

\*This is a provisional translation.

March 31, 2011

No. 0331007, Pharmaceutical and Food Safety Bureau, MHLW  
No. 5, Manufacturing Industries Bureau, METI (March 29, 2011)  
No. 100331009, Environmental Policy Bureau, MOE

Director General of Pharmaceutical and Food Safety Bureau, MHLW  
Director General of Manufacturing Industries Bureau, METI  
Director-General of Environmental Policy Bureau, MOE

Testing Methods for New Chemical Substances etc.

According to the “Ministerial Ordinance Abolishing the Ministerial Ordinance Specifying Items Concerning the Study of the Hazardous Properties of Type III Monitoring Chemical Substances and the Ministerial Ordinance on Instructions to Conduct a Study of the Hazardous Properties of Type III Monitoring Chemical Substances etc.(the METI and MOE Ordinance No. 1, 2010),” the Ministerial Ordinance Specifying Items Concerning the Study of the Hazardous Properties of Type III Monitoring Chemical Substances etc. (the METI and MOE Ordinance No. 10, 2003: hereinafter referred to as “former Ministerial Ordinance”) was abolished; thus, the items concerning the study of the hazardous properties etc. specified in the former Ministerial Ordinance have been added to the provisions of the “Ministerial Ordinance Specifying Items Concerning the Testing of New Chemical Substances and the Study of the Hazardous Properties of Priority Assessment Chemical Substances and Monitoring Chemical Substances etc.” (the MHLW, METI and MOE Ordinance No. 3, 2003: hereinafter referred to as “new Ministerial Ordinance”), which was newly established as a result of full revision of the “Ministerial Ordinance Specifying Items Concerning the Testing of New Chemical Substances and the Study of the Hazardous Properties of Type I Monitoring Chemical Substances and Type II Monitoring Chemical Substances etc.” (Minister’s Office, MHLW, and MITI Ordinance No. 1, 1974). As a result of the enforcement of the new Ministerial Ordinance, “combined repeated dose toxicity study with reproduction/development toxicity screening test conducted with mammals,” which are deemed to be equivalent to or higher than the effectiveness of 28-day repeated dose toxicity studies, was added to the provisions in the “Studies Separately Specified by the Minister of Health, Labor and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment, pursuant to the provisions as provided in Article 2 and Article 4, Item (4) of the Ministerial Ordinance Specifying Items Concerning the Testing of New Chemical Substances and the Study of the Hazardous Properties of Priority Assessment Chemical Substances and Monitoring Chemical Substances (MHLW, MITI and MOE Notification No. 5, 2011).” Additionally, in response to the revision of the OECD (Organization for Economic Co-operation and Development) test guidelines for testing of chemicals (hereinafter referred to as “OECD test

guidelines”) etc., the review of existing test methods was undertaken.

For these reasons, the tests as listed in Item (2) of Paragraph 1 of Article 1, Paragraphs 2 and 3 of the same article, Article 2, Paragraph 2 of Article 3, and Paragraphs 2 through 5 of Article 4 in the new Ministerial Ordinance and those, as stipulated in Articles 5 and 6 in the same ordinance, for investigating chronic toxicity, effects on reproductive ability and subsequent generations, teratogenesis, mutagenicity, carcinogenicity, toxicokinetics and pharmacological characteristics, effects on algal growth, effects on *Daphnia magna* reproduction, effects on inhabitation and growth of fish in the early life stages, and effects on inhabitation or growth of flora and fauna in the human living environment, especially when the Ministers of METI and MOE find the test necessary in consideration of the levels of Priority Assessment Chemical Substances remaining in the environment, and or effects on avian reproduction as of and from April 1, 2011, shall be, in principle, performed in accordance with the methods in the following Part 1 and treated as provided in Part 2.

In addition, the “Testing Methods for New Chemical Substances, etc., (joint notification by the Director General of Pharmaceutical and Food Safety Bureau, MHLW (November 21, 2003: No. 1121002, Pharmaceutical and Food Safety Bureau, MHLW), the Director-General of Manufacturing Industries Bureau, METI (November 13, 2003: No. 2, Manufacturing Industries Bureau, METI) and the Director-General of Environmental Policy Bureau, MOE (No. 031121002, Environmental Policy Bureau, MOE)” (hereinafter referred to as “2003 Joint Notification”) shall be abolished as of March 31, 2011.

This is the beginning of a series of the Provisions.

Part 1: Testing Methods for New Chemical Substances, etc.

Tests for new chemical substances, etc., shall, in principle, be in compliance with the methods as in Attachment.

Part 2: Handling of Testing Methods for New Chemical Substances, etc.

1 Transitional Measures

1 ) With regard to the handling of tests started on and before March 31, 2011, which have been conducted in accordance with the methods of each test as specified in 2011 Joint Notification and the “Testing Method for the Study of the Hazardous Properties of Type III Monitored Chemical Substances (March 25, 2004: No. 6, Manufacturing Industries Bureau, METI (March 19, 2004); No. 040325004, Environmental Policy Bureau, MOE),” the provisions then in force shall remain applicable.

2 ) Among the tests started on and before March 31, 2011, whose purpose meet the purposes in the “combined repeated dose toxicity study with reproduction/development toxicity screening test conducted with mammals” specified in the above Part 1, those which have been performed in accordance with OECD Test Guidelines shall be able to be handled as a test that meets the purpose of this joint notification.

## 2 Others

Among tests whose purpose meets the purposes of chronic toxicity study, studies for effects on reproductive ability and subsequent generations, teratogenesis study, mutagenicity study, carcinogenicity study, study on metabolic fate, or pharmacological studies, those which have been performed in accordance with OECD Test Guidelines shall, in principle, be able to be handled as a test that meets the purpose of this joint notification.