

UNDERSTANDING RISK ASSESSMENT



This course will give you an introduction to risk assessment for consumer products and describes the steps you need to take to assess the risk within a given product.



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)’.

The content of this course represents the views of the author/s only; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.



TO NOTE . . .

Click on the “Resources” button to view some documents which are related to this course.

Try out the “search” function (right-hand side) to find text from within any part of this course.



MAIN MENU



Click on the subjects that you are interested in:

Introduction & Background

The Theory behind Risk Assessment

A Worked Example

Risk Assessment of Chemicals

Some Final Questions



INTRODUCTION & BACKGROUND

WHAT IS RISK ASSESSMENT?

Risk assessment is the process whereby you determine how dangerous a product is to the user.

A manufacturer must use risk assessment from the very beginning to determine which risks a product might pose. From a legal point of view, products have to be safe. This means that they may only pose an acceptable risk level to the user and to society.

It can be applied by businesses and by authorities at any stage during the life cycle of a product.

INTRODUCTION & BACKGROUND

WHAT IS RISK ASSESSMENT?

In practice, adequate safety is often achieved by manufacturing the product so it meets the requirements of a relevant safety standard.

The manufacturer will have to repeat this risk assessment whenever the product is modified.



INTRODUCTION & BACKGROUND

WHAT IS RISK ASSESSMENT?

- Later on risk assessment may become necessary if it is discovered that a product does not comply with the safety requirements.

- The manufacturer and the authority will then use the method to determine the level of risk to find out which measure will be the most appropriate to remove the risk.

INTRODUCTION & BACKGROUND

WHY RISK ASSESSMENT?

So risk assessment plays an important role, but why is it an issue for a market surveillance authority?

Why don't we simply take all products that don't comply with the regulation off the market?

To answer this, we need to take a look at some of the European legislation.



INTRODUCTION & BACKGROUND

WHY RISK ASSESSMENT?

The General Product Safety Directive mentions that products must be “safe”.

- According to the directive this means that the product doesn't present any risk or only minimum risk to the user.
- The directive also introduces the term **“serious risk”**.



INTRODUCTION & BACKGROUND

WHY RISK ASSESSMENT?

If you look at the New Legislative Framework it also states that products must be safe.

Furthermore it requires that Member States ensure that products presenting a serious risk are taken from the market and it explicitly says that “The decision whether or not a product represents a serious risk shall be based on an appropriate risk assessment ...”.



INTRODUCTION & BACKGROUND

WHY RISK ASSESSMENT?

So legislation requires that products on the market are safe and that authorities take measures against products presenting a serious risk. So you may ask . . . when is risk serious?

Furthermore the European legislation requires that measures respect the principle of proportionality. How do you ensure this?

Both these questions can be answered with a risk assessment.



INTRODUCTION & BACKGROUND

WHY RISK ASSESSMENT?

Why risk assessment is important and required.

- It supports the decision-making process and makes your decision more objective
- It offers plausible explanations of the decisions you take
- It increases the transparency and opens a qualified discussion of risk levels and countermeasures between you and the economic operator.
- It makes it possible for you to communicate results to the general public and legal prosecutors among others.



**TO BE
NOTED !!**

INTRODUCTION & BACKGROUND

ADDITIONAL INFORMATION

In 2009, the European Commission adopted [Decision 2010/15/EU](#) that among other things describes the risk assessment method that is recommended to assess the safety of consumer products.

This method was developed by a dedicated working group of Member State experts and is today considered best practice for risk assessment for consumer products.



INTRODUCTION & BACKGROUND

ADDITIONAL INFORMATION

The method results in:

- A grading of risks that enables the authority to decide on a proportionate measure.
- A description of choices made which results in a transparent path from estimates made to the final result.

Such input is very useful when you want to explain the rationale behind a decision. This e-learning course is based on this method described in Commission Decision 2010/15/EU.



INTRODUCTION & BACKGROUND

ADDITIONAL INFORMATION

A word of caution to end this section:
Risk assessment is not an exact science.
It includes estimation of scenarios,
probabilities and behaviour.

So even if the method comes up with
exact numbers you must not take it as
the truth and nothing but the truth.



INTRODUCTION & BACKGROUND

Complete
the quiz . . .

CORRECT - The aim of risk assessment is to analyse the risks that a non-compliant product poses to the users. This in particular also addresses the question whether a risk is serious or not.

What is risk assessment ?

A

The process whereby the risk level of a given product is determined



The process whereby the appropriate measure against a non-compliant product is determined



The process where a producer checks whether the product complies with standards and legal requirements

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

INTRODUCTION & BACKGROUND

Complete the quiz . . .

CORRECT - Standards are only one means to assure that a product is safe. If the product is safe, it is legal to place it on the market even though it does not comply with a safety standard.

Answer "A" is partly true, as you would also need to find out if you need to issue a Rapid Alert Notification. It requires a risk assessment to decide if the risk is serious.

Why do you have to do a risk assessment when a product fails to comply with a standard?



Because you have to find out whether the risk is serious so you should issue a Rapid Alert Notification



Because you need to assess whether the product is unsafe



Because you need it to convince the manufacturer

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

INTRODUCTION & BACKGROUND

Complete
the quiz . . .

CORRECT - Risk assessment is used by the manufacturer to ensure that the risk level of the product is acceptable for the user and for society.

If it is later on discovered that a product does not comply with the safety requirements, the manufacturer and the authority will use risk assessment to determine the most appropriate measure to remove the risk.

Who will do a risk assessment ?



The market surveillance authority



The manufacturer



Both the market surveillance authority and the manufacturer

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

INTRODUCTION & BACKGROUND

Well done!
You have now completed this topic.



INTRODUCTION & BACKGROUND



< Back to Main Menu

Next Topic >

Click above to go where you wish to proceed.

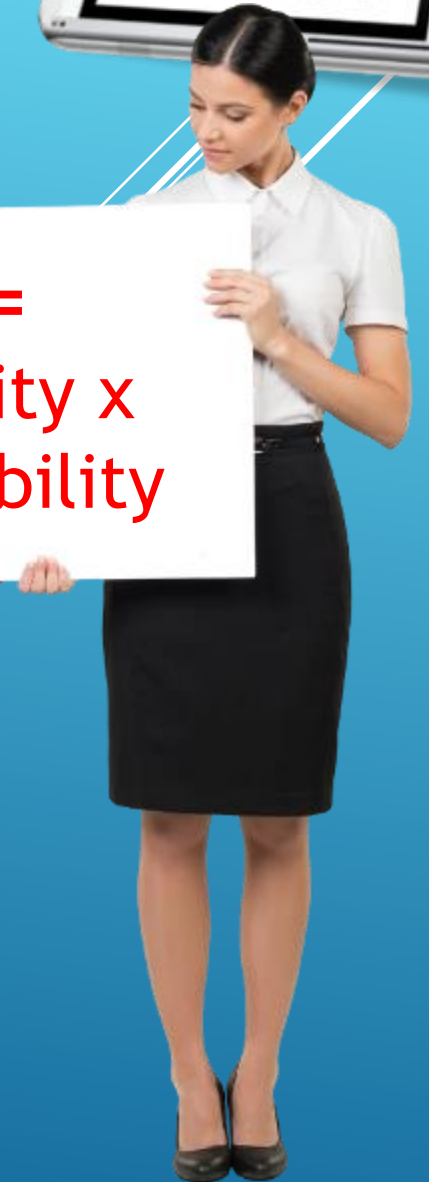
RISK ASSESSMENT

The Theory behind Risk Assessment

You heard before that risk assessment is the process whereby you determine how dangerous a product is to the user.

In more mathematical terms, risk equals severity multiplied by probability.

**Risk =
Severity x
Probability**



RISK ASSESSMENT

The Theory behind Risk Assessment

Severity is understood as the outcome of the event.

In practice, this is often a verbal description of an injury or damage caused by a dangerous property in the product.

Probability is understood as the likelihood that the event happens.



Probability of damage during the foreseeable lifetime of the product	Severity of injury			
	1	2	3	4
> 50 %	H	S	S	S
> 1/10	M	S	S	S
> 1/100	M	S	S	S
> 1/1,000	L	H	S	S
> 1/10,000	L	M	H	S
> 1/100,000	L	L	M	H
> 1/1,000,000	L	L	L	M
< 1/1,000,000	L	L	L	L

S - Serious risk
H - High risk
M - Medium risk
L - Low risk

RISK ASSESSMENT

The Theory behind Risk Assessment

The method behind this course was developed to deal with consumer products and it focuses on risks posed to people.

Further information may also be found in the book “Best Practice Techniques in Market Surveillance” that was published by PROSAFE.



RISK ASSESSMENT

The Theory behind Risk Assessment

A number of different situations can initiate a risk assessment. The most common ones are that:

- a test has shown that a product does not comply with the safety requirements or
- an accident has suggested that a product may be unsafe.

In such cases you need to find the level of risk the consumer is exposed to.



Identify non-compliance / then initiate risk assessment

RISK ASSESSMENT

The Theory behind Risk Assessment

You can also imagine that a new product emerges on a market or a product displays new and innovative characteristics where an authority would want to examine whether this could pose risks to consumers.



RISK ASSESSMENT

The Theory behind Risk Assessment

Risk assessment always focuses on three basic questions.

- 1) What can go wrong?
- 2) What are the consequences if it happens?
- 3) How likely is it that it will happen?



RISK ASSESSMENT

The Theory behind Risk Assessment

Risk assessment uses several sources of input.

- Often the product itself is available for inspection.
- Data and information about the specific product.
- Injury scenarios that may occur.
- Accident statistics.
- Specific injury data.
- Test reports.



**SOURCES
OF INPUT**

RISK ASSESSMENT

The Theory behind Risk Assessment

Similarly the person doing the risk assessment will normally also use a number of tools.

- Various databases
- General injury statistics
- Product or risk specific toolboxes



**TOOLS
USED**

RISK ASSESSMENT

The Theory behind Risk Assessment

This summarises the inputs, tools and output of a risk assessment process:



INPUT

- Often the product itself is available for inspection.
- Data and information about the specific product.
- Injury scenarios that may occur.
- Accident statistics.
- Specific injury data.
- Test reports.

Risk Assessment (of an individual product)

OUTPUT

- Risk Level
- Uncertainty

TOOLS

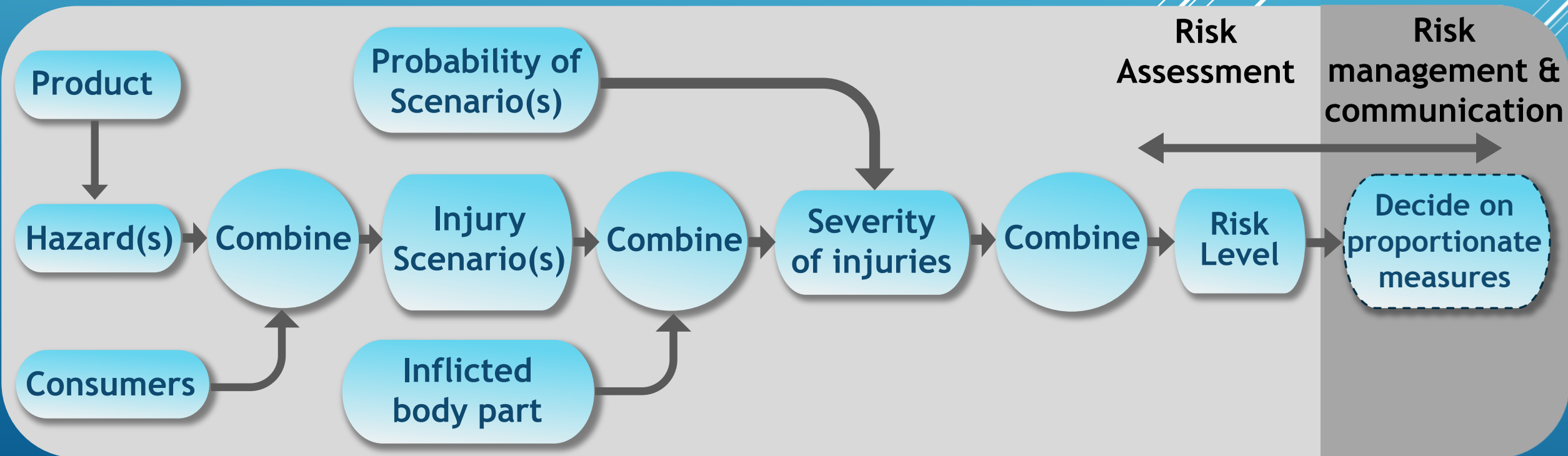
- Various databases
- General injury statistics
- Product or risk specific toolboxes.



RISK ASSESSMENT

The Theory behind Risk Assessment

A risk assessment will normally go through a number of steps as can be seen in the figure below:

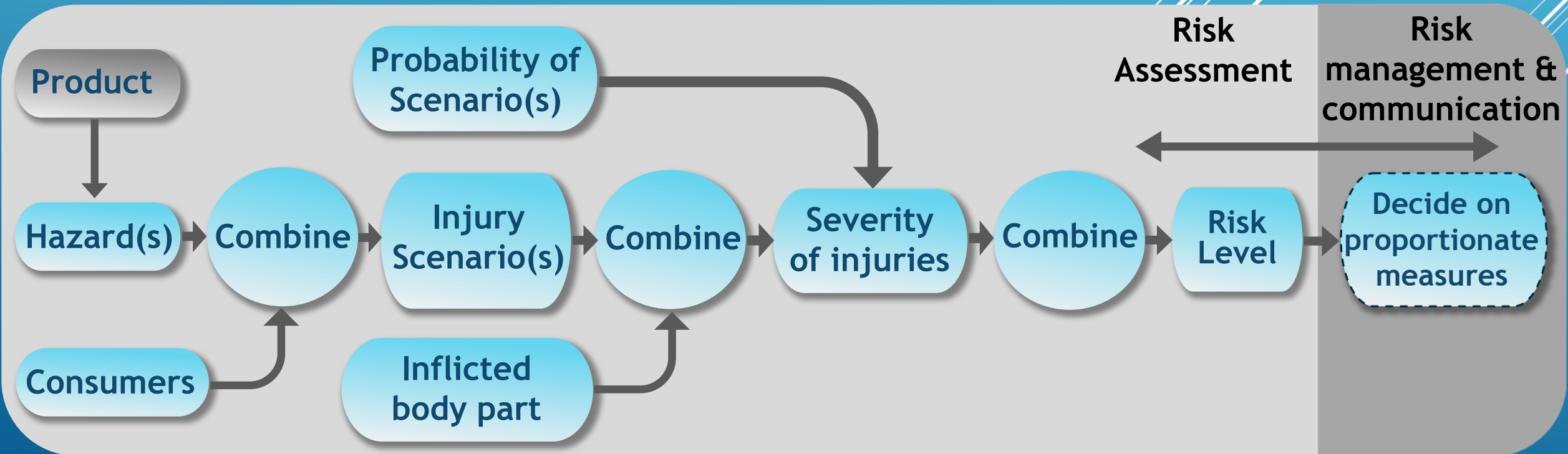


RISK ASSESSMENT



The Theory behind Risk Assessment

1. You must identify the **product** that is being assessed. It may be important to include not only product brand and exact type, but also serial number or batch number, EAN code etc. Product hazards may be due to a defect that is only present in a particular batch.

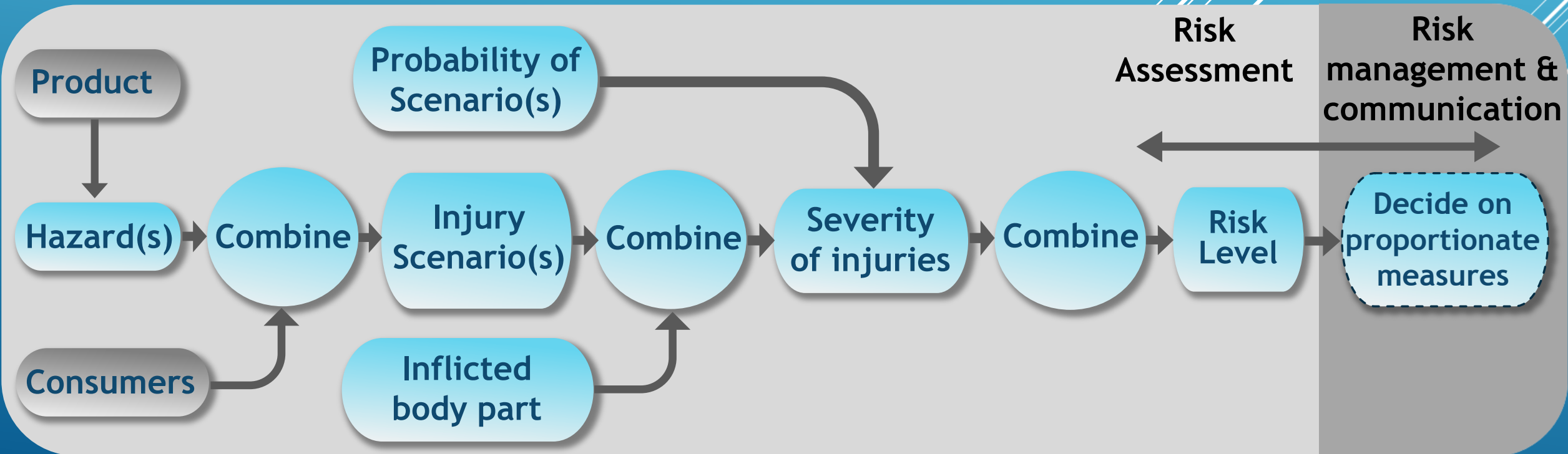


RISK ASSESSMENT



The Theory behind Risk Assessment

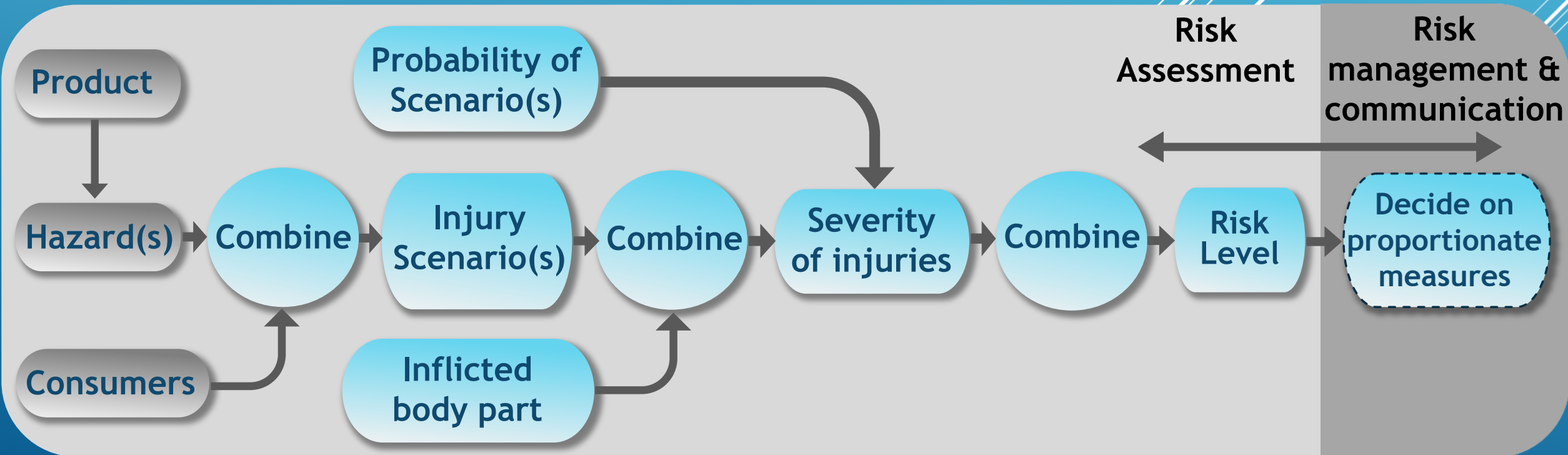
2. You need to also identify **the type of consumer**. Are children, elderly people or other vulnerable groups involved? Are there spectators or other “indirect” users inadvertently involved besides the primary user?



RISK ASSESSMENT

The Theory behind Risk Assessment

3. Then you need to describe the **hazards** under consideration. What could go wrong and what is causing the injury?

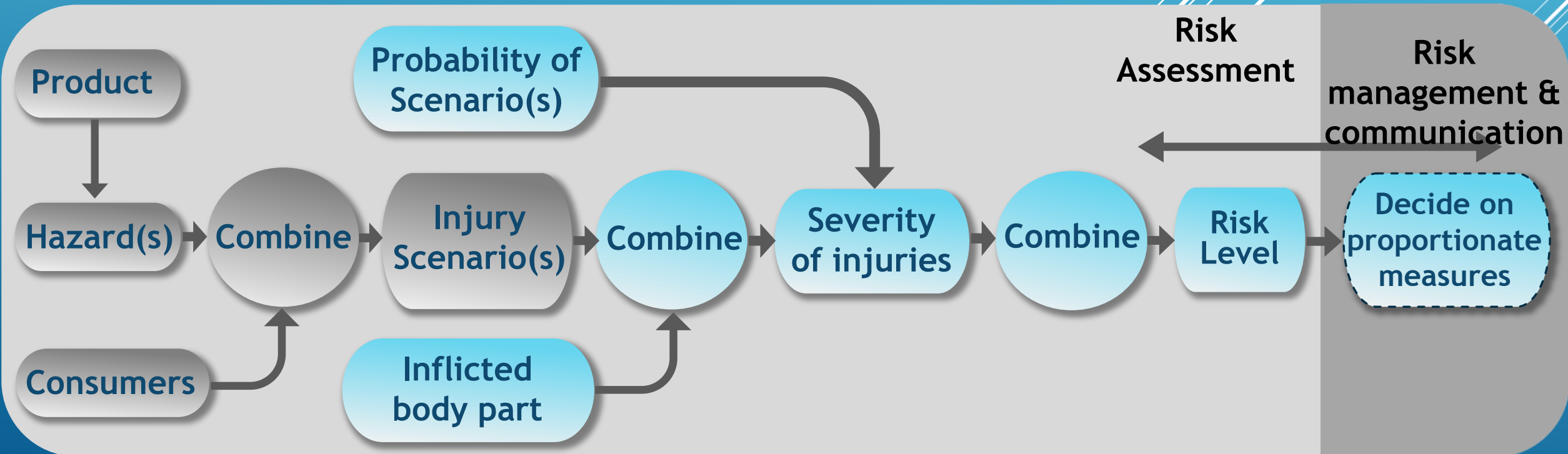




RISK ASSESSMENT

The Theory behind Risk Assessment

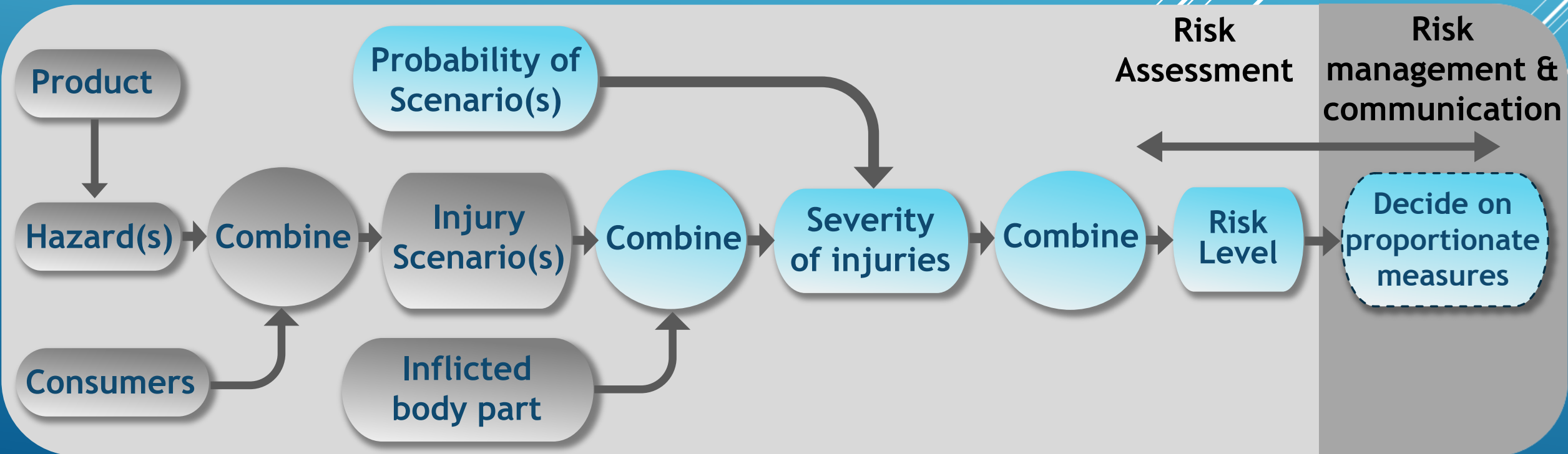
4. You must describe how the hazard causes the injury to the consumer, in other words, develop an **injury scenario**. Try to be as precise as possible and identify the least number of steps that lead from the product hazard to the injury: the “**shortest path to injury**”.



RISK ASSESSMENT

The Theory behind Risk Assessment

5. You should identify the part of the body that is **injured** and combine it with the injury scenario to obtain the nature and severity of the injury.

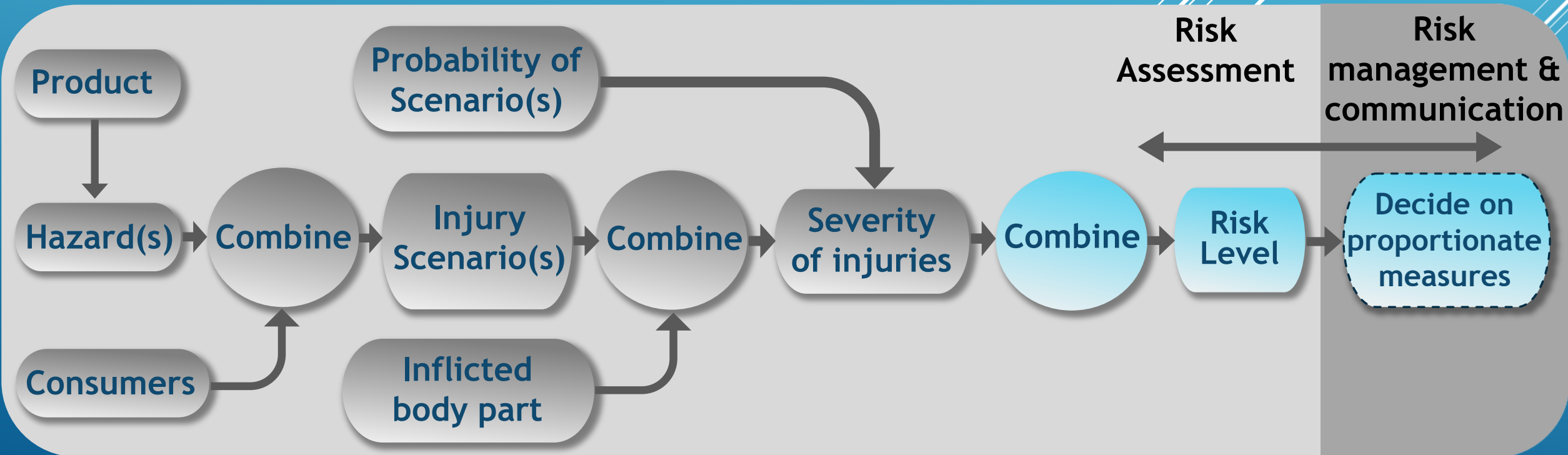




RISK ASSESSMENT

The Theory behind Risk Assessment

6. You calculate the **probability of the scenario** by assigning probabilities between 0 and 100% to each step in the injury scenario. Be careful to explain the reasoning behind the estimates in your scenario.

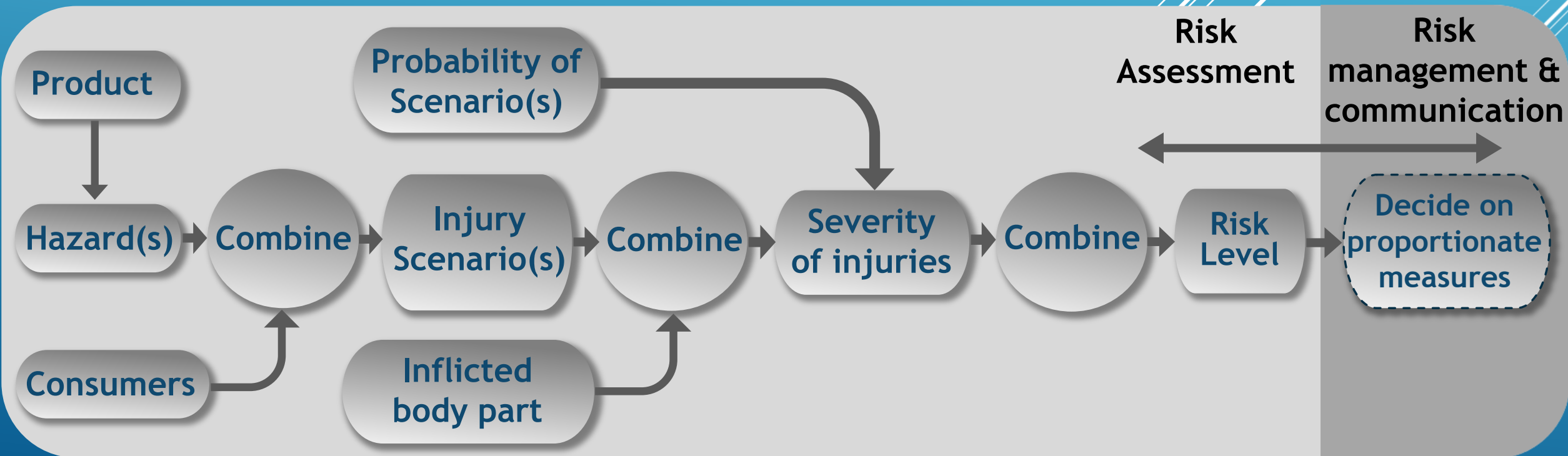




RISK ASSESSMENT

The Theory behind Risk Assessment

Finally, you combine the probability with the severity to determine a unique level of risk, which is then used to determine an appropriate and proportionate measure. Deciding on measures is called 'risk management' which is outside the scope of this training module.



RISK ASSESSMENT

A Worked Example

Now, let's try to do this on a practical case. We will use the risk assessment tool developed by the European Commission.

The tool is available on the Commission's website:

<https://ec.europa.eu/consumers/consumer-safety/rag/>



Risk Assessment Guidelines English EN

Risk Assessment for RAPEX

General Information and Overview

Product	Risk assessor
Product name <input type="text"/>	First name <input type="text"/>
Product category <input type="text"/>	Last name <input type="text"/>
Description <input type="text"/>	Organisation <input type="text"/>
	Address <input type="text"/>

Actions

- New
- Save
- Load
- Print
- Create a scenario

This tool allows the user to perform risk assessment stepwise. More guidance on how to use this tool can be found here:

<https://ec.europa.eu/consumers/consumer-safety/rag/assets/help/RAG.pdf>

RISK ASSESSMENT

A Worked Example

It is worth noting that the following example is simplified as much as possible in order to help explain the basic principles involved in this risk assessment process.

More information and templates can be found in the [risk assessment webpages](#) of the PROSAFE website or in the case studies.



RISK ASSESSMENT

A Worked Example

The case concerns a cross pein hammer with metal handle and plastic grip.

The hammer has several shortcomings. In this example we will focus on the fact that the plastic grip is insufficiently fastened to the shaft, which means that the upper metal part of the hammer may fall off when the user is using the hammer.



This can also be found in Chapter 10 of the PROSAFE's Best Practice Handbook.

RISK ASSESSMENT

A Worked Example

Try to identify the product that is being assessed. In this case the product is a hammer with metal handle and plastic grip.

This information is entered in the first two fields in the risk assessment webtool.

In the 3rd field you can add a more detailed description of the case, the product or other relevant information.

A laptop computer is shown from a front-facing perspective, displaying a web-based risk assessment tool. The screen shows a form titled "General Information and Overview" with a "Product" section. The form has three input fields: "Product name" with the value "Cross Pein Hammer", "Product category" with the value "Tools", and "Description" with the value "The hammer has a metal handle and a black plastic grip".

General Information and Overview	
Product	
Product name	Cross Pein Hammer
Product category	Tools
Description	The hammer has a metal handle and a black plastic grip.

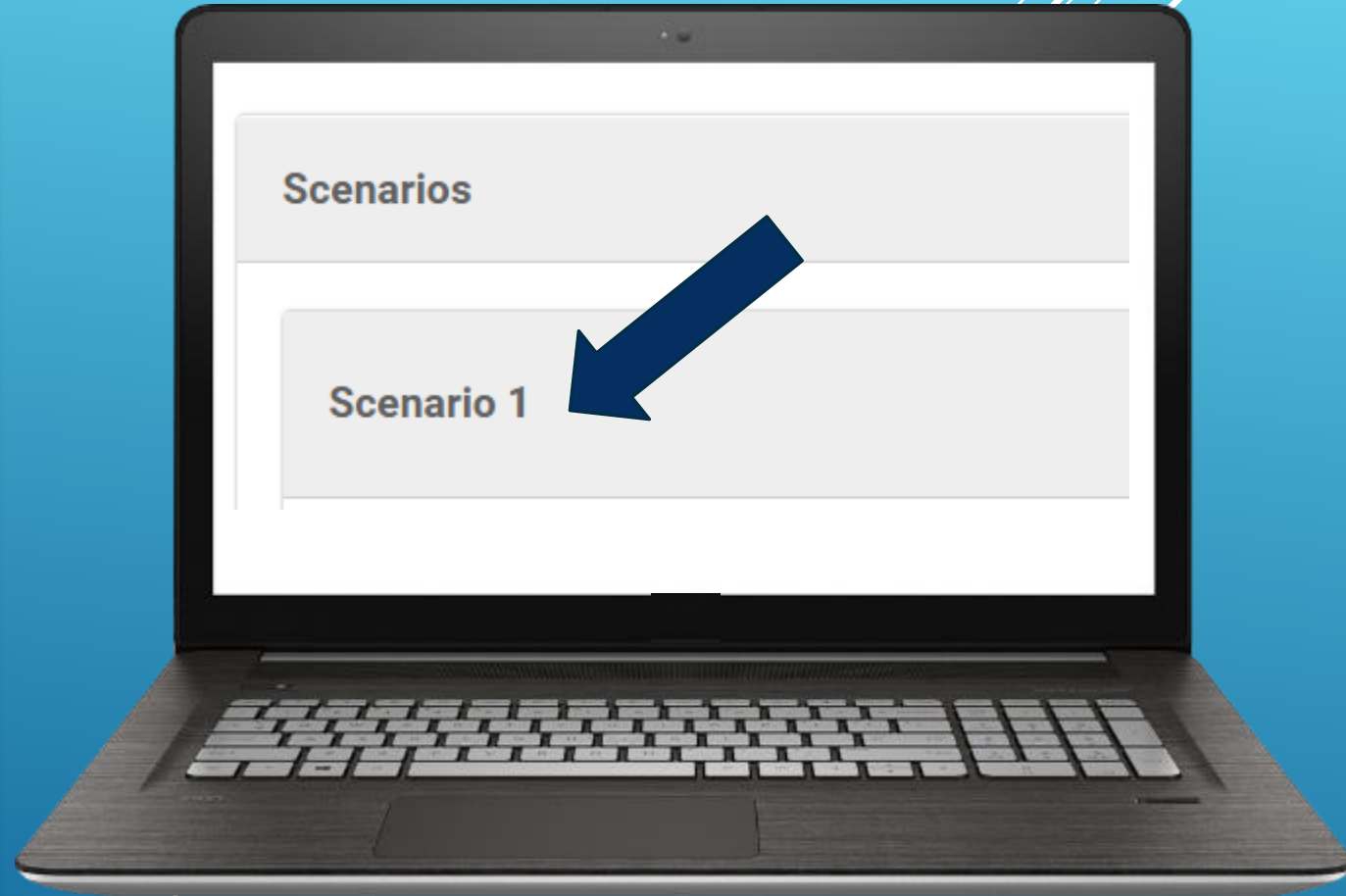
Next, you should identify the type of consumer that is concerned.

RISK ASSESSMENT

A Worked Example

A hammer is clearly intended to be used by adults, but take care. Children may want to stand nearby to watch the adult working. This may be taken into account by adding relevant scenarios.

This information is entered in the risk assessment webtool by creating a new scenario. Click on the button “Create a scenario” and choose from the drop box in the field Consumer type.



RISK ASSESSMENT

A Worked Example



The next step is to choose the appropriate consumer type from the drop-down menu.

- Very young children denote children less than the 3 years of age
- Young children denote children between 3 to 8 years of age
- Older children are older children up till age of 14 years of age
- Other consumers denote any other generic consumers.
- Vulnerable consumers usually denote very young children, consumers with disabilities or older consumers.
- Very vulnerable consumers - denote very young children (possibly less than 1 year old), and other more vulnerable people such as very old persons.

Consumer type

Other consumers ▼

Please select

Very young children

Young children

Older children

Other consumers

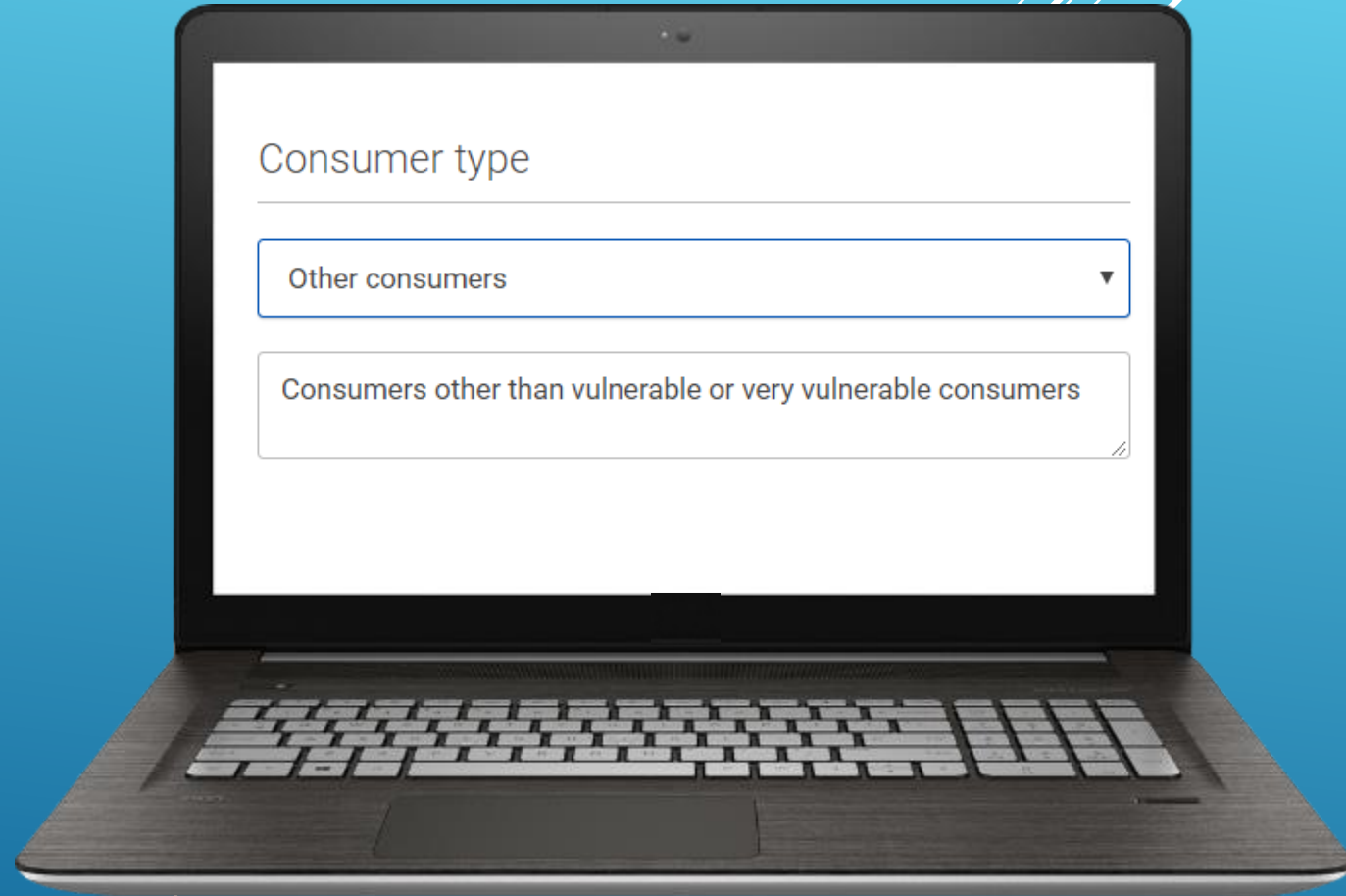
Vulnerable consumers

Very vulnerable consumers

RISK ASSESSMENT

A Worked Example

We want to develop a scenario where the user himself is hurt by the hammer, so we select the option “other consumers” that includes adults.



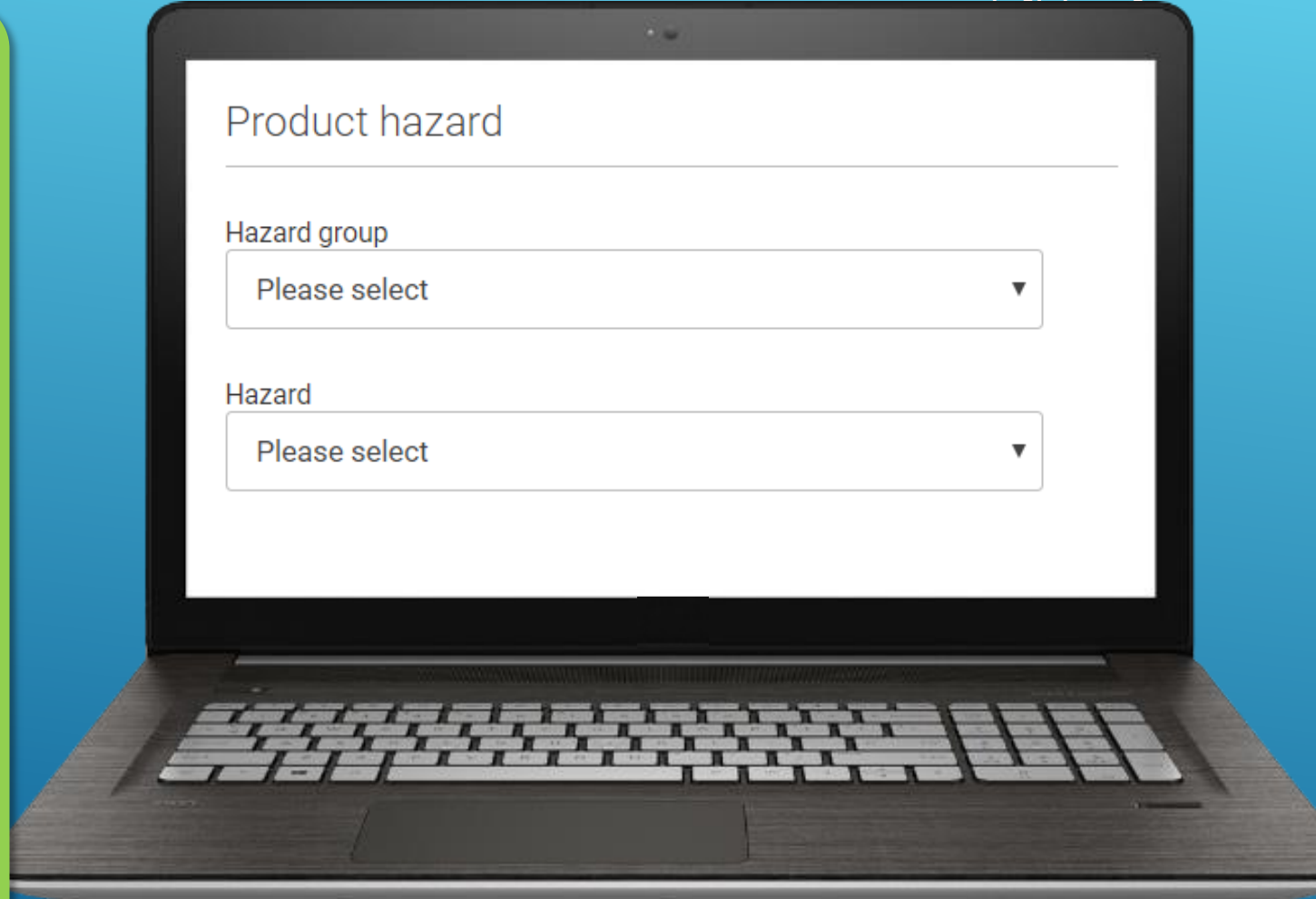
The next step should describe the hazard under consideration.

RISK ASSESSMENT

A Worked Example

The problem with this hammer is that the plastic grip partially slides off the shaft of the hammer when the user swings it around. It may then break and the upper part of the hammer may hit the user.

In order to have a short list of hazards to choose from, the risk assessment webtool splits this into two substeps. It is done under **Product hazard** in each scenario.



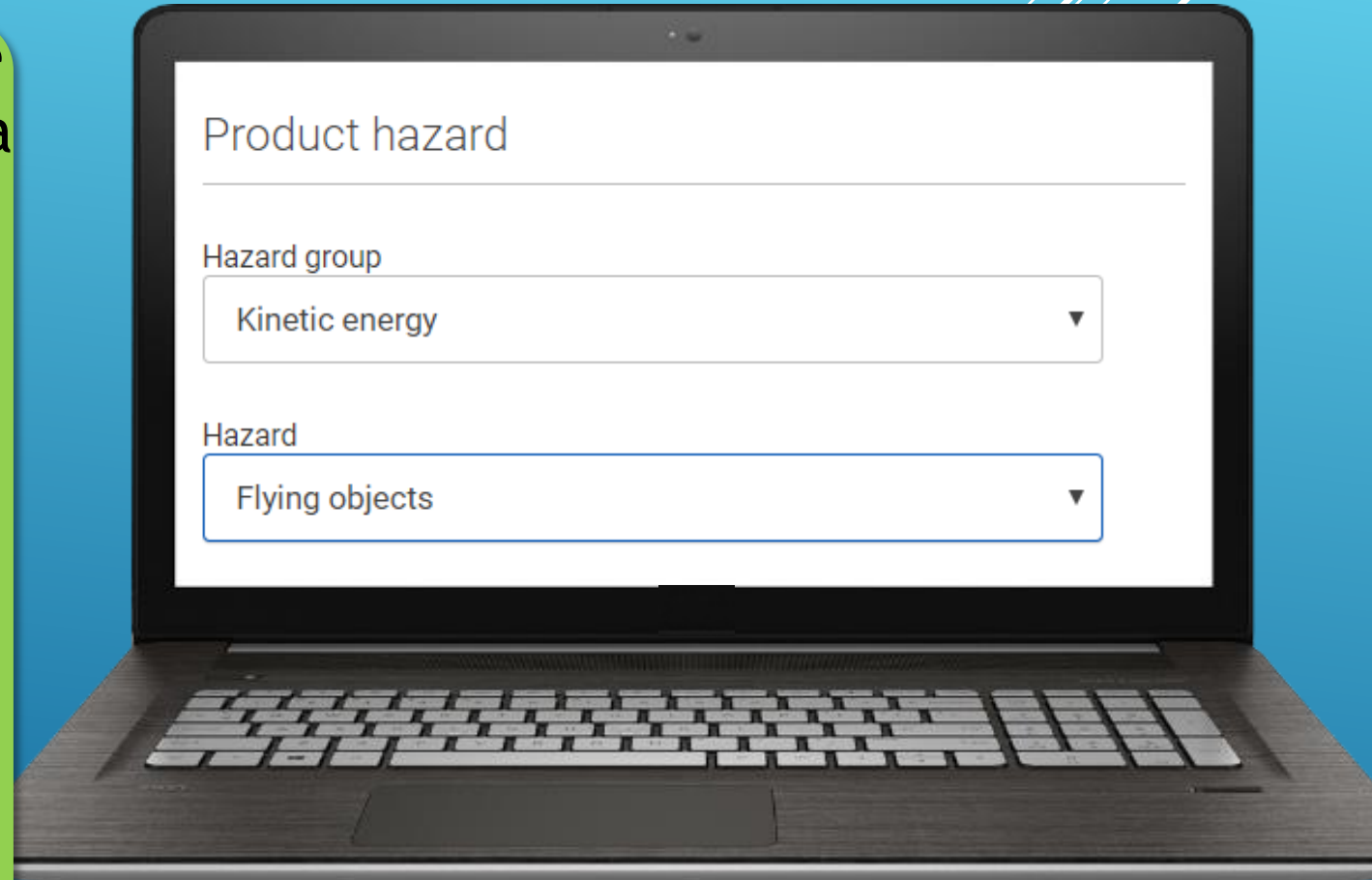
RISK ASSESSMENT

A Worked Example

The user must initially select the appropriate hazard group from a list.

The hazard has to do with parts that fly around with dangerously high speed so the proper hazard group is “**Kinetic energy**”.

Once the hazard group is identified, the webtool offers a new list with optional hazards. Here the user must select the hazard. We select “**Flying objects**”.



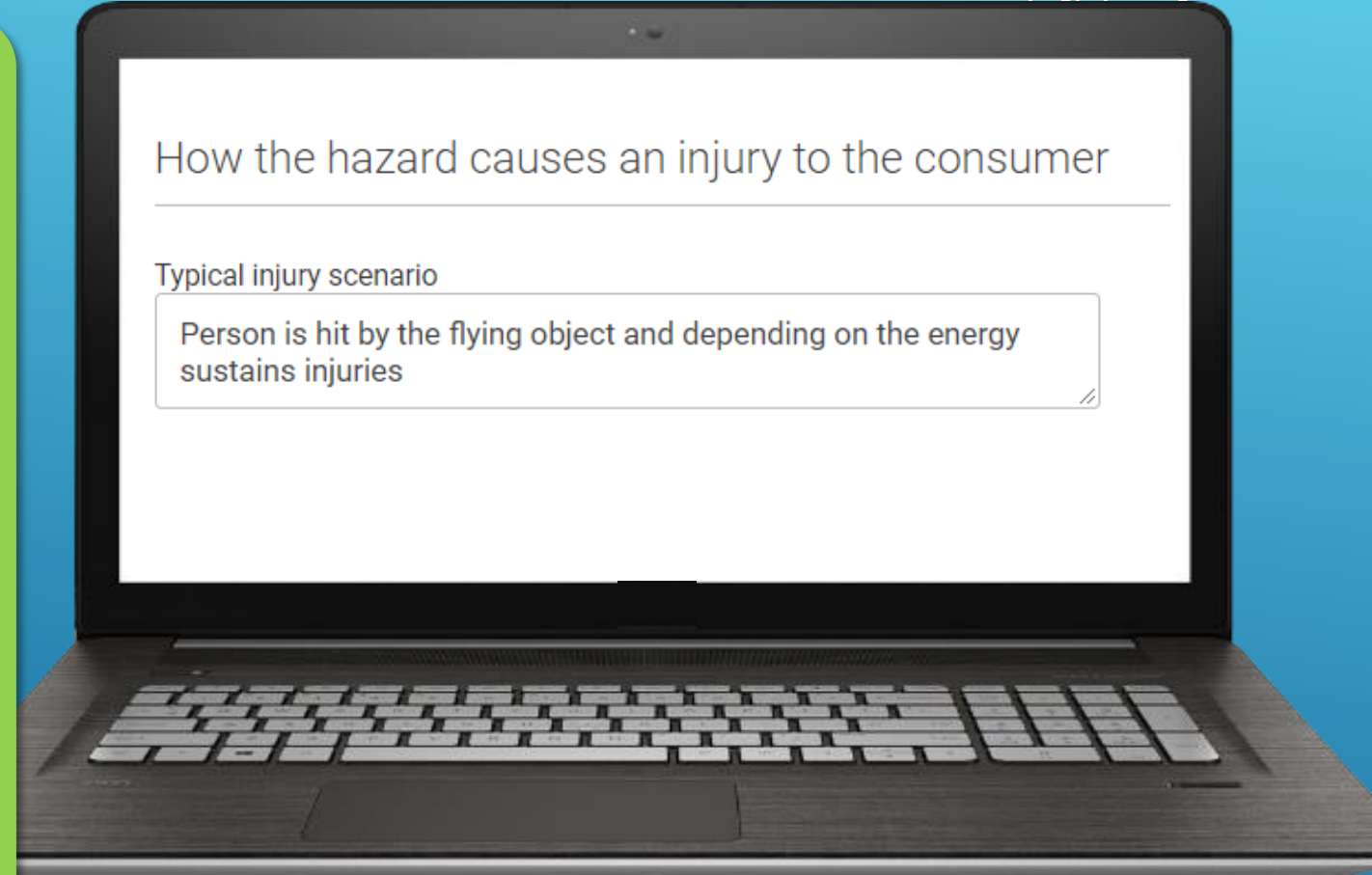
This means that we have identified the product hazard properly so we can move on to developing the injury scenario.

RISK ASSESSMENT

A Worked Example

An injury scenario is a description of how the hazard causes the injury to the consumer.

You will probably have noticed that the identification of the hazard itself implicitly leads to the injury scenario. The webtool even suggests a generic injury scenario once the product hazard has been properly described. That's why it is important to identify the product hazard properly.

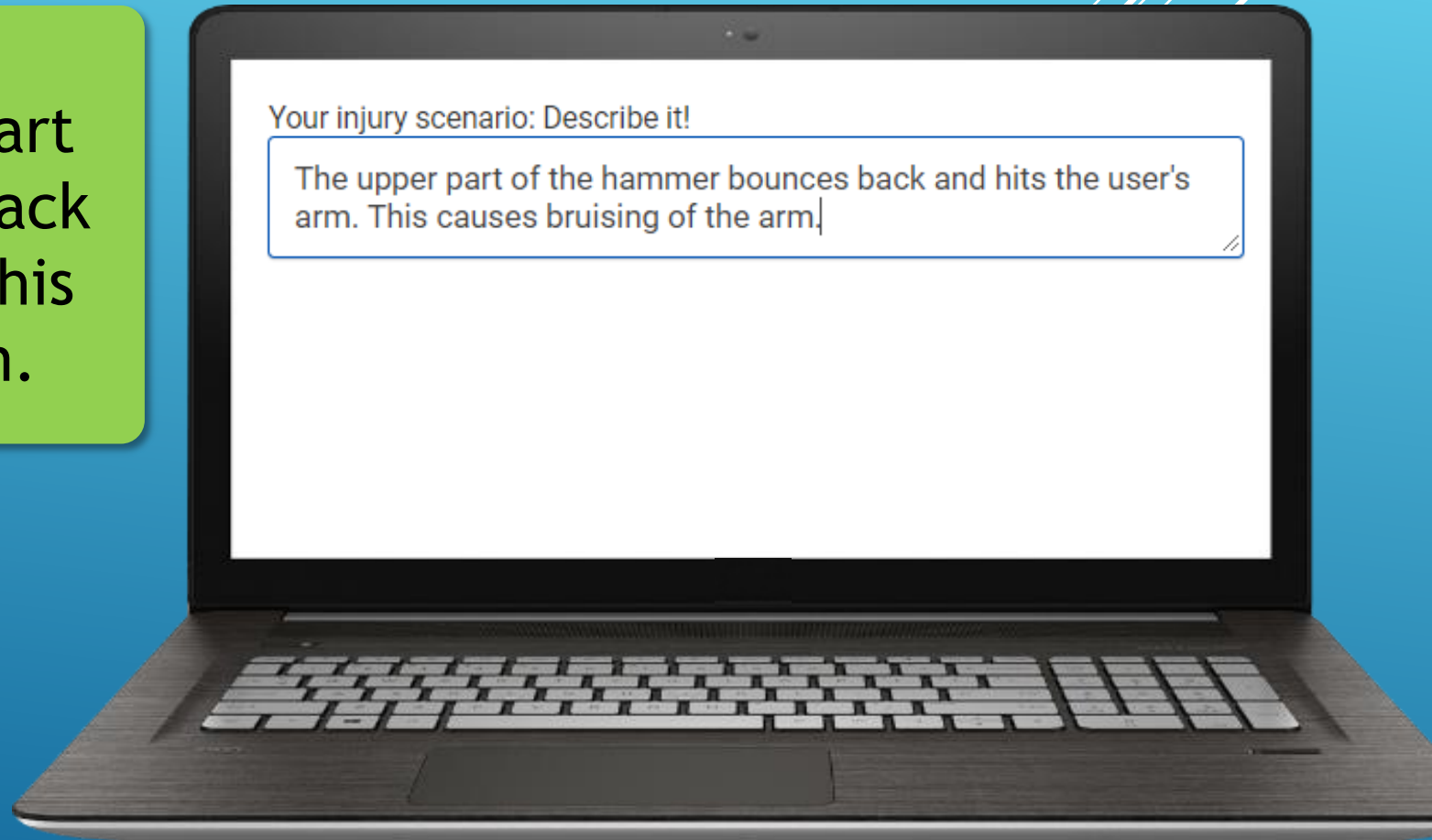


This information is entered in the field “Your injury scenario”.

RISK ASSESSMENT

A Worked Example

Here, we take the injury scenario that the upper part of the hammer bounces back and hits the user's arm. This causes bruising of the arm.



This information is entered in the field “Your injury scenario”.

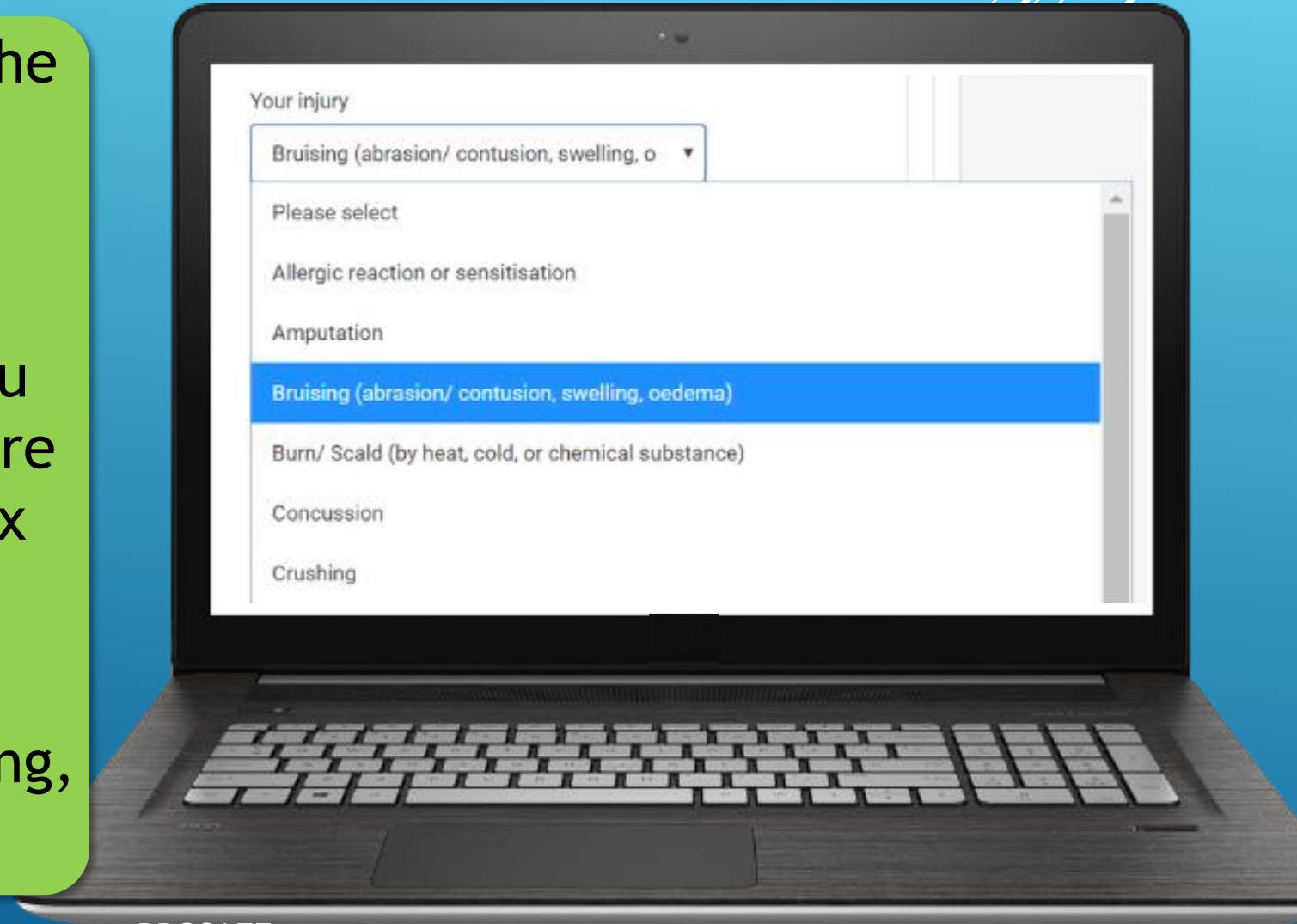
RISK ASSESSMENT

A Worked Example

Then you must determine the severity of the injury.

This is done in the section “Severity of injury”. It is found in two steps. First you select the appropriate nature of the injury in the drop box “Your injury”.

We select “Bruising (abrasion/contusion, swelling, oedema)”.

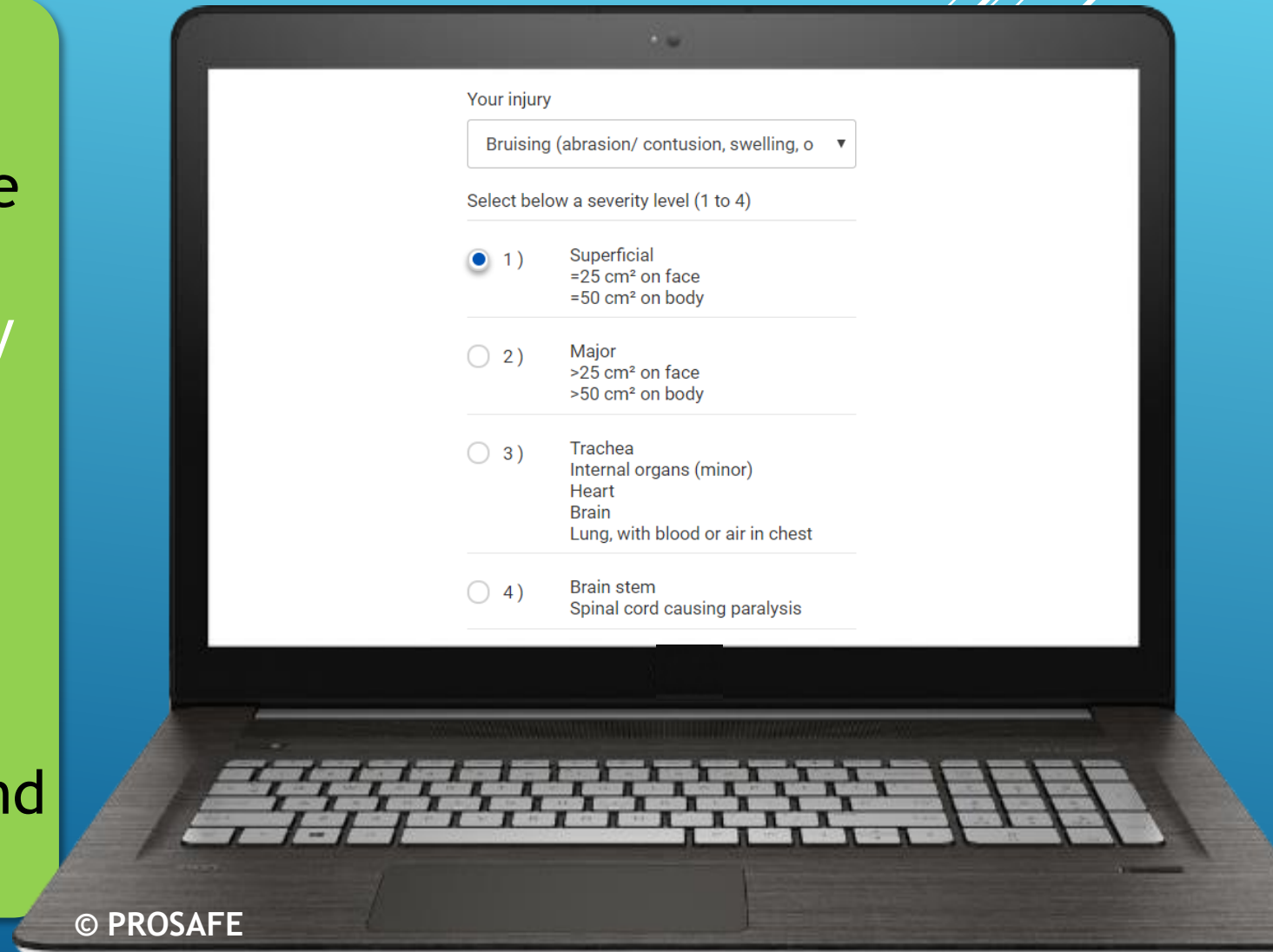


RISK ASSESSMENT

A Worked Example

The choice of “Bruising” means that the web tool provides four choices for the severity of the injury in the box “Select below a severity level”.

Bruising of the user’s arm because he is hit by the hammer head seems to fit best with the category “<50 cm² on body”, which is found to be a level 1 injury.



RISK ASSESSMENT

A Worked Example

After having determined the injury scenario, you should calculate its probability.

This is done by breaking up the scenario into small logical steps and assigning probabilities to each of them.



Probability



RISK ASSESSMENT

A Worked Example

Practically all risk assessments (of GPSD products) should follow a scenario like *"You take a non-compliant product, you put it in the hands of the consumer, and then you see what happens"*.

Experience shows that most scenarios will fit into a generic "standard scenario" made up of around 4 to 5 steps. Each step in a scenario represents one possible further development on the path to the injury.



RISK ASSESSMENT

A Worked Example

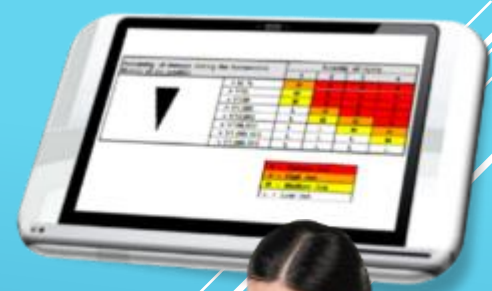
The proposed steps for this selected injury scenario are shown below:

Step 1: The hammer is non-compliant. The handle is too weak.

Step 2: The user uses the hammer.

Step 3: The handle breaks.

Step 4: The hammer head bounces back and hits the user.



Probability



RISK ASSESSMENT

A Worked Example

Assigning probability factors is more difficult.

They can be estimated in many ways, for instance based on test data, based on accident statistics or selected from the PROSAFE databases with probability factors.

In this particular case the following reasoning is applied.



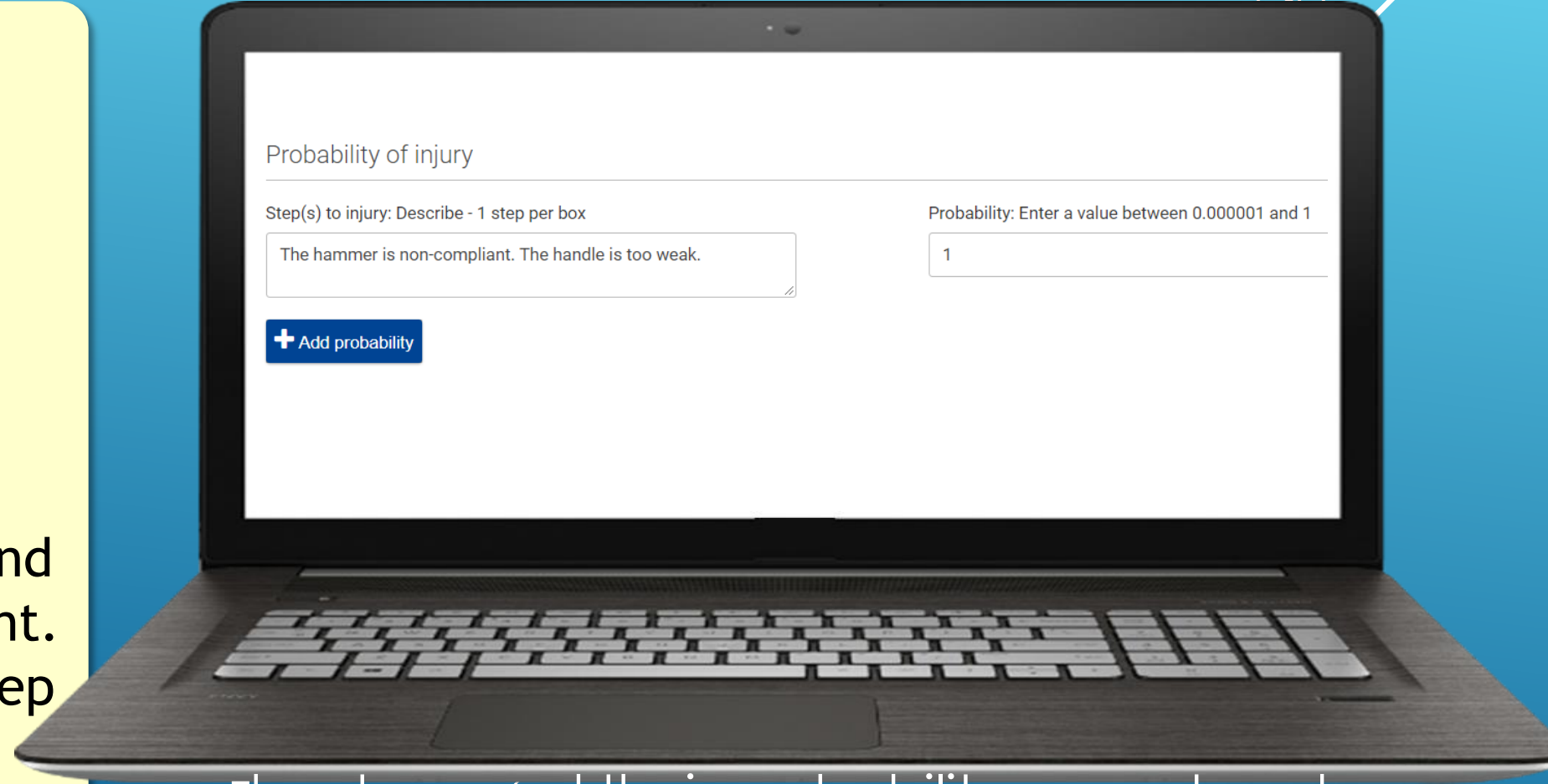
RISK ASSESSMENT

A Worked Example



Step 1: The hammer is non-compliant. The handle is too weak.

The probability is 100 % as this is a presumption behind the risk assessment. Therefore, this step could be left out.



The steps and their probability are entered in the fields under “Probability of an injury”

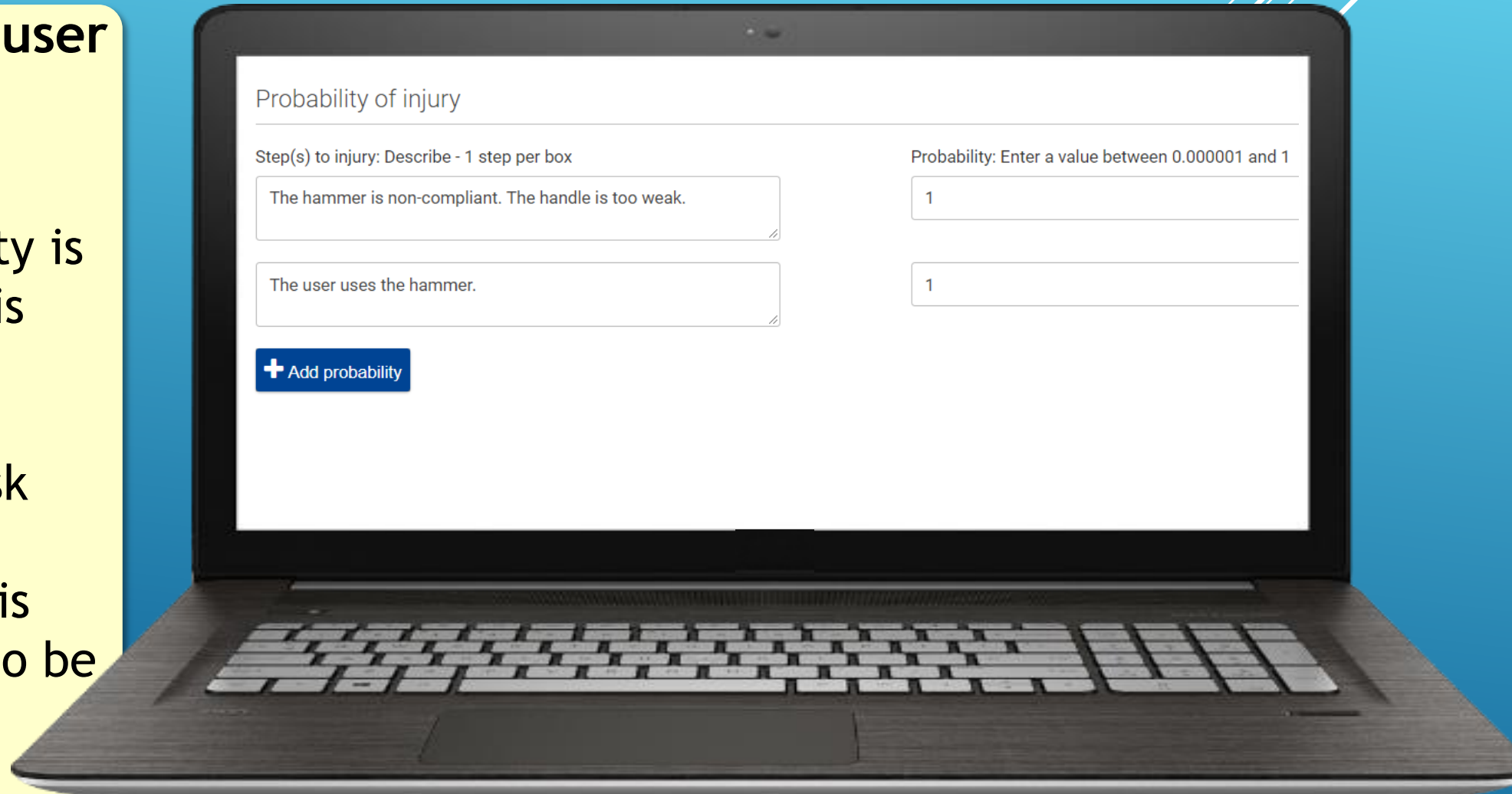
RISK ASSESSMENT

A Worked Example



Step 2: The user uses the hammer.

The probability is 100 % as this is another presumption behind the risk assessment. Therefore, this step could also be left out.



RISK ASSESSMENT

A Worked Example



Step 3: The handle breaks.

We estimate that the probability is **50%**. This is “an expert’s best estimate”: The expert assumes that a large share of these products will break during their lifetime.

Probability of injury

Step(s) to injury: Describe - 1 step per box

The hammer is non-compliant. The handle is too weak.	1
The user uses the hammer.	1
The handle breaks	0.5

[+ Add probability](#)

Probability: Enter a value between 0.000001 and 1

RISK ASSESSMENT

A Worked Example

The assumption is based on the nature of the non-compliance and the impact that is required to break the hammer. Test reports could be taken into account to confirm such an estimate - if they exist. It can also be an advantage to have the product at hand to get an impression of what it takes to damage the product



RISK ASSESSMENT

A Worked Example



Step 4: The hammer head bounces back and hits the user.

Here the probability is estimated to be **20%**. Again, this can best be described as an expert's best estimate. The reasoning behind the figure is that the handle will usually break while someone is holding it and hits a hard surface with the hammer.

Step(s) to injury: Describe - 1 step per box	Probability: Enter a value between 0.000001 and 1
The hammer is non-compliant. The handle is too weak.	1
The user uses the hammer.	1
The handle breaks	0.5
The hammer head bounces back and hits the user.	0.2

RISK ASSESSMENT

A Worked Example

It will not break while the hammer is lying on a table. Therefore the hammer head will bounce back more or less in the direction of the user.

However, if the blow with the hammer is not perpendicular to the surface, the hammer head may miss the arm.

Moreover, the hammer head should hit the arm so hard that it causes the injury - the superficial bruising.



RISK ASSESSMENT

A Worked Example

This example shows that there are a lot of considerations linked to the estimation of the probabilities.

You should note these considerations under each step in the scenario. It will make the risk assessment more transparent and make it easier for you to explain afterwards how you have arrived at your result.



RISK ASSESSMENT

A Worked Example

It will also lead to a more qualified discussion with economic operators should that be necessary.

Moreover it will allow you gradually to build up a knowledge base of probabilities that may be used in other scenarios where similar steps occur. A detailed description will even make it possible for you to adapt the probability to other situations.



RISK ASSESSMENT

A Worked Example

The last step in the risk assessment is the calculation of the level of risk. It is done by combining the severity with the probability.

The calculation is done by the webtool that multiplies the probabilities from the individual steps and compares the result to a scale.

**Risk =
Severity x
Probability**



RISK ASSESSMENT

A Worked Example



The resulting overall probability is combined with the severity of the injury and the resulting risk level is found.

The programme displays the result in the bottom line of the scenario.

A laptop is shown in the center, displaying a risk assessment form. The form is titled "Probability of injury" and contains several input fields for describing injury steps and their probabilities. A large blue arrow points down from the form to the summary table at the bottom. The summary table shows the severity of injury level, calculated probability, overall probability, and the resulting risk level.

Severity of injury level	Calculated probability	Overall probability	Risk of this scenario
1	0.1	= 1/10	Medium risk

RISK ASSESSMENT

A Worked Example

In this case the probabilities of each step in the injury scenario are multiplied to give “ >0.1 ”.

The programme only indicates the calculated probability as “0.1” even though it would be more correct to say “ >0.1 ” as the result arises from multiplying the sub-probabilities “ $>50\%$ ” and “ $>1/5$ ”.

This translates to an overall probability of “ $>1/10$ ”.



RISK ASSESSMENT

A Worked Example

The severity of the injury was level 1 as we decided in one of the previous steps.

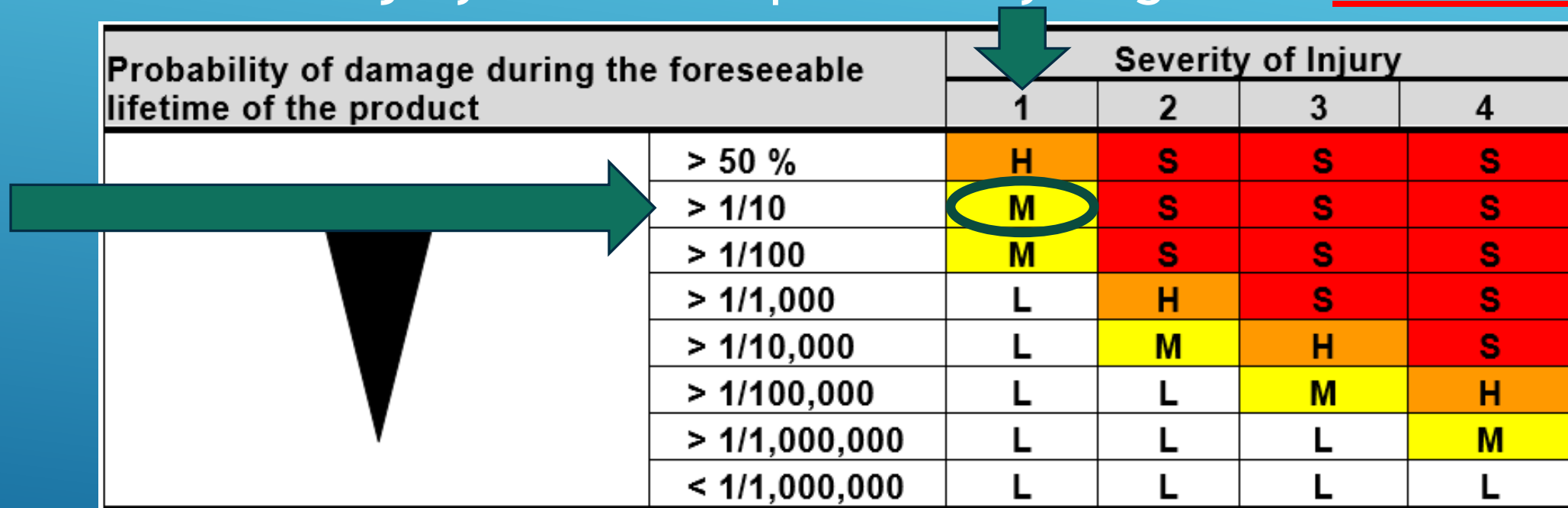
The combination of “>1/10” and injury level 1 gives “**medium risk**” as can be shown in the next slide.



RISK ASSESSMENT

A Worked Example

Combine the injury level with probability to get at “medium risk”



Probability of damage during the foreseeable lifetime of the product		Severity of Injury			
		1	2	3	4
	> 50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1,000	L	H	S	S
	> 1/10,000	L	M	H	S
	> 1/100,000	L	L	M	H
	> 1/1,000,000	L	L	L	M
	< 1/1,000,000	L	L	L	L

S – Serious risk
H – High risk
M – Medium risk
L – Low risk

RISK ASSESSMENT

A Worked Example

You still have a few more tasks to do before the risk assessment is finalised:

- ❑ Reality check of the risk assessment
- ❑ Sensitivity analysis
- ❑ Reporting
- ❑ Quality assurance



RISK ASSESSMENT

A Worked Example

Reality check - is the risk assessment realistic?

You should end all your risk assessments by checking the results against reality. This could for instance be done by use of accident statistics, the manufacturer's complaints register or other data from the manufacturer. The purpose is to check that the overall probability of the total risk assessment seems valid.



**Reality
Check**

RISK ASSESSMENT

A Worked Example

Reality check - is the risk assessment realistic?

You could for instance calculate the likely number of accidents per year if the estimated probability was indeed true.

When reviewing the risk assessment it is worth keeping in mind that market surveillance people tend to be “worst case thinkers” whereas manufacturers tend to be too optimistic.



**Reality
Check**

RISK ASSESSMENT

A Worked Example

Sensitivity analysis - how sensitive is the resulting risk level to uncertainties in probability?

The estimate of the probability is most often based on assumptions and often it is only possible to estimate the order of magnitude of the probability - e.g. whether the probability is closer to 1/10 than 1/1000. The influence of this uncertainty should be checked in a sensitivity analysis.



**Sensitivity
Analysis**

RISK ASSESSMENT

A Worked Example

Sensitivity analysis - how sensitive is the resulting risk level to uncertainties in probability?

A very practical way of doing the sensitivity analysis is to calculate how much the probability should change to affect the calculated risk level. This can easily be done with the webtool. Afterwards you should evaluate whether such a change is realistic.



**Sensitivity
Analysis**

RISK ASSESSMENT

A Worked Example

If the risk level changes, you should review the risk assessment to see if anything can be done to improve the estimates of any of the individual factors.

This could be done by consulting more experts or undertake more testing to obtain better estimates of the probabilities or an improved understanding of the scenario leading from the hazard to the injury. You could also ask the manufacturer to analyse and comment the risk assessment.



**Sensitivity
Analysis**

RISK ASSESSMENT

A Worked Example

If it is impossible to decrease the uncertainty, it should at least be noted that one of the injury scenarios might have a more severe outcome than estimated.

This should be taken into account when drawing the conclusion of the whole risk assessment.



**Sensitivity
Analysis**

RISK ASSESSMENT

A Worked Example

Reporting

The result from the risk assessment must be reported properly to ensure that the considerations are registered and that they can be used in the proper context, e.g. in the communication with the industry or in a court case.

Reporting



RISK ASSESSMENT

A Worked Example

Reporting

To ensure proper reporting it is recommended to use a reporting form that is simple, easy to use and that does not require the user to fill in unnecessary information.

Moreover, the advantage of using a form is that it assures that all necessary information is included.

Reporting



RISK ASSESSMENT

A Worked Example

A risk assessment report should as a minimum include the following headings:

- Identification of product and case, description of the context.
- Description of the hazards.
- Description of injury scenarios, injury levels, probabilities and sensitivity.
- Conclusion

The risk assessment web tool allows the user to print a report with the resulting risk assessment.

Reporting



RISK ASSESSMENT

A Worked Example

Quality Assurance - how to ensure the best possible quality in the risk assessments?

The risk assessment method includes a lot of estimation and individual judgements so there is a risk for subjective judgements in the method.

The best way to handle this is by working in pairs or groups where all participants work out a common risk assessment based on individual risk assessments from all participants.



RISK ASSESSMENT

A Worked Example

This might be difficult to achieve in practice and often the authority would look for less time consuming or resource demanding ways. Two alternatives are:

- Have one market surveillance officer do the risk assessment and have another officer check the result. The second person should co-sign the risk assessment report or should file a note on the case with his or her comments to the report.



RISK ASSESSMENT

A Worked Example

- In projects where many similar products are investigated, it might be possible to do the risk assessment of the first product in common in a group and use this as a base for the assessments of the other products. Still, it is recommendable to have another person to check all the final risk assessments.



RISK ASSESSMENT

Complete
the quiz . . .

CORRECT -

Probability factors have to be determined from whatever relevant information you can get hold of. Do remember to explain your reasoning when you report your risk assessment.

How do you estimate the probabilities in the scenario?



I will choose from the lists in the risk assessment tool.



I will look them up in the risk assessment guidelines on the Commission's website.



I will use data from test reports, my own examination of the product, accident data and other studies for the estimate.

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

RISK ASSESSMENT

Complete
the quiz . . .

D is CORRECT - All 3 options are valid ways to obtain information about injury scenarios and you would probably have to explore all 3 options to get the full overview.

A is partially correct

B is partially correct

C is partially correct

How do you decide on an appropriate scenario?

A

I will check the media and the web for description of accidents

B

I will ask the laboratory

C

I will ask a market surveillance officer

D

All of the above

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

RISK ASSESSMENT

Complete
the quiz . . .

CORRECT - The risk assessment tool has definitions for the injury levels and two tables that will help you select the appropriate injury level once you know the nature of the injury.

How do you determine the appropriate injury level?



I will look it up in the risk assessment tool.



I will use data from hospitals and the victims to estimate the injury level.



I will search the internet for valid statistical information.

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

RISK ASSESSMENT

Complete
the quiz . . .

CORRECT - You would need to do a reality check. The probability is quite high and the injuries are so severe that accidents wouldn't go unnoticed. Have you heard of such accidents? Have there been reports in the press? Has the manufacturer heard of such accidents?

The injury level is 4 and the probability is 1/125. This corresponds to serious risk, and ...



... you will do a reality check to confirm that the probability seems realistic and then take further action.



... you should contact the manufacturer, order him to take the product off the market and report this in the Rapid Alert System.



... the result is very certain as the probability must decrease almost 100 times before the risk level changes to high

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

RISK ASSESSMENT

Well done!
You have now completed this topic.



RISK ASSESSMENT



[< Back to Main Menu](#) [Next Topic >](#)



Click above to go where you wish to proceed.

RISK ASSESSMENT

Risk Assessment of Chemicals

Risk assessment of chemicals follow specific guidelines. Still there are similarities with regards to the basic principles.



RISK ASSESSMENT

Risk Assessment of Chemicals

1. The first step is to identify the hazard presented by the chemical. This corresponds to determining the product hazard and the injury severity.
2. The second step is to assess the exposure and the exposure route. This corresponds to describing the injury scenario with the probabilities.
3. The third step is to characterise the risk. This corresponds to determining the risk level.



RISK ASSESSMENT

Risk Assessment of Chemicals

The third step, risk characterization, in practice means that the actual estimated exposure is compared with the exposure where no adverse effects are seen (the "derived no-effect level" or DNEL). If the actual exposure is sufficiently lower than the DNEL, then risk is considered to be adequately controlled.

Guidance documents on risk assessment of chemicals can be found on ECHA's website: <https://echa.europa.eu/support/guidance>



RISK ASSESSMENT

Risk Assessment of Chemicals

The European Commission and the Member States have adopted a simpler approach for risk assessment for Rapid Alert Notifications of chemicals that are banned or restricted in consumer products.



RISK ASSESSMENT

Risk Assessment of Chemicals

Several pieces of EU legislation, for instance the Cosmetic Regulation, the Toy Safety Directive, and the REACH Regulation ban or restrict the presence of certain chemicals in consumer products meaning that products containing any of these chemical substances in concentrations exceeding the limits established in the EU legislation must not be placed on the European market. These restrictions can be considered to be based on the risks posed by these chemicals.



RISK ASSESSMENT

Risk Assessment of Chemicals

Chemicals



The observations on the previous slide implies that the approach as described in the next slides can be used when considering the risk assessment for Rapid Alert notifications:



RISK ASSESSMENT

Risk Assessment of Chemicals

Observation No.1

If a consumer product contains a chemical substance that is banned under REACH, Annex XVII, or if the concentration exceeds the limit value given in REACH, Annex XVII, then a Rapid Alert Notification can be submitted without a detailed risk assessment.



RISK ASSESSMENT

Risk Assessment of Chemicals

Observation No.2

If a cosmetic product contains a chemical substance that is banned or restricted under the Regulation on Cosmetic Products and this is backed up by an EU scientific committee opinion, then a Rapid Alert Notification can be submitted without a detailed risk assessment.



RISK ASSESSMENT

Risk Assessment of Chemicals

Observation No.3

If a consumer product contains a chemical substance that is banned or restricted under relevant EU legislation and this is backed up by an EU scientific committee opinion, then a Rapid Alert Notification can be submitted without a detailed risk assessment.



RISK ASSESSMENT



< **Back to Main Menu**

Next Topic >



Click above to go where you wish to proceed.

RISK ASSESSMENT

Risk Assessment of Chemicals

If the authority is facing a chemical where no specific limit value is established by the legislation and it still can imply risks for consumers, the authority cannot apply these principles, but it will have to use an appropriate method for risk assessment of chemicals to assess whether the risk posed by the product to the health and safety of the consumers is adequately controlled.



FINAL QUESTIONS . . .

Complete the quiz . . .

CORRECT - The initial risk assessment will give you the first ideas about the risk level and the most probable factors that have the largest impact on the outcome.

Once you have determined this, you will have a good basis for going into a deeper and more thorough risk assessment of the product and the (few) injury scenarios that will determine the risk level.

You are considering two injury scenarios. One has many steps and results in a severe injury. The other one has a few steps and result in a light injury. Which one do you analyse first?



I analyse the scenario with the severest injury.



I analyse the scenario with the fewest steps.



I analyse both to find the one with the most severe outcome.

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

FINAL QUESTIONS . . .

Complete the quiz . . .

CORRECT - A high quality risk assessment is ensured through an independent review. You can either work together with a colleague or you can discuss the final result with him/her. Your colleague/s can also carry out the risk assessment on the same product and then compare and discuss your results. You should note that A and C are also part of best practices for carrying out risk assessment.

How do you ensure the appropriate quality of your risk assessment?



I carry out a sensitivity analysis and a reality check.



I discuss the result with at least one colleague.



I document all my considerations in the risk assessment report.

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

FINAL QUESTIONS . . .

Complete the quiz . . .

CORRECT - The risk assessment tool will classify the probability $1/11,111$ as “ $>1/100,000$ ” even though it is very close to the next class “ $>1/10,000$ ”. You should therefore do a **sensitivity analysis** to examine how much the probabilities should change to raise the risk level one step up. Afterwards, you should revisit your probabilities to see if they are realistic.

The resulting probability is $1/11,111$. Where do you put it in the risk assessment scale?



I put it in the class “ $>1/10,000$ ” because $1/11,111$ is very close to the border value.



I put it in the class “ $>1/100,000$ ” and carry out a sensitivity analysis.



I go back to the data to see if the probabilities are correct and arrange in order to have the final result in the class “ $>1/10,000$ ” .

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

FINAL QUESTIONS . . .

Complete
the quiz . . .

CORRECT The injury scenario is the “backbone” of the risk assessment. It describes the steps that are necessary to make a product hazard cause an injury to a person. A single accident description can be the starting point for a scenario, but is rarely sufficient.

What is an injury scenario?

- A A verbal description of a sequence of actions necessary for a product to cause an injury to the respective person.
- X A victims’s description of an accident.
- X The possible outcome of an injury.

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

FINAL QUESTIONS . . .

Complete
the quiz . . .

CORRECT - The purpose of the reality check is to check that the resulting probability and injury are realistic.

Is the number of injuries that you see in society in line with the probabilities you have calculated (taking the number of items on the market into consideration)?

When would you do a reality check?



When the probability for a severe injury is high.



When the scenario has critical probabilities with high impact on the result.



After each risk assessment.

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

UNDERSTANDING RISK ASSESSMENT

Well done!
You have now completed the final questions.



RISK ASSESSMENT



Click above to go back to the Main Menu