CASE STUDIES

This course will take you through some case studies to help you better understand how risk assessment is performed.

PROSAFE Joint Actions Best Practice

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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.

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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.

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

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CASE STUDIES

Click on the subjects that you are interested in:

- Case Study - Electric Toaster
- Case Study - A Candle
- Case Study - Socket Protector
- Case Study - Push-Along Toy

CASE STUDY

ELECTRIC TOASTER

This exercise works in the way that a case will be presented to you with a product hazard that could end in a particular injury.

Try to develop an injury scenario. When you have finished you can move on and compare your scenario to a scenario developed by PROSAFE's experts.

CASE STUDY

ELECTRIC TOASTER

Please note that there are no “rights” and “wrongs” in this exercise. Your scenario may very well be perfectly OK even if it is quite different from the scenario being presented.

The important issue in this exercise is that you will try to develop a scenario yourself and afterwards you can see the scenario and the reasoning that the experts have given.

CASE STUDY

ELECTRIC TOASTER

This case deals with a long-slots toaster with stainless steel housing in red or silver.

The case is based on Rapid Alert Notification 0244/08 from Germany.

The notification reports one accident where a person has had an electric shock when using the appliance.

Click on the pictures to go to the respective Rapid Alert.

CASE STUDY

ELECTRIC TOASTER

The toaster poses a **risk of electric shock**.

There is no protection against accidental contact with the heating elements. They are connected to AC mains via a one-pole switch, which means that the heating elements will be connected the neutral or the phase depending upon how the plug is inserted to the socket outlet.

Click on the pictures to go to the respective Rapid Alert.

CASE STUDY

ELECTRIC TOASTER

HAZARDS & INJURIES

First, consider what hazards are associated with this toaster?

CASE STUDY

ELECTRIC TOASTER

HAZARDS & INJURIES

The most predominant hazard with this toaster is the risk of touching live electrical wires with high voltage. This is possible if the user grabs the edge of the toaster and his fingers gets into the slot and down to the heating elements. These are accessible electric wires.

CASE STUDY

ELECTRIC TOASTER

HAZARDS & INJURIES

You may also want to consider the hazards associated with touching the hot heating elements as they are also exposed to the user touching them.

However, this hazard will not lead to as severe injuries as the user will probably burn his fingertips compared to getting an electric shock.

CASE STUDY

ELECTRIC TOASTER

HAZARDS & INJURIES

It is more or less equally likely that the two things happen, so it seems reasonable to focus on the **electric hazard** in the assessment, so that's what we will do.

CASE STUDY

ELECTRIC TOASTER

HAZARDS & INJURIES

Then consider what injuries the hazard we just identified may cause.

This is trickier as you can imagine more injuries:

- The electricity may burn the user's fingers and cause damage to muscles in his hand.
- The electricity may even cause the user's fingers to cramp leading to severe burns on the fingers and hands.
- The electricity may pass through the user's heart so the user is killed.

CASE STUDY

ELECTRIC TOASTER

HAZARDS & INJURIES

You will actually end up with likely injuries in all four injury levels. It is difficult to decide which one will produce the most serious risk. In practice you will have to try several combinations.

Here, we will pick the most severe injury, **the fatal electric shock**. This relates to **Severity Level 4**.

CASE STUDY

ELECTRIC TOASTER

PROBABILITY

Now it becomes difficult. Develop an injury scenario and assign a probability to each step in the scenario.

There are many, many possible scenarios, so to limit ourselves you should only consider scenarios that link the selected product hazard – touchable live electric wires – to the selected injury – a fatal electric shock.

CASE STUDY

ELECTRIC TOASTER

PROBABILITY

This was tricky, and you will probably have developed a scenario that is different from the one presented.

That is OK, but try to follow the line of reasoning and see if you have taken the same conditions into consideration.

CASE STUDY

ELECTRIC TOASTER

Calculating the total probability

The scenario that has been developed by the PROSAFE experts, has the following steps:

STEP 1

The toaster is plugged in a socket so both heating elements are connected to the phase.

Probability 50% (or ½)

The plug can be inserted into the socket in two ways that are equally likely. The circuit interrupter in the toaster only interrupts one pole so the heating element will be energised even if the toaster is switched off.

CASE STUDY

ELECTRIC TOASTER

Calculating the total probability

The scenario that has been developed by the PROSAFE experts, has the following steps:

STEP 1

The toaster is plugged in a socket so both heating elements are connected to the phase.

Probability 50% (or ½)

STEP 2

The person touches the heating element.

Probability 1% (or 1/100)

This is an "expert's estimate" based on assumptions of how easy it is to get the fingers into the slot while moving the toaster around. The probability is to be understood as "over the lifetime of the toaster".

CASE STUDY

ELECTRIC TOASTER

Calculating the total probability

The scenario that has been developed by the PROSAFE experts, has the following steps:

STEP 1

The toaster is plugged in a socket so both heating elements are connected to the phase.

Probability 50% (or ½)

STEP 2

The person touches the heating element.

Probability 1% (or 1/100)

STEP 3

The person sustains electric shock.

Probability 100% (or 1)

If the user touches the heating elements he will get an electric shock.

CASE STUDY

ELECTRIC TOASTER

Calculating the total probability

The scenario that has been developed by the PROSAFE experts, has the following steps:

STEP 1

The toaster is plugged in a socket so both heating elements are connected to the phase.

Probability 50% (or ½)

STEP 2

The person touches the heating element.

Probability 1% (or 1/100)

STEP 3

The person sustains electric shock.

Probability 100% (or 1)

STEP 4

The user is electrocuted.

Probability 25% (or ¼)

This is estimated from accident statistics and the expert's knowledge of how probable it is that people will die when they are standing on a floor touching an electric wire with the fingers on one hand.

CASE STUDY

ELECTRIC TOASTER

Calculating the total probability

The scenario that has been developed by the PROSAFE experts, has the following steps:

STEP 1

The toaster is plugged in a socket so both heating elements are connected to the phase.

Probability 50% (or ½)

STEP 2

The person touches the heating element.

Probability 1% (or 1/100)

STEP 3

The person sustains electric shock.

Probability 100% (or 1)

STEP 4

The user is electrocuted.

Probability 25% (or ¼)

STEP 5

If you multiply all these probabilities you end up with 1/800

(which corresponds to the probability class > 1/1,000)

CASE STUDY

ELECTRIC TOASTER

Combine this with the injury level and you arrive at "serious 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

CASE STUDY

ELECTRIC TOASTER

The product is electric and falls under the Low Voltage Directive. This means that there are numerous safety standards defining the safety requirements. This is a huge advantage as it may often help you decide on probabilities. If a given property is slightly over the limit in the standard it is reasonable to estimate that the probability for something going wrong is lower than when the requirements is largely exceeded.

Many if not all of the non-compliances in electric products are due to design flaws. This means that all samples of that particular product will have the same non-compliance.

CASE STUDY

ELECTRIC TOASTER

The trickiest probability to estimate is linked to the user's behaviour:

How likely is it that the user will touch the heating elements while moving the toaster?

This is a general observation. Estimating behaviour is the most difficult in all risk assessments.

CASE STUDY

ELECTRIC TOASTER

Well done!
You have now completed this topic.

CASE STUDY

ELECTRIC TOASTER

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CASE STUDY

A CANDLE

This case deals with a candle that contains small plant parts, e.g. sunflower seeds or coffee beans that are moulded into the candle for decorative purposes.

Such candles have been reported to burn intensely with high flames and there have been several Rapid Alert notifications for candles.

Two examples are found in Rapid Alerts 0351/06 and 0563/06.

Click on the pictures to find more information.

CASE STUDY

A CANDLE

Hazards & Injuries

First, consider what hazards are associated with this candle.

Click on the pictures to find more information.

CASE STUDY

A CANDLE

Hazards & Injuries

There are several hazards associated with this product.

- ✓ The candle may cause a fire that creates toxic fumes
- ✓ The candle may cause a large fire
- ✓ The user may move the candle and get hot wax on his hands
- ✓ A child may pull small seeds off and swallow them.

There will probably be even more hazards.

We will concentrate on the first hazard – the candle causes a fire that creates toxic fumes.

CASE STUDY

A CANDLE

Hazards & Injuries

Then consider what **injuries** this hazard may cause.

CASE STUDY

A CANDLE

Hazards & Injuries

This is fairly easy. When you have toxic fumes, the main injury is linked to person inhaling the fumes and getting intoxicated.

The tricky thing is that you can imagine that this can cause injuries of several different severities. The least severe injury happens if user inhales the fumes, coughs and escapes from the fire. The most severe injury is a fatal poisoning.

Here, we will pick the most severe injury, **the fatal poisoning**.

CASE STUDY

A CANDLE

Probability

Now it becomes difficult. You should try to develop an injury scenario and assign a probability to each step in the scenario.

There are many, many possible scenarios. Consider scenarios that link the selected product hazard:

- generation of toxic fumes – to the selected injury – a fatal poisoning

CASE STUDY

A CANDLE

Calculating the total probability

The scenario that has been developed by the PROSAFE experts, has the following steps:

STEP 1

The candle is burning and burns so far down that the seeds or beans catch fire.

Probability 90%

This is an estimate based on observations and tests. If such candles burn for long enough they will almost always end up setting the seeds on fire.

CASE STUDY

A CANDLE

Calculating the total probability

The scenario that has been developed by the PROSAFE experts, has the following steps:

STEP 1

The candle is burning and burns so far down that the seeds or beans catch fire.

Probability 90%

STEP 2

Nearby furniture or curtains catch fire.

Probability 50%

This estimate is an “expert’s estimate” based on assumption of how often candles will stand on flammable surfaces or near curtains. Remember that the flame becomes much larger than the user expects.

CASE STUDY

A CANDLE

Calculating the total probability

The scenario that has been developed by the PROSAFE experts, has the following steps:

STEP 1

The candle is burning and burns so far down that the seeds or beans catch fire.

Probability 90%

STEP 2

Nearby furniture or curtains catch fire.

Probability 50%

STEP 3

There is a person in the room, sleeping.

Probability 1%

This is also an “expert’s estimate” based on how likely it is that people will fall asleep with a burning candle near them.

CASE STUDY

A CANDLE

Calculating the total probability

The scenario that has been developed by the PROSAFE experts, has the following steps:

STEP 1

The candle is burning and burns so far down that the seeds or beans catch fire.

Probability 90%

STEP 2

Nearby furniture or curtains catch fire.

Probability 50%

STEP 3

There is a person in the room, sleeping.

Probability 1%

STEP 4

The person inhales toxic fumes and dies.

Probability 100%

If the person is sleeping in a room with toxic fumes, it is (almost) certain that they will inhale the fumes. This will cause unconsciousness first, which will gradually evolve into death if nobody can stop the fire and get the person out.

CASE STUDY

A CANDLE

Calculating the total probability

The scenario that has been developed by the PROSAFE experts, has the following steps:

STEP 1

The candle is burning and burns so far down that the seeds or beans catch fire.

Probability 90%

STEP 2

Nearby furniture or curtains catch fire.

Probability 50%

STEP 3

There is a person in the room, sleeping.

Probability 1%

STEP 4

The person inhales toxic fumes and dies.

Probability 100%

STEP 5

If you multiply all these probabilities you end up with 45/10,000

which corresponds to the probability class “>1/1,000”

CASE STUDY

A CANDLE

Combine this with the injury level and you arrive at "serious 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

CASE STUDY

A CANDLE

This case is tricky because many of the scenarios will not necessarily cause injuries. It is easy to imagine scenarios where a candle may cause a large fire that will burn down a house without people getting hurt.

There are two ways to handle this. Either you create a scenario where people are injured or you estimate the severity of the fire from the damages caused in your scenario.

CASE STUDY

A CANDLE

The trickiest probability to estimate is linked to the user's behaviour: How likely is it that the user will sleep nearby a burning candle?

This is general observation. Estimating behaviour is the most difficult in all risk assessments. In this case, you may get some help from fire statistics. Fire statistics show number of fires, number of casualties and normally also the cause of the fire. You may be able to estimate some probabilities using that data or you could at least do a **reality check** of your figures at the end of the risk assessment.

CASE STUDY
A CANDLE

Well done!
You have now completed this topic.

CASE STUDY

A CANDLE

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Click above to go where you wish to proceed.

CASE STUDY
SOCKET PROTECTOR

This case deals with socket protectors - devices that users (parents) put on the electrical socket outlets to avoid small children accessing live parts by putting long metal objects into one of the holes in the outlet and gets a (possibly fatal) electric shock.

This has been reported in e.g. the Rapid Alert Notification 0615/09

Click on the pictures to find more information.

CASE STUDY

SOCKET PROTECTOR

Hazards & Injuries

First, consider **what hazards** are associated with this product.

CASE STUDY

SOCKET PROTECTOR

Hazards & Injuries

The hazard with this product is actually not that it becomes dangerous in itself but rather that its protective function is ruined.

The holes in the protector where the pins of the plug go through are so narrow that the pins might get stuck. This would most likely mean that the user will pull the protector of the outlet when the plug is pulled out.

CASE STUDY

SOCKET PROTECTOR

Hazards & Injuries

If the user doesn't notice or doesn't put back the protector, the outlet is left unprotected for the children.

Therefore the product will not provide the protection that the parents rely on.

CASE STUDY

SOCKET PROTECTOR

Hazards & Injuries

In either case, the hazard is that the person will be able to put a thin metal object into the socket and get **an electric shock**.

CASE STUDY

SOCKET PROTECTOR

Hazards & Injuries

Then consider **what injuries** this hazard may cause.

CASE STUDY

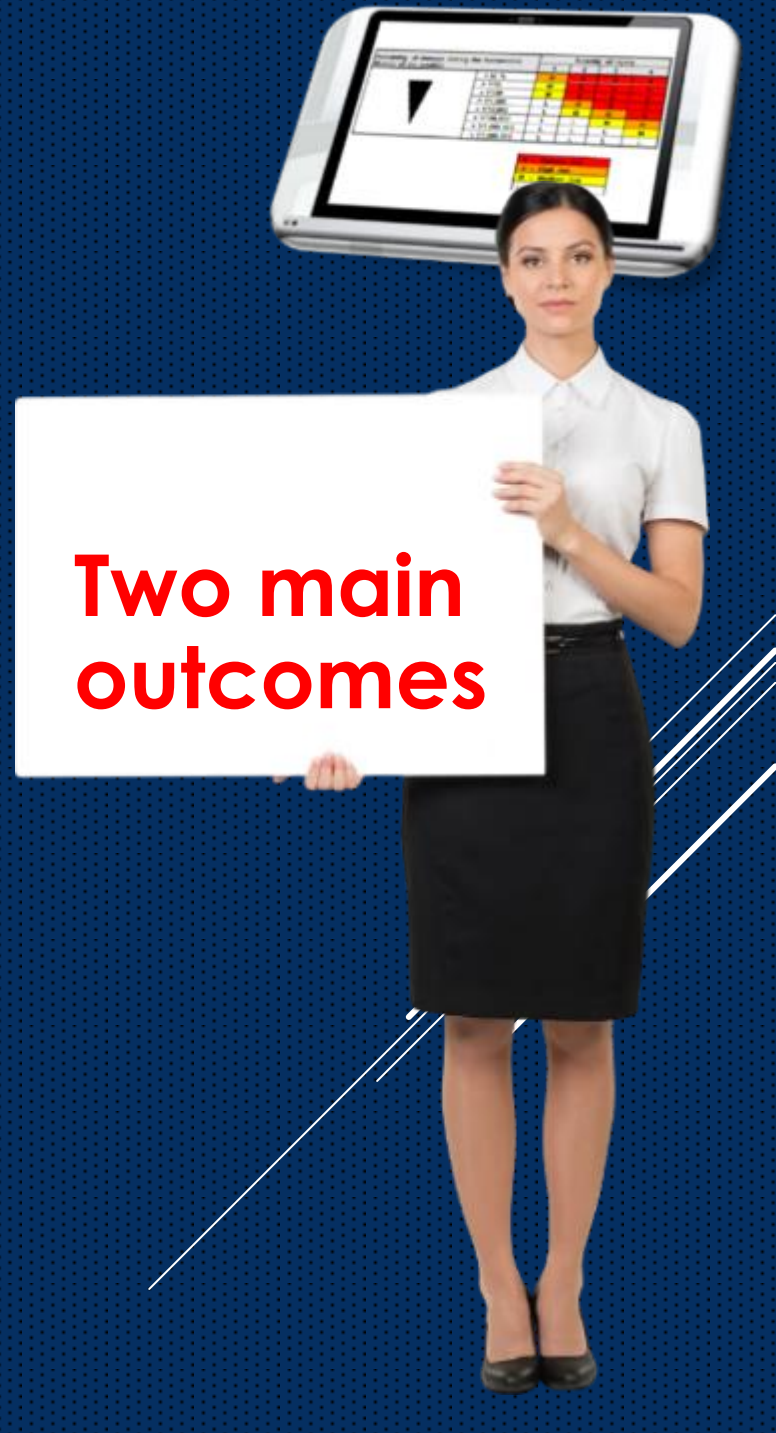
SOCKET PROTECTOR

Hazards & Injuries

This case is fairly easy. Basically there are two different injuries:

- The electricity may burn the user's fingers and cause damage to muscles in his hand.
- The electricity may pass through the user's heart so the user is killed.

Here, we will pick the most severe injury, **the fatal electric shock**.



CASE STUDY

SOCKET PROTECTOR

PROBABILITY

Now it becomes difficult. You should try to develop an injury scenario and assign a probability to each step in the scenario.

There are many possible scenarios. Please consider the ones that link the selected product hazard – the protector is removed from the socket – to the selected injury – a fatal electric shock.

CASE STUDY

SOCKET PROTECTOR

PROBABILITY

That was tricky, wasn't it?

There are many steps between the hazard and the injury. Let's have a look at the scenario from the PROSAFE experts. Your scenario will probably be different, which is quite OK.

What is important is the considerations you have been through on your way.

CASE STUDY
SOCKET PROTECTOR

Try to follow the line of reasoning in this scenario.
It has the following steps:

STEP 1

The protector is removed from the socket.
Probability 90%.

Investigations of the product reveal that it is highly likely that this will happen during the lifetime of the product.

CASE STUDY
SOCKET PROTECTOR

Try to follow the line of reasoning in this scenario.
It has the following steps:

STEP 1

The protector is removed from the socket.
Probability 90%.

STEP 2

The parent doesn't notice the removal of the protector.
Probability 1/10.

This is an "expert's estimate". The probability depends largely on how alert the parents are.

CASE STUDY
SOCKET PROTECTOR

Try to follow the line of reasoning in this scenario.
It has the following steps:

STEP 1	STEP 2	STEP 3
The protector is removed from the socket. Probability 90%.	The parent doesn't notice the removal of the protector. Probability 1/10.	The child is playing with a thin conductible object. Probability 1/10.

This is also an "expert's estimate". It is presumed that many children will find thin metal objects in their vicinity from time to time.

CASE STUDY
SOCKET PROTECTOR

Try to follow the line of reasoning in this scenario.
It has the following steps:

STEP 1

The protector is removed from the socket.
Probability 90%.

STEP 2

The parent doesn't notice the removal of the protector.
Probability 1/10.

STEP 3

The child is playing with a thin conductible object.
Probability 1/10.

STEP 4

The child is unattended when playing.
Probability 50%.

This is an "expert's estimate". Please note that this probability may vary depending upon culture. In some cultures it is common that parents leave their children unattended in the room next door. In others it may be rarer. You could also imagine that parents become more confident that it is safe to leave the child alone in a room after having installed such protectors.

CASE STUDY
SOCKET PROTECTOR

Try to follow the line of reasoning in this scenario.
It has the following steps:

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
The protector is removed from the socket. Probability 90%.	The parent doesn't notice the removal of the protector. Probability 1/10.	The child is playing with a thin conductible object. Probability 1/10.	The child is unattended when playing. Probability 50%.	The child inserts the object into the socket. Probability 1/3.

This is an "expert's estimate" based on the fact that children are curious and examine their surroundings which includes putting thin objects into holes.

CASE STUDY
SOCKET PROTECTOR

Try to follow the line of reasoning in this scenario.
It has the following steps:

STEP 1

The protector is removed from the socket.
Probability 90%.

STEP 2

The parent doesn't notice the removal of the protector.
Probability 1/10.

STEP 3

The child is playing with a thin conductible object.
Probability 1/10.

STEP 4

The child is unattended when playing.
Probability 50%.

STEP 5

The child inserts the object into the socket.
Probability 1/3.

STEP 6

The object touches the phase wire.
Probability 50%

This is estimated from the fact that most socket outlets have two holes. Only one is for the phase conductor which is the dangerous one to touch.

CASE STUDY
SOCKET PROTECTOR

Try to follow the line of reasoning in this scenario.
It has the following steps:

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6	STEP 7
The protector is removed from the socket. Probability 90%.	The parent doesn't notice the removal of the protector. Probability 1/10.	The child is playing with a thin conductible object. Probability 1/10.	The child is unattended when playing. Probability 50%.	The child inserts the object into the socket. Probability 1/3.	The object touches the phase wire. Probability 50%	The child is electrocuted due to voltage. Probability 1/5.

CASE STUDY
SOCKET PROTECTOR

If you multiply all these probabilities you end up with 15/100,000 which corresponds to the probability class ">1/1,000".
Combine this with the injury level and you arrive at serious 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

CASE STUDY
SOCKET PROTECTOR

What makes risk assessment of protective products tricky is that the non-compliance will not make the product dangerous in itself.

The risk arises because the users rely on the protective function and change their behaviour. In this case the parents leave their child unattended without ensuring that all long metal objects are removed.

CASE STUDY
SOCKET PROTECTOR

Many of the probabilities are related to behaviour which is very difficult to estimate. Therefore the probabilities are quite uncertain.

On the other hand this has limited influence on the resulting risk level. A **sensitivity analysis** was carried out and revealed that the total probability must be something like 1,000 times lower to alter the outcome from “serious risk” to “high risk”.

CASE STUDY
SOCKET PROTECTOR

Some homes have residual current breakers that will interrupt the power if a person touches the live wire. This can be included in the analyses as an extra factor in the calculation of the probability.

CASE STUDY
SOCKET PROTECTOR

Well done!
You have now completed this topic.

CASE STUDY
SOCKET PROTECTOR

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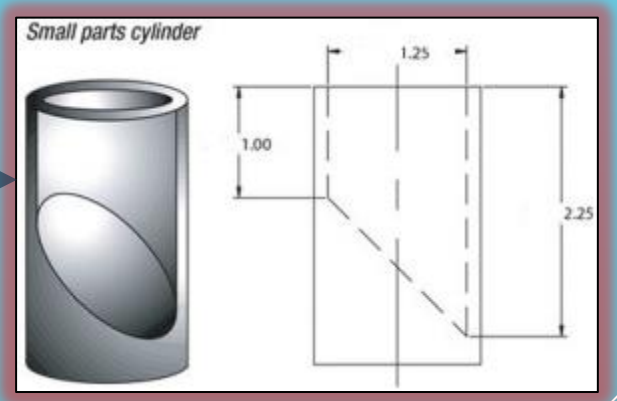
CASE STUDY

PUSH-ALONG TOY

This case deals with a push-along toy duck that was notified by Belgium in 2008 (Rapid Alert Notification 0265/08).



According to the notification, the toy poses a serious risk because the duck's beak can be detached at a force of 19 N. The requirement from the toys standard EN 71-1 is 100 N. The beak fits into the **small parts cylinder**.

Click on the pictures to find more information.

CASE STUDY

PUSH-ALONG TOY

Hazards & Injuries

First, consider what hazards are associated with this toy?

CASE STUDY

PUSH-ALONG TOY

Hazards & Injuries

The hazard with this product is that the **beak can be taken off at a low force** and that it is considered to be a "**small part**" according to the toys standard.

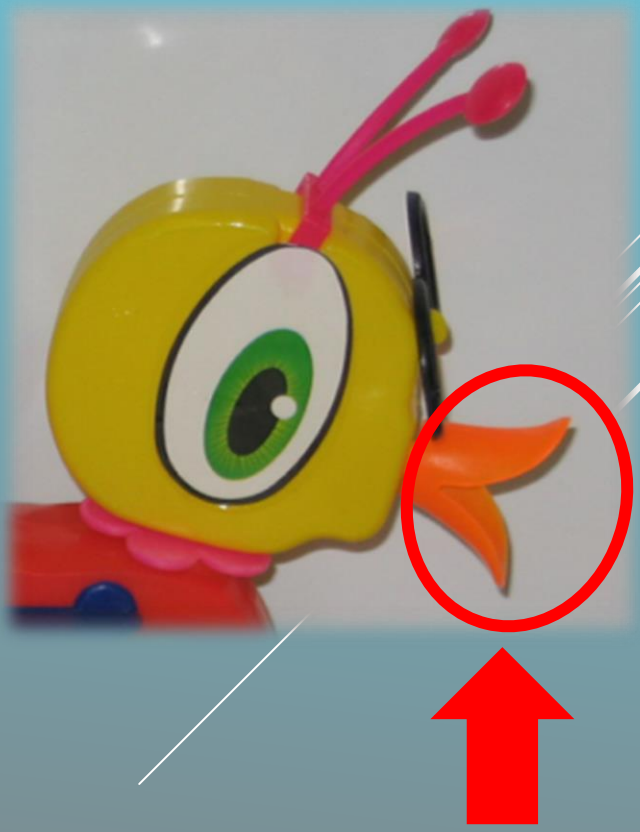
CASE STUDY

PUSH-ALONG TOY

Hazards & Injuries

Then consider what injuries this hazard may cause.

The hazard has to do with children swallowing the beak. There are a number of possible injury levels offered by the risk assessment tool, the most severe one being **death**.



CASE STUDY

PUSH-ALONG TOY

Hazards & Injuries

We will consider a less severe outcome taking into consideration that the beak has a shape that makes it unlikely that it will block a child's airway permanently.

Therefore the most likely injury is called "Oxygen flow to brain blocked without permanent consequences" which corresponds to <u>injury level 3</u>.

Your injury

Suffocation / Strangulation

Select below a severity level (1 to 4)

1	
2	
3	Oxygen flow to brain blocked without permanent consequences
4	Fatal suffocation / strangulation

CASE STUDY

PUSH-ALONG TOY

Injury Scenario

Now you should try to develop an **injury scenario** that links the selected product hazard – the small beak – to the selected injury – temporary blocking of the airways.

Then assign a probability to each step in the scenario.

CASE STUDY

PUSH-ALONG TOY

Injury Scenario

OK. Did you succeed making a scenario? It is tricky and you need to consider all steps in between.

Let’s have a look at the scenario from the PROSAFE experts. Your scenario will probably be different, which is quite OK. What matters is the considerations you gone through when you developed the scenario.

CASE STUDY

PUSH-ALONG TOY

Try to follow the line of reasoning in this scenario and see how many of the considerations you also have. The scenario has the following steps:

STEP 1

The beak is detached some time during the lifetime of the product.
Probability 100%.

The force required to remove the beak is very low – 19 N – much lower than the requirement from the standard – 100 N. Therefore it is estimated that most children will be able to pull off the beak.

CASE STUDY

PUSH-ALONG TOY

Try to follow the line of reasoning in this scenario and see how many of the considerations you also have. The scenario has the following steps:

STEP 1

The beak is detached some time during the lifetime of the product.
Probability 100%.

STEP 2

The parents don't notice that the beak has come off.
Probability 50%.

This is an "expert's estimate". It may vary from culture to culture depending upon how likely it is that the parents let their children play unattended.

CASE STUDY

PUSH-ALONG TOY

Try to follow the line of reasoning in this scenario and see how many of the considerations you also have. The scenario has the following steps:

STEP 1

The beak is detached some time during the lifetime of the product.
Probability 100%.

STEP 2

The parents don't notice that the beak has come off.
Probability 50%.

STEP 3

The child puts the beak in his/her mouth.
Probability 100%.

It is the natural behaviour of small children in a certain age range to examine things by putting them in their mouths.

CASE STUDY

PUSH-ALONG TOY

Try to follow the line of reasoning in this scenario and see how many of the considerations you also have. The scenario has the following steps:

STEP 1

The beak is detached some time during the lifetime of the product.
Probability 100%.

STEP 2

The parents don't notice that the beak has come off.
Probability 50%.

STEP 3

The child puts the beak in his/her mouth.
Probability 100%.

STEP 4

The beak gets in the child's airway.
Probability 1/1,000.

This is an "expert's estimate" based on accident statistics.

CASE STUDY

PUSH-ALONG TOY

Try to follow the line of reasoning in this scenario and see how many of the considerations you also have. The scenario has the following steps:

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
The beak is detached some time during the lifetime of the product. Probability 100%.	The parents don't notice that the beak has come off. Probability 50%.	The child puts the beak in his/her mouth. Probability 100%.	The beak gets in the child's airway. Probability 1/1,000.	If you multiply all these probabilities you end up with 5/10,000 which corresponds to the probability class ">1/10,000".

CASE STUDY

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Combine this with the injury level and you arrive at "high 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

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The product is a toy and it falls under the Toys Directive. This means that there are safety standards defining the safety requirements. This is a huge advantage as it may often help you decide on probabilities as you could also see a little while ago.

The force to detach the beak was much lower than the requirement in the standard so it seemed reasonable to estimate that it was very probable that children could pull it off.

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The resulting probability (**1/2,000**) is close to the next probability class (**"> 1/1,000"**). Therefore a **sensitivity analysis** was carried out.

Taking the uncertainties into account and applying the precautionary principle it seems fair to assume that the result of the risk assessment is "**serious risk**". The risk assessor must report such considerations in the final risk assessment report

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Well done!
You have now completed this topic.

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