

## Joint Action 2013 on GPSD Products

### GA N° 2013 82 01

## Risk Assessment Templates - User's Guide

### 1 Introduction - Risk Assessment Templates

Risk assessment is the process that a market surveillance authority would apply to assess the risk with a non-compliant product.

The risk is assessed by analysing the (hypothetical) situation where a non-compliant product is placed in the hands of the consumer so the accident happens. In practice, the analysis is done by establishing injury scenarios that describe how the non-compliant product may injure the consumer. Such a scenario consists of a number of steps, and the risk assessor has to estimate the probabilities for each step. The risk assessor also has to identify the severity of the injury. The combination of the overall probability and the severity gives the risk level.

This process contains some inherent uncertainties: Two risk assessors can disagree on the injury scenarios, on the steps in the scenarios, on the probabilities of the steps and on the severity of the injury.

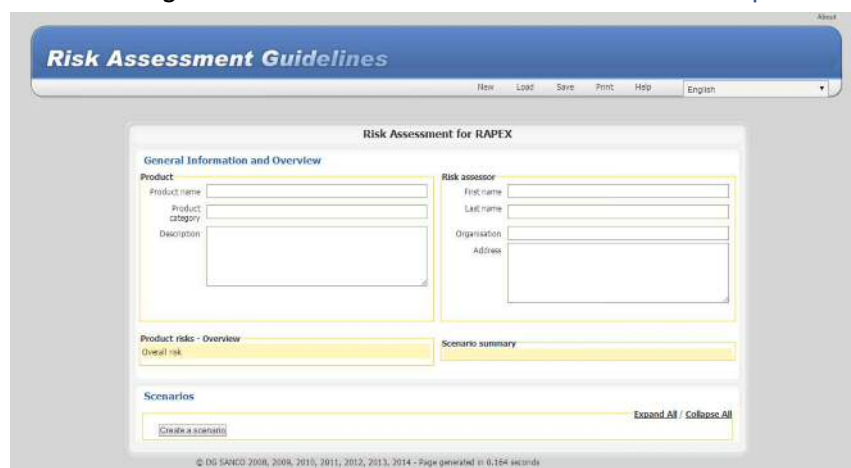
Therefore, PROSAFE has introduced risk assessment templates as a tool to facilitate the risk assessment process and increase the homogeneity of the results. A risk assessment template is a compilation of injury scenarios, one for each potential (major) non-conformity in the product that describes how each of the non-conformities may injure a consumer. The template may include guidance on the estimates of the probability factors but will not fix the probabilities.

A risk assessor applies a risk assessment template by deleting the irrelevant scenarios (that relate to non-compliances not present in the particular product), reviewing the remaining scenarios to ascertain that they give an adequate representation of the particular product that is being assessed, and finally estimating the probabilities in the steps in the scenario.

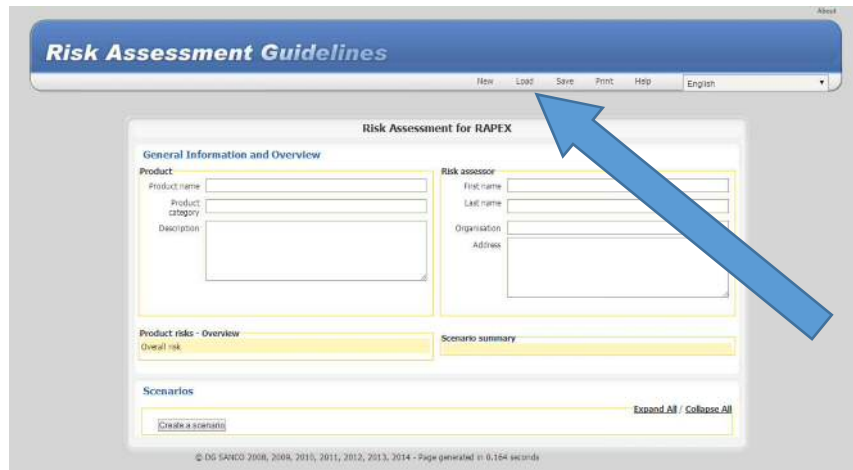
### 2 How to Use Risk Assessment Templates

To use the templates, the risk assessor will have to go through the following steps:

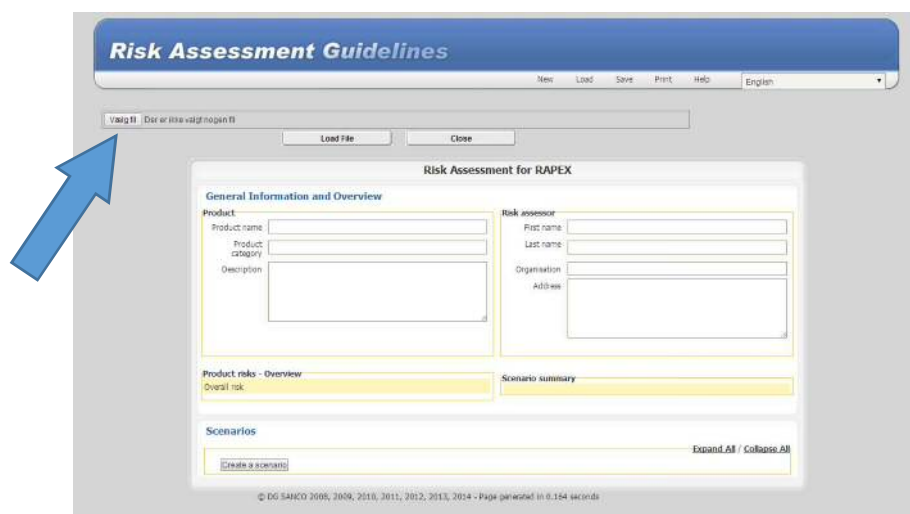
1. Open the browser and go to the Risk Assessment Guidelines tool at [europa.eu/sanco/rag](http://europa.eu/sanco/rag)



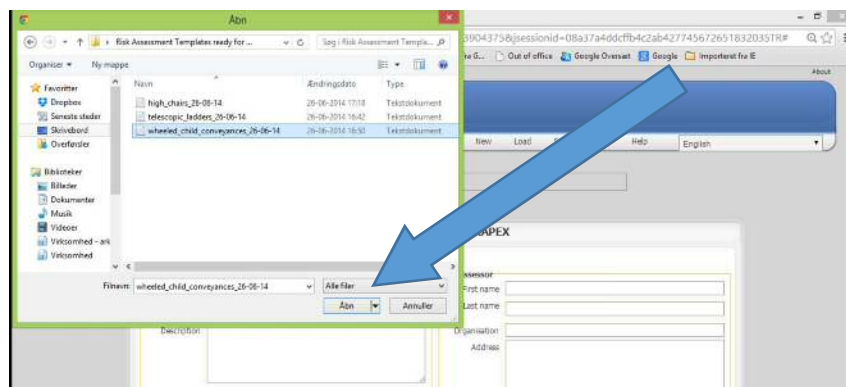
2. Open the relevant risk assessment template.
  - a. First, click on “Load” in the menu line.



- b. This opens a new area where you can select the file. Click on “Select file”. (The texts are in the language of your PC, in this example Danish.)

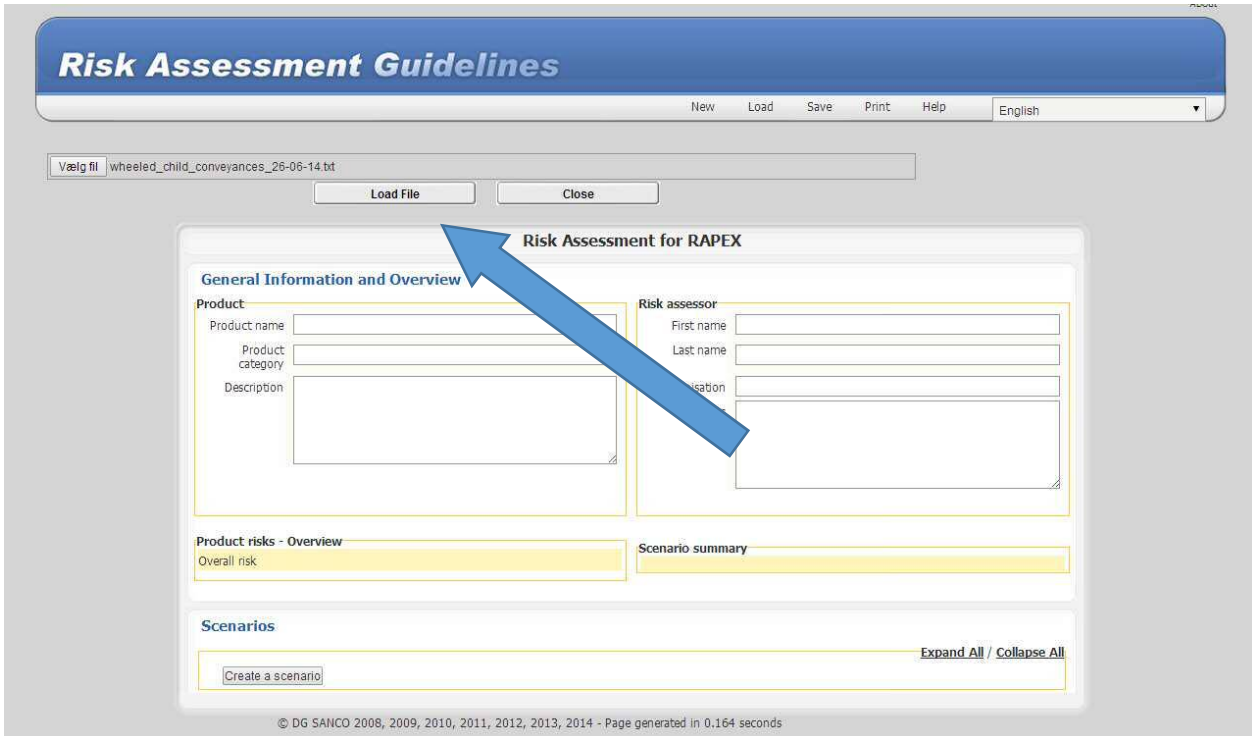


- c. This opens the Windows Pathfinder. Browse to the folder where you have the risk assessment template.



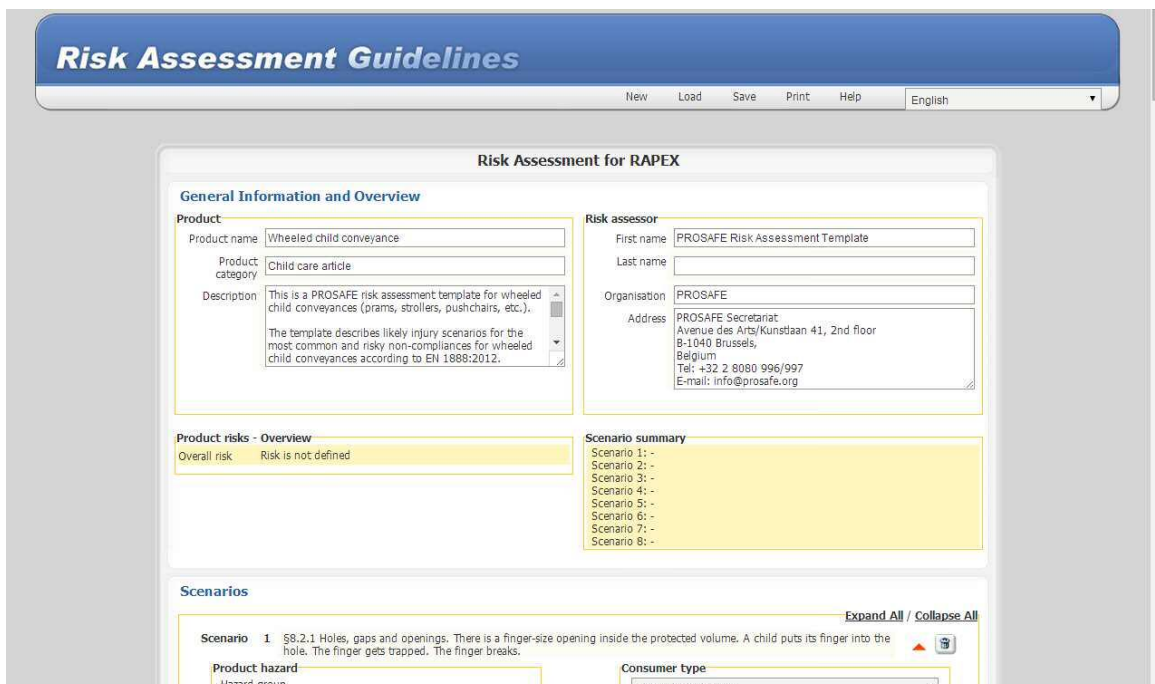
Select the relevant template and click the “Open” button.

d. Upload the file by clicking the “Load File” button.



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e. This will open the template:



3. Go through the template and erase those scenarios that consider non-conformities that are not present in the product you want to assess. (In this example, we only want to consider a product with a non-conforming locking mechanism, so scenarios 1, 2 and 4 - 8 are deleted.)
- 4.

**Scenarios** Expand All / Collapse All

**Scenario 3** §8.3.3 locking mechanism. A child is sitting in the stroller. The locking mechanism breaks or is incompletely engaged. The stroller folds unintended. A finger is entrapped. The finger breaks.

**Product hazard**

Hazard group: Potential energy

Hazard: Low mechanical stability

**Consumer type**

Very young children  
0 to 36 months (Very vulnerable consumers)

**How the hazard causes an injury to the consumer**

Typical injury scenario: Product tips; person on top of product falls from height, or person near product is hit by the product; electrical product tips, break and gives access to live parts, or continues to work heating nearby surfaces. Copy >

Your injury scenario: Describe it! §8.3.3 locking mechanism. A child is sitting in the stroller. The locking mechanism breaks or is incompletely engaged. The stroller folds unintended. A finger is entrapped. The finger breaks.

**Severity of injury**

Typical injury: Bruising; dislocation; sprain; fracture; crushing; electric shock; burns

Your injury: Fracture

Select below a severity level (1 to 4)

1

- Extremities (finger, toe, hand, foot)**
- Wrist
- Arm
- Rib

2

- Sternum**
- Nose
- Tooth
- Jaw
- Bones around eye

Ankle  
Leg (femur and lower leg)

5. Estimate the probabilities in the remaining scenario. (The figures in this example are purely fictive.)

Typical injury scenario: Product tips; person on top of product falls from height, or person near product is hit by the product; electrical product tips, break and gives access to live parts, or continues to work heating nearby surfaces. Copy >

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- Bones around eye

Ankle  
Leg (femur and lower leg)  
Hip  
Thigh  
Skull

3

- Spine (minor compression fracture)
- Jaw (severe)
- Larynx
- Multiple rib fractures
- Blood or air in chest

4

- Neck
- Spinal column

**Probability of injury**

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

A child is sitting in the stroller and the locking mechanism breaks or is incompletely engaged. Probability: Enter a value between 0.000001 and 1.

The stroller folds unintended. (The probability can be found from analysis of the test report and the

A finger is entrapped. (The probability depends upon the construction of the stroller and the folding mechanism.)

The finger breaks. (The probability depends upon the construction of the stroller and the folding mechanism.)

Add a step

1

0.2

0.01

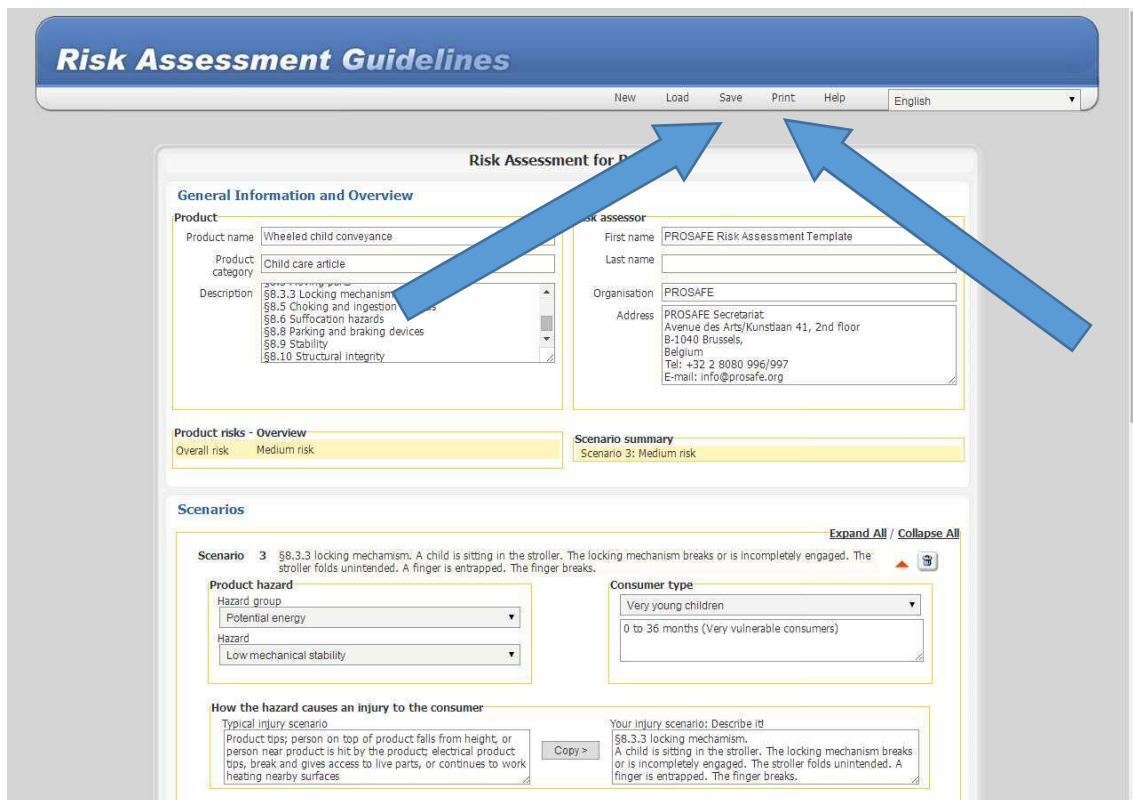
0.2

Severity of injury level	Calculated probability	Overall probability	Risk of this scenario
2	0.000400000	> 1/10,000	Medium risk

Create a scenario

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6. Review the result. Discuss it with your colleagues. Do a reality-check and a sensitivity analysis. When you have finished, save your result and print it.



**Risk Assessment Guidelines**

New Load Save Print Help English

**Risk Assessment for Product**

**General Information and Overview**

**Product**

Product name: Wheeled child conveyance  
 Product category: Child care article  
 Description: §8.3.3 Locking mechanism, §8.5 Choking and ingestion, §8.6 Suffocation hazards, §8.8 Parking and braking devices, §8.9 Stability, §8.10 Structural integrity

**Risk assessor**

First name: PROSAFE Risk Assessment Template  
 Last name: [empty]  
 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@prosafa.org

**Product risks - Overview**

Overall risk: Medium risk

**Scenario summary**

Scenario 3: Medium risk

**Scenarios**

Expand All / Collapse All

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Your injury scenario: Describe it! §8.3.3 locking mechanism. A child is sitting in the stroller. The locking mechanism breaks or is incompletely engaged. The stroller folds unintended. A finger is entrapped. The finger breaks.

Copy >

”Save” will download a .txt-file to your computer with the data from the case. This file has the same structure as the risk assessment template. The content is illegible.

”Print” will open a new browser window with a risk assessment report in a pdf-file that can be printed or saved.