AUSTRALIAN COMPETITION & CONSUMER COMMISSION

Risk assessment tool: European Union RAPEX risk assessment

Conducting a consumer product safety recall – Appendix 2

April 2023

Acknowledgment of country

The ACCC acknowledges the traditional owners and custodians of Country throughout Australia and recognises their continuing connection to the land, sea and community. We pay our respects to them and their cultures; and to their Elders past, present and future.

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Contents

Risk assessment tool: European Union RAPEX risk assessment

The European Union RAPEX risk assessment tool assesses the risk of a product.

The following steps and guidance will assist you to conduct your risk assessment.

Consult with your staff who have knowledge and experience of the product and its hazards to carry out the risk assessment.

European RAPEX risk assessment steps

Step 1: Describe the product and associated hazard(s)	
Product description	Describe the product
Hazard description	Describe the hazard(s). A hazard is something that can cause harm. e.g.: fall, choking, fire, electric shock Does the hazard concern the entire product or only a (detachable) part of the product? Is there only one hazard concerning the product? Are there several hazards?
Relevant safety standard, ban or legislation	List safety standards, product bans or other legislation relevant to the product ▪ identify what safety laws apply to the product ▪ work out how the product, or aspects of the product, do not meet the requirements of the relevant standard, ban or other legislation ▪ does the hazard need to be addressed through re-design or testing of the product to ensure compliance?
Step 2: Identify the type of customer you want to include in your injury scenario who may be affected by the hazard(s) associated with the product	
Intended user(s)	List the intended user(s). For example, consider the age group of the intended user and whether they are a vulnerable consumer e.g. A trampoline is intended for children and adults to jump on.
Intended use of the product	List the intended use of the product e.g. A trampoline is intended for jumping on by one child or adult.
Other users or different ways to use the product	List other consumers and scenarios, and different uses of the product, to capture reasonably foreseeable use and misuse of the product e.g. A trampoline is likely to be jumped on by 2 or more children or adults
Step 3: Describe a scenario, in which the product hazard(s) cause injury or adverse health effects to consumers who may use the product	
Describe how the injury (or injuries) may occur	When describing the injury, use the shortest path to the injury, or the critical path to injury (without exaggerating the details) ▪ Are there several paths to injury? ▪ Consider other reasons including: – the frequency and duration of use – can the consumer recognise the hazard (i.e. is it visible or hidden) – is the consumer vulnerable (e.g. children) – is protective equipment involved during the use of the product – what the consumer was doing when the accident happened? – consumer's cultural background – other factors important for the injury to occur.

Step 4: Work out the severity of the injury	
Level of severity (1-4) of the possible injury to the consumer	The level of severity is used to rate how seriously a person is likely to be hurt by the product. See Injury Severity Table for further guidance. If the consumer suffers from several injuries in the injury scenario noted above, estimate the severity of all those injuries together. Be objective – decide the severity of the different scenarios, not the acceptability of an injury.
Step 5: Work out the probability of the injury	
What is the likelihood of the injury occurring (e.g. low, moderate, high)	This section is to assess how likely it is that a person will be hurt by the product (probability of the injury). Assign a probability to each step of your injury scenario. See Probability Table for further guidance. Multiply the probability to work out the overall probability of your injury scenario.
Step 6: Work out the risk level	
Level of risk associated with using the product (e.g. low, medium, high, serious)	This is the rating we use to measure the likelihood that the product will hurt someone and if so, how badly they will be hurt. It is a combination of the injury severity and the injury probability. Also see the Risk Level Table.
Step 7: Review your assessment	
Is the injury severity and probability of the injury occurring accurate?	The injury severity and probability of the injury occurring should consider all hazards associated with the product which may lead to an injury. Consider how the product is used, including foreseeable use and misuse. Check that it makes logical sense.
Is the current risk level likely?	Will the risk level change if you change the severity and probability up or down? If the risk level remains the same, you can be quite confident of your risk assessment. If it changes, it means that your product is either at the higher or lower end of that risk rating. When this happens, select the higher risk. Discuss the likelihood of the risk level with experienced colleagues and compare it with an actual experience using the product.
Step 8: Finalise, document and pass on your risk assessment	
Issues or unknowns	Describe any difficulties you had when completing your assessment including when you felt you did not have enough information and had to make estimates.
Document next steps	Recall the product. Tell consumers about the hazard and risk with the product, particularly if the risk level changes. Fix the defect or why it is dangerous and hazardous by repairing, refunding and/or replacing the product.

Injury severity table

Injury (severity)	Consequence for consumers
4	Injury or consequence that is or could be fatal, including brain death; consequences that affect reproduction or offspring; severe loss of limbs and/or function, leading to more than approximately 10 per cent of disability.
3	Injury or consequence that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function.
2	Injury or consequence for which a visit to an emergency room may be necessary, but in general, hospitalisation is not required. Functioning may be affected for a limited period, not more than about 6 months, and recovery is more or less complete.
1	Injury or consequence that after basic treatment (first aid, normally not by a doctor) does not substantially hamper functioning or cause excessive pain; usually the consequences are completely reversible.

Source: page 43 PROSAFE (2011).

Probability table

Probability of damage during the foreseeable lifetime of the product	
High	> 50 %
	> 1/10
	> 1/100
	> 1/1 000
	> 1/10 000
	> 1/100 000
	> 1/1 000 000
Low	< 1/1 000 000

Source: page 44 PROSAFE (2011).

Risk level table

Probability of damage during the foreseeable lifetime of the product		Severity of Injury			
		1	2	3	4
High	> 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
Low	< 1/1 000 000	L	L	L	L

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

Source: page 44 PROSAFE (2011).

PROSAFE (Product Safety Enforcement Forum of Europe) (2011), Consumer product safety in Europe: Correction Action Guide, accessed 24 March 2020 [PDF]

European Commission (2015), EU General Risk Assessment Methodology (Action 5 of Multi-Annual Action Plan for the Surveillance of Products in the EU (COM(2013)76). Vol. 2015-IMP-M. http://ec.europa.eu/DocsRoom/documents/17107/attachments/1/translations/


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