

Annex C Examples of risk assessment

C.1 Toy with small partsP

C.1.1 Identification of product and case, description of the context

This case deals with a push-along toy that was notified by Belgium in 2008 (RAPEX notification 0265/08).



Figure C.5 A toy with detachable small parts.

C.1.2 Description of the hazards

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

C.1.3 Description of injury scenarios and sensitivity

The risk assessment is reported on the following pages using the report from the Commissions web tool "Risk Assessment Guidelines" [24].

The outcome of the analyses is a scenario resulting in "high risk". The assumptions behind this calculation are:

- The beak is so poorly attached that it will sooner or later over the lifetime of the product become detached. This is expected to happen for all products in this batch;
- The child will be alone while playing with the toy in 50 % of the cases when the beak detaches;
- It is considered to be normal behaviour for small children to examine objects by putting them in the mouth;
- It is assumed that the beak is so small that it does not get stuck in the larynx; only if it is aspirated it will cause (partial) blocking of the airways.

The resulting probability 1/2.000 falls in the category "> 1/10.000" but it is close to the category "> 1.000". A sensitivity analysis revealed that using this category instead will change the outcome to "serious risk". Moreover, the severity could increase as well: depending on the shape, size and material of the beak, the part might cause complete blocking of the airways leading to permanent damage or death. Taking the uncertainties into account the result of the risk assessment is changed to "serious risk".

C.1.4 Conclusion

The overall outcome of the analysis is that the risk is serious, i.e. rapid action against the product should be taken.

RAPEX Risk Assessment

General Information

Product

Name: Push toy (duck) with small part

Category: Toys

Description: This case deals with a push-along toy that was notified by Belgium in 2008 (RAPEX notification 0265/08). According to the RAPEX notification the toy poses a serious risk of choking because the duck's beak can be detached at a force of 19 N. (The requirement from EN 71-1 is 100 N.) The detached part fits into the small parts cylinder.

Risk assessor

First Name: Torben

Last Name: Rahbek

Organisation: PROSAFE

Address:

Product risks - Overview

Scenario 1 : **High risk** - The child detaches the beak. The parents don't notice or don't react. The child puts the beak in its mouth. The small part goes into the child's airways and surgery is necessary.

Overall Risk : **High risk**

Scenario 1 : Very young children - Product is or contains small part

Product hazard

Hazard Group: Size, shape and surface
 Hazard Type: Product is or contains small part

Consumer

Consumer Type: Very young children - 0 to 36 months (Very vulnerable consumers)

How the hazard causes an injury to the consumer

Injury scenario: The child detaches the beak. The parents don't notice or don't react. The child puts the beak in its mouth. The small part goes into the child's airways and surgery is necessary.

Severity of Injury

Injury: Internal airway obstruction
 Level: 3 Oxygen flow to brain blocked without permanent consequences

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The beak is detached	100 %
Step 2: The parents don't notice	> 50 %
Step 3: The child puts the beak in the mouth	100 %
Step 4: The beak gets in the child's airways	> 1/1,000

Calculated probability: 0.0005

Overall probability: > 1/10,000

Risk of this scenario: High risk

C.2 Hammer

C.2.1 Identification of product and case, description of the context

This case deals with a cross pane hammer with metal handle and black plastic grip where the hammer head can fly off. The hammer head is insufficiently fastened on the handle and the plastic grip breaks under normal strain.

The case is taken from the RAPEX notification number: 0125/06.

C.2.2 Description of the hazards

The hammer has three dangerous shortcomings:

- The hammer head is insufficiently fastened on the handle.
- The plastic grip breaks under normal strain.
- The hammer head is made of brittle material with insufficient dynamic impact strength.

All hazards may result in parts that break off if the hammer hits the user or on a spectator standing nearby.

C.2.3 Description of injury scenarios and sensitivity

The risk assessment is reported on the following pages using the report from the Commissions web tool "Risk Assessment Guidelines" [24].

A sensitivity analysis has not been carried out. However, the probability of the first injury scenario (which has the highest risk level) can be a factor of 6 higher before the risk changes to "serious risk". None of the scenarios will reach the "serious risk" level with reasonable assumptions for the probability.

C.2.4 Conclusion

The risk assessment is reported on the following pages using the report from the Commissions web tool "Risk Assessment Guidelines" [24].

The result of this analysis is that two scenarios have the outcome "high risk" (which happens to be the most serious outcome). Four scenarios result in "low risk" and the last one ends in "significant risk".

The overall outcome of the analysis is that the risk is high, i.e. action against the product should be taken, but there is no need for a rapid intervention and RAPEX-notifications.

RAPEX Risk Assessment

General Information

Product

Name: Hammer case

Category: Tools

Description: This case deals with a cross pane hammer with metal handle and black plastic grip where the hammer head can fly of. The hammer head is insufficiently fastened on the handle and the plastic grip breaks under normal strain. The case is taken from the RAPEX notification number: 0125/06. The hammer has three dangerous shortcomings: - The hammer head is insufficiently fastened on the handle. - The plastic grip breaks under normal strain. - The hammer head is made of brittle material with insufficient dynamic impact strength. All hazards may result in parts that break of the hammer hits the user or on a spectator standing nearby.

Risk assessor

First Name: Torben

Last Name: Rahbek

Organisation: PROSAFE

Address:

Product risks - Overview

Scenario 1 : **High risk** - Parts of head fly off when person uses hammer and hits hard surface. Part flies into eye.

Scenario 2 : **High risk** - Parts of head fly off when person uses hammer and hits hard surface. Large part hits head.

Scenario 3 : **Low risk** - Parts of head fly off when person uses hammer and hits hard surface. Large part hits hand, foot or other body part.

Scenario 4 : **Low risk** - Handle grip of hammer slides off shaft. Hammer flies off when person swings hammer and hits head of other person (child/person must be nearby).

Scenario 5 : **Low risk** - Handle grip of hammer slides off shaft. Hammer flies off when person swings hammer and hits head of other person (child/person must be nearby)

Scenario 6 : **Low risk** - Handle grip of hammer slides off shaft. Hammer flies off when person swings hammer and hits body part of user or other person

Scenario 7 : **Medium risk** - Tha handle grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm.

Overall Risk : High risk

Scenario 1 : Other consumers - Flying objects

Product hazard

Hazard Group: Kinetic energy
Hazard Type: Flying objects

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Parts of head fly off when person uses hammer and hits hard surface. Part flies into eye.

Severity of Injury

Injury: Eye injury, foreign body in eye
Level: 3 Partial loss of sight
Permanent loss of sight (one eye)

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: Hammer head breaks	> 1/10
Step 2: The broken parts fly off and hits the user	> 1/10
Step 3: The flying parts hit the head of the user	> 1/3
Step 4: the flying parts hit the eye	> 1/20

Calculated probability: 0.00017

Overall probability: > 1/10,000

Risk of this scenario: High risk

Scenario 2 : Other consumers - Flying objects

Product hazard

Hazard Group: Kinetic energy
Hazard Type: Flying objects

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Parts of head fly off when person uses hammer and hits hard surface.
Large part hits head.

Severity of Injury

Injury: Fracture
Level: 2 Extremities (finger, toe, hand, foot)
 Wrist
 Arm
 Rib
 Sternum
 Nose
 Tooth
 Jaw
 Bones around eye

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: Hammer head breaks	> 1/10
Step 2: The broken parts fly off and hits the user	> 1/10
Step 3: The flying parts hit the head of the user	> 1/3

Calculated probability: 0.0033

Overall probability: > 1/1,000

Risk of this scenario: High risk

Scenario 3 : Other consumers - Flying objects

Product hazard

Hazard Group: Kinetic energy
Hazard Type: Flying objects

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Parts of head fly off when person uses hammer and hits hard surface.
Large part hits hand, foot or other body part.

Severity of Injury

Injury: Bruising (abrasion/ contusion, swelling, oedema)
Level: 1 Superficial
=25 cm² on face
=50 cm² on body

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: Hammer head breaks	> 1/10
Step 2: The broken parts fly off and hits the user	> 1/10
Step 3: The flying parts hit body parts of the user	> 70 %

Calculated probability: 0.007

Overall probability: $\geq 1/1,000$

Risk of this scenario: Low risk

Scenario 4 : Other consumers - Flying objects

Product hazard

Hazard Group: Kinetic energy
Hazard Type: Flying objects

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Handle grip of hammer slides off shaft. Hammer flies off when person swings hammer and hits head of other person (child/person must be nearby).

Severity of Injury

Injury: Concussion
Level: 2 Very short unconsciousness (minutes)

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The grip slides off	> 1/5
Step 2: A person is nearby	> 1/10
Step 3: The flying part hits the spectator	> 1/100
Step 4: The part hits the spectator's head	> 1/10

Calculated probability: 0.00002

Overall probability: > 1/100,000

Risk of this scenario: Low risk

Scenario 5 : Other consumers - Flying objects

Product hazard

Hazard Group: Kinetic energy
Hazard Type: Flying objects

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Handle grip of hammer slides off shaft. Hammer flies off when person swings hammer and hits head of other person (child/person must be nearby)

Severity of Injury

Injury: Fracture
Level: 2 Extremities (finger, toe, hand, foot)
 Wrist
 Arm
 Rib
 Sternum
 Nose
 Tooth
 Jaw
 Bones around eye

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The grip slides off	> 1/5
Step 2: A person is nearby	> 1/10
Step 3: The flying part hits the person	> 1/100
Step 4: The flying part hits the spectator's head	> 1/10

Calculated probability: 0.00002

Overall probability: > 1/100,000

Risk of this scenario: Low risk

Scenario 6 : Other consumers - Flying objects

Product hazard

Hazard Group: Kinetic energy
Hazard Type: Flying objects

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Handle grip of hammer slides off shaft. Hammer flies off when person swings hammer and hits body part of user or other person

Severity of Injury

Injury: Bruising (abrasion/ contusion, swelling, oedema)
Level: 1 Superficial
=25 cm² on face
=50 cm² on body

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The grip slides off	> 1/5
Step 2: A person is nearby	> 1/10
Step 3: The flying part hits the person	> 1/100

Calculated probability: 0.0002

Overall probability: $\geq 1/10,000$

Risk of this scenario: Low risk

Scenario 7 : Other consumers - Moving product

Product hazard

Hazard Group: Kinetic energy
Hazard Type: Moving product

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: The handle grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm.

Severity of Injury

Injury: Bruising (abrasion/ contusion, swelling, oedema)
Level: 1 Superficial
=25 cm² on face
=50 cm² on body

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The handle breaks	> 50 %
Step 2: The top part of the hammer hits the arm	> 1/5

Calculated probability: 0.1

Overall probability: > 1/10

Risk of this scenario: Medium risk

C.3 Rubber luggage strap

C.3.1 Identification of product and case, description of the context.

This case deals with a rubber luggage strap with metal hooks in both ends. The strap is used for affixing luggage to bicycles, motorcycles or to the roof of a car.



Figure C2: Rubber strap used for affixing luggage to motorcycles or cars

The case is provided by VWA in the Netherlands. In the Netherlands some 30 accidents are reported each year. Half of them result in eye injuries of which 50 % result in permanent impairment. There are even a few cases of lost eyes and blindness on one eye.

C.3.2 Description of the hazards

The risk with this product comes from the hooks in the ends of the strap being of so poor quality that they bend open if the tension in the strap is too high. The result is that the hook hits the user quite hard. The most severe injury is supposed to occur if the hook in the opposite end of the strap opens.

Further to this, a number of accidents happen because the user attaches the hooks poorly, so that they loose their grip when the strap is tightened. These scenarios are not analysed here.

C.3.3 Description of injury scenarios and sensitivity

The risk assessment is reported on the following pages using the report from the Commissions web tool "Risk Assessment Guidelines" [24]. The scenario has been developed based on a case found in an article in a medical journal.

The estimate of the probability that a hook at the end of a strap will open carries the highest uncertainty in the calculation. If the resulting probability increases to 1/10,000 (a factor of 6) then the risk level increases to "high risk".

C.3.4 Conclusion

The result of the analysis is that the risk level is "medium risk".

A special problem arises because the probability of an accident might be low but the number of products is high. In the actual case, a low probability is "multiplied" by a serious consequence and the result is a medium risk. Still the fact is that the big number of products implies that there are quite a few injuries every year. These should be taken into account when deciding on the appropriate risk management measures.

RAPEX Risk Assessment

General Information

Product

Name: Rubber luggage straps

Category:

Description: This case deals with a rubber luggage strap with metal hooks in both ends. The strap is used for affixing luggage to bicycles, motorcycles or to the roof of a car. The case is provided by VWA in the Netherlands. In the Netherlands some 30 accidents are reported each year. Half of them result in eye injuries of which 50 % result in permanent impairment. There are even a few cases of lost eyes and blindness on one eye. The risk with this product comes from the hooks in the ends of the strap being of so poor quality that they bend open if the tension in the strap is too high. The result is that the hook hits the user quite hard. The most severe injury is supposed to occur if the hook in the opposite end of the strap opens. (Further to this scenario a number of accidents happen because the user attaches the hooks poorly, so that they loose their grip when the strap is tightened. These scenarios are not analysed here.)

Risk assessor

First Name: Torben

Last Name: Rahbek

Organisation: PROSAFE

Address:

Product risks - Overview

Scenario 1 : **Medium risk** - Person tries to fix luggage while standing in the line of the strap; hook on other end opens and hits person in the eye.

Overall Risk : **Medium risk**

Scenario 1 : Other consumers - Moving product

Product hazard

Hazard Group: Kinetic energy
Hazard Type: Moving product

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Person tries to fix luggage while standing in the line of the strap; hook on other end opens and hits person in the eye.

Severity of Injury

Injury: Eye injury, foreign body in eye
Level: 3 Partial loss of sight
Permanent loss of sight (one eye)

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The person stands in line with the suspended strap.	> 50 %
Step 2: The hook opens	> 1/100
Step 3: The hook hits the head	> 1/3
Step 4: The hook hits the eye	> 1/20
Step 5: The hook causes an eye injury	> 1/5

Calculated probability: 0.000017

Overall probability: > 1/100,000

Risk of this scenario: Medium risk

C.4 Cord extension set with 3-way socket outlet

C.4.1 Identification of product and case, description of the context

Cord extension set with 3-way socket outlet and switch. Mains cable 2,90 m with moulded earthed plug. The product was rejected by the German custom authorities. The product was notified by Germany in 2010, RAPEX notification 1520/10.



Figure C.6 Cord extension set with 3-way socket outlet.

C.4.2 Description of the hazards

The product poses a risk of electric shock because the contact surfaces are too weak and already deformed so there is no contact between the earth connector in the socket and the earth connector on the plug. If a defective electrical appliance is connected via the cord extension set, it will not be connected to protective earth. This means that a user will get an electrical shock when he touches the housing of the appliance.

Furthermore the cross-section of the conductors in the supply cord is too small and the live conductors are soldered to the contact surfaces, If an appliance with high power consumption is connected via the extension set and used for a longer time, the cords will overheat and may catch fire which may ignite surrounding objects.

C.4.3 Description of injury scenarios and sensitivity

The risk assessment is reported on the following pages using the report from the Commissions web tool "Risk Assessment Guidelines" [24].

Two scenarios have been considered. Both create a serious risk. A sensitivity analysis shows that this serious risk level remains valid, even if the probability would be a factor 10 lower.

The main uncertainty in this case is linked to the probability that a electric shock is fatal.

C.4.4 Conclusion

The overall outcome of the analysis is that the risk is serious.

RAPEX Risk Assessment

General Information

Product

Name: Cord extension set with 3 sockets and main switch

Category:

Description:

Risk assessor

First Name: Torben

Last Name: Rahbek

Organisation: PROSAFE

Address:

Product risks - Overview

Scenario 1 : **Serious risk** - The user connects a defect electrical appliance to the non-earthed cord extension set and gets an electric shock

Scenario 2 : **Serious risk** - An electrical appliance with high power consumption is connected to the cord extension set. It overheats the cord extension set that catches fire. The user gets injuries because of smoke and fire.

Overall Risk : **Serious risk**

Scenario 1 : Other consumers - High/low voltage

Product hazard

Hazard Group: Electrical energy
Hazard Type: High/low voltage

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: The user connects a defect electrical appliance to the non-earthed cord extension set and gets an electric shock

Severity of Injury

Injury: Electric shock
Level: 4 Electrocutation

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: Use of a defective electrical appliance	> 1/20
Step 2: Appliance is not earthed	> 1/10
Step 3: Appliance has (touchable) live parts and is in use	100 %
Step 4: User gets an electric shock	100 %
Step 5: Electric shock is fatal	> 1/5

Calculated probability: 0.001

Overall probability: > 1/1,000

Risk of this scenario: Serious risk

Scenario 2 : Other consumers - Heat production

Product hazard

Hazard Group: Electrical energy
Hazard Type: Heat production

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: An electrical appliance with high power consumption is connected to the cord extension set. It overheats the cord extension set that catches fire. The user gets injuries because of smoke and fire.

Severity of Injury

Injury: Burn/ Scald (by heat, cold, or chemical substance)
Level: 4 2° or 3°, >35% of body surface
Inhalation burn requiring respiratory assistance

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: Appliance with high power consumption is connected	> 1/20
Step 2: Appliance is used for a longer time	> 70 %
Step 3: Cord gets overheated	100 %
Step 4: Cord catches fire and ignites surrounding objects	> 70 %
Step 5: User gets injuries by smoke and fire	> 1/20

Calculated probability: 0.0012

Overall probability: > 1/1,000

Risk of this scenario: Serious risk

C.5 Socket protectors

C.5.1 Identification of product and case, description of the context

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

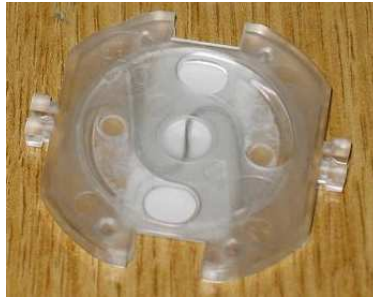


Figure C.3 Socket protector that prevents children from putting pointy things into socket outlets.

C.5.2 Description of the hazards

The holes in this 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 off the outlet when the plug is pulled out.

If the user doesn't notice (or doesn't put back the protector) then the outlet is left unprotected for the children. Therefore the product will not provide the protection that the parents rely on.

C.5.3 Description of injury scenarios and sensitivity

The risk assessment is reported on the following pages using the report from the Commissions web tool "Risk Assessment Guidelines" [24].

The outcomes of the analyses were one scenario resulting in "serious risk" and one in "low". The calculations are based on an estimated probability that the protector can be removed unintended over the lifetime of the product of 90 %. A sensitivity analysis revealed that only if this probability is less than 0.1 % the outcome would change to "high risk".

Some homes have residual current breakers that will interrupt the power if a person touches the live wire. This is included in the analyses as an extra factor in the calculation of the probability in the three scenarios. It does not affect the outcome.

For comparison, we have made an analysis for an unprotected socket outlet. The risk assessment report is annexed immediately after the report from the protected outlet.

C.5.4 Conclusion

The product in itself is not dangerous. The risk arises because the product tempts the users to change their habits because they rely on the protective properties of the product.

The overall outcome of the analysis is that the risk is serious, i.e. rapid action against the product should be taken.

RAPEX Risk Assessment

General Information

Product

Name: Socket protectors

Category: Protective equipment

Description: This case deals with socket protectors - devices that users (parents) put on the electrical socket outlets to avoid that small children access live parts by putting long metal object into one of the holes in the outlet and gets a (possibly fatal) electric shock. The holes in this 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 off the outlet when the plug is pulled out.

Risk assessor

First Name: Torben

Last Name: Rahbek

Organisation: PROSAFE

Address:

Product risks - Overview

Scenario 1 : **Serious risk** - Protector is removed from the plug, which becomes unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and is electrocuted.

Scenario 2 : **Low risk** - Protector is removed from the plug, which becomes unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and sustains shock.

Overall Risk : **Serious risk**

Scenario 1 : Young children - High/low voltage

Product hazard

Hazard Group: Electrical energy
Hazard Type: High/low voltage

Consumer

Consumer Type: Young children - Older than 36 months and younger than 8 years
(Vulnerable consumers)

How the hazard causes an injury to the consumer

Injury scenario: Protector is removed from the plug, which becomes unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and is electrocuted.

Severity of Injury

Injury: Electric shock
Level: 4 Electrocution

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The protector is removed from the socket	> 90 %
Step 2: The parent doesn't notice the removal of the protector	> 1/10
Step 3: The child is playing with a thin conductible object	> 1/10
Step 4: The child is unattended when playing	> 50 %
Step 5: The child inserts the object into the socket	> 1/3
Step 6: The object touches the phase wire	> 50 %
Step 7: The child is electrocuted due to voltage. (There is no residual current circuit interrupter in this scenario.)	> 1/5

Calculated probability: 0.00015

Overall probability: > 1/10,000

Risk of this scenario: Serious risk

Scenario 2 : Young children - High/low voltage

Product hazard

Hazard Group: Electrical energy
Hazard Type: High/low voltage

Consumer

Consumer Type: Young children - Older than 36 months and younger than 8 years
(Vulnerable consumers)

How the hazard causes an injury to the consumer

Injury scenario: Protector is removed from the plug, which becomes unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and sustains shock.

Severity of Injury

Injury: Burn/ Scald (by heat, cold, or chemical substance)
Level: 1 1°, up to 100% of body surface
2°, <6% of body surface

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The protector is removed from the socket	> 90 %
Step 2: The parent doesn't notice the removal of the protector	> 1/10
Step 3: The child is playing with a thin conductible object	> 1/10
Step 4: The child is unattended when playing	> 50 %
Step 5: The child inserts the object into the socket	> 1/3
Step 6: The object touches the phase wire	> 50 %
Step 7: The child is burned due to voltage. (There is no residual current circuit interrupter in this scenario.)	> 70 %

Calculated probability: 0.00053

Overall probability: > 1/10,000

Risk of this scenario: Low risk

RAPEX Risk Assessment

General Information

Product

Name: Socket protectors - REFERENCE SCENARIO
Category: Protective equipment
Description: THIS IS THE REFERENCE SCENARIO: For comparison, an analysis has been carried out for an unprotected socket outlet. In this case, the parent does not expect protection and therefore it seems less likely that the child will be left unattended near the outlet.

Risk assessor

First Name: Torben
Last Name: Rahbek
Organisation: PROSAFE
Address:

Product risks - Overview

Scenario 1 : **High risk** - Socket unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and is electrocuted.

Overall Risk : **High risk**

Scenario 1 : Young children - High/low voltage

Product hazard

Hazard Group: Electrical energy
Hazard Type: High/low voltage

Consumer

Consumer Type: Young children - Older than 36 months and younger than 8 years
(Vulnerable consumers)

How the hazard causes an injury to the consumer

Injury scenario: Socket unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and is electrocuted.

Severity of Injury

Injury: Electric shock
Level: 4 Electrocutation

Probability of the steps to injury

Step 1: The child is playing with a thin conductible object	> 1/10
Step 2: The child is unattended when playing	> 1/100
Step 3: The child inserts the object into the socket	> 1/3
Step 4: The object touches the phase wire	> 50 %
Step 5: The child is electrocuted due to voltage. (There is no residual current circuit interrupter in this scenario.)	> 1/5

Calculated probability: 0.000033

Overall probability: > 1/100,000

Risk of this scenario: High risk

C.6 Candle

C.6.1 Identification of product and case, description of the context

Candles containing plant parts, e.g. sunflower seeds or coffee beans, have been reported to burn intensely with high flames. There have been at least two RAPEX recalls for candles in 2006: 0351/06 and 0563/06.



Figure C.6 Candles containing plant parts may burn intensely with high flames and cause fires.

C.6.2 Description of the hazards

When the candle burns down and the wax melts, the plant parts begin to float in the melted wax. At this stage the plant parts will heat up or get stuck to the wick, which may cause the parts to catch fire. This fire will usually evolve rapidly, melt the rest of the candle and might put fire to the furniture where the candle is placed. If nobody is present at this stage this will most likely develop into a fire that can cause harm to people.

Another hazard is due to the fact that the plant parts may be easily detachable and fit into the small parts cylinder. This will make them dangerous if small children swallow them.

C.6.3 Description of injury scenarios and sensitivity

The risk assessment is reported on the following pages using the report from the Commissions web tool "Risk Assessment Guidelines" [24].

Several scenarios for these candles create a serious risk. A sensitivity analysis shows that this serious risk level remains valid, even if the probability would be a factor 10 lower.

The uncertainty in this case is rather high because several steps in the scenarios depend on behaviour rather than physical parameters.

It is noted that fires often result in considerable damage to property, even when there are no people injured. This risk cannot be estimated according to the standard RAPEX table. Instead, we have assumed for this assessment that a certain percentage of house fires leads to fatalities.

C.6.4 Conclusion

The overall outcome of the analysis is that the risk is serious.

RAPEX Risk Assessment

General Information

Product

Name: Candle containing small flammable parts
Category: Candle
Description: Candles containing plant parts, e.g. sunflower seeds or coffee beans, have been reported to burn intensely with high flames. There have been at least two RAPEX recalls for candles in 2006: 0351/06 and 0563/06. When the candle burns down and the wax melts, the plant parts begin to float in the melted wax. At this stage the plant parts will heat up or get stuck to the wick, which may cause the parts to catch fire. This fire will usually evolve rapidly, melt the rest of the candle and might put fire to the furniture where the candle is placed. If nobody is present at this stage this will most likely develop into a fire that can cause harm to people. Another hazard is due to the fact that the plant parts may be easily detachable and fit into the small parts cylinder. This will make them dangerous if small children swallow them.

Risk assessor

First Name: Torben
Last Name: Rahbek
Organisation: PROSAFE
Address:

Product risks - Overview

- Scenario 1 : **Medium risk** - Seeds or beans catch fire and generates high flames. The person blows out the flames and tries to move the candle. Hot wax flows over then hands of the person.
- Scenario 2 : **Medium risk** - Seeds or beans catch fire and generates high flames. The person tries to extinguish the flames by pouring liquid. The flames reaches the hands of the person.
- Scenario 3 : **Serious risk** - Seeds or beans catches fire generating high flames. Furniture or curtains catch fire. The person is not in the room, but inhales toxic fumes.
- Scenario 4 : **Serious risk** - Seeds or beans catches fire generating high flames. Furniture or curtains catch fire. The person is in the room and inhales toxic fumes.
- Scenario 5 : **Low risk** - Seeds or beans catches fire generating high flames. The person sits close to the candle. The flames ignite hair or clothing of the person.
- Scenario 6 : **Serious risk** - Seeds or beans are attractive to children. Children pick them out of the candle, put them in the mouth and it enters the trachea. The child is suffocated.

Overall Risk : **Serious risk**

Scenario 1 : Other consumers - Hot liquids

Product hazard

Hazard Group: Extreme temperatures
Hazard Type: Hot liquids

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Seeds or beans catch fire and generates high flames. The person blows out the flames and tries to move the candle. Hot wax flows over then hands of the person.

Severity of Injury

Injury: Burn/ Scald (by heat, cold, or chemical substance)
Level: 1 1°, up to 100% of body surface
2°, <6% of body surface

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: Seeds or beans catch fire	> 90 %
Step 2: The person tries to move the candle	> 1/5
Step 3: Hot wax flows over then hands of hte person	> 70 %

Calculated probability: 0.13

Overall probability: > 1/10

Risk of this scenario: Medium risk

Scenario 2 : Other consumers - Open flames

Product hazard

Hazard Group: Extreme temperatures
Hazard Type: Open flames

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Seeds or beans catch fire and generates high flames. The person tries to extinguish the flames by pouring liquid. The flames reaches the hands of the person.

Severity of Injury

Injury: Burn/ Scald (by heat, cold, or chemical substance)
Level: 1 1°, up to 100% of body surface
2°, <6% of body surface

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: Seeds or beans catch fire	> 90 %
Step 2: The person tries to extinguish the flames	> 90 %
Step 3: The flames reaches the hands of the person.	> 50 %

Calculated probability: 0.41

Overall probability: > 1/10

Risk of this scenario: Medium risk

Scenario 3 : Other consumers - Toxic gas

Product hazard

Hazard Group: Toxicity
Hazard Type: Toxic gas

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Seeds or beans catches fire generating high flames. Furniture or curtains catch fire. The person is not in the room, but inhales toxic fumes.

Severity of Injury

Injury: Poisoning from substances (ingestion, inhalation, dermal)
Level: 4 Irreversible damage to nerve system
Fatality

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: Seeds or beans catches fire generating high flames	> 90 %
Step 2: Nobody in the room for some time.	> 1/3
Step 3: Furniture or curtains catch fire	> 50 %
Step 4: The person inhales toxic fumes.	> 1/20

Calculated probability: 0.0075

Overall probability: > 1/1,000

Risk of this scenario: Serious risk

Scenario 4 : Other consumers - Toxic gas

Product hazard

Hazard Group: Toxicity
Hazard Type: Toxic gas

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Seeds or beans catches fire generating high flames. Furniture or curtains catch fire. The person is in the room and inhales toxic fumes.

Severity of Injury

Injury: Poisoning from substances (ingestion, inhalation, dermal)
Level: 4 Irreversible damage to nerve system
Fatality

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: Seeds or beans catches fire generating high flames	> 90 %
Step 2: Furniture or curtains catch fire	> 50 %
Step 3: The person is in the room (e.g. sleeping)	> 1/100
Step 4: The person inhales toxic fumes.	100 %

Calculated probability: 0.0045

Overall probability: > 1/1,000

Risk of this scenario: Serious risk

Scenario 5 : Other consumers - Open flames

Product hazard

Hazard Group: Extreme temperatures
Hazard Type: Open flames

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Seeds or beans catches fire generating high flames. The person sits close to the candle. The flames ignite hair or clothing of the person.

Severity of Injury

Injury: Burn/ Scald (by heat, cold, or chemical substance)
Level: 3 2°, 16-35% of body surface, or 3°, up to 35% of body surface
Inhalation burn

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: Seeds or beans catches fire generating high flames	> 90 %
Step 2: The person sits close to the candle	> 1/1,000
Step 3: The flames ignite hair or clothing of the person.	> 1/1,000

Calculated probability: 9e-7

Overall probability: < 1/1,000,000

Risk of this scenario: Low risk

Scenario 6 : Other consumers - Possibility to bite off small part from product

Product hazard

Hazard Group: Size, shape and surface
 Hazard Type: Possibility to bite off small part from product

Consumer

Consumer Type: Other consumers - Consumers other than vulnerable or very vulnerable consumers

How the hazard causes an injury to the consumer

Injury scenario: Seeds or beans are attractive to children. Children pick them out of the candle, put them in the mouth and it enters the trachea. The child is suffocated.

Severity of Injury

Injury: Suffocation / Strangulation
 Level: 4 Fatal suffocation / strangulation

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: Children pick seeds out of the candle	> 1/10
Step 2: Children put them in the mouth	> 1/10
Step 3: The seed enters the trachea	> 1/100
Step 4: The child is suffocated	100 %

Calculated probability: 0.0001

Overall probability: > 1/10,000

Risk of this scenario: Serious risk

C.7 Bathing mattresses

C.7.1 Identification of product and case, description of the context

This case deals with a type of bathing mattress, an inflatable airbed for seaside and pools made from PVC.



Figure C.4 Bathing mattress that emits phthalates.

C.7.2 Description of the hazards

The PVC contains a plasticizer: a substance to make the plastic flexible. In this case, the substance is bis(2-ethylhexyl)phthalate (DEHP). DEHP and other phthalates are classified in Annex I to Directive 67/548/EEC as a dangerous substance because of reproductive toxicity - Category 2 "Suspected human reproductive toxicant"; the packaging of this substance needs to carry the warning sentences R60-61 "R60: May impair fertility" and "R61: May cause harm to the unborn child".

In order to assess the risk of this particular product, we need to know whether DEHP can migrate out of the plastic and how much human exposure would take place. The first part of such a risk assessment is similar to the physical examples: describing one or more scenarios. After that, the probability is dealt with in a different way. We do not estimate how probable the scenario is, but how much of the substance the person is likely to get into his body. This can be done using (measured or estimated) data on release, transfer and absorption.

C.7.3 Description of injury scenarios and sensitivity

Injury scenarios	Injury type and location	Severity of injuries	Exposure parameters (Probability of injuries)	Resulting exposure (probability)	Risk
<p>Use by a 5 year old boy. The DEHP present in the air mattress is released from the surface.</p> <p>The released amount of DEHP is transferred to the skin via direct physical contact and rubbing with the skin.</p> <p>The transferred amount of DEHP to the skin is absorbed.</p>	Effects on reproduction	4	<ul style="list-style-type: none"> - Body weight: 16 kg - Release of DEHP: 7.4 $\mu\text{g}/\text{cm}^2/\text{h}$ - Transfer to skin: all released DEHP gets on an area of skin of 1500 cm^2, during 2 h per day - Absorption of DEHP: 5% 	104.6 $\mu\text{g}/\text{kg}_{\text{BW}}/\text{day}$	Margin of safety insufficient, Serious risk

Table C.4: Table of injury scenarios and associated risk levels for the bathing mattress case.

The risk in chemical cases cannot be directly be derived from the risk table, because there is no probability class such as '>1/100.000'. Instead, we have a dose, which is usually expressed in an amount per kg of body weight.

We then compare this dose with data on the levels that have been reported to produce the effect we mentioned under 'injury type'.

In this case, there are data on the highest tested level that did **not** produce the effect in rats: 4800 µg/kg_{BW}/day. Higher doses did give the effect of developmental toxicity. Toxicologists then say that the *No Observed Adverse Effect Level* (NOAEL) is 4800 µg/kg_{BW}/day.

The ratio between the NOAEL and the value calculated for the mattress is $4800/104.6 = 45.8$. This ratio is called the Margin of Safety (MoS). A MoS of 45.8 68.8 is not considered sufficient by toxicologists. It should be more than 100, because we need to take account that there may be differences in metabolism between rats and humans as well as between different persons (inter- and intra-species variability).

C.7.4 Conclusion

The MoS is not sufficient, therefore the product poses a risk. Because the effect that may occur is in the highest category and the margin of safety is well below 100, we consider this as a serious risk.

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