***Table II. of Annex 2* of the Government Decree No. 132/2004 (IV. 29.) on the authorisation procedure for gene technological activity as well as on liaison with the European Commission**

**Containment and other protective measures for other activities**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Specifications** | | **Containment levels** | | | | **Please indicate the appropriate containement level and provide details of any specific additional measures applicable to the installation, if relevant** |
|  | | **1** | **2** | **3** | **4** | Szöveg beírásához kattintson ide. |
| **General** | | | | | | |
| 1. | Viable micro-organisms should be contained in a system which separates the process from the environment (closed system) | Optional | Required | Required | Required | Szöveg beírásához kattintson ide. |
| 2. | Control of exhaust gases from the closed system | Not required | Required, minimise dissemination | Required, prevent dissemination | Required, prevent dissemination | Szöveg beírásához kattintson ide. |
| 3. | Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system | Optional | Required, minimise dissemination | Required, prevent dissemination | Required, prevent dissemination | Szöveg beírásához kattintson ide. |
| 4. | Inactivation of bulk culture fluids before removal from the closed system | Optional | Required, by validated means | Required, by validated means | Required, by validated means | Szöveg beírásához kattintson ide. |
| 5. | Seals should be designed so as to minimise or prevent release | No specific requirement | Minimise dissemination | Minimise dissemination | Minimise dissemination | Szöveg beírásához kattintson ide. |
| 6. | The controlled area should be designed to contain spillage of the entire contents of the closed system | Optional | Optional | Required | Required | Szöveg beírásához kattintson ide. |
| 7. | The controlled area should be sealable to permit fumigation | Not required | Optional | Optional | Required | Szöveg beírásához kattintson ide. |
| **Equipment** | | | | | | |
| 8. | Entry via airlock | Not required | Not required | Optional | Required | Szöveg beírásához kattintson ide. |
| 9. | Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents, and easy to clean | Required (bench if any) | Required (bench if any) | Required (bench if any, floor) | Required (bench, floor, ceiling, walls) | Szöveg beírásához kattintson ide. |
| 10. | Specific measures to adequately ventilate the controlled area in order to minimise air contamination | Optional | Optional | Optional | Required | Szöveg beírásához kattintson ide. |
| 11. | The controlled area should be maintained at an air pressure negative to the immediate surroundings | Not required | Not required | Optional | Required | Szöveg beírásához kattintson ide. |
| 12. | Extract and input air from the controlled area should be HEPA filtered | Not required | Not required | Required (extract air, optional for input air) | Required (input and extract air) | Szöveg beírásához kattintson ide. |
| **System of work** | | | | | | |
| 13. | Closed systems should be located within a controlled area | Not required | Optional | Required | Required | Szöveg beírásához kattintson ide. |
| 14. | Access should be restricted to nominated personnel only | Not required | Required | Required | Required | Szöveg beírásához kattintson ide. |
| 15. | Biohazard signs should be posted | Not required | Required | Required | Required | Szöveg beírásához kattintson ide. |
| 16. | Personnel should shower before leaving the controlled area | Not required | Not required | Optional | Required | Szöveg beírásához kattintson ide. |
| 17. | Personnel should wear protective clothing | Required (work clothing) | Required (work clothing) | Required | Complete change before exit and entry | Szöveg beírásához kattintson ide. |
| **Waste** | | | | | | |
| 18. | Inactivation of GMMs in effluent from hand-washing sinks and showers or similar effluents | Not required | Not required | Optional | Required | Szöveg beírásához kattintson ide. |
| 19. | Inactivation of GMMs in contaminated material and waste, including those in process effluent before final discharge | Optional | Required, by validated means | Required, by validated means | Required, by validated means | Szöveg beírásához kattintson ide. |