



Group Directive K 15

Dealing with Third Party Manufacturers and Service Providers

1 Scope

Group Directive K 15 is binding for all companies and divisions of the Roche Group. U.S. companies and their affiliates have to adopt this Directive in accordance with the "Policy on safety and environmental protection in the Roche Group".

2 Purpose

Roche considers its third-party manufacturers, suppliers and service providers (further on "third party") 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 third party's performance to generally meet internationally recognized standards of safety, health and environmental performance, ethical business practice and social responsibility (further on "social and environmental performance"). The benefits of a third-party social and environmental responsibility program 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>). 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.pharmaceuticalsupplychain.org>), and we are committed to integrating these Principles into our business principles and practices.

At a minimum, Roche expects every third party to operate in full compliance with all applicable laws, rules and regulations. 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.

The present directive defines the necessary measures which have to be taken before signing a contract and engaging the services of a third party. Although Roche cannot take the primary responsibility for the activities of a third party (and no legal responsibility at all), we recognize our ability and responsibility to positively influence the performance of third parties. The overall aim is to ensure that third parties doing business with Roche meet not only all relevant legal requirements, but Roche standards as well, thus reducing the risks of business interruptions and liabilities and also protecting Roche's general commitments, obligations, interests and the reputation.

See chapter 6 "Implementation" for the step-by-step phase-in of these requirements. For a short overview about the required standards see Annex 2.

Ensuring a consistent approach to continual improvement of third party social and environmental performance will require three core elements:

- Communication with suppliers about Roche's expectations
- Evaluation of suppliers' social and environmental performance
- Consideration of suppliers' social and environmental performance as part of the selection process and the customer relationship management



3 Principles

3.1 The degree of Roche's engagement at third parties depends on the nature of the business relationship. For this directive we use the following categories:

O: Outsourcing. The third party is producing a product under a specific contract exclusively for Roche, using specific Roche know-how or processes. This category also includes third parties producing Roche products for the local markets.

SP: Strategic Purchasing. The third party provides goods or services to Roche,

- which are business-critical for Roche, or
- which (or production of which) may have a considerable social (including safety and health), environmental or economic impact, or
- which are produced mainly for Roche in a relevant volume, or
- which involve considerable work on Roche premises, or
- where Roche is seen publicly as a major customer of this third party

P: Purchasing. Purchasing of all other goods or services

3.2 Before entering a new business relationship with **O** or **SP** third parties or prior to a contract renewal within an existing business connection with **O** or **SP** third parties the social and environmental management system, infrastructure and performance of the third party must be assessed. This evaluation process includes two distinctive phases:

- 1 study of all available pertinent documents (including a questionnaire duly completed by the third party) and, if necessary,
- 2 on-site audits (see 3.3 below)

If a type **P** third party is known to violate basic expectations Roche shall not enter in a business relationship (or terminate an existing one) if this unacceptable status is not corrected immediately.

3.3 An audit is carried out whenever

- the study of the documents leaves doubts about the performance of a third party, or
- the risks in connection with the contracted activity or service are more than negligible (to be decided by management; compare Group Directive K 9, Annex 3), or
- the cost exceeds a threshold set by management (this threshold can be different in different business areas or for different types of products and services)

When a third party has undisputed competence and an exemplary reputation regarding social and environmental performance, management in charge together with CSE (CESA in the US) may waive the requirement of an on-site audit.

3.4 Social and environmental audits are performed by designated specialists from the divisions or the sites in co-operation with the appropriate individuals engaged in concluding a contract with a third party. Specialists from CSE (CESA in the US) support the process as needed/feasible. These audits can be outsourced to a reliable, reputable third party only after consultation with CSE (CESA for the US).



3.5 For type **O** third parties Roche provides all available relevant information in connection with the contracted activities to the third party, and - if necessary and upon request - also gives special SHE instruction in order to enable safe and environmentally sound activities. Roche supports type **SP** third parties in SHE matters on their request as far as necessary and feasible.

3.6 Roche periodically verifies the social and environmental performance status of type **O** and **SP** third parties as outlined in 3.2 and 3.3. Sites and divisions keep a listing of the pertinent third party contracts and agreements.

3.7 A third party has the overall responsibility for all its activities and is obliged to guarantee compliance with the applicable laws and regulations and to fulfill the provisions of the contract. In case a third party is not able to meet these provisions and cannot fulfill the social and environmental requirements, Roche will interrupt or terminate the co-operation.

3.8 The principles listed above are equally applicable if the third party subcontracts any of the activities. Roche has to be informed about any subcontracting in types **O** and **SP**.

4 Measures

For type **O** or **SP** (or **P**, where necessary according to chapter 3.2) the Roche management in charge, the procurement functions and the representatives responsible for the contract and the negotiations with the third party shall:

- procure all relevant general information and data about the third party;
- collect all relevant information and data about the third party's social and environmental programs, performance, technical infrastructure and capabilities, and the organizational and personnel structures (see also Annex 1);
- with the support of SHE specialists assess the performance, qualification, reputation and the suitability of the third party with respect to the activities or services to be contracted, while taking into account potential negative impacts from other activities of this third party;
- check specifically the social and environmental matters and risks connected with the activities to be contracted in co-operation with the specialists on the basis of the available documents and by assessing the relevant topical areas in Annex 1;
- in co-operation with the appropriate specialists, determine whether an on-site audit must be performed;
- conduct, if necessary, an on-site audit according to Annex 1 by a designated specialist from a division or a site (where necessary together with the appropriate specialist(s) from CSE/CESA) and elaborate the corresponding report describing the social and environmental performance status of the third party and defining the provisions and recommendations to be followed by the third party;
- elaborate together with the third party a contract which covers not only the activities or services to be contracted, but also the social and environmental provisions, recommendations and conditions to be fulfilled and the obligation to report accidents/incidents in connection with the contracted activities;
- provide the third party with all available relevant information and data which are necessary to perform the contracted activity in a safe and environmentally sound manner; get Roche internal technical support as necessary;
- assist the third party as far as necessary and upon request with instruction and training for the contracted activity; get Roche internal technical support as necessary;
- in co-operation with SHE specialists verify compliance with the measures agreed upon in the contract;
- in co-operation with the appropriate specialists check periodically the social and environmental situation at the third party by assessing the relevant topical areas in Annex 1;



- require corrective measures if necessary or, in case of non-compliance with the social and environmental conditions defined in the contract, interrupt or terminate the co-operation with the third party
- Maintain a tracking system for corrective actions and assure that recommendations are addressed in a timely manner

The divisions assign these tasks and responsibilities to the appropriate departments and persons.

5 Assistance

CSE or CESA (US) 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.

The provisions for commercial type **O** third party relations have to be implemented immediately. Those for type **SP** and developmental type **O** relations have to be phased-in step-by-step depending on the availability of the required technical and SHE specialists. A phase-in plan has to be prepared and agreed with CSE/CESA. We have set a goal that by **2020**

- the directive has been implemented for all existing business relations,
- all not acceptable contracts have been cancelled (consider the time needed to switch to alternative suppliers) and
- a stable process for evaluation of new and regular reevaluation of existing suppliers and service providers has been implemented.

7 Annexes

Annex 1: Checklist for the Social and Environmental Performance Evaluation of Third Party Manufacturers and Service Providers.

Annex 2: Social and Environmental Performance Standards for Suppliers and Service Providers.