

373
Decree
of
the Ministry of the Environment

of October 6, 2000

laying down the requirements on contained space and protective measures for the individual risk categories in contained use of genetically modified organisms

Pursuant to § 24 letter g) of Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amending some related acts (hereinafter “the Act”), the Ministry of the Environment, in agreement with the Ministry of Health and the Ministry of Agriculture, hereby lays down:

§ 1

(1) The requirements on contained space and protective measures for contained use of genetically modified organisms (hereinafter "contained use") are set forth in Annexes Nos. 1 to 4 according to the type of workplace and risk category. Assignment of the use of a genetically modified organism or product to one of the risk categories [§ 2 letter m) of the Act] shall be the result of risk assessment [§ 2 letter l) of the Act] carried out pursuant to § 4 of the Act and § 4 of the Decree on detailed conditions for the use of genetically modified organisms and products¹⁾.

(2) The space and equipment corresponding to any higher risk category may be also used for contained use in a particular risk category.

(3) Compliance with the Code of Practice of the workplace and provisions for training and instruction of personnel shall also constitute part of the protective measures.

(4) The provisions of paragraphs 1 to 3 shall in no way prejudice the special legal regulations²⁾.

§ 2

This Decree shall come into effect on January 1, 2001.

¹⁾ Decree No. 374./2000, on detailed conditions for the use of genetically modified organisms and products.

²⁾ E.g., Decree No. 230/1999 Coll., laying down proper clinical practice and detailed conditions for clinical evaluation of medicinal substances, Decree No. 74/1998 Coll., laying down proper laboratory practice in the area of medicinal substances, Decree No. 311/1997 Coll., on the breeding and use of experimental animals.

Requirements on contained space and protective measures for microbiological laboratories

		For risk category			
		A (for the first category)	B (for the second category)	C (for the third category)	D (for the fourth category)
	Contained space				
1	Isolation inside of the building or location in a separate building	not required	isolation inside the building	isolation inside the building	location in a special building required
2	Sealable for fumigation	not required	not required	required	required
	Equipment				
3	Easily cleanable surfaces resistant to water, acids, alkalis, solvents; permitting effective disinfection and decontamination	required for the bench, floor and walls	required for the bench, floor and walls	required for the bench, floor and walls	required for the bench, floor, walls and ceiling
4	Entrance into the working area via airlock ¹⁾	not required	required only if this follows from the risk assessment	required	required
5	Decreased pressure relative to the pressure in the immediate surroundings	not required	not required	required	required
6	Extract and input of air through an aerosol filter (HEPA)	not required	not required	required for exit	required; where work is carried out with viruses, special measures against dissemination of viruses required
7	Sterile box - separate room	not required	required only if this follows from the risk assessment	required	required

8	Autoclave	required, in the building	required, in the building and conditions ad ² must be fulfilled	required, in the contained space	required, in the laboratory; it must be inserted between the "clean" and "unclean" space
	System of work				
9	Limited access	not required	required	required	required
10	Sign "biological hazard" at the entrance	not required	required	required	required
11	Special measures for limiting spread of aerosols	not required	required to minimize spread	required to prevent spread	required to prevent spread
12	Shower	not required	required in the building	required	required
13	Protective clothing	suitable working clothing required	suitable protective clothing required; protective footwear required only if this follows from the risk assessment	suitable protective clothing and protective footwear required	suitable protective clothing, footwear and glasses required, with complete change of underwear, clothing and footwear prior to entering and leaving the contained space
14	Protective gloves	required only if this follows from the risk assessment	required	required	required
15	Effective control and prevention of vectors of genetically modified organisms (e.g. insects and rodents)	required	required	required	required
	Wastes				
16	Inactivation of genetically	required	required	required	required

	modified organisms in effluent from washbasins, sinks, showers and in other waste waters	only if this follows from the risk assessment			
17	Inactivation of genetically modified organisms on used material and solid wastes in accord with the special legal regulations ³	required	required, including disinfecting of protective clothing	required, including disinfecting of protective clothing and footwear and other protective aids	required, including disinfecting of protective clothing and footwear and other protective aids
	Other measures				
18	The laboratory has its own equipment	required	required	required	required
19	An observation window or other equipment is installed so that the workers in the laboratory can be seen	required only if this follows from the risk assessment	required only if this follows from the risk assessment	required	required
20	Resting room outside of the work area	not required	required only if this follows from the risk assessment	required	required

Footnotes:

¹ An airlock means the entrance to the laboratory through separated spaces. Their "clean" side shall be separated from the laboratory by safety doors, a changing room for changing clothing and by a shower.

² A standard operational procedure shall be followed, permitting safe transfer of material to the autoclave outside the laboratory and ensuring the same level of protection.

³ E.g., Act No. 125/1997 Coll., on wastes, as amended.

Requirements on contained space and protective measures for glasshouses and growth-rooms

A glasshouse or growth-room means a contained space enclosed by walls, a floor and roof (ceiling), that is intended and predominantly used for cultivating plants. If other genetically modified organisms than plants are used in a glasshouse, the glasshouse must comply with the conditions laid down by this Decree for the appropriate workplace (e.g. Annex No. 1 for genetically modified microorganisms, Annex No. 3 for genetically modified animals).

Glasshouses and growth-rooms must comply with the following requirements:

		For risk category			
		A (for the first category)	B (for the second category)	C (for the third category)	D (for the fourth category)
	Contained space				
1	The glasshouse or growth-room is resistant to weather extremes in the given region	not required	required	required	required
2	Isolation inside the building or located in a separate building	not required	required only if this follows from the risk assessment	required only if this follows from the risk assessment	location in a special building required
3	Sealable for fumigation	not required	not required	required	required
	Equipment				
4	Entrance into the work area through a separate room with two interlocking doors	not required	required	entrance via an airlock ¹ required	entrance through an airlock ¹ required
5	Decreased pressure relative to the pressure in the immediate surroundings	not required	not required	required	required
6	Extract and input of air through an aerosol filter (HEPA)	not required	not required	required for exit	required
7	Autoclave	required, in the premises	required, in the building	required, in the building and conditions ad ² must be fulfilled	required, in the contained space; it must be inserted between the "clean" and

					"unclean" space
	System of work				
8	Limited access	not required	required	required	required
9	Sign "biological hazard" at the entrance	not required	required	required	required
10	Shower	not required	required in the building	required	required
11	Protective clothing	suitable protective clothing required	suitable protective clothing required; protective footwear required only if this follows from the risk assessment	suitable protective clothing and protective footwear required	suitable protective clothing, footwear required, with complete change of clothing and footwear prior to entering and leaving the contained space
12	Protective gloves	required only if this follows from the risk assessment	required	required	required
	Wastes				
13	Inactivation of genetically modified organisms in the effluent from washbasins, sinks, showers and other waste waters in accord with the special regulations ³	required only if this follows from the risk assessment	required	required	required
14	Inactivation of genetically modified organisms on used material and solid wastes in accord with the special regulations ³	required	required, including of protective clothing	required, including protective clothing and footwear and other aids	required, including protective clothing and footwear and other aids
	Other measures				
15	Limiting the occurrence of undesirable animals, insects, rodents, etc. by preventing access and regular treatment	required	required	prevention of occurrence required	prevention of occurrence required

	of the space and equipment with effective means				
16	The glasshouse or growth-room has its own equipment	required	required	required	required
17	Water outflow only into an outlet that undergoes inactivation pursuant to point 13	required only if this follows from the risk assessment	required control of outflow outside the outlet	prevention of outflow outside the outlet required	prevention of outflow outside the outlet required
18	Treatment of waste soil in an autoclave or hot-air sterilizer	not required	required only if this follows from the risk assessment	required	required
19	The procedure of transferring organisms to other equipment must permit control over dissemination of genetically modified organisms	dissemination outside to the space to which it is relocated must be limited to the smallest possible degree	prevention of dissemination outside to the space to which it is relocated is required	prevention of dissemination outside to the space to which it is relocated is required	prevention of dissemination outside to the space to which it is relocated is required
20	Resting room	not required	required only if this follows from the risk assessment	required	required

Footnotes:

¹ An airlock means entrance to the glasshouse or growth-room through separated spaces. Their "clean" side shall be separated from the laboratory by safety doors, a changing room for changing clothing and a shower.

² A standard operational procedure shall be followed, permitting safe transfer of material to the autoclave outside the glasshouse or growth-room and ensuring the same level of protection as in these spaces.

³ E.g., Act No. 125/1997 Coll., on wastes, as amended.

Requirements on contained space and protective measures for animal units

If genetically modified microorganisms are used in animal units, these spaces must simultaneously comply with the conditions specified by Annex No. 1 to this Decree. If clinical evaluation of human or veterinary medicinal substances containing genetically modified organisms is involved, the requirements on contained spaces and protective measures in accord with the special regulations shall be applied (e.g. Act No. 79/1997 Coll., on medicinal substances and amending and supplementing some related acts, as amended by Act No. 149/2000 Coll., Decree No. 230/1999 Coll., laying down proper clinical practice and the detailed conditions for clinical evaluation of medicinal substances).

In addition to the requirements following from the special legal regulations (e.g. Act No. 246/1992 Coll., on protection of animals against cruelty, as amended, Decree No. 311/1997 Coll., on the breeding and use of experimental animals, Law No. 166/1999 Coll., on veterinary care and amending related acts, the Veterinary Act, Act No. 20/1966 Coll., on care for the health of the population, as amended), the user installation for animals must also comply with the following requirements:

		For risk category			
		A (for the first category)	B (for the second category)	C (for the third category)	D (for the fourth category)
	Contained space				
1	The animal unit ¹ is a separate unit	required only if this follows from the risk assessment	required	required	required
2	Animal facilities ² are separated by lockable doors	required only if this follows from the risk assessment	required	required	required
3	Animal facilities and auxiliary facilities are designed so that they can be easily cleaned and decontaminated (material impermeable for water, easily washed and disinfected)	required	required	required	required
4	The floor and walls of the chambers are easily washable	required only if this follows	required for the floor	required for the floor and walls	required for the floor and walls

		from the risk assessment			
5	The animals are kept in suitable containment facilities, such as boxes, pens or tanks	required	required	required	required
6	Filters on isolators ³ or isolated rooms	not required	required only if this follows from the risk assessment	required	required
7	In case of the use of products of animal origin provisions for control thereof (e.g. veterinary hygienic control)	required	required	required	required
In case of animal units for water animals					
8	Inactivation of the animals in waste waters	required	required	required	required
9	Design of the space preventing, in case of breakage, leaks or overflow of the vessels for the water animals, outflow into the sewers, surface or ground waters	required for escape of organisms	required for escape of organisms	required for leakage of water	required for leakage of water

Footnotes:

¹ Animal unit means a separate building or space inside a building containing facilities for animals and other auxiliary spaces (e.g. storehouse for feedingstuff, bedding and other aids), including the facilities for the personnel (e.g. changing rooms, showers, sterilizers, spaces for storing foodstuffs, etc.).

² Animal facility means installations and equipment, specialized according to the kind of animals for their housing and carrying out experimental procedures.

³ An isolator means a transparent box in which small animals are kept; isolated rooms are preferable for larger animals.

**Requirements on containment and other protective measures for other activities
(e.g. for production operations, pilot plants)**

		For risk category			
		A (for the first category)	B (for the second category)	C (for the third category)	D (for the fourth category)
	Contained system				
1	Viable organisms must be maintained in a contained system ¹ , which is separated from the surroundings	required only if this follows from the risk assessment	required	required	required
2	Safeguarding and regulation of spread of aerosols leaving the contained system	not required	limitation of dissemination to a minimum required	prevention of dissemination required	prevention of dissemination required
3	Safeguarding and regulation of spread of aerosols during taking samples or adding material to the contained system or transfer of material to another system	required only if this follows from the risk assessment	limitation of dissemination to the lowest possible degree required	prevention of dissemination required	prevention of dissemination required
4	Inactivation of the cultivation medium (fluids) prior to removal from the contained system	inactivation by a physical or chemical method necessary	inactivation by a physical or chemical method necessary	inactivation by a physical or chemical method with proven 100% efficiency necessary	inactivation by a physical or chemical method with proven 100% efficiency necessary
5	Design of the sealing and closings preventing dissemination of the organisms from the contained system	limitation of dissemination to the lowest possible degree required	complete prevention of dissemination required	complete prevention of dissemination required	complete prevention of dissemination required
	Other requirements on the contained space				
6	The capture tank of the	required	required	required	required

	cultivation installation must contain the entire volume of the contained system if spillage occurs	only if this follows from the risk assessment			
7	Sealing for fumigation	not required	required only if this follows from the risk assessment	required only if this follows from the risk assessment	required
8	Entrance through a airlock ²	not required	not required	required only if this follows from the risk assessment	required
9	Easily cleanable surface resistant to water, acids, alkalis, solvents, permits effective disinfection and decontamination	required for the working surface, floor and walls	required for the working surface, floor and walls	required for the working surface, floor and walls	required for the working surface, floors, walls and ceiling
10	Special ventilation equipment intended to limit contamination of the air to a minimum	required only if this follows from the risk assessment	required only if this follows from the risk assessment	required	required
11	Maintaining decreased pressure relative to the pressure in the immediate surroundings	not required	not required	required	required
12	Extract and input of air through an HEPA filter	not required	not required	required for exit; required for entrance only if this follows from the risk assessment	required for entrance and exit
	System of work				
13	The entire contained system is located in a contained space	not required	required only if this follows from the risk assessment	required	required

14	Limited access	required	required	required	required
15	Sign "biological hazard" at the entrance	not required	required	required	required
16	Personnel must shower prior to leaving the contained space	not required	not required	required	required
17	Protective clothing	working clothing required	working clothing required; working footwear required only if this follows from the risk assessment	protective clothing and protective footwear required	protective clothing and footwear required, with complete exchange of underwear, clothing and footwear prior to entering and leaving the contained space
	Wastes				
18	Inactivation of genetically modified organisms in the effluent from washbasins, sinks, showers etc.	required only if this follows from the risk assessment	required	required	required
19	Disinfection of protective clothing, footwear and individual protective aids after use	required only if this follows from the risk assessment	required	required	required
20	Inactivation of genetically modified organisms on the used material and in liquid and solid wastes during the process in accord with the special legal regulations ³	inactivation by a physical or chemical method necessary	inactivation by a physical or chemical method necessary	inactivation by a physical or chemical method with proven 100% efficiency necessary	inactivation by a physical or chemical method with proven 100% efficiency necessary
	Other measures				
21	Resting room	not required	required only if this follows from the	required	required

			risk assessment		
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Footnotes

- ¹ A contained system means an installation permanently located in a contained space intended for the storage and cultivation of genetically modified organisms, usually in large volumes.
- ² An airlock means entrance to the contained space through separated spaces. Their "clean" side shall be separated from the contained space by safety doors, a changing room for changing clothing and a shower.
- ³ E.g., Act No. 125/1997 Coll., on wastes, as amended.