

Group Directive K 1

Occupational Hygiene and Health

1 Scope

This directive is binding for all companies of the Roche Group.

2 Purpose

This directive is issued to fulfil Roche's commitment to provide healthy workplaces. It establishes a common basis for local management to define the fundamental measures that need to be taken in order to protect the health of the employees from occupational hazards.

3 Principles

The following measures are to be applied as a continuous process:

- written workplace health risk assessments (risk assessment); cf. Annex 1.
- elimination or appropriate reduction of exposures (risk management)
- information and education of the workforce (risk communication)

Occupational hazards as defined by this directive are chemical, biological, ergonomic, physical (noise, vibration, heat/cold, ionising and non-ionising radiation etc) hazards of all types as well as psycho-social hazards. In consideration of the nature of the company's business, particular emphasis is put on the safe handling of chemicals.

4 Measures

4.1 General Measures

4.1.1 Exposure of employees to occupational hazards must be prevented or where this is not reasonably practical, exposure must be adequately controlled.

4.1.2 The absence of undue exposure to occupational hazards must be documented in written workplace health risk assessments (cf. Annex 1: "Performing a Workplace Health Risk Assessment"). Risk assessments must be made by individuals who have the appropriate expertise. Relevant risk assessment and risk management records must be kept for at least 50 years.

4.1.3 The prevention of occupational overexposure shall be ensured primarily by collective protection measures (technical measures, engineering controls) and not by the provision of personal protective equipment.

4.1.4 It must be ensured that any control measures provided are kept in an efficient state and in good repair. Protocols for periodic tests of engineering controls and re-usable personal protective equipment need to be established.

4.1.5 If the work undertaken exposes, or potentially exposes, employees to relevant health hazards, sufficient information, instruction and training must be provided to ensure that the employee:

- has sufficient knowledge about the risks to health created by such exposure,



- knows and understands the precautions taken by the company and those to be taken by the employee him/herself.

The information given to the employee generally includes information on the hazards themselves, the results of the workplace health risk assessments including industrial hygiene measurements performed and information on the collective results of health surveillance.

The type of workplace and the risks/hazards involved determine the quality, quantity and means of information and training necessary.

4.1.6 Adverse effects on mental wellbeing have become the biggest contributor to work-related ill health. Therefore, the mental health of its employees is a particular concern to Roche. Numerous publications have shown that measures to improve mental health are highly beneficial to the workforce and profitable for the employer. Assessment tools for these conditions and corrective measures must be defined locally and be tailor-made for each individual situation. Annex 5 of this Directive gives general guidance.

4.2 Measures for workplaces with chemical hazards

If there is chemical exposure to a compound for which an occupational exposure limit (OEL) has been specified (cf. Annex 2: "Occupational Exposure Limits Valid in the Roche Group"), control shall be considered adequate if the level of exposure is reduced as far as reasonably practical and in any case below the occupational exposure limit. The OEL valid in the Roche Group is the lowest limit value applicable either in Germany, set by the ACGIH or by the relevant local authority (cf. Annex 2). For chemicals without such limit values, the Roche Industrial Hygiene Committee, chaired by LSH, sets internal occupational exposure limits (IOELs) as needed.

The following exposure levels are defined:

The figures in the table below are expressed as average exposures over an 8-hour work-shift or as percentages of the Short Term Exposure Limit, where one has been set.

<ul style="list-style-type: none"> • Exposure below 25% of the OEL: No adverse effects in healthy individuals. Document situation appropriately by means of a written risk assessment. Re-evaluation of risk whenever process is changed. No special medical surveillance necessary other than to determine fitness for the job where appropriate. Routine surveillance intervals can generally be long.
ALERT LEVEL: 25% OF OEL
<ul style="list-style-type: none"> • Exposure between 25% and 50% of the OEL: Adverse effects very unlikely in healthy individuals. Attempt to reduce exposures below the alert level. Written risk assessment with proposals to improve exposure situation and determination of time for next assessment. Periodic medical surveillance to determine fitness for the job and to show that certain specific potential adverse effects are not detectable.
ACTION LEVEL: 50% OF OEL
<ul style="list-style-type: none"> • Exposure between 50% and 100% of the OEL: Adverse effects unlikely in healthy individuals. Situation must be improved in the long run. Establish and implement action plan with clear time frame to reduce exposure at least below action level. Written risk assessment, with description of industrial hygiene surveillance measures, to demonstrate that exposures do not exceed the OEL.



Sufficiently frequent medical surveillance to determine fitness for the job and to show that certain specific adverse effects are not detectable.

ALARM LEVEL: 100% OF OEL

- **Exposure above 100% of the OEL: Adverse effects may occur.**
Situation not tolerable.
Take immediate steps to reduce exposure.
Strict medical surveillance to assess and where necessary treat possible adverse effects.

4.2.1 Measures for workplaces with chemical hazards without a defined OEL

For chemical hazards without a defined OEL, the same risk assessment and risk management principles apply as for those compounds with specified OELs. Exposure must be reduced as far as reasonably practical. The "Roche Health Hazard Based Categorisation System for Raw Materials, Intermediates and Final Products" (cf. Annex 3) determines the level of maximum acceptable exposure to data-poor substances.

5 Reporting

As part of the annual reporting procedure, copies of all workplace assessment documents showing exposures of more than 50% of the OEL must be sent to LS. Workplace risk assessments showing exposures of more than 100% of the OEL must be copied to LS within the same time limits that apply for the reporting of accidents and incidents (cf SHE Group Directive K 11).

6 Definitions

- **Exposure**
means the amount of chemical that actually reaches the skin or mucous membranes of the worker; e.g.: if a hazard is only respiratory and the atmosphere contains 1 mg/m³ of this compound, but the worker wears respiratory protection with a protection factor of 10, the exposure is not 1 mg/m³ but 0.1 mg/m³.
Note that exposures need to be controlled by technical measures wherever feasible, and not by personal protective equipment (cf. section 4.1.3).
- **OEL (Occupational Exposure Limit)**
Annex 2 of this directive defines the OELs valid in the Roche Group.

7 Implementation

This directive becomes effective immediately and replaces any earlier editions of "Group Directive K 1".

Existing local directives have to comply with this directive and must be revised or adapted accordingly.

8 Assistance

Group Safety, Security, Health and Environmental Protection (LS) at Roche Basel may be contacted for all questions arising in connection with this directive.

Annexes:

1. *Performing a Workplace Health Risk Assessment.* http://rochenet.roche.com/k1_annex_1.pdf
2. *Occupational Exposure Limits Valid in the Roche Group.*
http://rochenet.roche.com/k1_annex_2_occupational_exposure_limits_valid_for_the_roche_group.pdf
3. *Roche Health Hazard Based Categorisation System for Raw Materials, Intermediates and Final Products.*
http://rochenet.roche.com/k1_annex_3_roche_health_hazard_based_categorisation_rev2011.pdf
4. *Occupational Health Requirements for Equipment and Facilities Handling Pharmaceuticals.*
http://rochenet.roche.com/k1_annex_4_occupational_health_requirements_for_equipment_and_facilities_handling_pharmaceuticals.pdf
5. *Guide to Mental Health Protection.* http://rochenet.roche.com/k1_annex_5.pdf