RISK ASSESSMENT – GUIDE

1. Introduction

Risk Assessment is a term used to describe the process of identification of the risk factors that have potential to cause harm (hazard identification) and analysis/evaluation of the risk (risk analysis). If the hazard cannot be eliminated, in the last step of a Risk Assessment (risk control) is the last step of a risk assessment and its purpose is to determine appropriate ways to control the risk (following general principles of occupational hygiene).

There might be several reasons why a risk assessment is needed. Common reasons include safety concerns regarding the use of a hazardous product (or combination of products) or required as part of a permit validation process. Risk Management Services (RMS) can assist with the risk analysis and risk control steps of the assessment as long as details about the project are provided.

An overview of the Risk Assessment process is depicted in Figure 1 below. The purpose of the Risk Assessment Guide is to give you information on the individual steps of the assessment and how to submit the right information in order to expedite the process.

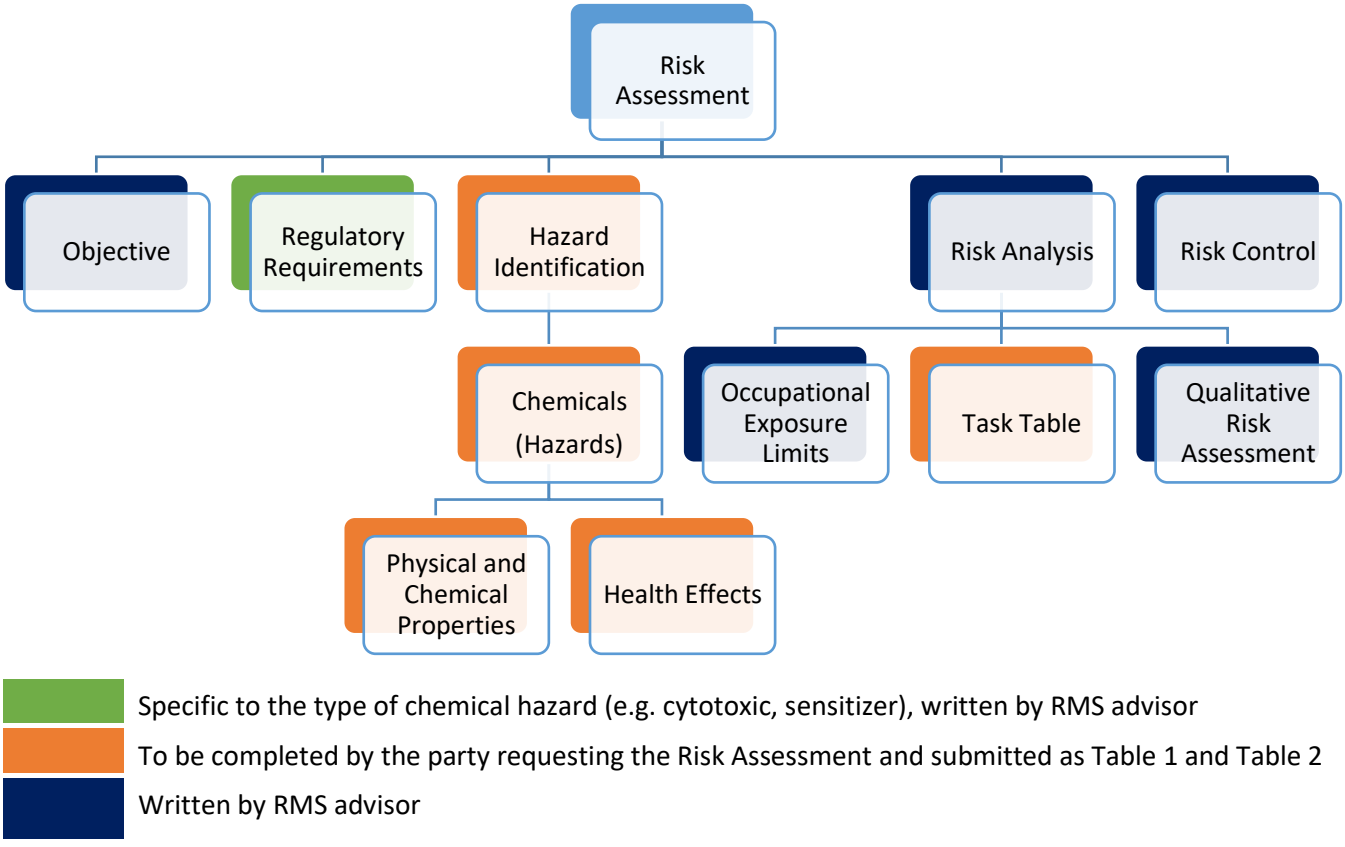

Figure 1. Overview of the Risk Assessment Process

To obtain a Risk Assessment you need to forward Table 1 and Table 2 (see below) together with a copy of the research protocol to the RMS advisor.

Risk can be defined as the likelihood of occurrence of an event resulting in certain consequences. Different chemicals have different properties and toxicity. Exposure to toxic chemicals can result in different effects depending on the routes and levels of exposure. A risk assessment of toxic or harmful chemicals determines the risk

levels they present to the users. It also enables decisions to be made on whether measures need to be taken to safeguard or protect persons against the chemicals.

Hazard is the general term for anything that has the ability or potential to cause injury. Hazards can be of chemical, biological or physical (e.g. radiation, ergonomics) nature. The objective of these risk assessments will include only chemical hazards.

Risk is the term applied to the predicted or actual frequency or likelihood of occurrence of an adverse effect of a chemical or other hazard.

Risk assessment is the identification and quantification of the risk resulting from a specific use of a chemical, taking into account the possible harmful effects on people using the chemical in the amount and manner proposed and all the possible routes of exposure.

2. Regulatory Requirements

Work with certain classes of chemical hazards is regulated by WorkSafe BC. Regulated chemicals include cytotoxics, carcinogens, reproductive toxins, sensitizers, perchloric and picric acid and peroxide-forming compounds. Less used in research but also regulated are asbestos, lead, pesticides and silica.

When you submit the list of chemical hazards, they will be evaluated and if any is found in a class that is regulated, the relevant regulation will be included in the risk assessment document.

Read the regulatory requirements carefully! It is the responsibility of the project lead (e.g. Principal Investigator or lab manager) to make sure all requirements stipulated in the regulation are fulfilled (e.g. record keeping).

3. Hazard Identification

This risk assessment is designed to consider only hazards of a chemical nature. If the risk assessment is done for an animal protocol, the information on the chemical hazards is listed in section 6 “Drugs and Chemicals” of the protocol. Most drugs (anesthetics, sedatives, analgesics, antibiotics – sections 6.1 to 6.3) are chemicals and part of the assessment. Section 6.4 “Other drugs, chemicals, biohazardous materials and radioisotopes” can list more than just chemical hazards. If in doubt, provide a list with all the drugs and chemicals listed in section 6 and you will be told which chemicals are the subject of the assessment (only hazardous chemicals are considered).

The physical form of the hazard is very important for the step of risk analysis. A hazard in powder form adds a risk of inhalation and requires more handling in comparison with a ready to use solution. The solvent(s) used for dilutions are important as well since there could be added risks due to the presence of certain solvent (e.g. dimethyl sulfoxide, methanol).

For the chemicals part of the risk assessment, submit the following table (explanation of column headings, below).

Table 1 Chemical Hazards (example)

Name of chemical	Physical state	Solvent for dilution	Toxicology data	Acute health hazards	Chronic health effects
Meloxicam	Ready to use solution	NA	TDLO=1 mg/kg (oral, rat)	Toxic if swallowed	May damage fertility or the unborn child.
Tamoxifen	Powder	Sunflower oil	LD50=4100 mg/kg (oral, rat)	NA	Carcinogenic to humans. Cytotoxic May damage fertility or the unborn child. May cause harm to breast-fed children.

Name of the chemical – the name of the chemical hazard identified as part of the risk assessment
Physical state - this refers to the physical state of the purchased chemical (solid -powder or tablet, stock solution - needing dilution prior to use, ready to use solution)
Solvent for dilution – the solvent used to dilute the stock solution or to solubilize the powder; if multiple solvents are use, list all of them.
Toxicology data – LD50 or other similar data. Information can be found in section 11 of the SDS or in various drugs/chemical databases.
Acute health hazards – refer to the immediate effects of the hazard on human health. Information can be found in sections 2 and 11 of the SDS or in various drugs/chemical databases.
Chronic health hazards – refer to the long-term effects of the hazard on human health. Information can be found in sections 2 and 11 of the SDS or in various drugs/chemical databases.

4. Risk Analysis

There are several categories of information that need to be considered in order to do a risk analysis. A task table (example below) must be submitted in order for the RMS advisor to be able to complete a risk analysis.

When completing the table, consider the following:

- The same task can involve multiple hazards, combined (e.g. cage changing) or individual (e.g. dilution of stock solutions)
- The same hazard can be listed for multiple tasks
- Carefully consider all tasks/procedure necessary to complete the project even if they do not involve you directly (e.g. tasks done by animal care personnel, veterinarians) and list each one. Include anesthesia for various procedures and euthanasia.
- Describe the tasks thoroughly, especially the less commonly known procedures – it will allow to determine correctly the risk of exposure.

Table 2 Description of the tasks and associated hazardous substances (example)

Task/procedure	Task description / exposure route	Hazard
Preparation of solutions from solid chemical compounds	Stock solution will be prepared by weighing the solid and adding the solvent of choice (list solvent(s)) Exposure route: inhalation and dermal	Tamoxifen
Dilution of stock solutions	Stock solutions will be diluted to desired concentration using various solvents (list them). Exposure route: dermal	Example X
Intraperitoneal or injections	Solutions of the chemical will be injected into the animal subjects. Exposure route: dermal, needle injury	Example Y

Occupational Exposure Limits

The occupational exposure limit (OEL) or permissible exposure level (PEL) represents the maximum airborne concentration of a toxic substance to which a worker can be exposed over a period of time without suffering any harmful consequences. These limits are set out by many professional organizations around the world, such as the American Conference of Governmental Industrial Hygienists (ACGIH), and the National Institute for Occupational Safety and Health (NIOSH) in the United States. They are established based on the chemical properties of the substance, experimental studies on animals and humans, toxicological and epidemiological data.

In British Columbia, the Occupational Health and Safety Regulations (B.C. Reg. 296/97) made under the Workers' Compensation Act (R.S.B.C. 1979, c. 437) maintains a Table of exposure limits for chemical and biological substances. There are three categories of threshold limit values:

Threshold Limit Value – Time-Weighted Average (TLV-TWA): The concentration of a hazardous substance in the air averaged over an 8-hour workday and a 40-hour workweek to which it is believed that workers may be repeatedly exposed, day after day, for a working lifetime without adverse effects.

Threshold Limit Value – Short-term exposure (TLV-STEL): A 15-minute time weighted average exposure that should not be exceeded at any time during a workday, even if the overall 8-hour TLV-TWA is below the TLV-TWA. Workers should not be exposed more than four times per day to concentrations between TLV-TWA and TLV-STEL. There should be at least a 60 minute interval between exposures. The short-term exposure threshold has been adopted to account for the acute effects of substances that have primarily chronic affects.

Threshold Limit Value – Ceiling (TLV-C): This is the concentration that should not be exceeded during any part of the working exposure. Peak exposures should be always controlled. For substances that do not have TLV-TWA or TLV-C established, the maximum admissible peak concentrations must not exceed:

- Three-times the value of the TLV-TWA for no more than 15 minutes, no more than four times per workday. Exposures must be at least 1 hour apart during the workday.
- Five times the TLV-TWA under any circumstances.

Action Level: is the level of exposure to a hazardous substance at which an employer must take the required precautions to protect the workers; it is normally one-half of the permissible exposure limit.

Whenever the chemical hazards you are working with have published occupational exposure limits, the OELs will be mentioned and considered in the Risk Assessment.

5. The Results of the Risk Assessment

The assessment provided is a qualitative assessment with the main purpose to provide guidance on how the risk can be controlled. The risk is not calculated; the designations high, medium and low result from analysis of the risk factors (e.g. exposure route, health effects, frequency of tasks, regulation) and rely on the expertise of the RMS advisor.

The results of the risk assessment will be communicated at the end of the risk assessment document, in paragraph form and in a table format. The results table will have a format similar to the one in the example below (

Table 3). The risk rating assumes all the suggested controls to mitigate the risk are in place (e.g. the risk for first task is “medium” if the task is done inside a fume hood, wearing all suggested PPE).

Risk assessments are highly dependent on each factor analyzed and small changes in a research protocol can drastically change the results of the assessment. Therefore, any changes in a protocol (e.g. new tasks, hazards) will require a re-assessment.

Table 3 Suggested controls for the tasks performed (example)

Activity / Task	Hazard	Exposure Type Route	Hazard Controls	PPE Requirements	Risk
Preparation of stock solutions	Tamoxifen	Inhalation, dermal	Prepare solution in a laboratory fume hood or biological safety cabinet (class II Type B). When chemical is cytotoxic or reproductive toxin, preparation must be done over adsorbent pads that will be disposed of as hazardous waste. Weighing must be done inside the fume hood or by difference.	Lab coat, nitrile gloves (secured over the lab coat sleeves), safety glasses with side-shields or goggles. If lab coat or other garments come in contact with the chemical, they need to be washed before being used again.	Medium
Dilution of stock solution	Tamoxifen	Dermal	Recommended to be done inside a fume hood but can be done on the bench as well. Immediately clean any spills and dispose of cleaning material as hazardous waste.	Lab coat, nitrile gloves (secured over the lab coat sleeves), safety glasses with side-shields or goggles.	Low