Kihatsu No. 491
July 14, 2000

To Directors of Prefectural Labour Bureaus

Director-General
Labour Standards Bureau of the Ministry of Labour

Enforcement of Public Notice that Revises Part of the Standards to be Provided at the Test Facilities

The Public Notice that Revises Part of the Standards to be Provided at the Test Facilities (Notification No. 13 of the Ministry of Labour, 2000) based on the provisions of Article 34-3, paragraph (2) of the Ordinance on Industrial Safety and Health was promulgated on March 29, 2000 and was enacted from October 1, 2000.

Along with the revision of the Good Laboratory Practice standards on the safety testing of chemical substances (hereinafter referred to as "OECD-GLP") by the OECD (Organisation for Economic Co-operation and Development), it shall provide, in order to ensure the international consistency, to further clarify the definitions on the duty of the Study Director and the Quality Assurance Personnel, and the notification shall apply for test facilities that conduct carcinogenicity tests, and so forth.

We expect you to pay attention to the following matters without omissions of their operation.

1. Points of revision

(1) Response to the carcinogenicity test (Related to Articles 1, 10 and 13)

The investigation of toxicity under the provisions of Article 34-3, paragraph (1), item (i) of the Ordinance on Industrial Safety and Health (Ordinance of the Ministry of Labour No. 32 of 1972) also specifies carcinogenicity tests. Although the notification was applicable only to the test facilities where mutagenicity tests were conducted so far, and this time, such notification is also to be applicable to test facilities under which the carcinogenicity test is conducted.

As a result, we have made prescribed improvements, such as specifying to include "concerning animals breeding and handling" in the standard operating procedures.

(2) Consistence with the OECD Principles of GLP (Articles 2 through 8, Article 10, Articles 11 and 13 through 16 related matters)

With regards to the standards to be provided to the test facility, which is deemed to have the necessary technical basis for properly conducting investigation of toxicity, and this standard was revised in 1997 for the purpose of clarifying definitions, responsibilities for the OECD Principles of GLP. Accordingly, in order to maintain consistency of the standard, prescribed improvements were provided as follows.

A. Article 4 related matters

Duties for the Study Director were added as below:

(A) A copy of the study plan approved by the Test Facility Management shall be sent to the Quality Assurance Personnel.

(B) The tests shall be conducted according to the study plan and the standard operating procedures.

(C) Corrective actions shall be taken regarding deviations from the study plan or the standard operating procedures and the results therefrom shall be recorded.

(D) When using a computer system for testing, it shall be confirmed that whether the computer system operates properly.

(E) When correcting the final report, a document shall be prepared, including the date of correction and the details and reasons for the correction.

B. Article 5 related matters

Duties of the Quality Assurance Personnel were added as follows:

(A) It shall be confirmed whether the prescribed items are included in the study plan.

(B) It shall be confirmed that whether corrective measures are appropriately taken regarding deviations from the study plan or the standard operating procedures carried out by the Study Director.

C. Article 6 related matters

The matters to be observed by the staff were added as follows:

(A) Raw data shall be promptly and accurately recorded.

(B) Any deviations recognized from the study plan or the standard operating procedures shall be reported to the Study Director with the contents to be recorded.

D. Article 10 related matters

Confirmation regarding the operation of the computer system shall be included in the standard operating procedures.

E. Article 11 related matters

It is not required to include the “name and affiliation of the Quality Assurance Personnel” in the study plan.

F. Article 14 related matters

(A) When conducting a test under consignment, "name and address of the sponsor, etc." shall be included in the final report.

(B) It is required the “name and affiliation of the Study Director” in the final report.

G. Article 15 related matters

Any materials carried in/transferred out of the archive facilities shall be recorded thereof.

(3) Review of seal (related to Articles 4, 5 and 13)

Although "signature and seal" was required when preparing or approving documents (the study plan, final report, and quality assurance document) until now, it was changed into "printed name/seal or signature." Also, when the matters in the document were corrected, the places of correction and those that used to require "signature and seal" were changed to "signature or seal."

2. Details

(1) Article 3 related matters

The "Archive Director" referred to paragraph (1), item (viii), has been renamed to clarify that test items, specimens, etc. are included as storage objects, whose scope is the same as the "archives storage qualifying personnel" before revision.

Also, the same purpose shall be applicable to the "archive facilities" in Article 8, paragraph (1), item (iii).

(2) Article 4 related matters

Regarding the phrase "to check beforehand that the computer system works properly" referred to item (iv), it is not always necessary to do it for each test, but to the extent that it is enough to do it periodically.

(3) Article 7 related matters

The "test items, etc." referred to item (ix) contain reference item in the carcinogenicity test. However, it may be acceptable not to include reference item in the mutagenicity test.

(4) Article 10 related matters

The "handling" referred to item (iv) shall include slaughter, isolation, expulsion and capture.

(5) Article 15 related matters

The person authorized by Test Facility Management in paragraph (2), item (i), may be recognized as the Archive Director or a person authorized by the Archive Director, and it is acceptable to apply the same item thereto.

3. Handling of related notification

(1) No. 3 of “Application of the standards of investigation of toxicity and the standards to be provided at the test facilities carrying out investigation of toxicity” (Kihatsu No. 603, dated September 16, 1988) shall be revised as follows, and enacted from October 1, 2000.

A. The “Article 57-2 of the Act” shall be revised to the “Article 57-3 of the Act.”

B. The “mutagenicity test” shall be revised to the “mutagenicity test and carcinogenicity test.”

C. The “Archive Director” specified under paragraph 2(2) G shall be revised to the “person related to the archives.”

D. The provisions of paragraph 2 (3) A shall be revised into “A. Deletion.”

E. The provisions of “Article 5, item (v)” specified under paragraph 2(3) C shall be revised into “Article 5, item (vii).”

F. The “[2] signature and seal” specified under paragraph 2 (3) C shall be revised to “printed name/seal or signature.”

(2) "The standards to be provided at the test facility conducting carcinogenicity tests" (Kihatsu No. 145 dated March 11, 1997) shall be abolished as of September 30, 2000.