Helps strengthen the risk assessment methodology by making it more comprehensive. Supports proportionate response to risks. Provides for greater confidence in conclusions.	

Conclusions

- Need to collaborate internationally to develop common tools; training and education.
- Publication of risk assessment methods is critical to transparency; common understanding and enhanced integration of product safety into the design.
- Challenge of refining probability is a long term issue and requires collaboration.
- Risk tolerance should be a factor influencing risk treatment and need not influence risk assessment.

Group 2

Key attributes of an effective product risk assessment

- Should facilitate identification of products: if we don't correctly identify the product, the results will not be helpful.

- The following tables and frameworks could assist with this attribute:
 - Photographes,
 - Samples,
 - Detailed description,
 - Use of standards,
 - Use of object identifiers (UPC codes, HTC codes, customs codes),
 - Results from previous assessments; databases of previous assessments of similar products (*e.g.* Denmark product registry; cosmetics registry),
 - Reference to relevant legislation.
- Should facilitate identification of intended user groups of a product (*e.g.* children under three-years old): *i)* identifies different exposure scenarios; and *ii)* identifies sub categories of the populations that are vulnerable.
 - The following tables and frameworks could assist with this attribute:
 - Manufacturer's information,
 - Information on the chemical composition of the product.
- Should facilitate identification of foreseeable use and misuse: helps to determine risk scenarios.
 - The following tables and frameworks could assist with this attribute:
 - Standards,
 - Best practices,
 - Manufacturers' information.
- Should be based on sound scientific evidence: *i)* supports repeatability, *ii)* is contestable, *iii)* can be based on expertise, but it can be based on other things too, such as costs, and *ii)* needs to be distinguished from a "judgment", which is not an "expertise".
 - The following tables and frameworks could assist with this attribute:
 - Historical assessments of similar products,
 - Knowledge of form, fit and function of a product,
 - Knowledge of product's composition, and materials,
 - To preserve scientific integrity and independence of the process, consider changing the risk assessor on a rotational basis (*e.g.* so that the same person isn't assessing the same products/companies all the time).
- Should ensure clear difference between risk assessment and risk management (this may seem obvious, but in practice, it can be very difficult to separate): not separating them could compromise the integrity and the scientific independence of the process.
 - The following tables and frameworks could assist with this attribute:
 - It was noted that "estimate how widely available the product is" and "take into account the risk tolerance of stakeholders" are both risk management items – not risk assessment issues.
 - It is important for there to be a linkage – risk assessors can provide options to risk managers for them to choose from.

Suggestions for future actions to achieve the risk vision presented in session I

Action	Why is it important?	Who should do it?
Create legal requirements that would require risk assessments for products/ product categories (as with cosmetics in the EU).	This can help to ensure that the manufacturers can provide the assessment to the authorities if there are questions.	Government to introduce requirement; manufacturers to maintain dossier.
Share tools on how to authenticate non-genuine products (e.g. anti-counterfeit measures).	Avoid economic harm to genuine brands, only if the counterfeit products are presenting a health or safety problem.	Assessor, in collaboration with trade/economic operator.
Risk assessment should be supported by scientific committees; not for day-to-day, but to discuss principles.	Issues can be complex; it is useful to have a community to discuss best practices.	Fora of competent authorities at regional levels (e.g. global bodies, Codex for food).
Global harmonisation, where appropriate.	A pool of information that various jurisdictions can draw from will promote more consistency.	International/ regional bodies.
Equivalency among jurisdictions.	Developing options for mutual acceptance of assessments from different jurisdictions can reduce barriers.	Inter-jurisdictional bodies (e.g. OECD).

Conclusions

- Improvement of product risk assessment is a longer term process which can be facilitated by drawing lessons from other scientific fields, *i.e.* food safety. Stakeholders shouldn't be discouraged in these efforts.

Group 3

Key attributes of an effective product risk assessment

- Should be based on a very well-defined process to identify the probabilities and a well-specified problem: *i)* it is necessary to know the context; *ii)* probability can only be estimated when the reference class is clear, and *iii)* frequency of occurrence of an event.
- Should capture uncertainties (e.g. ranges for probabilities): *i)* to deal with the fact that probabilities are estimations; *ii)* to show the limits of methods, and *iii)* to give the level of confidence of the result.
- Should encompass a protocol with rules of probability and logic: process/methodology should be science-based.

- Should be transparent: *i)* the process should be understandable to everyone and documented; *ii)* opportunities should be explored to use methodology more exactly; *iii)* build bridges to stakeholders.

Suggestions for future actions to achieve the risk vision presented in session I

Action	Why is it important?
Work on probabilities – Guidelines, examples, database.	Higher certainty.
Share the background of results of investigations, reasons for special measures (and the different methods).	Higher level of trust, understanding and consistency between authorities and other stakeholders.
Create an inventory of methodologies used.	Comparison, understanding.
Create a nomograph from the RAPEX-method.	Transparency, visualisation, comparison.
Create a matrix version of the nomograph.	Transparency, visualisation, comparison.
Trainings for risk assessors.	Safer performance and higher transparency.

Conclusions

- Risk assessment is important for effective risk management and should not be bypassed.
- Transparency of risk assessment methodologies is crucial.
- It is important to have trainings for experts performing risk assessments.
- Events like risk assessment workshops are helpful and lead to better understanding, transparency and identification of similarities of different approaches.