

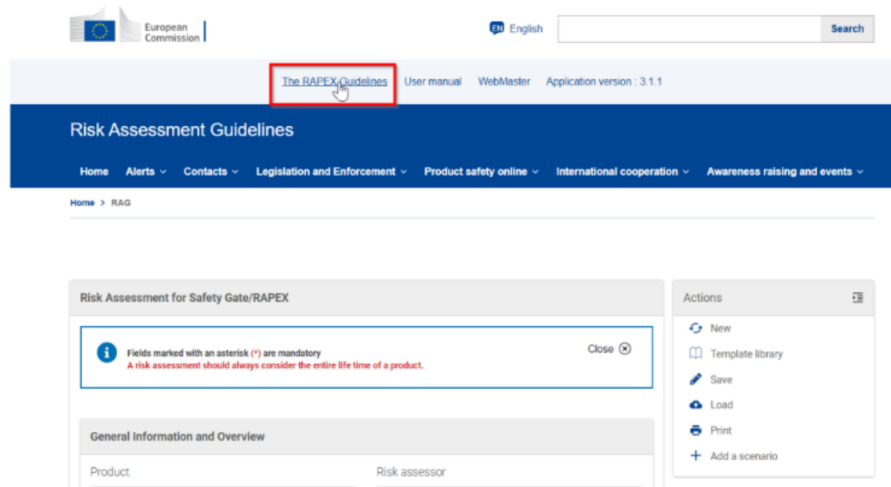
# How to use this tool

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# Welcome

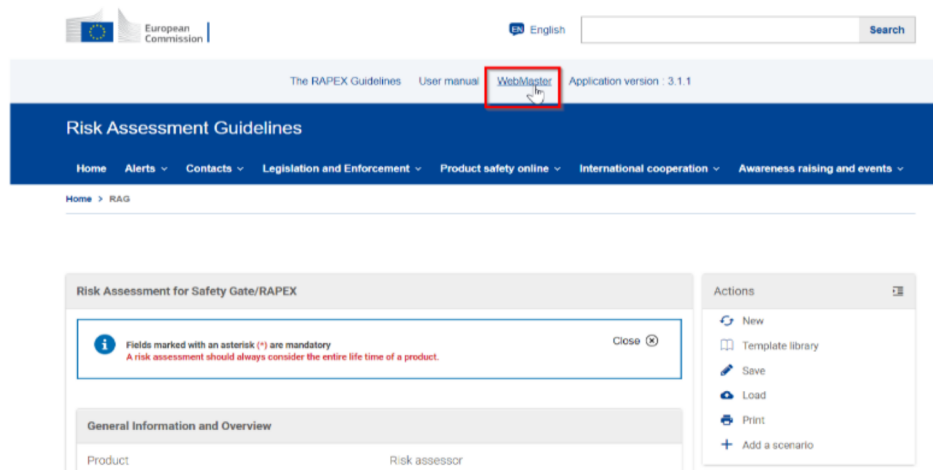
This user manual provides guidance on how to use the **Risk Assessment Guidelines** (RAGs), an IT application developed to facilitate the risk assessment of products notified through the Rapid Alert System, in accordance with the principles laid down in Commission Decision 2019/417<sup>1</sup>. A copy of the Decision is available via ‘**The RAPEX Guidelines**’ feature on the homepage of the application.



The IT application is the property of the European Commission. By accessing it, you accept to use it in accordance with European Commission policies, local laws and regulations.

Appropriate use of the application is entirely under your responsibility: please always check whether the results you obtain are reliable. The best user experience can be obtained by opening the application in Chrome or Firefox browser.

Should you have any remarks on the application, please click on the ‘**WebMaster**’ feature or send an e-mail directly to [JUST-RAG@ec.europa.eu](mailto:JUST-RAG@ec.europa.eu).



<sup>1</sup> Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System ‘RAPEX’ established under Article 12 of Directive 2001/95/EC on general product safety and its notification system (notified under document C(2018) 7334)

Please note that the application does not keep or save any of your data. Therefore, you should save your data regularly by saving a copy of the file on your computer. You can upload the information in the file at any time to access the data you have encoded.

The application is available in all official EU languages and in Chinese. You can change the language settings by clicking on the language icon in the top middle-hand as shown below:

The screenshot displays the top navigation bar of the RAPEX Guidelines application. On the left, the European Commission logo is visible. In the center, a language selection menu is highlighted with a red box, showing 'English' as the selected language. To the right of the language menu is a search bar with a 'Search' button. Below the navigation bar, a blue header contains the text 'Risk Assessment Guidelines'. A secondary navigation bar includes links for 'Home', 'Alerts', 'Contacts', 'Legislation and Enforcement', 'Product safety online', 'International cooperation', and 'Awareness raising and events'. Below this, a breadcrumb trail shows 'Home > RAG'. The main content area is titled 'Risk Assessment for Safety Gate/RAPEX' and features a message box stating: 'Fields marked with an asterisk (\*) are mandatory. A risk assessment should always consider the entire life time of a product.' Below the message is a section for 'General Information and Overview' with input fields for 'Product', 'Risk assessor', 'Product \*', and 'Organisation'. On the right side, an 'Actions' menu is open, listing options: 'New', 'Template library', 'Save', 'Load', 'Print', and 'Add a scenario'.

## How to prepare a risk assessment – Step by Step

Risk Assessment for Safety Gate/RAPEX

Fields marked with an asterisk (\*) are mandatory  
A risk assessment should always consider the entire life time of a product. Close

### General Information and Overview

Product	Risk assessor
<b>Product *</b>	<b>Organisation</b>
<input type="text"/>	<input type="text"/>
<b>Product category *</b>	<b>Country</b>
Please select	Please select
<input type="button" value="v"/>	<input type="button" value="v"/>
<b>Description</b>	
<input type="text"/>	

Actions

- New
- Template library
- Save
- Load
- Print
- + Add a scenario

### Section 1: General information and Overview

Fill in the fields with the relevant data, taking particular care when describing the product you are assessing. You should indicate the **'Product name'**, **'Product category'** (from the drop-down menu available) and a short **'Description'** of the product; you may also complete the fields **'Organisation'** and **'Country'** in the section **'Risk assessor'**, as shown in the image below, but these fields are not compulsory.

### General Information and Overview

Product	Risk assessor
<b>Product *</b>	<b>Organisation</b>
<input type="text"/>	<input type="text"/>
<b>Product category *</b>	<b>Country</b>
Please select	Please select
<input type="button" value="v"/>	<input type="button" value="v"/>
<b>Description</b>	
<input type="text"/>	

## Section 2: Scenarios

For each safety issue, a scenario should be defined.

— Scenario 1

**Delete Scenario >**

Product hazard

**Hazard group \***  
Please select

**Hazard \***

User type

**User type \***  
Please select

How the hazard causes an injury to the consumer

**Typical injury scenario**  **Copy >** **Your injury scenario: Describe it!**

Severity of injury

**Typical injury**  **Your injury \***  
Please select

Probability of injury

Step(s) to injury: Describe - 1 step per box \*  **Probability: Enter a value between 0.000001 and 1 \***

Severity of injury level	Calculated probability	Overall probability	Risk of this scenario To be determined
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Please remember that the scenario should take into consideration the **lifetime of the product**.

Risk Assessment for Safety Gate/RAPEX

**i** Fields marked with an asterisk (\*) are mandatory  
**A risk assessment should always consider the entire life time of a product.**

Close (x)

## Product hazard and User type

This section allows you to define the possible scenarios relevant for the assessment of the risk(s) related to the product in question: **Hazard group** (general category), **Hazard** (more specifically) and **User type** (people that would mainly be affected by the hazard). There are drop-down menus to allow you to choose from a pre-defined set of values published in Commission Decision 2019/417.

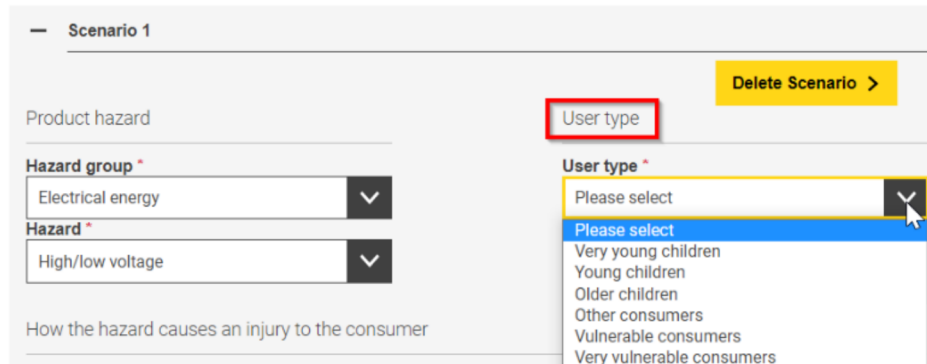
To select a specific hazard, you should first select a **'Hazard group'** from the drop-down menu, and then the hazard itself from the **'Hazard'** drop-down menu.

The screenshot shows the 'Scenario 1' form. The 'Product hazard' section has a 'Hazard group' dropdown menu open, displaying a list of options: 'Please select', 'Size, shape and surface', 'Potential energy', 'Kinetic energy', 'Electrical energy' (highlighted), 'Extreme temperatures', 'Radiation', 'Fire and explosion', 'Toxicity', 'Microbiological contamination', 'Product operating hazards', and 'Environmental'. A 'Copy >' button is visible next to the dropdown. The 'User type' section has a 'User type' dropdown menu with 'Please select' selected. Below this are two text input fields: 'Your injury scenario: Describe it!' and 'Your injury'. The 'Probability of injury' section has a 'Step(s) to injury: Describe - 1 step per box' input field and a 'Probability: Enter a value between 0.000001 and 1' input field with a 'Delete' button. At the bottom, there are four columns: 'Severity of injury level', 'Calculated probability', 'Overall probability', and 'Risk of this scenario To be determined'. A 'Delete Scenario >' button is in the top right corner.

The screenshot shows the 'Scenario 1' form. The 'Product hazard' section has a 'Hazard' dropdown menu open, displaying a list of options: 'Please select', 'High/low voltage' (highlighted), 'Heat production', and 'Live parts too close'. A 'Copy >' button is visible next to the dropdown. The 'User type' section has a 'User type' dropdown menu with 'Please select' selected. Below this are two text input fields: 'Your injury scenario: Describe it!' and 'Your injury'. The 'Probability of injury' section has a 'Step(s) to injury: Describe - 1 step per box' input field and a 'Probability: Enter a value between 0.000001 and 1' input field with a 'Delete' button. At the bottom, there are four columns: 'Severity of injury level', 'Calculated probability', 'Overall probability', and 'Risk of this scenario To be determined'. A 'Delete Scenario >' button is in the top right corner.

As soon as you select a specific hazard, a description of an injury scenario related to the hazard will appear in the following fields: **‘Typical injury scenario’** and **‘Typical injury’**.

Select the **‘User type’** that you wish to include in your risk assessment from the drop-down menu.

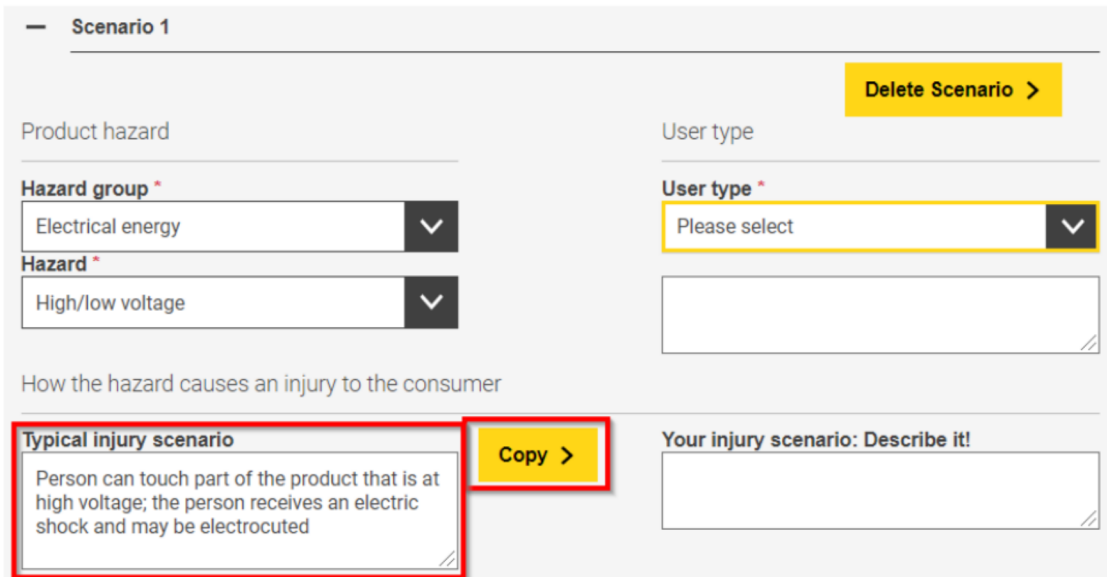


The screenshot shows a form titled "Scenario 1" with a "Delete Scenario >" button in the top right. Under "Product hazard", there are two dropdown menus: "Hazard group \*" with "Electrical energy" selected, and "Hazard \*" with "High/low voltage" selected. Below these is a section "How the hazard causes an injury to the consumer". To the right, the "User type" dropdown menu is open, showing options: "Please select", "Very young children", "Young children", "Older children", "Other consumers", "Vulnerable consumers", and "Very vulnerable consumers". A red box highlights the "User type" label, and a yellow box highlights the dropdown menu.

### How the hazard causes an injury

As mentioned above, the field **‘Typical injury scenario’** will automatically show a standard definition of an injury scenario related to the specific hazard you have selected. If the description in this field is suitable, click on the **‘Copy’** button to insert the same text in the box **‘Your injury scenario’** (as shown in the picture below).

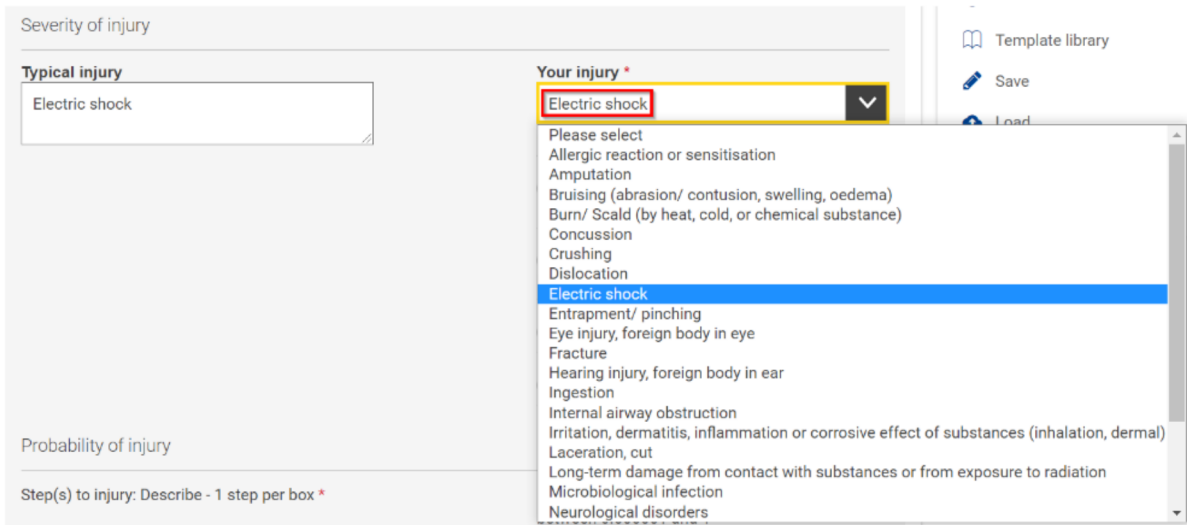
You can then modify the copied text according to your needs or, if necessary, you can formulate your own specific **‘Injury Scenario’** for the product concerned.



The screenshot shows the same "Scenario 1" form. The "User type" dropdown menu is now closed. The "Typical injury scenario" field is highlighted with a red box and contains the text: "Person can touch part of the product that is at high voltage; the person receives an electric shock and may be electrocuted". A yellow "Copy >" button is positioned to the right of this field. The "Your injury scenario: Describe it!" field is empty.

## Severity of injury

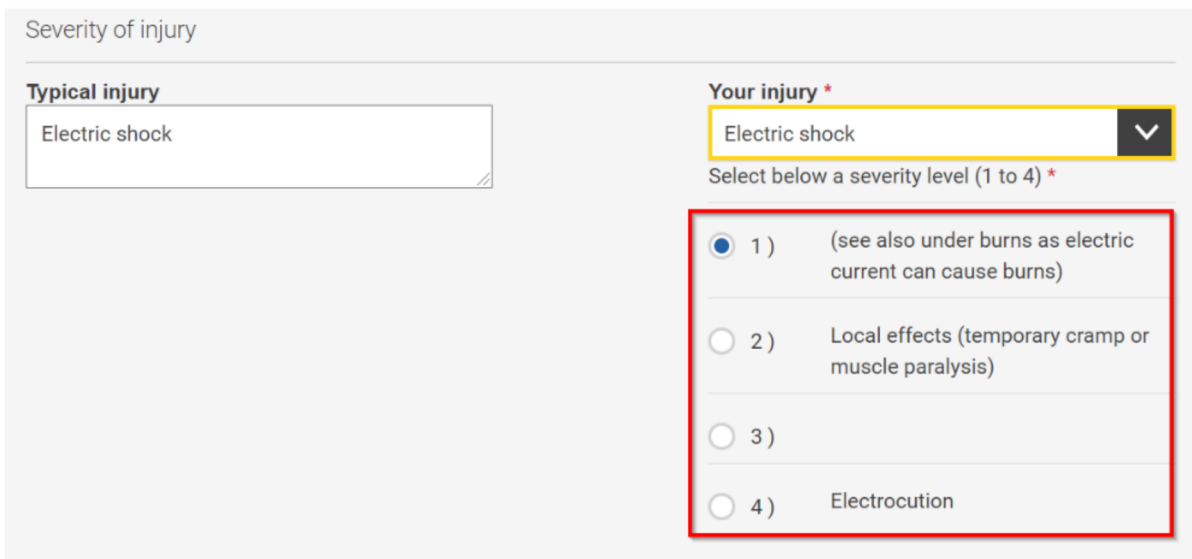
Based on the selection of the hazard and hazard group, the field ‘**Typical injury**’ will be pre-defined (see below). You can accept this pre-defined text or make modifications to it. To identify ‘**Your injury**’, select it from the drop-down menu.



The screenshot shows a web form titled "Severity of injury". On the left, there is a text input field labeled "Typical injury" containing the text "Electric shock". To the right, a dropdown menu labeled "Your injury \*" is open, displaying a list of injury types. The "Electric shock" option is highlighted in blue. Below the dropdown, there is a section labeled "Probability of injury" and a note: "Step(s) to injury: Describe - 1 step per box \*". On the far right, there are buttons for "Template library", "Save", and "Load".

Once you select an injury type, a new section will appear allowing you to select the appropriate level of severity related to the chosen injury and your injury scenario. The severity of injury will also appear within the next section (Probability of injury, at the next page).

The proposed injuries are simply suggestions. The important thing is that you select the correct severity level, because this will be taken into account by the application in order to calculate the level of risk.



The screenshot shows the same "Severity of injury" form. The "Typical injury" field still contains "Electric shock". The "Your injury \*" dropdown is now closed and displays "Electric shock". Below the dropdown, the text "Select below a severity level (1 to 4) \*" is visible. A red box highlights a list of four radio button options: "1) (see also under burns as electric current can cause burns)", "2) Local effects (temporary cramp or muscle paralysis)", "3)", and "4) Electrocutation". The "1)" option is selected.



## Probability of the injury

In the section **‘Probability of injury’**, it is very important to carefully describe each step that leads from the product defect and hazard to the injury, taking into consideration all relevant factors and applying the adequate probability of each step occurring.

Probability of injury

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


Probability: Enter a value between 0.000001 and 1 \*

Chemical leaking	0.2	<a href="#" style="background-color: #ffc107; color: black; padding: 2px 5px; text-decoration: none;">Delete</a>
Risk of burns	0.25	<a href="#" style="background-color: #ffc107; color: black; padding: 2px 5px; text-decoration: none;">Delete</a>

[Add a step](#)

Once you have assigned a probability value to each step, the application will calculate and display the **‘Calculated probability’** (which is the result of the multiplication of the probabilities that you assigned to the different steps of your injury scenario), the **‘Overall probability’** and the **‘Risk of this scenario’** as described in the table below:

**Risk level from the combination of the severity of injury and probability**

Probability of damage during the foreseeable lifetime of the product		Severity of injury			
		1	2	3	4
<div style="display: flex; flex-direction: column; align-items: center;"> <div>High</div>  <div>Low</div> </div>	> 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
	< 1/1 000 000	L	L	L	L

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

Probability of injury

---

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

Probability: Enter a value between 0.000001 and 1 \*

Chemical leaking	0.2	Delete
Risk of burns	0.25	Delete

Add a step

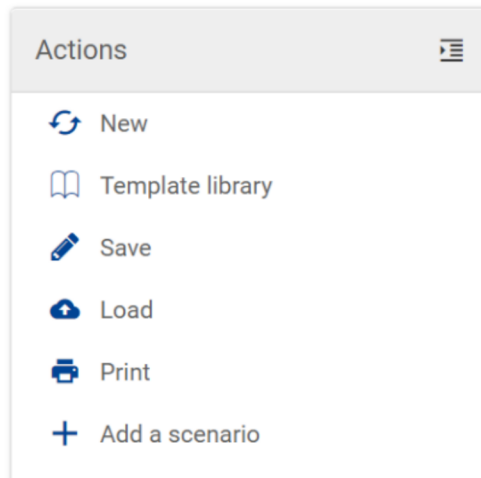
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Severity of injury level 1	Calculated probability 0.05	Overall probability > 1/100	Risk of this scenario Medium risk
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## ACTIONS: New – Load – Save – Print – Help

### New risk assessment

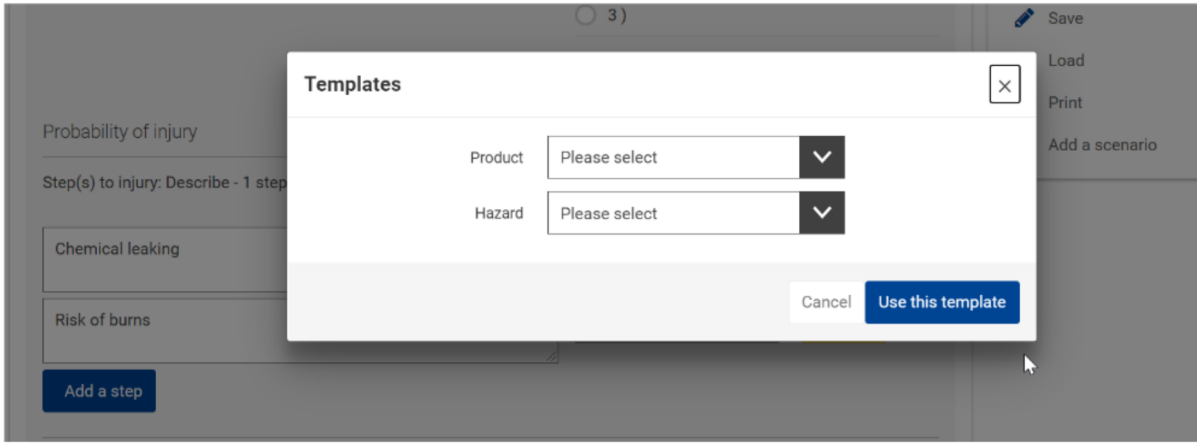
The application also allows you to clear the fields, removing all the data currently on your screen, in order to perform a new risk assessment. You can click on ‘New’ on the menu shown on the right-hand side of the screen:



### Use a template from the library for your risk assessment

Risk assessment templates resulting from the EU coordinated market surveillance activities carried out since 2009 are now available in the template library.

These Joint Actions focus on horizontal and product-specific, cross-border, cooperation activities and include sampling, testing and market surveillance operations. Click on ‘**Template library**’, select the ‘**Product**’ and the ‘**Associated hazard**’ from the drop-down menus and load the template. Check whether the scenario described and the injury level are suitable, and apply the appropriate probabilities to the individual steps. You may add, modify or remove steps if deemed appropriate. Please note that the template is not endorsed in any way.

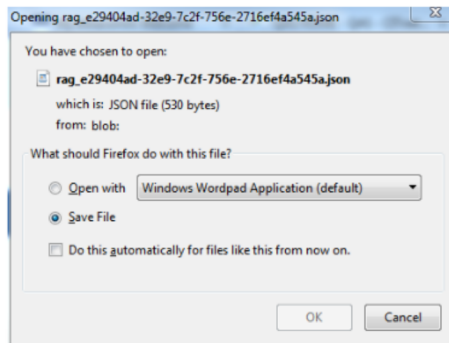


### Save your new risk assessment

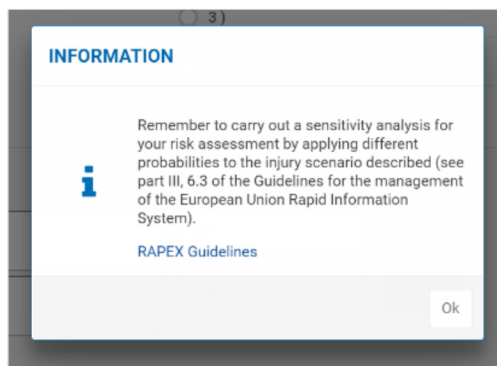
In order to save a copy of a Risk Assessment on your computer, click on **‘Save’**; we advise you to save your data regularly while you are filling in the scenarios to avoid losing any information.

Please note that the application does not keep your data automatically; you can only save your data if you click on the **‘Save’**; button.

The data will be saved in **‘.json’** format, as shown in the image below. You should not worry about opening the file: you just need to save a copy on your computer. This is necessary if you want to re-use the file or the data in the application at a later stage (see section **‘Load risk assessment’** on the next page).



When saving the risk assessment, a pop-up will appear, reminding users of the importance to carry out a sensitivity analysis.



## Load a previous risk assessment

You can upload a risk assessment from a **‘.json’** file that you have previously saved on your computer, as shown in the image below. This can be useful if you have similar scenarios in mind for the assessment of a different product as it prevents you from having to complete the form again. Simply click on **‘Load’** and browse for the relevant file on your PC. The data encoded will automatically appear in the relevant boxes and you can modify it according to your needs.

### Upload file



To load a previous version of an assessment, please use the file selector below.  
File types allowed are .txt or .json.

Choose file

Cancel

Load

## Print your risk assessment

Click on **‘Print’** whenever you need a paper version of the risk assessment or if you need a pdf version for your files or in order to attach the risk assessment to a RAPEX notification.

Please be aware that a pdf file cannot be modified in the application, so we advise you to save your risk assessment in **‘.json’** format as explained in the **‘Save your new risk assessment’** paragraph above.

When printing/downloading a pdf of the risk assessment, a pop-up will appear reminding users of the importance to carry out a sensitivity analysis.

### INFORMATION

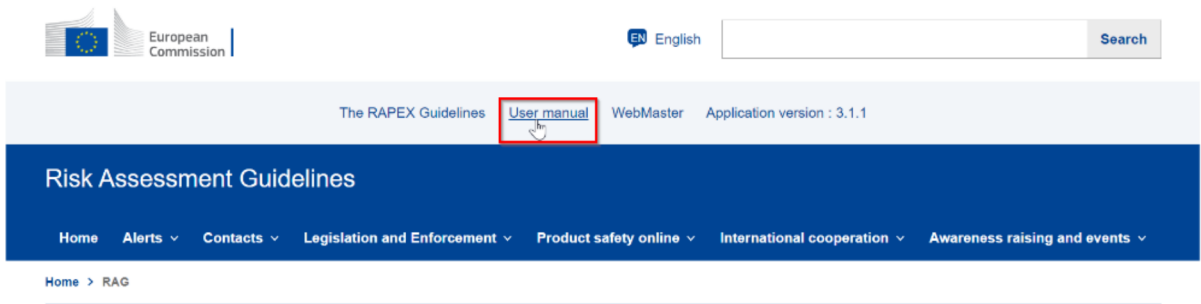


Remember to carry out a sensitivity analysis for your risk assessment by applying different probabilities to the injury scenario described (see part III, 6.3 of the Guidelines for the management of the European Union Rapid Information System).

[RAPEX Guidelines](#)

Ok

A copy of this manual and the **Risk Assessment Guidelines** are available by clicking on the **'User manual'** feature on the homepage.



The screenshot shows the top navigation bar of the European Commission website. On the left is the European Commission logo. On the right, there is a language selector set to 'English' and a search box with a 'Search' button. Below this is a light blue banner with the text 'The RAPEX Guidelines' followed by a red-bordered box containing the text 'User manual' with a mouse cursor pointing to it. To the right of this box are the links 'WebMaster' and 'Application version : 3.1.1'. Below the banner is a dark blue navigation bar with the title 'Risk Assessment Guidelines' and a list of menu items: 'Home', 'Alerts', 'Contacts', 'Legislation and Enforcement', 'Product safety online', 'International cooperation', and 'Awareness raising and events'. At the bottom left of the page, there is a breadcrumb trail: 'Home > RAG'.