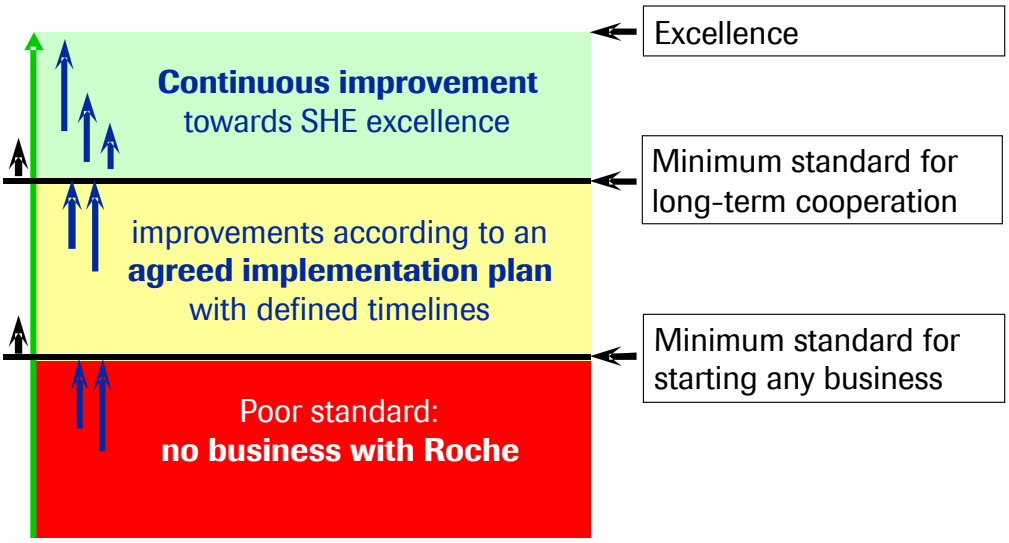
Annex 1 to Group Directive K15

SHE Performance Expectations

1 Principles

Roche's suppliers shall aim for the same SHE Standard as Roche in its own operations.

There are different levels of expectations of compliance with this requirement, based on the nature and extent of the business relationship with Roche:



Suppliers as required by the Group Directive K15 must

- comply with the **minimum standard** by fulfilling the expectations highlighted in bold in the table below

and

- agree on a defined action plan to attain the **standard for longer term business with Roche** at a fixed target date (normally not later than 1 year after starting the business with Roche)

before Roche starts doing business with them.

2 Expectations

The following table summarizes the SHE performance expectations for long term collaboration. The subset of expectations for the minimum standard is highlighted in bold characters.

Depending on the size and type of operation, some aspects or expectations may not be applicable.

SHE Aspects	Expectations
01. SHE Management System	• Management commitment to Safety, Security, Health and Environmental Protection • Commitment implemented in a systematic manner by means of all necessary technical, organizational and personnel measures • **SHE organization implemented which is adapted to the site's size and type of operation; adequately skilled staff available** • **Duties and responsibilities of all staff involved into SHE matters defined and documented in the respective job descriptions** • SHE relevant processes developed, documented and documentation well maintained • Annual SHE targets defined and monitored • SHE performance periodically assessed through evaluation of appropriate performance indicators • Regular management review of SHE topics and of SHE performance carried out • SHE training needs identified and assigned to all job functions; training programs established, executed and monitored • Processes, tools or platforms in place to assure communication of SHE information throughout the organization • **Processes and resources available to verify and assure legal compliance; responsibilities for compliance checks clearly assigned** • **Full legal compliance achieved** • **Suppliers and service providers of Roche suppliers managed similarly for SHE performance** • **SHE audits by Roche auditors allowed**
02. Accident and Incident Prevention	• **Appropriate methodologies used to identify, assess and mitigate risks in all relevant areas (e.g. business, processes, installations etc.); documented risk assessments available and regularly reviewed** • **Implementation of action plans derived from risk assessments assured** • Risk assessments integral part of the Management of Change process • **Effective incident reporting, investigation and follow up program established consisting of timely reporting, methodical and thorough analysis, identification and closure of Corrective and Preventive Actions (CAPA's) and communication of "lessons learned"; timely reporting of all relevant incidents (including major findings of audits / inspections of authorities) to Roche** • Documented internal SHE inspections performed on a periodic basis; recommendations followed up to completion • Adequate work permit system established and enforced

SHE Aspects	Expectations
03. Emergency Management	03.01 Emergency Management • **An Emergency Management (EM) program, adapted to a site's operational risks, with local site management support, and the resources, personnel, planning, equipment and necessary training to implement the program in place** • Written Incident Response Plan encompassing the phases of pre-emergency (e.g. identification of credible emergency scenarios) and emergency response planning available, periodically updated and trained regularly. • Need for external support (e.g. mutual aid) evaluated, and when applicable, written agreements established with local responders • Capability to direct, control and coordinate response and recovery operations via an incident command/management system • Installations and procedures for emergency shut-down of equipment in place • Provisions for emergency supply of energies / utilities considered and where appropriate implemented • **Emergency exits, egress routes and re-grouping areas clearly posted and all egress routes free of obstructions and adequately protected** • **Regular evacuation drills performed and critiqued** • All relevant natural hazards identified and adequate level of emergency preparedness implemented (e.g. flood prevention plan, storm preparation plan, etc.) 03.02 Business Continuity Management: • Management commitment to the principles of ISO23001 • Business Impact Analysis (BIA) performed and documented • Documented recovery strategies with management endorsement available • Regular Business Interruption exercises performed

SHE Aspects	Expectations
04. Fire Safety	• Adequately staffed, trained and equipped interior firefighting organization in place • Written agreements established, if an external fire brigade is relied on • **Alarm chain allowing reliable and fast alarming of the fire brigade (internal / external) established** • External fire department / emergency responder familiar with the site and all associated fire risks (visits, on-site trainings etc.) • **Full coverage with appropriate early warning systems (e.g. smoke / fire / heat detection) and/or fixed fire protection systems (e.g. sprinklers, deluge systems, gaseous extinguishing systems); systems installed, inspected, tested, and maintained as required by commonly accepted codes and standards (e.g. NFPA 13, 72)** • **Reliable fire water supply systems (fire pumps, hydrants and associated piping) and suppression systems installed; design criteria, maintenance, inspection and testing according to commonly accepted standards (e.g. NFPA 25)** • **Appropriate class and size of fire extinguishers installed throughout the facility, with appropriate inspection, testing and maintenance programs in place; regular training exercises performed** • Proper impairment handling procedures in place for repairs, alterations and additions of fire protection equipment • Change management process implemented to control modifications to existing fire protection features and fire alarm/suppression systems • Fire resistance rated assemblies, walls, floors, ceilings maintained, repaired, restored or replaced when damaged, altered or penetrated

05. Operational Safety	• Process Safety Management addressed: management commitment demonstrated, risk understanding at high level (hazard identification, risk analyses, thermal process safety aspects), safe working practices implemented (e.g. powder handling), reliable and safe equipment installed
	• Hazardous activities (e.g. hazardous chemical handling, confined spaces, work at height, electrical work, work with asphyxiating gases, hot work etc.) identified and assessed, with proper mitigation measures implemented and maintained (e.g. documented explosion protection concept, inventory of rooms with asphyxiation risk, oxygen sensors / alarms, appropriate permits to work etc.)
	• **Effective maintenance program implemented and monitored by appropriate KPI**
	• **Appropriate storage concepts and facilities implemented, taking into account compatibility, stability, toxicity, flammability, fire-fighting, value of the goods, security of supply, etc.**
	• Good level of housekeeping maintained
	• Laboratory safety adequately addressed:
	  o Safety training sessions
	  o Exposure control (e.g. lab hoods, weighing hoods, ventilation and respective maintenance and performance tests)
	  o Provision, selection and use of PPE
	  o Storage of chemicals
	  o Waste handling

SHE Aspects	Expectations
06. Chemical Safety / Bio Safety	06.01 Chemical Safety • **Processes established to assure collection, updating and documentation (typically SDS) of all necessary SHE data for all relevant materials** • **SHE data (e.g. SDS) made available to all relevant staff** • **Control of specially regulated materials (e.g. narcotics, precursors of chemical or biological weapons, radioactive materials, etc.) according to legal requirements** • **Resources and processes established assuring transport of goods according to applicable regulations (e.g. classification, labeling, packaging, documentation, security)** • **Full compliance to chemical legislations achieved (e.g. REACH, GHS)** 06.02 Bio Safety • **Person appointed who is in charge of supervising biosafety relevant activities** • **Classification of relevant agents into appropriate risk groups established** • **Bio Safety Levels (BSLs) and waste handling practices in accordance with the risk groups of the agents** • Appropriate vaccination programmes in place and enforced (e.g. HBV for BBP) • **Accident scenarios addressed by assessments and measures (e.g. spill kits, medical emergency advice)**
07. Security	• **Security ensured by appropriate supervision of the site premises and suitable organizational, building-related and technical measures** • **Security assigned to a responsible individual with a backup individual "deputy" capable of managing security in absence of primary contact; tasks and duties defined and documented (job description)** • Documented security concept for the site, buildings and areas based on a security / vulnerability analysis implemented (e.g. physical protection, access rights and controls, surveillance, staff and visitor management, alarm chain and response) • Selection processes and regular vetting of Security personnel implemented and aligned with corresponding needs • **Trained emergency responses and adequate staffing or resources to provide 24/7 monitoring of alarms** • Security rounds/patrols established • Strictly controlled processes for the disposal of defective products from production and of returned or expired goods (including packaging material, labels and leaflets) in place
08. IT Security and Data Protection	• Appropriate arrangements made for the storage of important/confidential documentation and data: hardcopies stored in secured places with defined access rights and access control systems; electronic files / data stored in adequately protected IT systems (firewall) with back-up solutions • Installations adequately protected from viruses, worms, etc. • Written IT Disaster Recovery Plan for hardware, software applications, data, etc. in place • Procedures for the controlled disposal of sensitive documents and of electronic hardware implemented • Photograph restriction policies in place

SHE Aspects	Expectations
09. Occupational Health	• Workplace health risks identified by means of documented workplace health risk assessments • Access to expertise in occupational safety, occupational hygiene, occupational medicine and ergonomics (in-house or through third parties) • **System for characterisation and communication of chemical hazards (OEL, OEB, SDS) established; setting or verification of OELs and OEBs by adequately qualified people** • **Exposures to workplace hazards (e.g. chemical hazards, noise, ergonomics, etc.) quantified, assessed and documented for each relevant unit operation** • **Exposure to workplace hazards (chemicals, noise, ergonomics, etc.) addressed by means of engineering controls (e.g. containment solutions) whenever technically feasible** • **All necessary PPE provided to the employees at no cost; proper use trained and enforced** • **Proven adequacy of PPE (e.g. with quantitative exposure monitoring data)** • Accident scenarios (upset conditions, loss of containment etc.) addressed by risk assessments and corresponding measures established and documented (SOPs) • Adequately staffed and trained first aid organization implemented • **Medical surveillance consisting of initial health assessments and a risk based health monitoring program implemented and overseen by a specialist in occupational medicine**

10. Environmental Management	• **All necessary environmental permits (e.g. air, waste water, hazardous waste, etc.) obtained from local regulatory authority, with permit requirements fulfilled (e.g. compliance monitoring, analytical testing, timely reporting, etc.)**
	• Good compliance record (no penalties, no major observations from official inspections, no recent major incidents or releases)
	• Comprehensive environmental documentation available (e.g. waste inventory, data on recycling and valorization emission data, waste water parameters, permits, etc.)
	• Ambitious environmental goals and objectives defined and monitored (e.g. energy savings, CO2 reduction, waste reduction, etc.)
	• Inventory of greenhouse gases and ozone depleting substances (e.g. refrigerants, extinguishing agents, etc.) available; phase-out plans elaborated and at least compliant to relevant regulations (e.g. Montreal / Kigali Protocols, etc.)
	• Waste management strategies following the sequence outlined below:
	  ○ Avoid the generation of waste by developing environmentally friendly processes, devices and packaging,
	  ○ Reduce/minimize the amount of unavoidable waste,
	  ○ Re-use,
	  ○ Recycle to the original starting material. Down-cycle to a lower-value product, e.g. paper to cardboard.
	  ○ Valorize (e.g. heat recovery),
	  ○ Incinerate without heat recovery, but with state-of-the-art flue gas treatment as a minimum.
	• **No landfilling of hazardous chemicals performed at all**

SHE Aspects	Expectations
11. Environmental Performance – Technical Set-up	• **No health or environmental risk from exhaust air; state-of-the-art air emission control facilities installed and maintained to meet or outperform official emission limits. Adequate performance assured through monitoring and /or testing** • Modeling and impact of potential worst case release scenarios considered • Adequate provisions made for the retention of spills, leakages, contaminated storm waters and firefighting waters • **Measures taken to ensure that waste water and storm water discharges are compliant with all applicable regulatory limits (waste water treatment plant, monitoring)** • Documented environmental assessments for all relevant materials (e.g. API) performed; concentration of relevant materials in waste waters reduced to no-effect levels through adequate treatment or segregation for proper off-site disposal • Waste collected, classified and stored separately in dedicated waste storage areas that meet all local regulatory requirements including fire protection and safety
12. Contractors	• SHE criteria elaborated, documented and applied in the contractor selection process (e.g. qualification, reputation, compliance, insurance coverage, etc.) • SHE matters adequately covered in contracts • Formalized induction program (e.g. to working areas, emergency organization, relevant safety rules) implemented • Equipment checks established • SHE performance of contractors continuously assessed through documented on-site inspections • Formalized close-out including inspection of working areas and evaluation of contractor's performance • Key suppliers / service providers (e.g. waste contractors) identified, SHE audit program established and executed, compliance to Roche's SHE performance expectations assured