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Swiss Expert Committee for Biosafety SECB

Recommendation of the SECB

Catalogue of criteria: Microbiological safety cabinet in safety level 2

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1 Purpose and field of application

In accordance with the ContainO Annex 4 and the PEMO Annex 3, at safety level 2 a microbiological safety cabinet (MSC) must be available for work with microorganisms (safety measure no. 21) during production and laboratory activities or when working in greenhouses or installations with animals. In the ContainO's field of application, this safety measure may be modified, replaced or omitted on application if the competent federal office approves it. Under the PEMO, a risk assessment should be undertaken to show that deviating from this measure is acceptable. Nevertheless, a duty of care always remains.

This Recommendation is addressed to the enforcement authorities and further specialists concerned with biosafety. It is intended to support users in making a risk assessment to decide whether the omission of the MSC is justifiable.

1.1 Principle

Using an MSC when handling microorganisms is generally recommended in order to protect people and products, and to prevent contamination, particularly if aerosols could be created. In principle, wherever possible, the exposure of workers to microorganisms should be prevented through technical measures. Only if this is not possible should other measures, such as additional personal protective equipment, be used.

1.2 Using the MSC

An MSC must be used for activities involving human pathogenic or animal pathogenic group 2 microorganisms, if it cannot be excluded that any aerosols produced might result in transmission with subsequent infection of workers – with or without clinical symptoms[1]. In principle all safety level 3 or 4 activities should be carried out inside an MSC. To protect workers effectively from aerosols, the MSC must be used correctly.

1.3 Modifying, replacing or omitting

An MSC need not be used for activities with group 2 human pathogenic microorganisms, if transmission through aerosols with subsequent infection of workers can effectively be ruled out under laboratory conditions. It must also be shown that the protection of humans and animals can still be guaranteed. A case-by-case risk assessment is made to decide whether an MSC is necessary or not, and what substitute measures must be taken[2]. If modifying, replacing or omitting an MSC is under consideration, the applicant may use the criteria given in this Recommendation as a guideline when providing evidence in accordance with ContainO Article 12, para. 3, letter a.

An application to omit the MSC may also make sense if the work cannot be safely carried out inside an MSC for technical or ergonomic reasons, or for reasons of space (large equipment, lack of space in the MSC; e.g. inoculation of large animals with microorganisms, or autopsies).

2 Catalogue of criteria for the risk assessment

This catalogue of criteria is intended to serve as an aid, and is not legally binding. The individual questions or points are part of a detailed risk assessment and contribute to a differentiated risk management. The list is not exhaustive.

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1 See FOEN-FOPH Guideline "Microbiological safety cabinets (MSC). Guideline for the use of microbiological safety cabinets when handling human-pathogenic microorganisms" (2008).

2 See Section 3.1 of the FOEN-FOPH Guideline "Safety measures in medical microbiology diagnostic laboratories for the use of microbiological safety cabinets when handling human-pathogenic microorganisms" (2008).

2.1 Organism properties

Criteria for decision	Notes, examples
- Are only known and defined bacteria, viruses or parasites being used?	- Microorganisms from a strain collection? - Microorganisms that are not aerogenically transmissible? - No risk groups 3 or 4 microorganisms?
- How broad is the host spectrum (tropism)?	- When working with microorganisms that have a broad host spectrum, a primary barrier system[3] (e.g. an MSC) is recommended.
- Can the work be carried out using a less dangerous microorganism?	- A vaccine strain or attenuated microorganism could permit the work to be carried out with aerosol protection while observing the rules of good microbiological practice.
- What is the relation of the quantity used, or the maximum aerosolised quantity, to the infective dose?	- Precise details of the infective dose are not usually available. In many cases the infective dose can however still be estimated. Handling small or micro quantities can also contribute to reducing the quantities of aerosol.
- How long is the estimated survival on surfaces (tenacity)?	- When working with microorganisms with great tenacity, a primary barrier system (e.g. an MSC) is recommended.
- What are the possible transmission paths in the laboratory: • Contact infection: oral, mucous membranes/eyes • Splashes: oral, mucous membranes/eyes • Percutaneous: wounds, injury with sharps • Inhalation of aerosols	- When selecting safety measures, the transmission paths of the microorganism should also be considered. - Can the possible transmission paths be interrupted under laboratory conditions even without an MSC? - Can possible transmission through aerosols or splashes be ruled out under laboratory conditions? - Can transmission be prevented through other suitable protective measures?

[3] Primary barrier system: This is usually an MSC or other technical barrier system

2.2 Engineering Alternatives

Criteria for decision	Notes, examples
- Is another primary barrier system a more appropriate technical measure for protection against aerosols than an MSC?	- When using bulky aerosol-producing equipment, such as FACS, diluters, dispensers etc., custom-made MSC, isolators, negative pressure tents or chambers may be more suitable than a mass-produced MSC.
- Is an alternative measure possible (e.g. local exhaust ventilation with subsequent HEPA filtering)?	- If used properly, exhaust units with HEPA filtration can greatly reduce exposure to aerosols.
- Is a (further) miniaturisation of the experiment possible (minimising the quantity or dose of aerosol)?	- Handling small or micro quantities can also contribute to reducing the quantities of aerosol.

2.3 Safe handling outside the MSC or other primary barrier system

Criteria for decision	Notes, examples
- Can transmission via droplets or aerosols be ruled out?	- Also important for diagnostics (e.g. encapsulated or contained kits).
- Are the cultures or samples in liquid, gel or solid form?	- Manipulation of liquids is generally associated with larger quantities of aerosols than handling gels or solid cultures.
- What is the best working technique to minimise contamination of work surfaces and equipment, and droplet and aerosol formation?	- Aerosols are produced when mechanical shear forces act on liquids. Good working technique and suitable aids[4] contribute significantly to reducing aerosols.
- What is the most suitable, effective decontamination agent (where necessary with evidence of efficacy: spectrum and time to take effect)	- Effective decontamination of work surfaces, tools, and personal protective equipment must be used (hygiene plan).
- What are the most suitable measures to prevent spreading via gloves, sleeves (PPE), equipment etc.?	- The spread of contamination can be prevented or reduced by analysing possible transmission paths and identifying suitable hygiene measures.
- What are the measures to prevent the contamination of experimental animals during inoculation or sample taking?	- When inoculating or taking samples from experimental animals, their exteriors may also be contaminated (e.g. if syringes are used incorrectly).
- How are the experimental animals (site of infection) decontaminated if necessary?	- What is the procedure in case of accidents?
- How are inoculated experimental animals handled?	- Do infected animals pose a risk to humans, other animals or the environment? How are animals kept? Are pathogens being excreted? If yes, for how long?

[4] Suitable tools: Biosafety centrifuge, electrical loop sterilisers (microincinerators or glass bead incinerators"), one-way inoculating loops, sonicators, syringes used only if there are no alternatives, breakage-proof vessels with screw top for mixing and homogenising, second vessel available in case first vessel is not breakage or leakage proof, transport of larger vessels on a trolley etc.

2.4 Further safety measures

Criteria for decision	Notes, examples
- Are SOPs / instruction manuals for the activity and for accidents (spillages etc.) available?	- Operating manuals need to be drawn up, not just for normal work but also to cover extraordinary situations (e.g. accidents). Staff must be instructed and trained. SOPs with implications for safety must contain safety guidelines.
- Are the staff trained in minimising aerosols and in managing accidents?	- See above. Staff training must be documented. - The staff should be trained in the exact transmission paths and the symptoms of an exposure; they should know how to proceed in the event of exposure.
- Is the activity covered by the hygiene plan?	- Safety-relevant activities outside the MSC must be dealt with in the hygiene plan.
- Is a vaccine available? - Is there post-exposure prophylaxis (PEP)? - Is personal protective equipment (PPE) used?	- Staff who are not yet immune should be vaccinated where possible, if an effective vaccine is available and vaccination is sensible. It may be recommended to check the success of vaccination by monitoring the titre.
- Are vulnerable groups of people involved?	- If vulnerable (young, old, pregnant, immune suppressed) persons are involved, an MSC should be used or the person assigned to different work.