Procedure Manual for Integrated GSSMaker

1. Download Integrated GSSMaker and the ECETOC TRA Tool

✧ Download both Integrated GSSMaker and the ECETOC TRA Tool and save them in an appropriate location on your computer.

✧ The versions of Integrated GSSMaker and the ECETOC TRA Tool must match. The file name of Integrated GSSMaker contains the compatibility information for TRA Tool. The file naming rule of Integrated GSSMaker is as explained below.

GSSMaker_3.1en_v1d_2015XXXX.xls

(1) (2) (3)

(1) The version number of the compatible TRA Tool is shown here. In this example, Integrated GSSMaker is compatible with TRA 3.1.
(2) The language of Integrated GSSMaker is shown here. The Japanese version is indicated as "jp" and the English version as "en." In this example, Integrated GSSMaker is a Japanese version.
(3) The version and the release date of Integrated GSSMaker are shown here.

✧ To download the TRA Tool, first open the download URL below and click the "Download Integrated Tool button" at the right side of the screen (indicated with a red circle in the screenshot image below). Then, send the user information to start the download.

✧ For detailed instruction on how to download, please refer to "GPS/JIPS Risk Assessment - Use of ECETOC-TRA-" under "GPS/JIPS Seminar (Practice II)" in the Information Materials page of BIGDr.

[TRA Tool download URL] http://www.ecetoc.org/tra

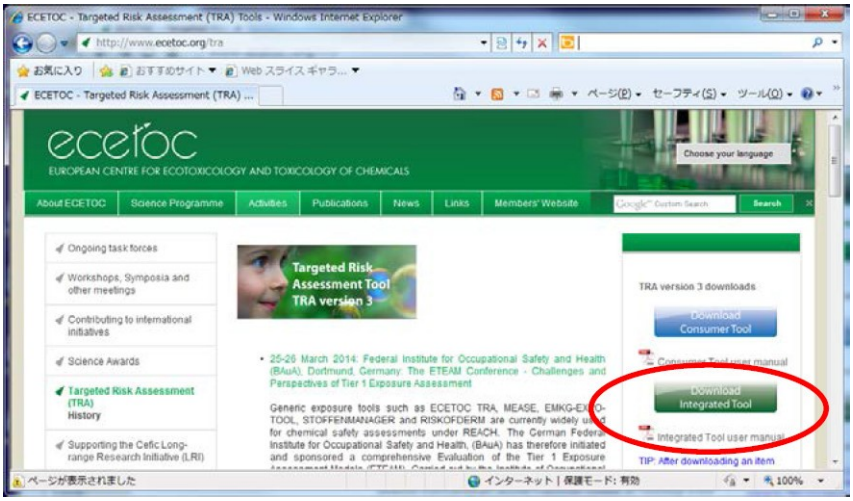


Figure 1: TRA Tool download screen

2. Enter the File Location of the TRA Tool in Integrated GSSMaker

✧ Open Integrated GSSMaker. If a security warning is displayed, click the “Activate the contents” or “Activate macro” button.

✧ Once macro is activated, the following message appears: “Going to website BIGDr To enable linkage to the Help.Are you sure? (If you are already logged in,select "no")(Either do not affect the normal operation.)”

Please select either “Yes” or “No.”

✧ Select the “Configuration” sheet and enter the file location (path) of the TRA Tool. In the example below, the path is “C:\Users\1018795\Documents\GSSMaker\TRAv3.1/”. Please do not forget to put “/” at the end of the path.

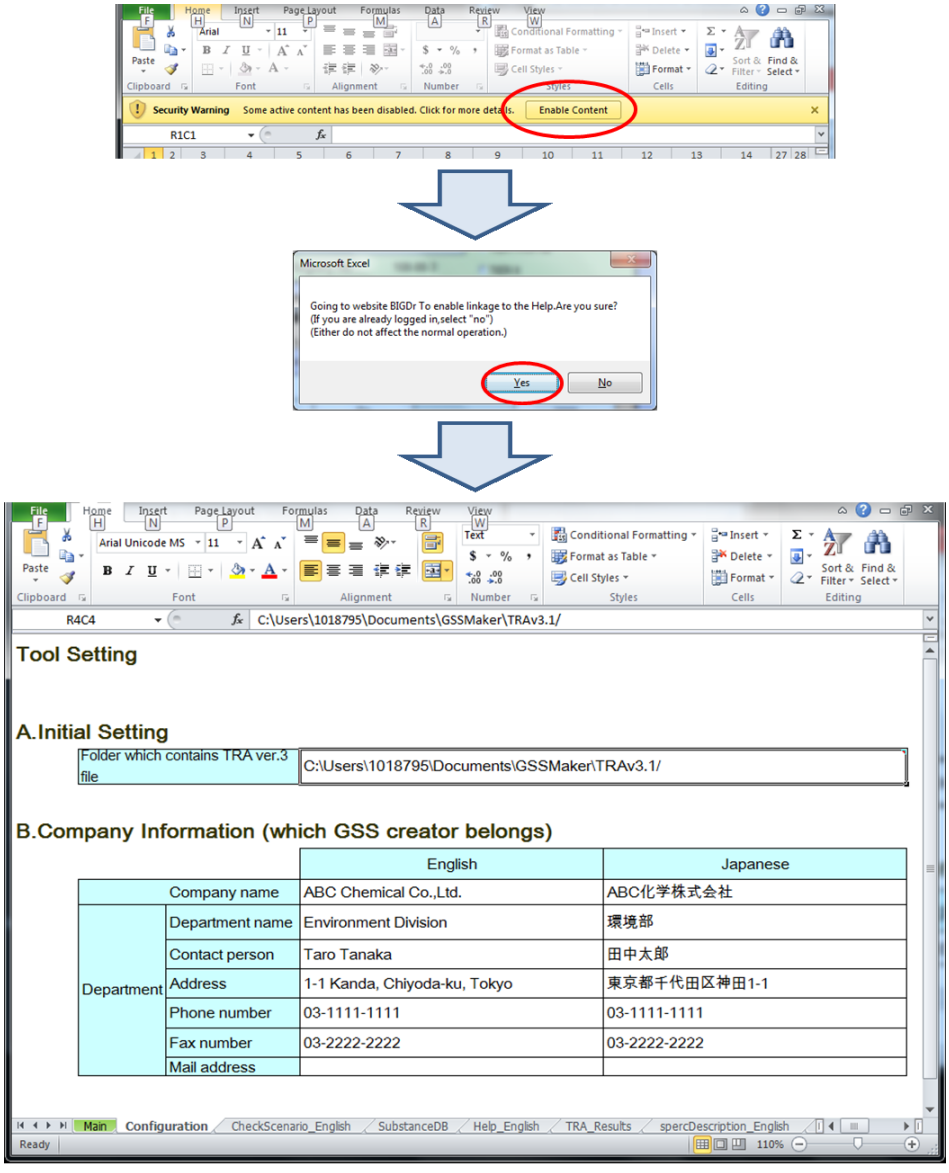


Figure 2: The Configuration sheet of Integrated GSSMaker

3. Run the Tutorials

✧ Integrated GSSMaker is equipped with the tutorial function in the "CheckScenario_English" sheet to help the users learn how to use the program.

✧ The tutorial follows the steps described in the table below. By following these steps, you can go through the general functions of Integrated GSSMaker.

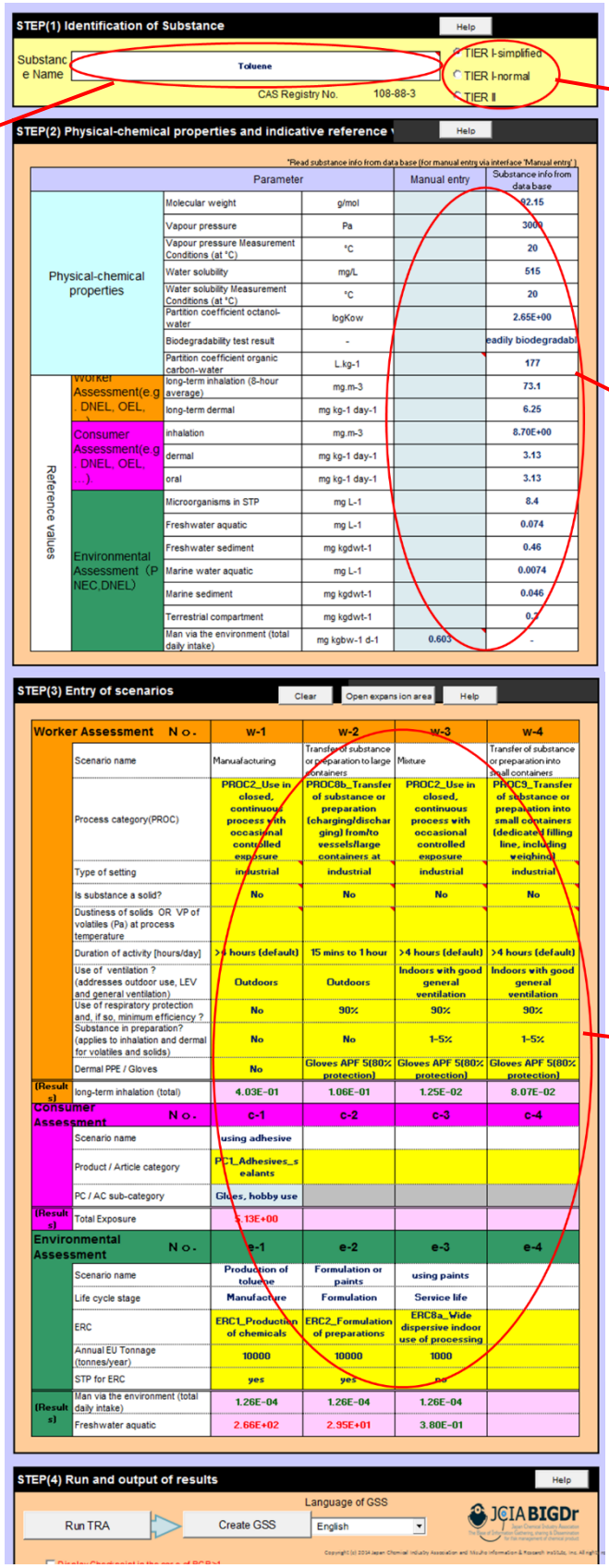
Table 1: The procedure of tutorial

Step	Actions	Notes
1)	Select "toluene" in the Chemical Substance Name field	Toluene is selected as a default. If the default has not been changed, there is no need to select again.
2)	Enter the physiochemical properties and hazard assessment values (hazard reference values)	Enter values directly in the User-specified Values column when specifying the "Human exposure via environment (total daily intake)."
[Calculate using Tier I – <u>simplified mode</u>]		
3)	Select "Tier I – **<u>simplified</u>** mode"	The **<u>simplified</u>** mode is selected as default. If the default has not been changed, there is no need to select again.
4)	Build scenarios	Scenarios are built as default. If the default has not been changed, there is no need to build again.
5)	Click the "Run TRA" button	The calculations take about 30 seconds.
6)	Confirm the results	• Worker scenarios: No. 1 – No. 4 resulted in RCRs < 1 → Risk is controlled • Consumer scenarios: No. 1 resulted in RCR ≥ 1 → Risk is of concern (need refinement) • Environmental scenarios: No. 1 – No. 2 resulted in RCRs ≥ 1 → Need refinement No. 3 resulted in an RCR < 1 → Risk is controlled
7)	A GSS cannot be created	Integrated GSSMaker is designed so that a GSS cannot be created if any scenario has RCR ≥ 1.
[Calculate using the Tier I – <u>normal mode</u>] (Refine the scenarios that resulted in RCR > 1 using the Specific Environmental Release Categories (SPERCs) provided by CEFIC, instead of the environmental release categories (ERCs))		
8)	Select the Tier I – normal mode	Confirm that the Tier I – normal mode is check-marked.
9)	Add a mixing rate to consumer scenario No. 1. Select SPERCs for environmental scenarios.	Change the sections indicated with a red circle in the Confirmation scenario. (Refer to the "CheckScenario_English" sheet.)
10)	Click the "Run TRA" button	The calculations take about 30 seconds.
11)	Confirm the results	• Consumer scenarios: No. 1 resulted in RCR < 1 → Risk is controlled • Environmental scenarios: No. 1 resulted in RCR ≥ 1 → Risk is of concern (needs refinement) No. 2 resulted in RCR < 1 → Risk is controlled
12)	A GSS cannot be created	-
[Calculate with the Tier II mode] (Refine the scenarios that resulted in RCR > 1 using the actual amounts of releases, such as a PRTR release amount, instead of using the emission factors set up for the ERCs and SPERCs.)		
13)	Select the Tier II mode	Confirm that the Tier II Mode is check-marked.
14)	Add an amount of release to environmental scenario No. 1	Change the section indicated with a red circle in the Confirmation Scenario. (Refer to the "CheckScenario_English" sheet.)
15)	Click the "Run TRA" button	The calculations take about 2-3 minutes.
16)	Confirm the results	Environmental scenario: No. 1 resulted in RCR < 1 → Risk is controlled
17)	Click the Create GSS button → A GSS sheet is created	The created GSS will be overwritten the next time you click the button. If you wish to save the GSS, move or copy the sheet and save it as a different file.

4. Enter the Calculation Mode, Name and Information of the Chemical Substance, and Build Scenarios

✧ Enter the name and information of a chemical substance and build scenarios in the Main sheet.

(1) Enter substance name. If the substance of interest is available in the chemical DB, select the substance name from the pull-down list.



(2) Select calculation mode. Please refer to the other sheet for the details of each mode. (Select Tier I if you just wish to try the calculations. Select Tier II if you wish to set up the parameters in detail.)

(3) Enter physicochemical properties and hazard information of the substance to be evaluated.
If the substance is selected from the pull-down list mentioned in (1), the stored information for the substance (default values) appears automatically. If you wish to use different values, enter them manually in the User-specified values column on the left. (Enter the values for only the parameters you wish to specify.)

(4) Select and build the use scenarios for the substance from the pull-down list. Four scenarios are built as default. Delete the ones that are unnecessary. If you wish to add more than five scenarios, click the "Open expansion area" button to build a maximum of ten scenarios.

Figure 3: The "Main" sheet of Integrated GSSMaker

✧ When the “Tier I - normal mode” is selected as the calculation mode, SPERC codes can be selected as parameters for environmental exposure assessment. To see the descriptions of the codes, right click the SPERC code selection cell and choose “GSSMaker: Show Description” from the menu displayed. The list of selectable codes and their descriptions is opened in a different sheet. Select the applicable code on the main sheet after confirming the list.

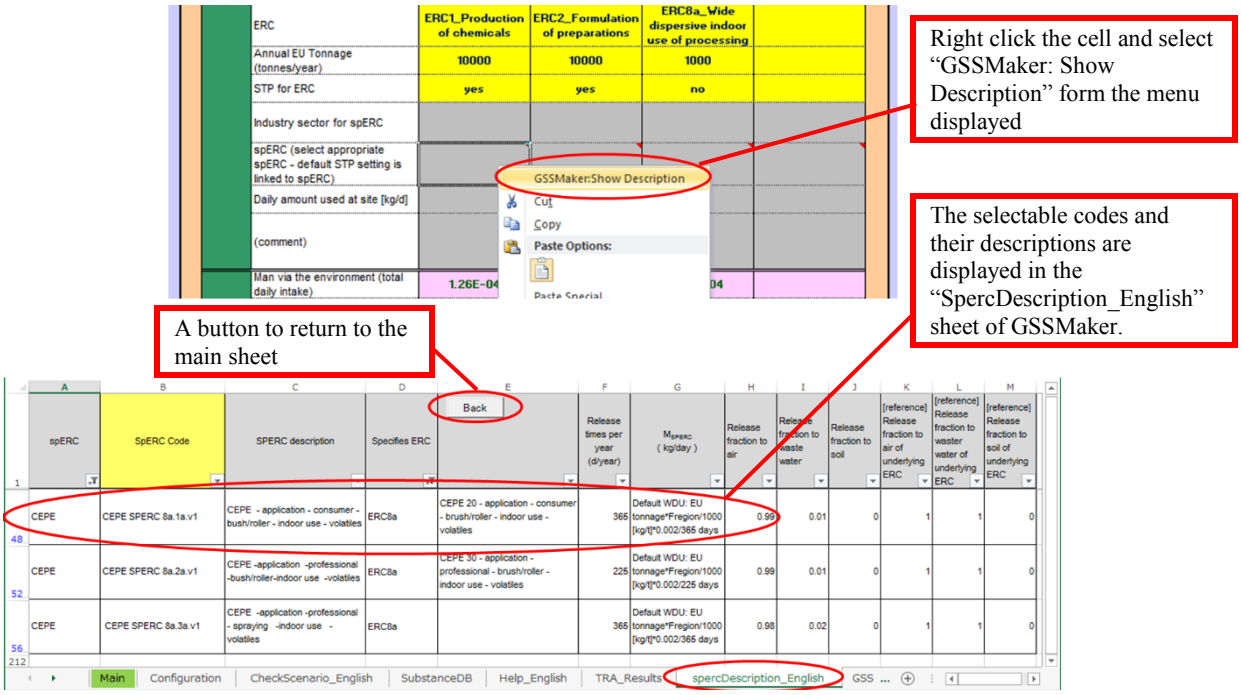
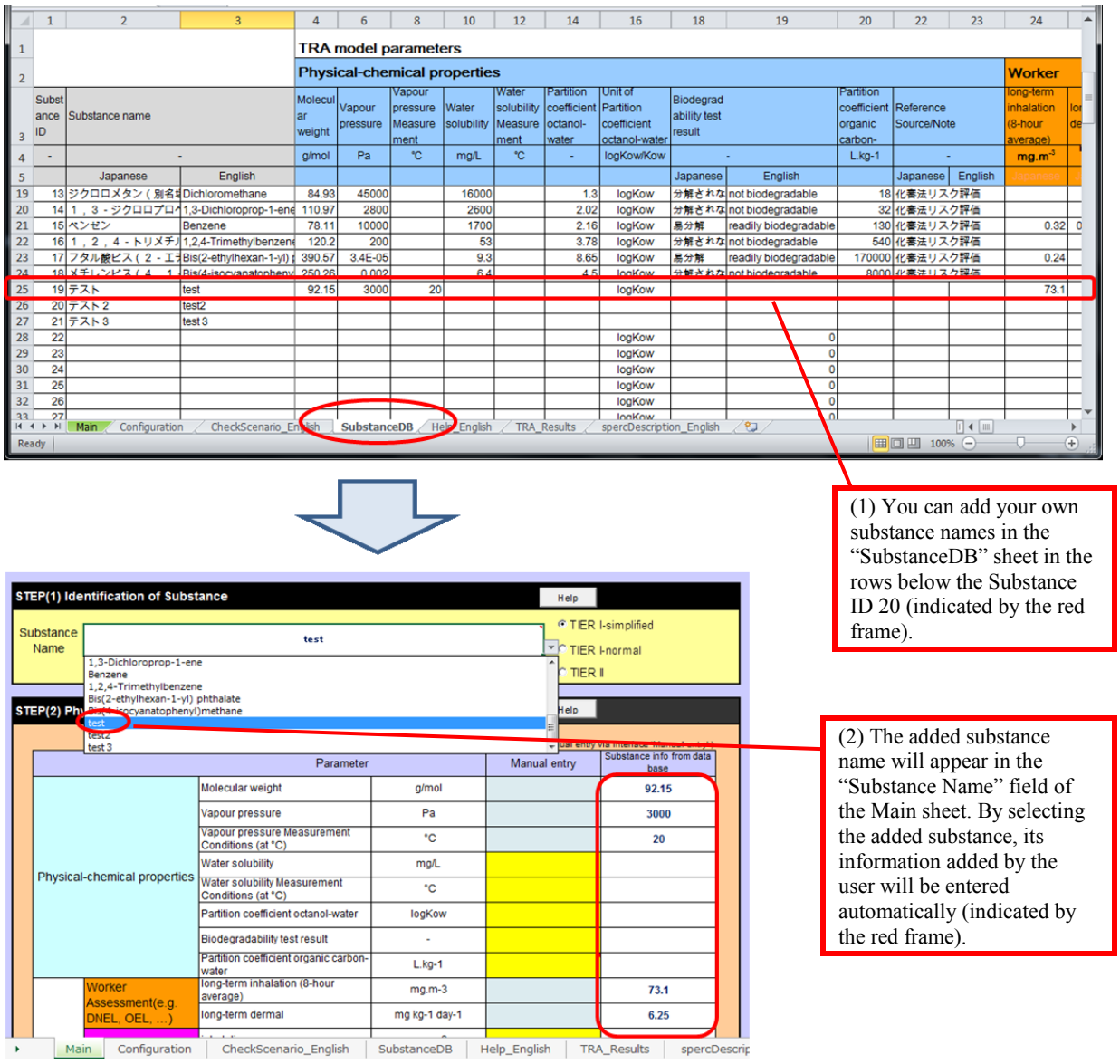


Figure 4: Refer to the code descriptions when selecting the SPERC codes (Only for Tier I - normal mode)

✧ Information of the substances that can be selected in the “Substance Name” field of the “Main” sheet is available in the “SubstanceDB” sheet.

✧ You can add and save your own substance names, physiochemical properties, and hazard information in the rows below the Substance ID 20. By selecting an added substance name which appears in the “Substance Name” field of the “Main” sheet, the information added by the user will be entered automatically.



(1) You can add your own substance names in the "SubstanceDB" sheet in the rows below the Substance ID 20 (indicated by the red frame).

(2) The added substance name will appear in the "Substance Name" field of the Main sheet. By selecting the added substance, its information added by the user will be entered automatically (indicated by the red frame).

Figure 5: How to save a new substance to the "SubstanceDB"

5. Perform the TRA Calculations and Confirm the Results

(1) Perform the TRA calculations

✧ After entering all the necessary information, press the “Run TRA” button. The TRA tool is launched and the calculations will be performed.

Figure 6: The Run TRA button on the “Main” sheet of Integrated GSSMaker

*How to stop the message about link updates

A message stating “**This workbook contains links to other data sources. If you update the links, Excel attempts to retrieve the latest data. If you don't update, Excel uses the previous information**” may appear by clicking the “Run TRA” button. This message appears when you open a workbook that contains links to the other workbooks.
To prevent this message from appearing, please follow the steps below. Once you configure this setting, the message will not reappear.

(1) Display a configuration file of the TRA Tool titled “ecetocTRAM.xls.”
(2) From the Excel menu, select “Data → Edit Links” to open the Edit Links dialog box.
(3) Click the “Startup Prompt” button to open the Startup Prompt dialog. Select “Don’t display the alert and don’t update automatic links.”
(4) Save the ecetocTRAM.xls file. (Saving other configuration files for the TRA Tool is not necessary.)

(2) Confirmation and evaluation of the results

✧ Once the calculations are completed, the risk characterization ratios (RCRs) are updated.
✧ The RCRs are displayed in blue when RCR < 1 and in red when RCR ≥ 1. For the scenarios that resulted in RCR ≥ 1, refine the scenario buildings. (GSSMaker is designed so that a GSS cannot be created if any scenario has RCR ≥ 1.)

* The image below shows the results of an assessment performed by the ECETOC TRA 3.1. The results vary depending on the version of a TRA.

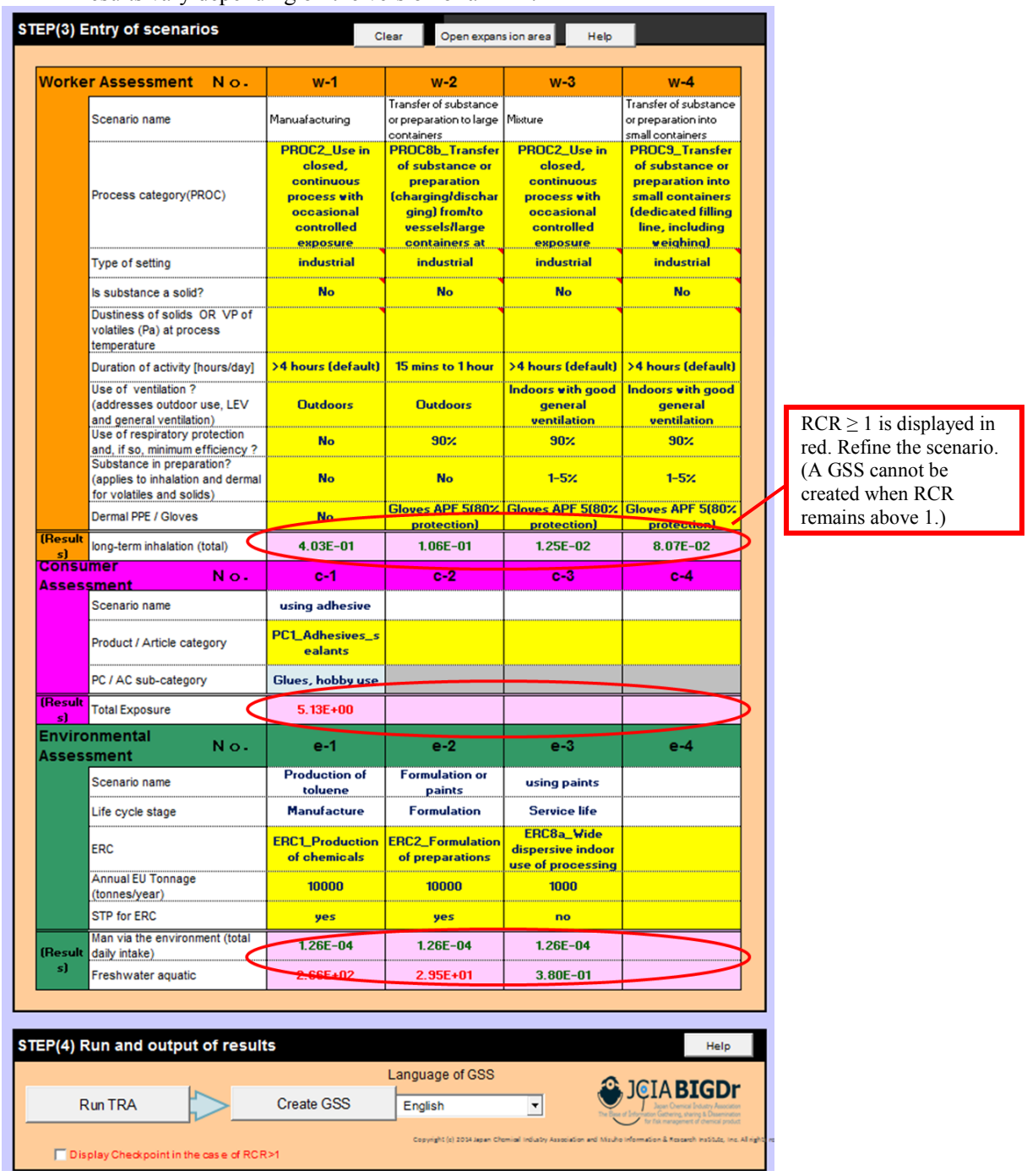


Figure 7: The results of an assessment performed by the ECETOC TRA 3.1.

✧ When RCRs exceed 1, display and refer to the “Checkpoint” for considering how to deal with the results. Choose “Display the Checkpoint when an RCR > 1” to show the points in popup balloons.

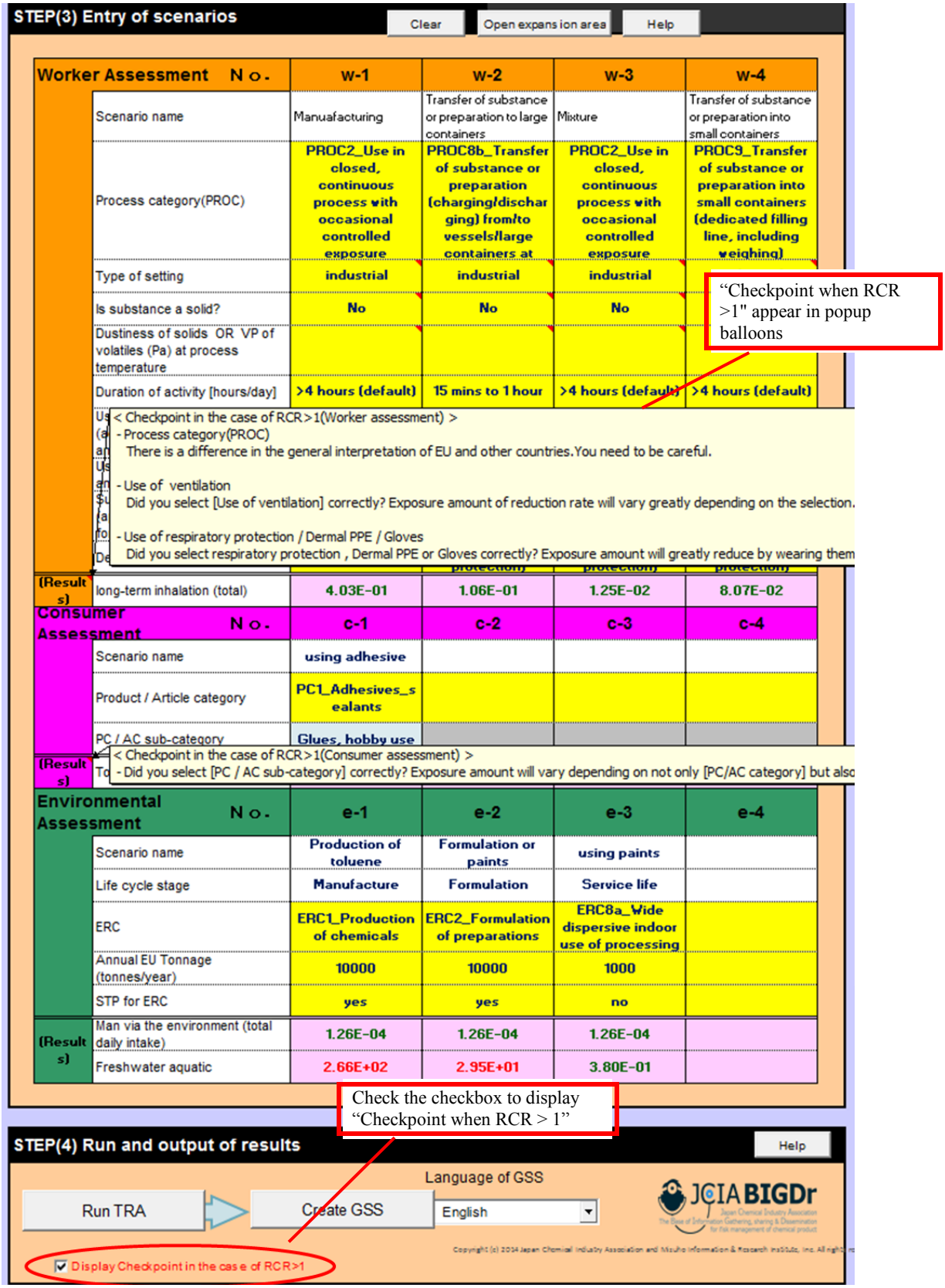


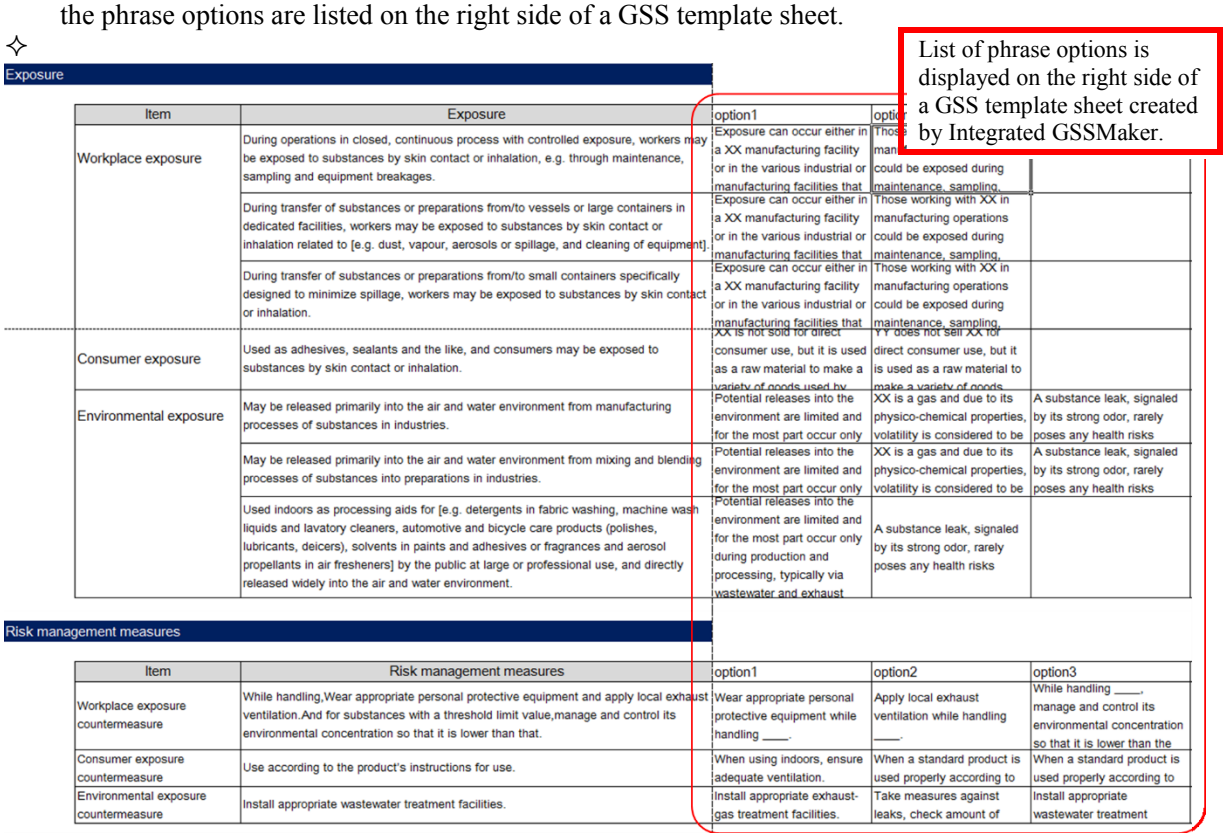
Figure 8: Display of the Checkpoint when RCR > 1

6. Create and Save a GPS Safety Summary (GSS)

✧ After the TRA calculations, confirm that all RCRs are below 1. Then, click the "Create GSS" button to create a GPS Safety Summary (GSS). A GSS is created automatically. (Diagram 10)

✧ A "GSS" sheet appears once the GSS is completed. The contents of the GSS can be edited. Edit and/or correct the contents as necessary. In the "Exposure" and the "Risk Management Measures" sections, the phrase options are listed on the right side of a GSS template sheet.

✧



List of phrase options is displayed on the right side of a GSS template sheet created by Integrated GSSMaker.

Exposure

Item	Exposure	option1	option2	option3
Workplace exposure	During operations in closed, continuous process with controlled exposure, workers may be exposed to substances by skin contact or inhalation, e.g. through maintenance, sampling and equipment breakages.	Exposure can occur either in a XX manufacturing facility or in the various industrial or manufacturing facilities that	Those wor... could be exposed during maintenance, sampling,	
	During transfer of substances or preparations from/to vessels or large containers in dedicated facilities, workers may be exposed to substances by skin contact or inhalation related to [e.g. dust, vapour, aerosols or spillage, and cleaning of equipment].	Exposure can occur either in a XX manufacturing facility or in the various industrial or manufacturing facilities that	Those working with XX in manufacturing operations could be exposed during maintenance, sampling,	
	During transfer of substances or preparations from/to small containers specifically designed to minimize spillage, workers may be exposed to substances by skin contact or inhalation.	Exposure can occur either in a XX manufacturing facility or in the various industrial or manufacturing facilities that	Those working with XX in manufacturing operations could be exposed during maintenance, sampling,	
Consumer exposure	Used as adhesives, sealants and the like, and consumers may be exposed to substances by skin contact or inhalation.	XX is not sold for direct consumer use, but it is used as a raw material to make a variety of goods used by	YY does not sell XX for direct consumer use, but it is used as a raw material to make a variety of goods	
Environmental exposure	May be released primarily into the air and water environment from manufacturing processes of substances in industries.	Potential releases into the environment are limited and for the most part occur only	XX is a gas and due to its physico-chemical properties, volatility is considered to be	A substance leak, signaled by its strong odor, rarely poses any health risks
	May be released primarily into the air and water environment from mixing and blending processes of substances into preparations in industries.	Potential releases into the environment are limited and for the most part occur only	XX is a gas and due to its physico-chemical properties, volatility is considered to be	A substance leak, signaled by its strong odor, rarely poses any health risks
	Used indoors as processing aids for [e.g. detergents in fabric washing, machine wash liquids and lavatory cleaners, automotive and bicycle care products (polishes, lubricants, deicers), solvents in paints and adhesives or fragrances and aerosol propellants in air fresheners] by the public at large or professional use, and directly released widely into the air and water environment.	Potential releases into the environment are limited and for the most part occur only during production and processing, typically via wastewater and exhaust	A substance leak, signaled by its strong odor, rarely poses any health risks	

Risk management measures

Item	Risk management measures	option1	option2	option3
Workplace exposure countermeasure	While handling,Wear appropriate personal protective equipment and apply local exhaust ventilation.And for substances with a threshold limit value,manage and control its environmental concentration so that it is lower than that.	Wear appropriate personal protective equipment while handling ____.	Apply local exhaust ventilation while handling ____.	While handling ____, manage and control its environmental concentration so that it is lower than the
Consumer exposure countermeasure	Use according to the product's instructions for use.	When using indoors, ensure adequate ventilation.	When a standard product is used properly according to	When a standard product is used properly according to
Environmental exposure countermeasure	Install appropriate wastewater treatment facilities.	Install appropriate exhaust-gas treatment facilities.	Take measures against leaks, check amount of	Install appropriate wastewater treatment

Figure 9: List of phrase options on GSS sheet

✧ The GSS and "TRA_Results" sheets will be overwritten. If you wish to keep the created contents, copy the sheets and save them as a different file. (Figure 11, 12)

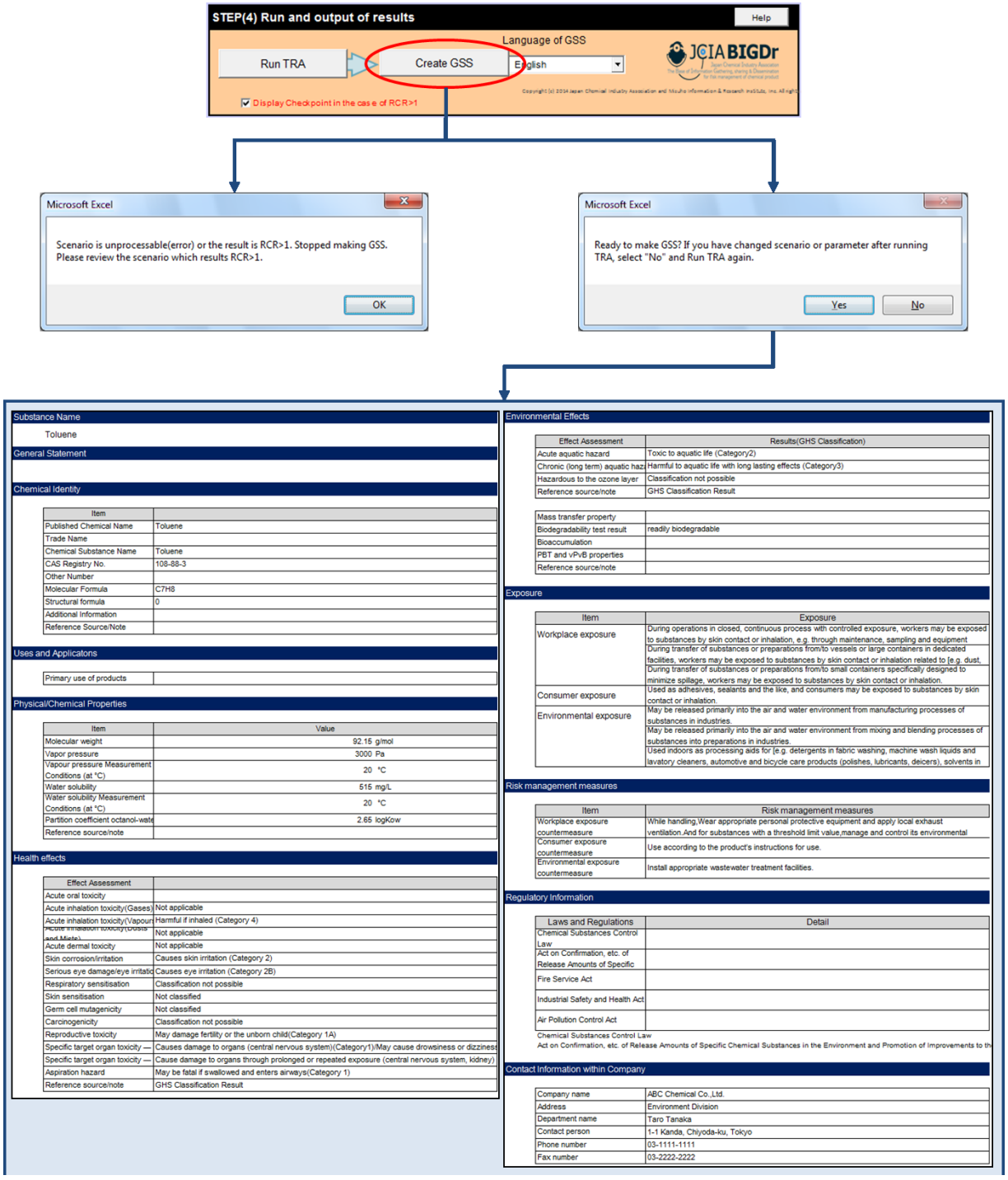
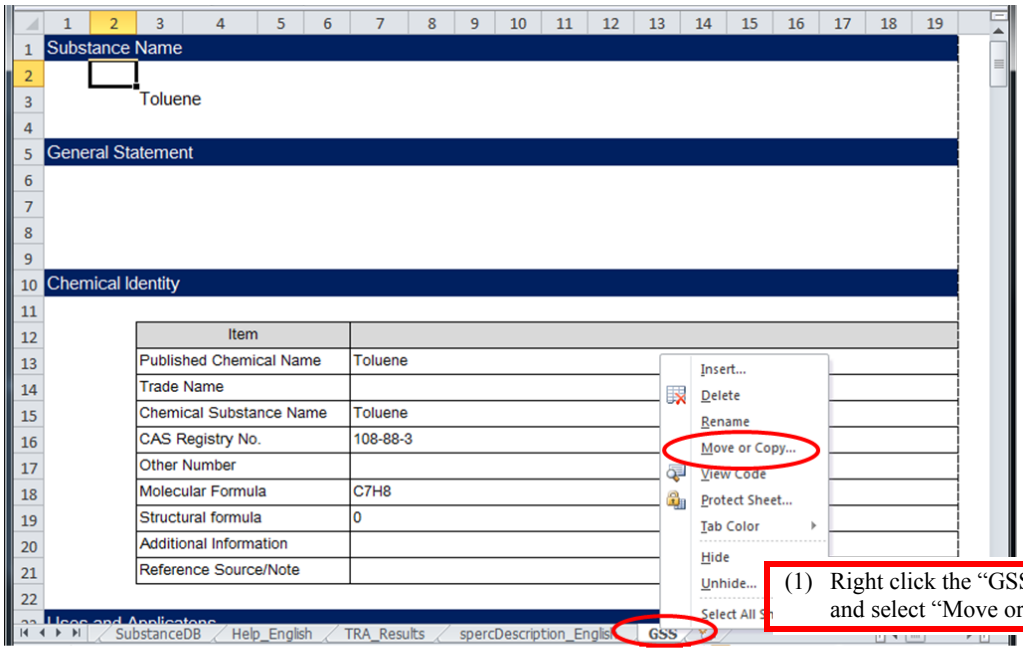
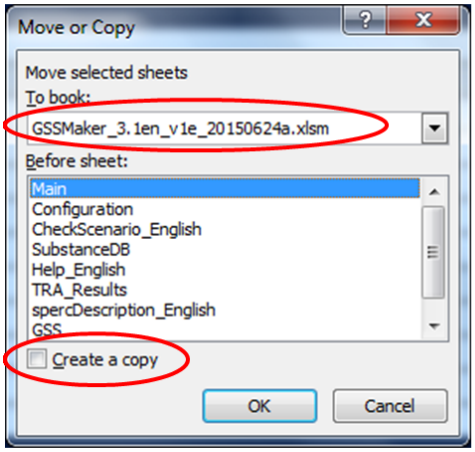


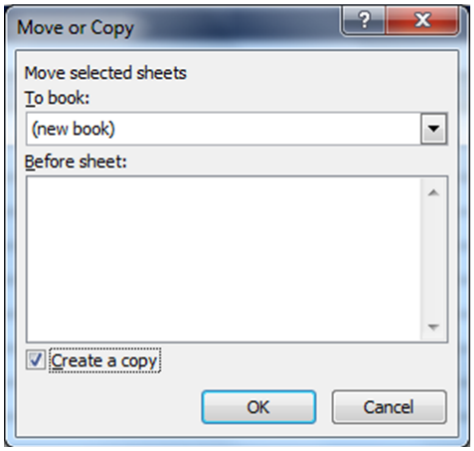
Figure 10: GSS Creation Process of Integrated GSSMaker



(1) Right click the "GSS" sheet tab and select "Move or Copy".



(2) Choose (new book) from the "To book" drop-down list. In addition, check the "Create a copy" checkbox at the bottom.



(3) After (2), it should look like the image on the left. Click "OK" to copy the GSS sheet into a new Excel file. Name and save the file to complete the saving process of a GSS.

Figure 11: How to copy a GSS sheet to another file.

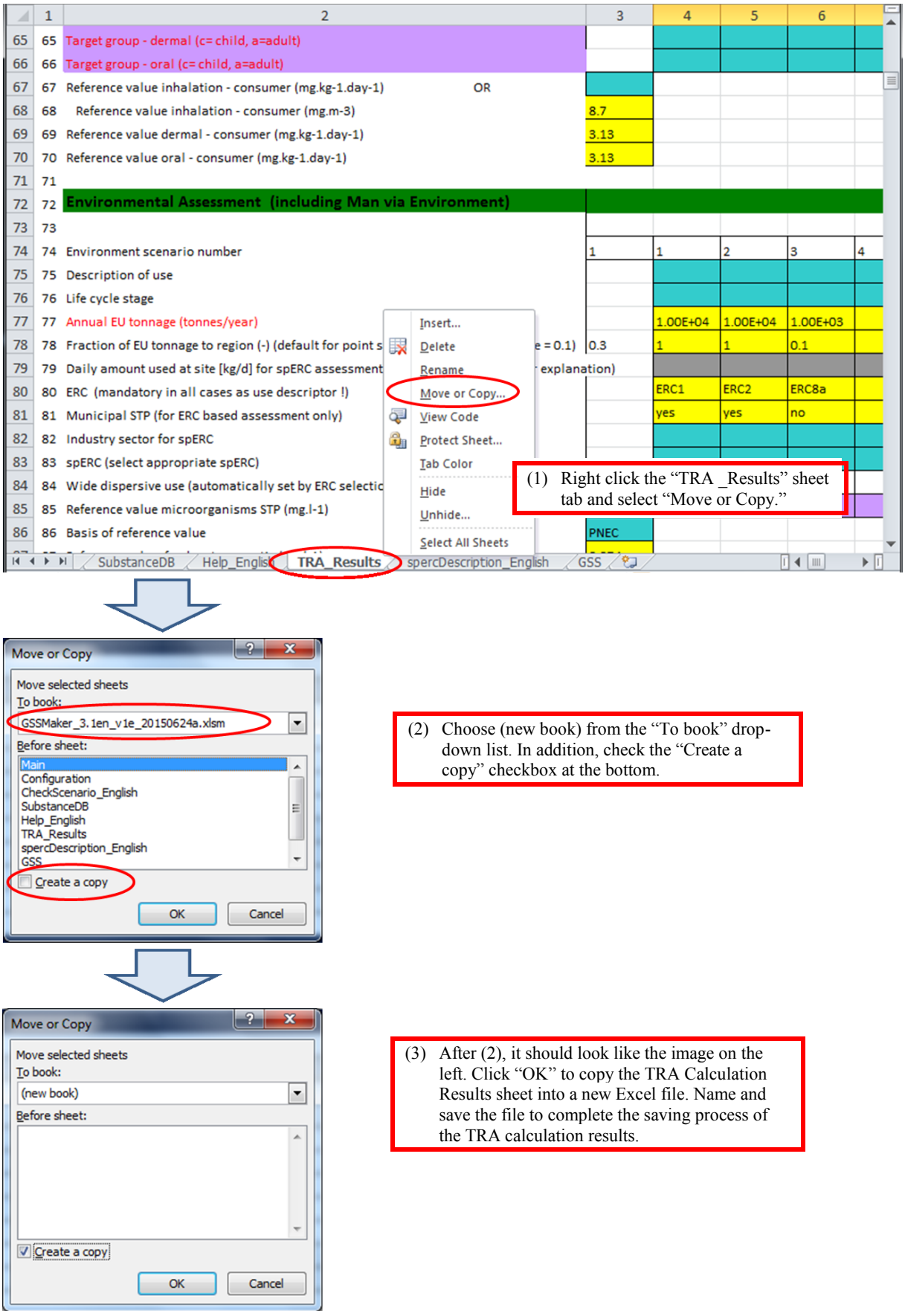


Figure 12: How to copy the "TRA_Results" sheet to another file.

The language of a GSS (Japanese or English) can be selected with the English version of Integrated GSSMaker. Choose a language for a GSS and click Create GSS. A GSS will be created in the selected language.