

RISK ASSESSMENT: CHALLENGES

This course will try to identify some of the main challenges associated with performing risk assessment.



INTRODUCTION

The course takes the perspective of a market surveillance authority and presents the way a market surveillance authority would carry out a risk assessment.



DISCLAIMER



This course arises from the Joint Market Surveillance Action on GPSD Products - JA2016, which received funding from the European Union in the framework of the ‘Programme of Community Action in the field of Consumer Policy (2014-2020)’.

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TO NOTE . . .

Click on the “[Resources](#)” button to view some documents which are related to this course.

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MAIN MENU

Click on the subjects that you are interested in:

Risk Assessment: Challenges

The Methodology

Vulnerable Users

Subjectivity

Non-compliance = risk?

Damage to Property

Quiz



RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

The method seems simple but experience shows that most risk assessors will encounter a number of practical challenges when they apply the method.



The method tempts people to perceive risk assessment as more “scientific” than it is. Risk assessment includes estimation of scenarios, probabilities and behaviour. The method will produce exact numbers, but the result can only be taken as a plausible input to industry’s or authorities’ risk management decision process.

RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

We will now go on and explain a number of pitfalls that may occur in practice and suggest approaches to avoiding them.



RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

Often the risks are so obvious that it seems superfluous to do a risk assessment. “Why bother with the paperwork?” you would say, “Everybody knows that this is deadly dangerous, so let’s ban it.”

That’s not the way to proceed. It is considered best practice always to carry out a risk assessment.



RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

First, an authority can only take measures against unsafe products so you have to prove that a non-conforming product is indeed unsafe. Standards are not mandatory.

A manufacturer can choose other ways to make a product safe. Therefore lack of compliance with a standard does not necessarily mean that the product is unsafe. The legal argument behind a measure must always describe the associated risk.

RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

Secondly, an economic operator may disagree with the opinion of the market surveillance authority and take it to court.

In such cases, the authority will have a stronger case when it can refer to a proper and well documented risk assessment.



RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

Doesn't serious injury
mean serious risk?

NO



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THE METHODOLOGY

If an injury scenario leads to a serious injury, you might expect to arrive at a serious risk. This will however not necessarily be the case.

Risk also depends on the probability of the scenario. If the scenario is virtually impossible then serious injuries may lead to a moderate or even low risk.



RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

Risk assessment of products that are supposed to have a protective function is tricky.

Such products include personal protective equipment, socket protectors and fire extinguishers.



RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

The challenge is that a non-compliance with such a product almost never makes it dangerous in itself. Instead the hazard arises because the user relies on a failing or insufficient protective function.

You can imagine a protective mask intended to protect the user against poisonous fumes. If the mask doesn't provide adequate protection, the user will be at risk because he will rely on the mask and wear it in a polluted environment where he will inhale dangerous fumes and get intoxicated.



RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

The approach to the risk assessment is basically the same, but the injury scenarios should work from the presumption that the person is exposed to the dangerous conditions that the equipment was supposed to protect him from.



RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

A particularly tricky case arises if:

- the potential injury is very severe,
- the probability for injury is low and
- there are many products on the market.



The challenge is that if the probability is low enough, the risk level will be medium or even low, no matter how severe the injury may be.

If the product at the same time is sold in very large numbers like millions then the exposure for society as a whole would be high and serious accidents would be likely to happen at regular intervals.

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THE METHODOLOGY

You should recall two things:

First, low risk does not mean that you cannot or should not do anything.

It may be necessary to take action even against products that pose very low levels of risk, particularly in cases where it is easy to mend the non-compliances or where the exposure is high.



RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

You should recall two things:

Secondly, the decision on proper action is risk management, not risk assessment.

The aim of risk assessment is solely to determine the level of risk. That is, to determine how unsafe a single product is. The aim of risk management is to determine how to handle the risk.



RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

Therefore you should note any such observations in your risk assessment report so it can be taken into account in the risk management phase.



RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

The first question when you are doing a risk assessment is how the product hazard will cause an injury to the user.

Unfortunately it is possible to imagine almost any chain of events that will lead to an injury, so there is clearly a chance that the list of scenarios grows very long.

How do you avoid that?



RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

You should note that every extra step added to a scenario introduces an extra factor.

This factor will be below 100% so the total probability and therefore also the total risk will decrease the more steps you introduce.

Therefore the best scenarios will be those that present the shortest way from hazard to injury. More complicated scenarios may normally be disregarded.



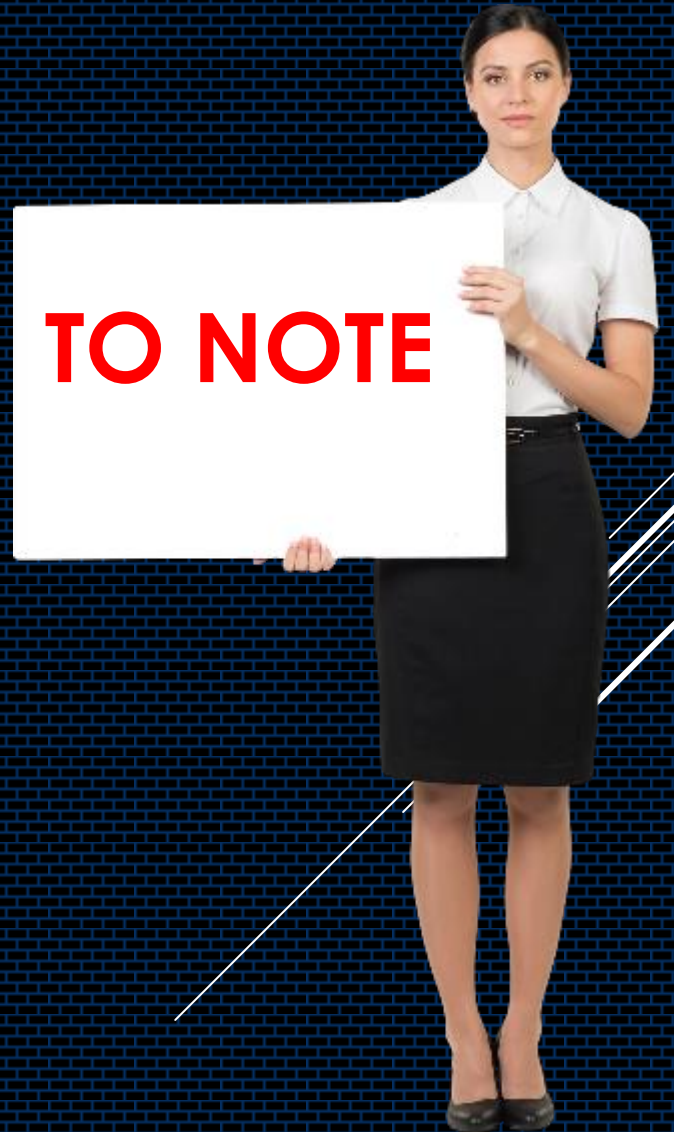
TO NOTE

RISK ASSESSMENT: CHALLENGES

THE METHODOLOGY

You should also focus on those scenarios with the highest combination of probability and severity.

Normally you will develop a good sense for this after having carried out a few risk assessments.



RISK ASSESSMENT: CHALLENGES

VULNERABLE USERS

Much attention has been given to vulnerable users, for instance children, elderly, people with disabilities, etc.

Although the present RAG webtool does have a feature to include such a special place for vulnerable people, it does not feature in the final calculation itself. This means that the risk assessor would have to take this into account when developing the risk scenario.



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VULNERABLE USERS

First, there may be special scenarios that involve vulnerable users.

As an example, you may think of children that watch adults using products or elderly people that don't understand how to use products properly or don't have the sufficient strength to do so.



RISK ASSESSMENT: CHALLENGES

VULNERABLE USERS

Secondly, vulnerable users could suffer more serious injuries.

Think of very small children that grip hot products and don't let go but call for their parents to help them. They will have more severe burns than an adult who will instinctively let go when they sense the heat.



RISK ASSESSMENT: CHALLENGES

VULNERABLE USERS

Thirdly, the probabilities of some of the steps in the scenario may increase if the product is used by vulnerable users.

Small parts are not dangerous to adults, as it is highly unlikely that they will put such objects in their mouth, but small parts can be very dangerous to babies as it is very likely that they will put them in the mouth and potentially swallow them.



RISK ASSESSMENT: CHALLENGES

SUBJECTIVITY

If a single expert does an assessment, his or her personal opinion and experience may influence the estimation of the injury severity and the probabilities so one important question is how to avoid subjectivity?

A number of approaches help to cope with this.



Subjectivity

RISK ASSESSMENT: CHALLENGES

SUBJECTIVITY

First, the risk assessor should use quantitative measures and data as much as possible.

As an example, the table of injury levels in the risk assessment tool will improve the consistency in the determination of the severity of an injury. Data from accident statistics, test reports and other sources are also useful in this context.



Subjectivity

RISK ASSESSMENT: CHALLENGES

SUBJECTIVITY

A second method is to work with colleagues or external experts.

You may involve them right from the beginning of the risk assessment or you may ask them to review your results at the end.



Subjectivity

RISK ASSESSMENT: CHALLENGES

NON-COMPLIANCE = RISK ?

What if a product doesn't comply with the relevant safety standard?

Doesn't it mean that it is risky?



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NON-COMPLIANCE = RISK ?

No, not necessarily.

The manufacturer doesn't have to follow a standard as long as the product is safe, so the mere fact that a product doesn't comply with a standard is not sufficient to decide whether it is unsafe.

You still have to develop a risk assessment with scenarios etc. Moreover the level of risk depends upon the specific requirement and how much the measured value deviates from that.



RISK ASSESSMENT: CHALLENGES

NON-COMPLIANCE = RISK ?

However, the risk assessment could be fairly short if the hazard and the injury are well-known.

Alternatively existing risk assessments of such well-known hazards could be re-used to quickly decide on measures.



RISK ASSESSMENT: CHALLENGES

DAMAGE TO PROPERTY

The risk assessment method works from the presumption that products cause injuries to people. Obviously this is not always the case.

Think of a candle for instance. The most likely scenarios will describe how candles put fire to property. So how do you assess such cases?

You can choose different approaches.



RISK ASSESSMENT: CHALLENGES

DAMAGE TO PROPERTY

One approach is to write injury scenarios where a person is injured.

You could imagine that the fire causes burns or the person is poisoned by smoke or dies, etc. An example of such a scenario could be “A candle puts fire to a curtain, which ignites the room. A person is asleep and does not wake up. The person dies from smoke poisoning.” Of course, the condition that a sleeping person needs to be present lowers the probability: of all fires caused by candles, many may be detected and extinguished by people in the house.



RISK ASSESSMENT: CHALLENGES

DAMAGE TO PROPERTY

Another approach is to categorise the fire according to its extent and the resulting damage. One example is shown in this table. Similar categorisations can be developed for damages to other kinds of property or injuries to animals.

Severity Level	Description of Fire
4	A whole building or several rooms are destroyed by the fire.
3	One room is destroyed by the fire or several rooms are affected e.g. By smoke
2	Few pieces of furniture or curtains are destroyed or one room is affected e.g. by smoke or burn marks
1	Few pieces of furniture are affected e.g. by smoke or burn marks



RISK ASSESSMENT: CHALLENGES

Complete
the quiz . . .

C is CORRECT - Standards are always voluntary and a manufacturer may choose other ways than those presumed in the standards to make the product safe.

B is only partially correct since one cannot conclude that there is a risk for each non-compliance

This product does not comply with the standard so it is unsafe.



A non-compliance will only be unsafe if the standard is referenced in the Official Journal. If the standard is not referenced you have to do a risk assessment

B

The standards committee has defined the requirements for a safe product after a risk assessment, so there is a risk in case of non-compliance

C

You have to prove that the non-compliance will make the product unsafe

► Click [here](#) for the next question

RISK ASSESSMENT: CHALLENGES

Complete
the quiz . . .

CORRECT - You must develop your scenarios taking into account that this group of users may use the product in a different way than ordinary consumers, they may react slower, they may not have the physical strength, etc

This product is used by vulnerable consumers. How do I take that into account in my risk assessment?



It is not possible to take the category of consumers into consideration as they are not included in the risk assessment model



You develop a scenario that allows for the specific characteristics of this group of consumers



You select the appropriate group of consumers in the risk assessment tool

► Click [here](#) for the next question

RISK ASSESSMENT: CHALLENGES

Complete
the quiz . . .

CORRECT - Risk is the combination of injury and probability so if the probability goes low, the risk level also become low.

The scenario results in a severe injury to a child, so the assessment will end in serious risk.



If the injury is severe, the risk should be serious.



The risk will only become serious if the number of products is high enough to give a significant exposure to society.



If the probability is low enough, the risk level may be medium or low

► Click [here](#) for the next question

RISK ASSESSMENT: CHALLENGES

Complete
the quiz . . .

CORRECT - If the product is intended for children under 36 months of age, it does not comply with the toy standard, but you always need to prove that a non-compliant product is dangerous and to take proportionate measures.

You have a toy with a small part that easily comes off. This is clearly dangerous, so you can skip the risk assessment.



You still have to do the risk assessment. A small part is a non-compliance according to the toys standard, but you have to justify that it makes the toy unsafe.



There are many such cases in the Rapid Alert System that proves that authorities have taken action against small parts in toys.



That depends on the intended age of the child that should play with the toy. The requirements only applies to toys for small children under 36 months of age.

► Click [here](#) for the next question

RISK ASSESSMENT: CHALLENGES

Well done!
You have now completed this topic.



RISK ASSESSMENT: CHALLENGES



< **Back to Main Menu**