

Basic Policy on the Internal Control System

Kyowa Hakko Kirin Co., Ltd. (“the Company”) has stipulated the following set of systems, based on the fundamental principles of the internal control system of its parent company, Kirin Holdings Company, Limited and in line with the Companies Act, Article 362, paragraph 4, item vi: "The development of systems necessary to ensure that the execution of duties by directors complies with laws and regulations and the articles of incorporation, and other systems prescribed by the applicable Ordinance of the Ministry of Justice as systems necessary to ensure the properness of operations of a Stock Company."

1. System to ensure compliance of execution of duties by the Directors and employees of the Company and its subsidiaries (hereinafter referred to as “the Kyowa Hakko Kirin Group”) with laws and regulations and the articles of incorporation ("Compliance System")

In order to promote compliance within the Kyowa Hakko Kirin Group, the Company shall;

- Establishing a basic policy on compliance for the Kyowa Hakko Kirin Group, maintain an organization and corporate regulations to materialize the policy.
- Establish an organization to supervise compliance, which undertakes developing awareness of compliance among employees through educational programs and awareness-raising activities, and also clarify procedures in case of compliance violations and make the procedures well-known to any of the Kyowa Hakko Kirin Group.
- Ensure that a department dedicated to internal audit shall conduct audits into the design and operation of the compliance system.
- Establish an internal control reporting system to ensure reliability of the financial reports, and conduct and evaluate its effective and efficient operation.

2. System to ensure the proper preservation and maintenance of information regarding the execution of duties by the Directors of the Company ("System of Information Preservation and Maintenance")

Regarding information relating to the execution of duties by the Company’s Directors, the Company shall implement appropriate preservation and maintenance based on corporate regulations and make them available for inspection by the Directors and Company Auditors of the Company.

3. Regulations and other systems related to the risk management of the Kyowa Hakko Kirin Group in the event of loss and other circumstances ("System for Risk Management")

In order to appropriately manage risk within the Kyowa Hakko Kirin Group, the Company shall;

- Establish a basic policy on risk management of the Kyowa Hakko Kirin Group, and maintain an organization and regulations to materialize the policy.
- Establish an organization to supervise risk management, which ensures the effectiveness of risk management through risk management activities all at each of the Kyowa Hakko Kirin Group. Also, clarify procedures in case of disclosure of risk factors and responses to the occurrence of a crisis situation, and make the procedures well-known to any of the Group.
- Ensure that the department dedicated to internal audit shall conduct audits into the design and operation of the system for risk management.

4. System to ensure the effective and efficient execution of duties by the Directors of the Kyowa Hakko Kirin Group ("Effective and Efficient Performance System")

In order to ensure the effective and efficient execution of duties by the Directors of the Kyowa Hakko Kirin Group, the Company shall;

- Establish organizational regulations and standards on allocation of duties, limits of authority and decision making.
- Appoint Executive Officers in charge of the execution of operations by a resolution of the Board of Directors. Also, as necessary, dispatch Director(s) to each Group company to oversee appropriate execution of operations and decision making.
- Establish the Executive Committee and accelerate decision making.
- Ensure, regarding the limits of authority and responsibility in the execution of duties by the Directors of the Group subsidiaries, that each Group subsidiary shall stipulate own regulations on allocation of duties, limits of authority and others and shall execute efficient operations.
- Periodically manage the Kyowa Hakko Kirin Group's business performance in comparison to their annual plans through performance monitoring tools.

5. System for reporting to the Company on matters concerning the execution of duties by the Directors of Kyowa Hakko Kirin Group and system to ensure the properness of operations of other duties by the corporate group comprising the Kyowa Hakko Kirin Group and the parent company ("System for reporting for execution of duties and other Group internal control system")

In order to ensure system for reporting to the Company on matters concerning the execution of duties by the Directors of the Kyowa Hakko Kirin Group and system to ensure appropriate operations of other duties by the corporate group comprising the Kyowa Hakko Kirin Group and the parent company, Kirin Holdings

Company, Limited, based on the basic group management policies of the parent company, the Company shall;

- Establish a relevant department in charge of each Group subsidiary, which receives regular reports concerning the business conditions of such subsidiary, and which provides with guidance and advice such as prior consultations for important issues as necessary, while continuing to respect the autonomy of the subsidiaries.
 - Establish responsibilities and limits of authority relating to the execution of operations of the Group subsidiaries and make the department dedicated to internal audit conduct audits on operations of each Group subsidiary.
- 6. Matters related to employees that assist the Company Auditors of the Company upon their request for assistance, matters related to the independence of the relevant employees from the Directors of the Company and matters related to effectiveness of directions given to such employees by the Company Auditors of the Company (hereinafter collectively referred to as "Systems related to Company Auditors")**

The Company shall assign a small number of employees to handle support duties for the Company Auditors of the Company upon their request for assistance. In order to ensure independence of the relevant employees from the Directors of the Company, the consent of the Company Auditors of the Company shall be required for any decision related to personnel affairs such as appointments, transfers and evaluation of such employees. Such employees shall not simultaneously assume any other appointment related to the execution of operation and shall only follow instructions of the Company Auditors of the Company while they are responsible for support duties for the Company Auditors of the Company.

7. System to ensure reporting to the Company Auditors of the Company by the Directors and employees of the Company, and by the Directors, Company Auditors and employees of the Kyowa Hakko Kirin Group subsidiaries

- (1) The Directors of the Company shall report to the Company Auditors of the Company;
- Among matters referred to the Board of Directors Meetings for resolution, the ones which are considered useful for prior reporting to the Company Auditors of the Company in terms of contents and their audits.
 - Any matter that may cause material damage to any of the Kyowa Hakko Kirin Group when such a matter is discovered.
 - Any occasion in which a Director or an employee of the Kyowa Hakko Kirin Group has committed an act in violation of laws or articles of incorporation or in which there is a risk that such acts may occur.
 - Legal matters requiring the consent of the Company Auditors of the Company.

- Status of the design and operation of the Internal Control System of the Company.

Not limited to the matters listed above, the Company Auditors of the Company may well request the Directors and employees of the Company, and the Directors, Company Auditors and employees of each Group subsidiary to report other matters at any time as necessary.

- (2) The Directors and employees of the Company, and the Directors, Company Auditors and employees of the Group subsidiaries (including those who receive reports from those Directors, Company Auditors and employees) may directly report to the Company Auditors of the Company when matters arise that are considered reasonable to do so, in order to ensure appropriate execution of operations of each of the Kyowa Hakko Kirin Group. The Company Auditors of the Company shall regularly receive the status of the company hotline systems, including methods for whistle-blowing from relevant departments in charge, and also may well make the status of the operation reported immediately if it is found necessary by themselves.

8. System to ensure that anyone who has made a report as described in the preceding provision to the Company Auditors of the Company, shall not be subjected to any unfair treatment due to the report made

The Company shall set forth common group regulations to ensure that anyone who makes a report as described in the preceding provision shall not be subjected to any unfair treatment for that reason, and shall make the common regulations well-known and in operation to any of the Kyowa Hakko Kirin Group.

9. Matters regarding procedures for advance payment or reimbursement of expenses incurred in connection with the execution of duties of the Company Auditors of the Company

The Company shall promptly process the relevant expenses or liabilities relating to advance payment or reimbursement of expenses incurred in connection with the execution of duties of the Company Auditors of the Company.

10. Other systems to ensure the effectiveness of audit by the Company Auditors of the Company

The Company Auditors of the Company shall hold a regular meeting with the representative and outside Directors of the Company for the exchange of opinions. The Company Auditors of the Company shall be able to implement audits in cooperation with the department dedicated to internal audit. Also, the Company shall establish systems to ensure the effectiveness of audit by the Company Auditors of the Company, for instance, by providing them with opportunities to attend the meetings of the Kyowa Hakko Group upon their request.