

RAFT version 1.0

Risk Assessment Formulation Tool

User Guide

DRAFT

Contents

List of Figures.....	2
1. Overview of the RAFT	3
2. Getting started.....	3
3. Using the RAFT.....	4
3.1 Source	4
3.2 Exposed Media	5
3.3 Exposure Route.....	6
3.4 Receptor	6
3.5 Adding Vertical Connectors	6
3.5 Finishing the model	7
4. Working with your conceptual model	7

List of Figures

Figure 1. Example of an environmental risk assessment problem formulation conceptual model produced using the RAFT.....	3
Figure 2. Screenshot of the Source input form.....	5
Figure 3. Exposed Media form.....	6
Figure 4. Screenshot of the RAFT, including the Environmental Receptor input form.	7

1. Overview of the RAFT

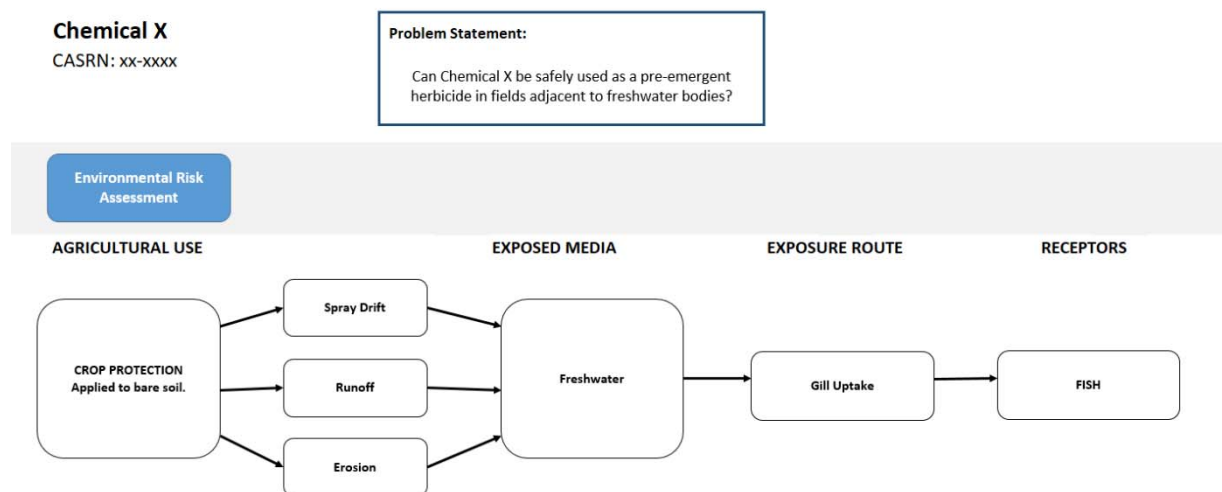
The problem formulation step of a human health or environmental risk assessment seeks to define the scope of the assessment in order to best determine the data, tools and procedures required to complete the evaluation. One outcome of this step is a conceptual model that summarizes the connections between sources or stressors, exposure pathways, human or ecological receptors and toxicological or other risk endpoints.

RISK21[®] is an initiative developed by the Health and Environmental Sciences Institute (HESI) to address a need for a cohesive, efficient, and transparent risk assessment methodology. The Risk Assessment Formulation Tool (RAFT) was developed to help streamline the problem formulation step in the RISK21[®] framework by providing a fill-in-the-blanks template for a diagrammatic conceptual model and guidance in choosing its contents.

2. Getting started

The RAFT is a Microsoft Excel[®]-based tool that can be used to produce Human Health Risk Assessment (HRA) or Environmental Risk Assessment (ERA) conceptual models. The conceptual model is in the form of a horizontal flow chart that describes the exposure process from source (or stressor) to receptor of concern. Figure 1 is an example of such a model. In this scenario, the hypothetical chemical is applied to a bare field (source/stressor). The chemical is not volatile, but is water soluble, and is transported to freshwater (exposed medium) via runoff, erosion and leaching. There it is taken up by gill respiration (exposure route/mechanism) by small fish (receptor).

Figure 1. Example of an environmental risk assessment problem formulation conceptual model produced using the RAFT.



Defining an exposure problem may not be as straightforward. A single stressor may result in several pathways that lead to contamination of multiple media, not all of which may be relevant to the human or ecological receptors of interest. An HRA conceptual model addressing the same hypothetical chemical will be different for a farmer spraying the field, a homeowner with a neighboring well, or a consumer of the crop grown on the field. Different models for each receptor can be produced, or for each stressor, or in some cases they can all be included in the same chart.

The RAFT includes some suggestions for content depending on the risk assessment type. It will guide you step-by-step to create a box-and-arrow type chart on a worksheet. This chart can be saved to a different worksheet by clicking the “Save” command button, after which it can be modified in any way in the current workbook or copied to whatever compatible spreadsheet, presentation, or word processing program desired.

This version of the tool does not allow individual boxes or arrows to be deleted in the production stage (i.e. in the “RAFT” worksheet), but will allow the last five steps to be undone by clicking the “Undo” button. At any time you may click the Restart command button to clear the chart and start again, or delete the boxes and arrows after it is saved to another worksheet.

3. Using the RAFT

The first step in creating your conceptual model will be to click “Start”. A form will appear asking you to enter the chemical name and CAS registry number, as well as a brief (200 characters or less) problem statement. The problem statement should aim to be a concise and complete description of the problem. In the example provided, the problem statement is in the form of a question: “Can Chemical X be safely used as a pre-emergent herbicide in fields adjacent to freshwater bodies?”

When you have filled out the form, click OK and the chemical name, CAS number and problem statement will appear on the worksheet, along with a blue button that reads “Click to choose a risk assessment type”. The problem statement may be modified anytime by clicking the text below “Problem Statement” once.

Choose a risk assessment type by clicking on the blue button. The RA Type form includes a drop-down list of suggestions. Risk assessments fall into two categories: Human Health or Environmental. You may choose to specify a sector or context (e.g., agricultural use, consumer use, etc.) by choosing from the options listed or by clicking “Other...” and adding another category. Any additions will be saved to the model for future applications.

3.1 Source

What activities cause the release of chemical to the environment? What products contain the chemical, and how are they used? The source (sometimes called “stressor”) describes the introduction of chemical to an ecosystem, or a workplace, or home environment, etc. Sources can be chosen from the provided list or entered.

After a source has been added, clicking on its textbox in the chart will allow you to edit the source text. A new text box labelled “Click here to add a source description” will appear that can be used to add another source or stressor.

Figure 2. Screenshot of the Source input form.

Sources/Uses

Specify the source of the exposure by describing the activity or activities responsible. You can choose from the drop-down list provided or enter your own. Additional details can be entered in the text box and will be included in the chart. Choose "OK" to save the entered values to the chart or close this form to discard changes and return to the chart.

Crop Protection

Enter Details (optional)

Applied to a bare field.

Example

Personal Care

Ingredient in soap, shampoo, body wash.

OK

3.2 Exposed Media

After at least one Source has been described, a new box will appear under the "Exposed Media" heading. Clicking it will launch a form in which a description of an exposed medium can be entered. In this case "medium" refers to an environmental, food, or human compartment (e.g., soil, cow milk, or skin) that is contaminated as a result of the activity or activities described in the "Sources" part of the conceptual model, or it can mean the the phase of the chemical itself (e.g., neat chemical in the liquid phase). This contamination can occur as a result of direct exposure (e.g, a spill into surface water) or by way of some intermediate mechanism or process (e.g., surface water contamination via runoff after application to field) which can also be defined at this stage.

After the exposed medium has been entered, clicking on its textbox will allow you two options:

1. Edit the medium text, or
2. Add an exposure pathway to that medium.

In this version of the RAFT, exposure pathways can be undone using the "Undo" button, but cannot be edited in any other way.

Figure 3. Exposed Media form.

Exposed Media

Source: Crop Protection - Applied to a bare field.

Exposed Medium: Please choose a Medium that is contaminated as a result of the selected "Source". You can choose from the drop-down list provided or enter your own.

Freshwater

Exposure Pathway (optional): Media can be exposed either directly as a result of the selected "Source" activity or indirectly by way of intermediate processes (e.g., volatilization, leaching, etc.). If you wish to add a pathway please choose from the list below, or enter your own.

Leaching

OK

3.3 Exposure Route

The Exposure Route describes, in one or two steps, how the chemical of concern is taken up by the receptors of concern from the exposed media or directly from the source. Exposure routes can be edited and pathways added much the same way as for the exposed media.

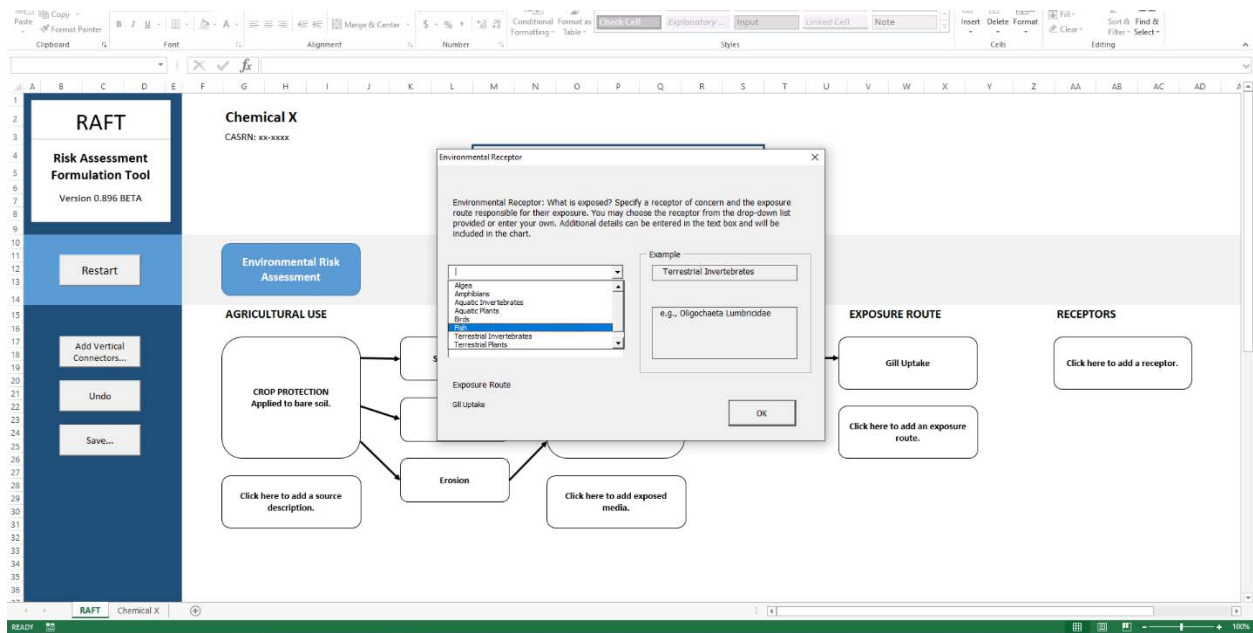
3.4 Receptor

This category includes all human (for HRA) or ecological (for ERA) receptors that are exposed to the chemical via the entered exposure routes. Inputting and editing the receptors is accomplished similarly to the sources, and pathways can be added the same as for exposure routes and exposed media.

3.5 Adding Vertical Connectors

Clicking the "Add Vertical Connectors..." button will launch a form from which you can choose the starting and end points of a vertical connector. You can choose these connection points from a list of existing boxes or you can add a new box by choosing the appropriate entry in the drop-down list (e.g., "New Source").

Figure 4. Screenshot of the RAFT, including the Environmental Receptor input form.



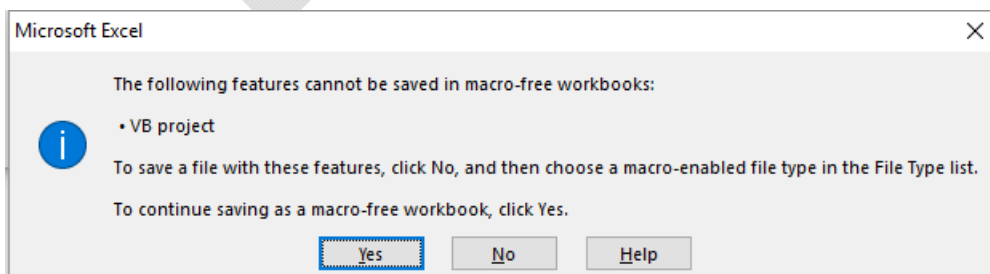
3.5 Finishing the model

Clicking the “Excel Worksheet” command button will produce a “finished” version of the conceptual model in a new worksheet in the RAFT workbook. All boxes labelled “Click here...” will be removed, as will the command buttons. This worksheet is not password-protected, so it can be edited however you like. The worksheet is automatically saved, and if you go back to the main “RAFT” worksheet and click “Restart”, no information from the saved conceptual model will be altered.

4. Working with your conceptual model

Here are some tips for working with your conceptual model after it has been saved to another worksheet:

1. Move boxes, not connectors: The arrows in chart are attached to connection points on the boxes, and will stay connected as the boxes are clicked and dragged around the chart.
2. If you decide to move or copy the worksheet to another workbook and then save it as macro-free (.xlsx) file, this message box may appear:



It can safely be ignored, and you can click Yes.

3. Excel does not do connector line jumps. To show that connectors that cross each other are not themselves connected, right click on a connector and choose Outline > Dashes from the menu that pops up. Choose a dash style that differentiates it from a crossing connector.
4. There are three connector types available in Excel: Straight, Curve, and Elbow. Working with different connector types can add to the readability of the conceptual model. Right click on a connector to change the connector types. This will not result in the arrow becoming disconnected from its boxes.

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