Safety Management in Contained Use

❑ Report and permits regarding LMO research facilities

○ Biosafety Level 1 and/or 2 in terms of safety management requires reporting, while Biosafety Levels 3 and/or 4 require permits.

※ The safety management level of research facilities are classified according to the degree of risk of the LMOs that are treated within the facilities (risk degree: Biosafety Level 1 < Biosafety Level 2 < Biosafety Level 3 < Biosafety Level 4).

※ Research facilities at Biosafety Level 3 and/or 4 in terms of environmental risk are to receive permits from the Ministry of Science, ICT and Future Planning. Research facilities at Biosafety Level 3 and/or 4 in terms of risk to humans are to receive permits from the Ministry of Health and Welfare. If the facilities are divided into separate walls or doors, they must be reported as one facility.

Report of facilities for LMO research (unit: no. of cases)

Type	2008	2009	2010	2011	2012	2013	2014	Total
Hospital	26	25	3	3	9	38	6	110
University	910	162	181	121	343	224	411	2,352
National/ public (research centers)	182	23	20	84	71	94	72	546
Corporate/ other	146	19	12	20	32	54	50	333
Total	3,126	2,219	2,214	2,219	2,435	2,369	2,503	17,085

Source: KBCH

New permits for facilities in LMO research (unit: no. of cases)

Type	2008	2009	2010	2011	2012	2013	2014	Total
Total	7	8	6	14	12	3	7	57

Source: KBCH

○ Observance to standards for installation and operation of research facilities with Biosafety Level 2

※ Organizations that operate research facilities of Biosafety Level 2 or higher must

mandatorily establish an Institutional Biosafety Committee(hereinafter IBC) and designate a biosafety officer. The institutional biosafety officer must have at least 4 hours of official study/training in biosafety management. The users of the research facility must have at least 2 hours of official biosafety education.

○ Observance to standards for installation and operation of research facilities with Biosafety Level 3 and/or 4 of biosafety

※ Must mandatorily set up an IBC and designate the institutional biosafety officer.

※ Personnel related to biosafety management must receive official education/training in biosafety.

※ The biosafety officer of the organization that operates research facilities that have acquired a permit must receive official education/training in biosafety conducted by an agency specializing in safety management.

※ Provision of manual regarding installation and operation, and technical guide on verification.

Education requirements of biosafety management personnel according to research facility biosafety level

Target and conditions \ Research facilities		Biosafety level 2	Biosafety level 3 and/or higher
Conditions for designation (Prior education)	institutional biosafety officer and biosafety officer	at least 8 hours	at least 20 hours
	Biosafety officer of a outside expert agency	non-applicable	at least 20 hours
	Maintenance and repair personnel of a outside expert agency	non-applicable	at least 12 hours of training in operation of research facilities (at least 4 hours in biosafety areas)
Conditions for operation (Annual education)	institutional biosafety officer and biosafety officer	at least 4 hours	at least 4 hours of operation training from a expert agency
	Biosafety officer of a outside expert agency	non-applicable	at least 8 hours (at least twice a year)
	Research facility users	at least 2 hours	at least 2 hours of operation training by a expert agency

○ Observance to preparation of records for import/export of LMOs and management/operation of research facilities

※ Management ledger, transportation management ledger, storage management ledger for LMOs for research and development purposes, Management and operation ledger for research facilities: Records are kept for 5 years.

❑ National approval of genetically modified experiments for research and development purposes

○ Principle: Organizations that have registered (report/permit) its research facilities to the government can freely conduct all experiments within the research facilities after an independent verification procedure by the IBC.

○ However, for LMOs that require government control, when developing them or using them for experiments, a prior approval must be acquired from the Center for Disease Control and Prevention of the Ministry of Health and Welfare.

※ Categories that require approval: Use of unidentified organisms, toxic genes with protein quality of LD_{50}<100ng for vertebrates, and use of genes that are drug resistance or pathogenic microorganisms that require government control due to national health issues.

※ Prior biosafety evaluation must be received from the organization's IBC.

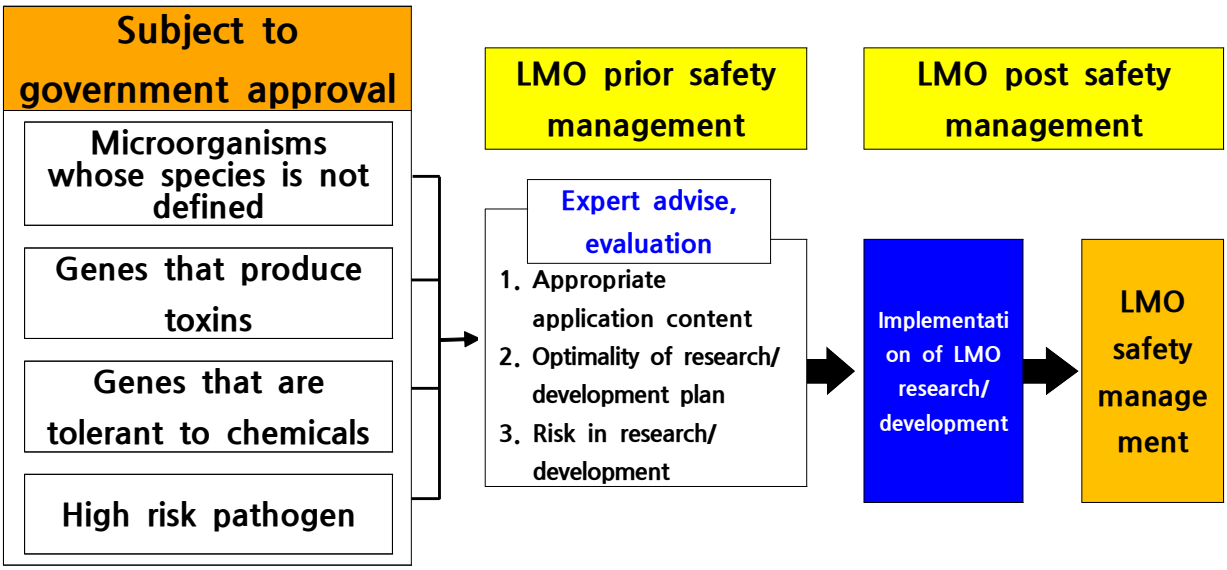
※ Before applying for approval, permit acquisition/reporting procedure for research facilities must be completed.

※ Exceptions in the case of research and development for the purpose for sequencing.

○ Biosafety management for research and development of LMOs subject to government control

※ Provision of skills and techniques in connection with WHO International Health Regulations to comprehensively manage contagious pathogens and risks in the laboratory.

※ Provision and operation of risk assessment system in genetically modified experiments focused on experiment conduct procedure.



○ In addition, in case of conducting experiments in which LMOs are released into the environment, approval must be received from the relevant central administrative agency according to each intended use.

※ Prevention of unintentional environmental release, or use other than that approved.

National approval of research and development of LMOs (unit: no. of cases)

Type	2008	2009	2010	2011	2012	2013	2014	Total
Release into the environment	31	71	77	233	260	273	332	1,277
High risk pathogens	13	6	1	2	12	16	39	89
Total	2,039	2,080	2,087	2,244	2,272	2,286	347	1,277

Source: KBCH

❑ Contained use at industrialization stage

○ According to the current LMO Act, the subject to contained use is prescribed as only Living modified microorganisms(hereinafter LMMs).

○ As of April 2016, the law is in the process of being revised so that subjects of contained use are expanded from LMMs to LMOs.

○ Ministries involved in biosafety management of LMMs for contained use

※ 7 related central administrative agencies conduct safety management according to intended purpose.

Ministry	Task
Ministry of Science, ICT and Future Planning	• Biosafety level 1 and/or 2 facilities
Ministry of Agriculture, Food and Rural Affairs	• LMMs for agricultural purposes and contained use facilities.
Ministry of Trade, Industry and Energy	• LMMs for industrial purposes and contained use facilities.
Ministry of Health and Welfare	• Biosafety level 3 and/or 4 facilities in terms of risk to humans. • LMMs for health and medical purposes and contained use facilities.
Ministry of Environment	• Biosafety level 3 and/or 4 facilities in terms of environmental risk. • LMMs for environmental purification and contained use facilities.
Ministry of Oceans and Fisheries	• LMMs for maritime and fisheries purposes and contained use facilities.
Ministry of Food and Drug Safety	• LMMs for food and medical equipment purposes and contained use facilities.

○ Risk Review of LMMs

※ In the case of LMMs for environmental release, and LMMs for contained use, a risk assessment must be received after submitting risk assessment data in accordance with Article 2 of Appendix 10-1 of the Consolidated Notice on the transboundary movements of living modified organisms(hereinafter Consolidated Notice).

※ Assessment categories for LMMs for environmental release: 13 categories, 118 items.

※ Assessment categories of LMMs for contained use: 11 categories, 105 items.

※ Consultative review regarding risk to humans (Center for Disease Control and Prevention), consultative review regarding risk to environment (Ministry of Agriculture, Food and Rural Affairs, Ministry of Environment, Ministry of Oceans and Fisheries) are conducted.

※ Statutory period for risk review: 270 days (supplementary period not included).

○ Simplification of Risk Review of LMMs

※ When industrial LMMs with no or negligible risk are to be subject to contained use, risk assessment data according to Appendix 4-2 of the Consolidated Notice must be submitted to receive risk review.

※ Assessment categories: 6 categories, 35 items.

※ Consultative review regarding risk to only humans is conducted (Center for Disease Control and Prevention).

※ Statutory period for risk review: 90 days (supplementary period not included)

○ Acquiring permits and reporting for installation and operation of contained use facilities

※ In the case of installing/operating Level 3 and/or 4 facilities that use highly risk LMMs, a permit must be received from the relevant central administrative agency according to the purpose.

※ When installing/operating Level 1 and/or 2 facilities a report must be made to the relevant central administrative agency according to the purpose.

※ Approval and report processing period: 60 days

※ When intending to close contained use facilities, a report must be made to the related central administrative agency to which approval application and reporting was made for installation and operation.

○ Approval for use of LMMs

※ When an entity has received risk assessment and registered (acquisition of permit/report) contained use facilities to the government, and wishes to use LMMs in these facilities, approval for use must be received from the related central administrative agency depending on intended use (approval processing period: 10 days).

※ Matters for use approval: A confirmation must be made that the facilities have been equipped, and that the pertinent LMMs are the same ones that received the risk assessment.

❑ Statistics regarding contained use at industrialization stage

○ Risk Review of LMMs for contained use (as of April 2016)

※ Completion of review of LMMs for contained use for purpose of producing food materials: 2 cases, under review: 2 cases.

※ Review underway for LMMs for contained use for the purpose of producing industrial materials: 2 cases.

○ Approval of use of LMMs for contained use (as of April 2016)

※ Approval of use of LMMs for contained use for production of food materials: 2 cases

○ Status of facility reports (as of April 2016)

※ Report of facilities for contained use for production of food materials: 2 cases.

※ Report expected for facilities for contained use for production of industrial materials: 2 cases.