



Group Directive K15

Assuring SHE Performance at Suppliers and Service Providers

1 Scope

Group Directive K15 is binding for all companies and divisions (further on “divisions”) of the Roche Group.

2 Purpose

Roche considers its suppliers, service providers and licensees (further on “suppliers”) to be important stakeholders in the Company’s overall success. In line with Roche’s commitment to the principles of sustainable development, Roche expects each supplier’s performance to generally meet internationally recognized standards of safety, health and environmental performance, ethical business practice and social responsibility (further on “SHE performance”). The benefits of assuring SHE performance of suppliers are not only societal and environmental, but also financial.

Roche’s approach is based on the International Chamber of Commerce’s (ICC) Policy statement “ICC guidance on supply chain responsibility” (see <http://www.iccwbo.org>) and on the “OECD Due Diligence Guidance for Responsible Business Conduct” (see <http://mneguidelines.oecd.org/>). Roche has also endorsed the Pharmaceutical Industry Principles for Responsible Supply Chain Management for ethics, labor, environment, health and safety (PSCI Principles, see <http://www.pscinitiative.org>), and we are committed to integrating these Principles into our business processes and practices.

Roche is aware of differences in culture and the challenges associated with interpreting and applying these Principles globally. Therefore, while we believe that what is expected is universal, it is understood that the approach for meeting these expectations may be different and must be consistent with the laws, values and cultural expectations of the different societies of the world.

This Directive defines the necessary measures to assure SHE performance which must be taken before engaging the services of a supplier (e.g. through purchase orders, supply agreements or other contractual agreements, further on “contracts”), and on an ongoing basis during the relationship with the supplier. Although Roche cannot take the primary responsibility for the activities of a supplier (beyond that which is already legally required), we recognize our ability and responsibility to positively influence their SHE performance. The overall objective is to ensure that suppliers doing business with Roche are in compliance with local laws, rules and regulations and that they meet Roche’s SHE performance expectations (see Annex 1). This will reduce the risks of business interruptions and liabilities and also protect Roche’s general commitments, obligations, interests and reputation.

Ensuring a consistent approach to the assessment and continuous improvement of suppliers’ SHE performance requires four core elements:

- Communication of Roche’s SHE performance expectations to suppliers
- Evaluation of the supplier’s SHE performance
- Consideration of supplier’s SHE performance as part of the selection process and on an ongoing basis during the relationship with the supplier
- Continuous improvement regarding SHE



3 Principles

- 3.1** We generally expect from our suppliers the same SHE performance as we do from our own operations. There is only one standard. These SHE performance expectations apply to all suppliers. However, Roche's suppliers, their local conditions (e.g. regulatory environment) as well as the contracted services and the resulting risks are highly diverse. Therefore, a risk based approach taking into consideration local and industry specific conditions must be implemented.
- 3.2** For the purpose of this Directive, divisions must elaborate criteria for what constitutes a high Environmental, Social (including Health, Safety and Security) and Governance (further on "ESG") risk of a supplier. Suppliers who have a high ESG risk must be identified and listed (K15 lists).
- 3.3** Suppliers of individual sites must also be considered in this identification process.
- 3.4** The SHE performance of suppliers with high ESG risk must be assessed:
- Before entering a new business relationship
 - When changes to a contracted activity may result in an increased ESG risk
 - Prior to a contract renewal with an existing supplier
 - On an ongoing basis during the relationship with the supplier
- 3.5** Assessments are typically conducted in two phases:
- Review of relevant social and environmental information (i.e. PSCI questionnaire, previous audits, etc.) and
 - On-site SHE audits performed by designated specialists from the divisions or the sites if justified by the inherent risk of the contracted activity and/or the review of relevant social and environmental information is insufficient and/or the described performance is not as required. A reliable, reputable third party may also be used for on-site SHE audits. Designation of internal as well as third party auditors needs confirmation by Group SHE.
- In the case that a supplier is known to violate basic SHE expectations, improvement actions can be requested even without any comprehensive SHE performance assessment.
- 3.6** New contracts of suppliers who have high ESG risks must incorporate social and environmental performance expectations, and will not be finalized unless the supplier meets these expectations. In case a supplier is unable or unwilling to meet Roche's SHE performance expectations in a timely manner, Roche reserves the right to suspend or terminate existing contracts. Contracts must be written with a suspension / termination clause.
- 3.7** These principles are equally applicable if the supplier subcontracts any of the contracted activities. Roche must be informed in advance regarding any subcontracting.



4 Responsibilities

4.1 For the management of suppliers with high ESG risk, the divisions are responsible for:

- Elaborating criteria and maintaining K15 lists
- Communicating Roche's SHE performance expectations to all suppliers on the K15 lists and to other suppliers whenever feasible
- Including a SHE performance assessment, by appropriate subject matter experts, as part of the selection process for new suppliers
- Assuring that only suppliers meeting Roche's SHE performance expectations have a business relationship with Roche
- Including SHE performance expectations in K15 supplier contracts and in contracts with other suppliers whenever feasible
- Providing the supplier with the information necessary to perform the contracted activity in a safe and environmentally sound manner
- Establishing a process to ensure that the SHE performance of suppliers is assessed and periodically verified by appropriate subject matter experts
- Assuring that action plans are developed and implemented to address identified deficiencies in a timely manner
- Providing key stakeholders with ready access to the SHE performance information for all suppliers
- Periodically reporting (within the division, at least annually) the status of the:
 - overall effectiveness of program implementation
 - suppliers' SHE performance
 - suppliers' progress on established action plans

The divisions assign these tasks to the appropriate departments and people.

4.2 Group SHE is responsible for:

- Establishing and maintaining Roche's SHE performance expectations for suppliers
- Evaluating if the processes established assure that:
 - only suppliers meeting Roche's SHE performance expectations are selected
 - existing suppliers meet (or have action plans in place to meet) Roche's expectations

Group SHE retains the authority to perform on-site supplier audits to, for example, assess high risk suppliers and verify the effectiveness of processes implemented to meet K15 requirements. Group SHE also retains the authority to stop production for Roche at suppliers in critical cases.

4.3 Local SHE Organizations are responsible for:

- Supporting the SHE performance assessments for their sites as per 3.2. - 3.4.

5 Assistance

Group SHE may be contacted for all questions arising in connection with this Directive.

6 Implementation

This Directive becomes effective immediately. Existing local directives or guidelines must be revised or adapted accordingly.

7 Annexes

Annex 1: SHE Performance Expectations