Risk Assessment for RAPEX

General Information

Product

Product name:	Smoke alarm devices
Product category:	Smoke alarm devices
Description:	This is a PROSAFE risk assessment template for smoke alarm devises. It describes likely injury scenarios linked to non-conformity with the following clauses of EN14604:2005: §4.19.1 Marking - scenario 1 §5.2 Repeatability - scenario 2 §5.3 Directional dependence - scenario 2 §5.4 Initial sensitivity - scenario 2 §5.15 Fire sensitivity - scenario 2 §5.16 Battery fault warning - scenario 3 §5.17 Sound output - scenario 4 How to use Users of the template should select the scenario(s) corresponding to the non-conformities identified for the product under assessment. All other scenarios can then be deleted. The probabilities are estimated in the remaining scenarios. The scenarios presented in the template are likely scenarios. Users should ensure that the scenarios are suitable, that the steps are correct and that the injury level is appropriate. Disclaimer The template has been developed by a PROSAFE working group composed of market surveillance experts. The intention is to support market surveillance officials assessing the risk with a particular product as part of a market surveillance case. The template is not authorized or endorsed in any way and it is not binding for Member State market surveillance authorities. The contents of the original template is subject to change without notice.

Risk assessor

First name:	PROSAFE Risk Assessment Template
Last name:	
Organisation:	PROSAFE

Address: PROSAFE Secretariat
Avenue des Arts/Kunstlaan 41, 2nd floor
B-1040 Brussels,
Belgium
Tel: +32 2 8080 996/997
E-mail: info@prosafe.org

Product risks - Overview

Scenario 1 : **Risk to be determined** - The smoke alarm device does not give appropriate instructions for installation so the user installs it in a place where it can't detect smoke soon enough. A glowing fire producing smoke breaks out while the user is asleep. The smoke alarm does not detect the smoke. The user inhales smoke. The user dies from smoke poisoning.

Scenario 2 : **Risk to be determined** - A user has installed a smoke alarm that is too insensitive. A glowing fire producing smoke breaks out while the user is asleep. The smoke alarm does not detect the smoke. The user inhales smoke and dies from smoke poisoning.

Scenario 3 : **Risk to be determined** - A user has installed a smoke alarm where the battery fault warning doesn't work. A glowing fire producing smoke breaks out while the user is asleep. The smoke alarm does not detect the smoke. The user inhales smoke. The user dies from smoke poisoning.

Scenario 4 : **Risk to be determined** - A user has installed a smoke alarm that provides an inadequate sound level. A glowing fire producing smoke breaks out while the user is asleep. The smoke alarm detects the smoke, but the alarm doesn't wake the user. The user inhales smoke and dies from smoke poisoning.

Overall risk : **Risk to be determined**

Scenario 1 : Other consumers - Insufficient warning texts and symbols

Product hazard

Hazard Group: Product operating hazards
Hazard Type: Insufficient warning texts and symbols

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 smoke alarm device does not give appropriate instructions for installation so the user installs it in a place where it can't detect smoke soon enough. A glowing fire producing smoke breaks out while the user is asleep. The smoke alarm does not detect the smoke. The user inhales smoke. The user dies from smoke poisoning.

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:	The smoke alarm device does not give appropriate instructions for installation so the user installs it in a place where it can't detect smoke soon enough.	1
Step 2:	A glowing fire producing smoke breaks out while the user is asleep.	1
Step 3:	The smoke alarm does not detect the smoke.	
Step 4:	The user inhales smoke and dies from smoke poisoning. (Other injury types and levels are possible.)	

Calculated probability: To be determined
Overall probability: To be determined
Risk of this scenario: Risk to be determined

Scenario 2 : Other consumers - Operational inadequacy

Product hazard

Hazard Group: Product operating hazards
Hazard Type: Operational inadequacy

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: A user has installed a smoke alarm that is too insensitive. A glowing fire producing smoke breaks out while the user is asleep. The smoke alarm does not detect the smoke. The user inhales smoke and dies from smoke poisoning.

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:	A user has installed a smoke alarm that is too insensitive.	1
Step 2:	A glowing fire producing smoke breaks out while the user is asleep.	1
Step 3:	The smoke alarm does not detect the smoke. (The probability depends upon the actual level of insensitivity that was found in the laboratory test.)	
Step 4:	The user inhales smoke and dies from smoke poisoning. (Other injury types and levels are possible.)	

Calculated probability: To be determined
Overall probability: To be determined
Risk of this scenario: Risk to be determined

Scenario 3 : Other consumers - Operational inadequacy

Product hazard

Hazard Group: Product operating hazards
Hazard Type: Operational inadequacy

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: A user has installed a smoke alarm where the battery fault warning doesn't work. A glowing fire producing smoke breaks out while the user is asleep. The smoke alarm does not detect the smoke. The user inhales smoke. The user dies from smoke poisoning.

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:	A user has installed a smoke alarm where the battery fault warning doesn't work.	1
Step 2:	A glowing fire producing smoke breaks out while the user is asleep.	1
Step 3:	The smoke alarm does not detect the smoke because the battery is out. (The probability depends upon the nature of the non-compliance, e.g. will the alarm give warnings other than audible, is the warning completely absent or does it warn at too low battery voltages, etc.)	
Step 4:	The user inhales smoke and dies from smoke poisoning. (Other injury types and levels are possible.)	

Calculated probability: To be determined
Overall probability: To be determined
Risk of this scenario: Risk to be determined

Scenario 4 : Other consumers - Insufficient warning signals

Product hazard

Hazard Group: Product operating hazards
Hazard Type: Insufficient warning signals

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: A user has installed a smoke alarm that provides an inadequate sound level. A glowing fire producing smoke breaks out while the user is asleep. The smoke alarm detects the smoke, but the alarm doesn't wake the user. The user inhales smoke and dies from smoke poisoning.

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:	A user has installed a smoke alarm that provides an inadequate sound level.	1
Step 2:	A glowing fire producing smoke breaks out while the user is asleep.	1
Step 3:	The smoke alarm detects the smoke, but the alarm doesn't wake the user.	
Step 4:	The user inhales smoke and dies from smoke poisoning. (Other injury types and levels are possible.)	

Calculated probability: To be determined
Overall probability: To be determined
Risk of this scenario: Risk to be determined