

Ministry of Health and Welfare Announcement No. 232

According to the provision defined in paragraph 1 of Article 7 of the Food Sanitation Law (Law No. 233), certain parts of Specifications and Standards for Foods, Food Additives and Other Related Products (Ministry of Health and Welfare Announcement No.370 - Dec. 1959) are hereby amended as follows, and this amendment is effective on April 1, 2001. Under the amended Specifications and Standards, only two provisions regarding procedure for examination of safety assessment and for confirmation of compliance with the standards for manufacturing process can be applied before April 1, 2001. The former is related to the provision defined in paragraphs 3 and 4 of Part 1, Section A and in Part 2, Section D and the latter is in paragraph 5 of Part 1, Section B and in paragraph 3 of Part 2, Section E of the Specifications and Standards.

1st May, 2000

Minister for Health and Welfare Yuya Niwa

The following paragraphs are added to Section A-“Standards Regarding Composition of Foods in General” of Part 1- “Foods”:

3. When foods are all or part of organisms produced by recombinant DNA techniques, or include organisms produced by recombinant DNA techniques either partially or entirely, such organisms shall undergo examination procedure for safety assessment made by the Minister for Health and Welfare and shall be announced to the public in the Official Gazette.

4. When foods are produced by use of microorganisms produced by recombinant DNA techniques, or include such microorganisms, such foods or microorganisms shall undergo examination for safety assessment by the Minister for Health and Welfare and shall be announced to the public in the Official Gazette. .

The following two paragraphs are added to Section B-“Standards Regarding Manufacturing, Processing and Preparation of Foods in General” of Part 1-“Foods”:

5. When foods are manufactured by use of microorganisms produced by recombinant DNA techniques, such manufacturing process shall undergo confirmation of compliance with the standards for manufacturing process established by the Minister for Health and Welfare.

6. When foods are manufactured or processed, it shall be prohibited to use any food additives that are not in accordance with standards defined at Section D- “Monographs” and Section E- “Standards for Manufacturing” of Part 2-“Food Additives”.

The following sentences are added to Section D-“Monographs” in Part 2-“Food Additives”:

Food additives that have standards and/or specifications, these food additives shall comply with their standards and/or specifications

When food additives are manufactured by use of organisms produced by recombinant DNA techniques, such food additives shall undergo examination for safety assessment made by the Minister for Health and Welfare and shall be announced to the public in the Official Gazette.

The following paragraph is added to Section E-“Standards for Manufacturing” in Part 2-“Food Additives”:

3. When food additives are manufactured by use of organisms produced by recombinant DNA techniques, such manufacturing process shall comply with the standards established by the Minister for Health and Welfare.

Note: This English version of the Notice is translated to meet the need of the non-Japanese speaking people. In the case of any discrepancy between the Japanese original and the English translation, the former will take priority.