

第六章

环境化学物的安全性和健康危险度评价

§ 6-1 环境化学物的安全评价

- 环境化学物的安全性进行评价具有哪些重要意义?

一、基本概念

1.安全:

2.安全性:

3.实际安全剂量:

4.安全性评价:

安全性评价的目的:

What is a risk assessment?

Risk assessment is the process where you:

identify hazards,

analyze or evaluate the risk associated with that hazard, and

determine appropriate ways to eliminate or control the hazard.

In practical terms, a risk assessment is a thorough look at your workplace to identify those things, situations, processes, etc that may cause harm, particularly to people. After identification is made, you evaluate how likely and severe the risk is, and then decide what measures should be in place to effectively prevent or control the harm from happening.

For definitions and more information about what hazards and risks are, please see the *OSH*

[Hazard and Risk](#)

二、安全性评价的内容

(一) 准备工作

1. 了解评价化学物的基本特性和相关数据
2. 了解该化学物可能的用途、使用范围和使用方式，人体暴露的途径和可能的摄入量等。
3. 实验过程中使用的受试物必须是规格、纯度完全一致的产品。

（二）安全性评价的程序

对化学品毒性安全性评价的四个阶段：

第一阶段：急性毒性阶段

通过急性毒性试验确定**LD50**或**LC50**，对化学物的毒性进行初步的评估，并确定其急性毒作用特征，为急性毒性定级、进一步试验的剂量设计和毒性判定指标的选择提供依据。

第二阶段：致突变试验

1. 原核细胞基因突变试验

2. 真核细胞染色体畸变试验

第三阶段：亚慢性毒性试验、致畸试验、生殖试验和代谢试验

亚慢性毒性试验：

致畸试验：

生殖试验：

代谢试验：

第四阶段：慢性毒性试验和致癌试验

慢性毒性试验的目的：

致癌试验用于确定受试物对实验动物的致癌性。

(三)安全性评价试验的选用原则

看教材**P137**,《工业化学品毒性鉴定规范》示例的部分内容

（四）安全性评价结果评价时应注意的问题

由于人和动物可能对化学物的一般毒性或特殊毒性存在易感性的差异，在对毒理学安全性评价的结果进行解释时，应尽可能考虑多方面的影响因素，以便作出客观的结论；在进行安全性评价时，**不仅要了解每项毒理试验所能说明的问题，还应该了解试验的局限性或难以说明的问题。**

人体资料对于评价化学物对人体的危害是最直接和可靠的依据。

Why is risk assessment important?

- Risk assessments are very important as they form an integral part of a good occupational health and safety management plan. They help to:
- create awareness of hazards and risks,
- identify who may be at risk (employees, cleaners, visitors, contractors, the public, etc),
- determine if existing control measures are adequate or if more should be done,
- prevent injuries or illnesses when done at the design or planning stage, and
- prioritize hazards and control measures.

What is the goal of risk assessment?

- The aim of the risk assessment process is to remove a hazard or reduce the level of its risk by adding precautions or control measures, as necessary. By doing so, you have created a safer and healthier workplace.

How do you do a risk assessment?

- Assessments should be done by a competent team of individuals who have a good working knowledge of the workplace. Staff should be involved always include supervisors and workers who work with the process under review as they are the most familiar with the operation.
- In general, to do an assessment, you should:

- identify hazards,
- evaluate the likelihood of an injury or illness occurring, and its severity,
- consider normal operational situations as well as non-standard events such as shutdowns, power outages, emergencies, etc.,
- review all available health and safety information about the hazard such as MSDSs, manufacturers literature, information from reputable organizations, results of testing, etc.,
- identify actions necessary to eliminate or control the risk,
- monitor and evaluate to confirm the risk is controlled,
- keep any documentation or records that may be necessary. Documentation may include detailing the process used to assess the risk, outlining any evaluations, or detailing how conclusions were made.

When doing an assessment, you must take into account:
the methods and procedures used in the processing, use,
handling or storage of the substance, etc..

the actual and the potential exposure of workers,
the measures and procedures necessary to control such
exposure by means of engineering controls, work practices,
and hygiene practices and facilities. 工具

By determining the level of risk associated with the hazard,
the employer and the joint health and safety committee can
decide whether a control program is required.

It is important to remember that the assessment must take
into account not only the current state of the workplace but
any potential situations as well.

How are the hazards identified?

- Overall, the goal is to find and record possible hazards that may be present in your workplace. As mentioned, it may help to work as a team and include both people familiar with the work area, as well as people who are not - this way you have both the "experienced" and "fresh" eye to conduct the inspection.

- **To be sure that all hazards are found:**
- **look at all aspects of the work,**
- **include non-routine activities such as maintenance, repair, or cleaning,**
- **look at accident / incident / near-miss records,**
- **include people who work "off site" either at home, on other job sites, drivers, teleworkers, with clients, etc.,**
- **look at the way the work is organised or "done" (include experience and age of people doing the work, systems being used, etc),**
- **look at foreseeable unusual conditions (for example: possible impact on hazard control procedures that may be unavailable in an emergency situation, power outage, etc.),**
- **examine risks to visitors or the public,**
- **include an assessment of groups that may have a different level of risk such as young or inexperienced workers, persons with disabilities, or new or expectant mothers.**

How do you know if the hazard is serious (poses a risk)?

- Each hazard should be studied to determine its' level of risk. To research the hazard, you can look at:
- product information / manufacturer documentation,
- past experience (workers, etc),
- legislated requirements and/or applicable standards,
- industry codes of practice / best practices,
- health and safety material about the hazard such as material safety data sheets (MSDSs), or other manufacturer information,
- information from reputable organizations,

- results of testing (atmospheric, air sampling of workplace, biological, etc),
- the expertise of a occupational health and safety professional,
- information about previous injuries, illnesses, “near misses/炸弹”, accident reports, etc.
- Remember to include factors that contribute to the level of risk such as the:
 - work environment (layout, condition, etc.),
 - capability, skill, experience of workers who do the work,
 - systems of work being used, or range of foreseeable conditions.

How do you rank or prioritize the risks?

- Ranking or prioritizing hazards is one way to help determine which hazard is the most serious and thus which hazard to control first. Priority is usually established by taking into account the employee exposure and the potential for accident, injury or illness. By assigning a priority to the hazards, you are creating a ranking or an action list. The following factors play an important role:
 - percentage of workforce exposed,
 - frequency of exposure,
 - degree of harm likely to result from the exposure,
 - probability of occurrence.
- There is no one simple or single way to determine the level of risk. Ranking hazards requires the knowledge of the workplace activities, urgency of situations, and most importantly, objective judgement.

三、国内外的化学物安全性评价法规简介

美国**1906**年颁布了第一部管理化学品危害的联邦法律《食品和药品法》

美国**1938**年又颁布了《食品、药品和化妆品法》

美国**1972**年又颁布了《杀虫剂、杀菌剂和杀鼠剂法》

经济与发展合作组织于**1982**年颁布了《化学物品管理法》，该法提出了一整套毒理实验指南、良好实验室规范和化学物投放市场前安全性评价资料的最低要求，和对新化学物的统一管理办法。

我国**1983**年卫生部颁布《食品安全性毒理学评价程序（试行）》；**1994**年又颁布了国家标准《食品安全性毒理学评价程序》。

1987年，卫生部颁布了国家标准《化妆品安全性评价程序和方法》，同年国务院颁布《化学危险品安全管理条例》

1988年卫生部颁布《新药（西药）毒理学研究指导原则》

1991年卫生部和农业部颁布了《农药安全性毒理学评价程序》

1995年颁布了《中华人民共和国食品卫生法》配套颁布了《食品安全性毒理学评价程序》，《农药登记毒理学试验方法》

§ 6-2 环境健康危险度评价

- 环境污染物健康危险度评价的步骤：
 - (1). 危害鉴定
 - (2). 剂量-反应关系评定
 - (3). 暴露评价
 - (4). 危险特征分析

二、环境健康危险度评价的基本步骤

(一) 危害鉴定: P141

(二) 剂量-反应评定/**Dose-response assessment**:

(三) 暴露评价:

(四) 危险特征分析

通过综合暴露评价和剂量-反应关系评定的结果，分析判断人群受到某种危害的可能性大小，比对其可信程度或不确定性加以阐述，最终以正规的文件形式提供给危险管理人员，作为他们进行管理决策的依据。

危险特征分析包括对上述三阶段的结果进行综合分析，以及评定结果的书面总结等。

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思考题：暴露评价的研究有什么意义？