

National Institute for Public Health and the Environment Ministry of Health, Welfare and Sport

A Framework for the Risk Assessment and Management of Gene Drive Technology in Contained Use

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Defining risk classes for a GDO activity

Risk class 1: negligible to low risk

GDO comprises a similar risk as the corresponding GMO, i.e. there is no increased spread of the GDO or its genetic trait in case of unintentional release.

		Severity of potential adverse effects (ecological impact)					
		Negligible	Low	Medium	High		
Likelihood of occurrence of potential adverse offects	High	Negligible Risk class 1	Medium Risk class 2	High Risk class 3	High Risk class 3		
	Medium	Negligible Risk class 1	Low Risk class 1	Medium Risk class 2	High Risk class 3		
	Low	Negligible Risk class 1	Low Risk class 1	Low Risk class 1	Medium Risk class 2		
	Negligible	Negligible Risk class 1	Negligible Risk class 1	Negligible Risk class 1	Negligible Risk class 1		

Risk class 2: medium risk

A non-permanent impact on the environment, i.e. the spread of the GDO or its trait is transient and the initial situation can be restored.

Risk class 3: high risk

A permanent and non-reversible impact on the environment.

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Risk	(Manageme	ent – Minir ^{imal control measure}	l Measures						
	Risk class 1	Risk class 2	Risk class 3						
Physical requirements	Two layers of physical containment: (1) species appropriate container (unbreakable, escape-proof) and (2) laboratory to include species-specific barriers	Additional layer of physical containment to enclose the species appropriate container							
			Two door system with interlock						
Work practice		Access to all areas used for GDO activities limited to trained personnel and instructed service personnel	Access to all areas used for GDO activities restricted to trained personnel and accompanied service personnel						
		Monitoring plan available the gene drive element(s) case of unintentional relea	to test for the presence of in the environment in ase	Additional control measures are specified for:					
			prepared in case of detection of gene drive element in the environment	 yeast, fungi arthropods 					
				> rodents					
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