

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





- 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.)



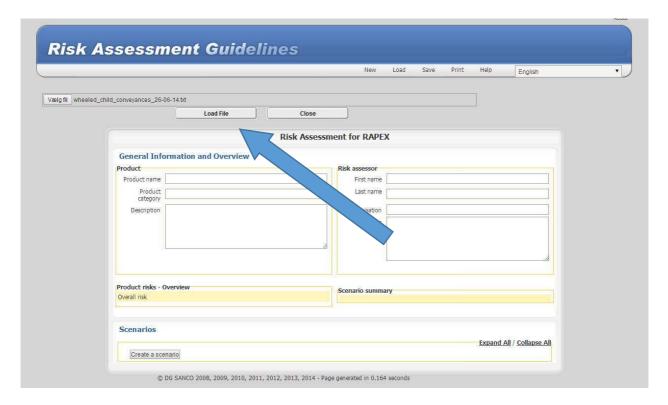
c. This opens the Windows Pathfinder. Browse to the folder where you have the risk assessment template.



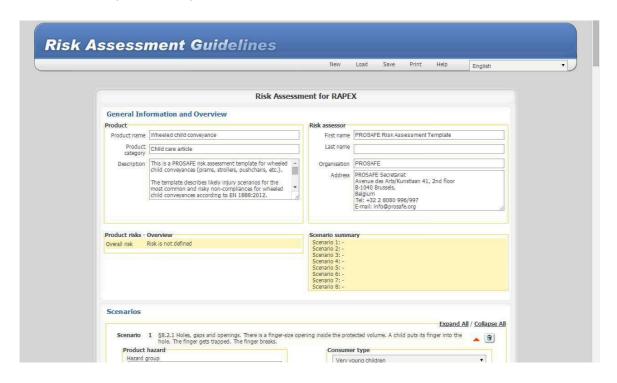


Select the relevant template and click the "Open" button.

d. Upload the file by clicking the "Load File" button.



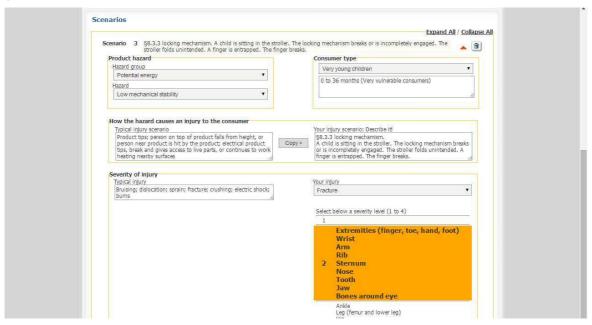
e. This will open the template:





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.

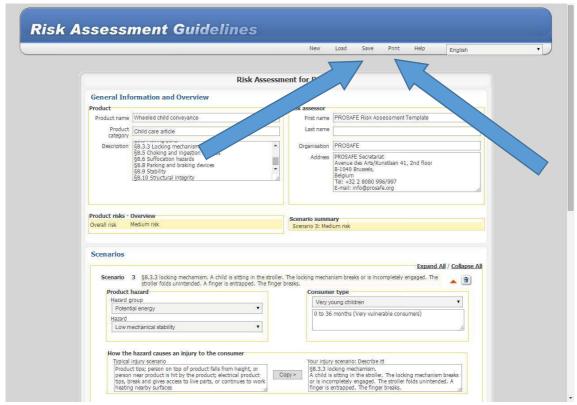


5. Estimate the probabilities in the remaining scenario. (The figures in this example are purely fictive.)





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.



"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.