Methodological guide to the assessment of biological safety and security risks

This guide was written based on the model proposed by ANSM (French National Agency for Medicines and Health Products Safety) entitled "Management method for biological safety and security risks", version of 3 May 2011.

Foreword

Laboratory activities using pathogenic micro-organisms or toxins pose potentially significant risks of harm to humans and the environment.

ANSES's Committee for the Control of Biological Risks in Laboratories (CMRBL) offers a ***general method for identifying hazards and analysing and assessing risks related to the use of micro-organisms and toxins (MOTs),*** *as defined by the Decree of 30 June 2010*[1]*, and in the rules for good practice drawn up by the French National Agency for Medicines and Health Products Safety (ANSM)*[2]*.*

This method is derived from the Failure Mode and Effects Analysis (FMEA) method. It is based on a model proposed by the ANSM ("Management method for biological safety and security risks", version of 3 May 2011), using the same general principles. However, the method presented in this guide takes into account the particularities of ANSES's reference and research laboratories. The hazard identification questionnaires have been adapted accordingly. The scales for ranking biological safety and security risks initially proposed by the ANSM have intentionally been qualitatively and quantitatively modified in order to reflect the activities of ANSES's laboratories. Likewise, the intervals defining risk levels as 'low', 'average' or 'unacceptable' have been modified. Regarding biological safety, the risk calculation method has been completely revised; the notion of extrinsic severity has been introduced and the method for calculating the criticality index has been modified. These calculation methods were tested with various pathogens used in ANSES's laboratories and then adjusted before being definitively adopted by the CMRBL.

This guide includes 4 separate sections:

- **Presentation of the risk assessment model**
- **Presentation of the micro-organism or toxin**
- **Booklet 1: Analysis of biological safety risks**
- **Booklet 2: Analysis of biological security risks**

It refers to the definitions as presented in the Ministerial Order on rules of good practice[2].

[1] Decree no. 2010-736 of 30 June 2010 on micro-organisms and toxins.
[2] Ministerial Order on rules of good practice tending to guarantee biological safety and security mentioned in Art. R.5139-18 of the French Public Health Code.

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Presentation of the risk assessment model

Each of the two booklets presented below is divided into the four stages required for risk assessment, i.e.

1. Hazard identification

A non-exhaustive series of questions helps identify hazardous situations that may arise when carrying out activities.

- Answer "Yes"

If this answer is given, details about the hazardous situation are requested in the "comments" section.
All identified hazardous situations should be listed in the table found in Chapter 3, "**Risk analysis**".

- Answer "No"

This answer indicates that the operation is either not applicable or considered free of risk.

2. Description of control measures

A non-exhaustive series of questions helps describe the risk control measures in force **in the establishment and for the MOT in question.**
If risk control measures are identified that have not been included in this document, they should be added.

- Answer "Yes"

This answer requires justification: compliance with the standards or regulatory requirements. For each identified hazardous situation, a description of the risk control measures should be entered in the table found in Chapter **3, "Risk Analysis".**

3. Risk analysis

- **Risk estimate**

For each hazardous situation identified in Chapter 1, the following should be assessed:

- the **intrinsic severity of the MOT:** accounts for the quantity of pathogen handled;
- **extrinsic severity:** accounts for the notions of exposure and dissemination of the pathogen;
- the **likelihood of occurrence of the event** responsible for the hazardous situation, taking into account the risk control measures in force in the laboratory;
- the **detectability** of the event: it accounts for the risk of not detecting the event **before** it occurs (should not be confused with the notion of detection).

For each parameter, a gradual rating scale is proposed for risk assessment purposes.

➢ **Risk level assessment: calculating the criticality index**

- For each identified hazardous situation, a **criticality index or risk priority index (RPI)** should be calculated by multiplying the four aforementioned parameters. Its value is used to prioritise the risks for corrective action.

A scale of priority is therefore defined based on the RPI value:

- acceptable risk:
- additional measures required;
- unacceptable risk.

4. Acceptability of residual risk

After verifying the implementation of risk control measures for each stage of the process, the applicant needs to decide whether he/she considers that the residual risks posed by the process, considered together, are acceptable.

If the criticality level is not acceptable, corrective actions may be proposed and should be listed in the table in Chapter 4: **Assessment and Acceptability of Residual Risk.** For each action, the deadline and the name of the responsible person must be mentioned.

MOT presentation

Knowledge of the micro-organism or toxin undergoing risk assessment:

<table>
<tr><td>Taxonomy</td><td>Comments:</td></tr>
<tr><td rowspan="2">Use of biological material likely to contain this micro-organism or toxin:
• biological sample of human or animal origin kept for more than 30 days,
• sample of environmental origin</td><td>yes ☐ no ☐</td></tr>
<tr><td>Comments</td></tr>
<tr><td>For a micro-organism, provide the classification of the at-risk group according to Article R.4421-3 of the French Labour Code, specifying whether there is any available preventive or curative treatment</td><td>Group 1 ☐
Group 2 ☐
Group 3 ☐
Group 4 ☐</td></tr>
</table>

BOOKLET 1
Analysis of biological safety risks

1. Hazard identification

For each operation using this MOT, provide the following information:

1.1. Acquisition (limited to the airlock entrance), storage, in-site transport operations

Risk of breach of the triple packaging (primary containment)	yes ☐ no ☐
	Comments
Implosion risk (freeze-dried ampoules)	yes ☐ no ☐
	Comments
Explosion risk	yes ☐ no ☐
	Comments
Risk of losing the MOT	yes ☐ no ☐
	Comments
Risk of exchange with another micro-organism or toxin	yes ☐ no ☐
	Comments
Risk of cut	yes ☐ no ☐
	Comments
Risk of eye damage	yes ☐ no ☐
	Comments
Risk of the MOT coming into contact with the skin	yes ☐ no ☐
	Comments
Risk of inhaling the MOT	yes ☐ no ☐
	Comments
Risk of breach of the secondary containment	yes ☐ no ☐
	Comments
Risk of the MOT splashing in the air	yes ☐ no ☐
	Comments
Risk of the MOT splashing on a surface (spillage, etc.)	yes ☐ no ☐
	Comments
Risk related to the water supply	yes ☐ no ☐
	Comments
Other risk (specify)	yes ☐ no ☐
	Comments

1.2. Implementation operations

Each operation should be numbered and described

OPERATION No. XX

Risk of cut	yes ☐ no ☐
	Comments
Risk of eye damage	yes ☐ no ☐
	Comments
Risk of the MOT coming into contact with a body part	yes ☐ no ☐
	Comments
Risk of inhaling the MOT	yes ☐ no ☐
	Comments
Risk related to the water supply	yes ☐ no ☐
	Comments
Risk of there being an animate vector of the MOT	yes ☐ no ☐
	If so, which one(s)?
Risk of exchanging genetic material from the MOT with another biological agent	yes ☐ no ☐
	If so, which one(s)?
Risk of breach of the primary containment	yes ☐ no ☐
	Comments
Risk of breach of the secondary containment	yes ☐ no ☐
	Comments
Risk of the MOT splashing in the air	yes ☐ no ☐
	Comments
Risk of the MOT splashing on a surface (spillage, etc.)	yes ☐ no ☐
	Comments
Implosion risk	yes ☐ no ☐
	Comments
Explosion risk	yes ☐ no ☐
	Comments
Risk related to aerosolisation (freeze-drying, centrifugation, grinding, etc.)	yes ☐ no ☐
	Comments

1.3. Decontamination, deactivation and disposal operations

Risk of non-deactivated biological material being discharged through piping	yes ☐ no ☐ Comments
Risk of handling biological *material* whose deactivation was not properly performed and validated	yes ☐ no ☐ Comments
Risk of handling biological *waste* whose deactivation was not properly performed and validated	yes ☐ no ☐ Comments
Risk of the MOT splashing on a surface (spillage, etc.)	yes ☐ no ☐ Comments
Implosion risk	yes ☐ no ☐ Comments
Explosion risk	yes ☐ no ☐ Comments
Incorrect disposal route	yes ☐ no ☐ Comments
Other risk (specify)	yes ☐ no ☐ Comments

1.4. Animal testing

All risks related to implementation operations should also be assessed for animal testing

Risk of cut, sting	yes ☐ no ☐ Comments
Risk of bite, scratch	yes ☐ no ☐ Comments
Risk of unintentional release of an animal infected with the MOT	yes ☐ no ☐ Comments
Risk of the MOT being excreted by an animal	yes ☐ no ☐ If so, which one(s)?
Risk of contact with the body fluids or tissues of the contaminated animal	yes ☐ no ☐ If so, which one(s)?
Risk related to MOT multiplication by the animal	yes ☐ no ☐ Comments
Risk of there being an animate vector	yes ☐ no ☐ Comments
Risk of animal exchange	yes ☐ no ☐ Comments

1.5. Off-site transport

To be completed as part of a transfer application

Risk of breach of the triple packaging	yes ☐ no ☐ Comments
Risk of the MOT splashing in the air	yes ☐ no ☐ Comments
Risk of the MOT splashing on a surface (spillage, etc.)	yes ☐ no ☐ Comments
Risk of loss	yes ☐ no ☐ Comments
Other risk (specify)	yes ☐ no ☐ Comments

2. Description of risk control measures

2.1. The laboratory's collective protective measures

Building no.	Level of physical containment according to the Ministerial Order of 16/7/2007*	Type of microbiological safety station	Animal containment system	Annexes related to the level of physical containment
	P1☐ P2 ☐ P3☐ P4 ☐ A1☐ A2 ☐ A3☐ A4 ☐	BSC* I ☐ BSC II ☐ BSC III ☐ Other: ☐ *Please specify*	Isolator ☐ Ventilated cage ☐ Other ☐ *Please specify*	Annex nos.

- Biosafety cabinet

Means of detecting the MOT outside of the containment structure	yes ☐ no ☐ Comment: describe which ones
Is there a programme for periodically verifying the integrity of the physical containment systems?	yes ☐ no ☐ Comments (particularly if tests and controls are periodically undertaken in accordance with the NF ISO EN 14644-1; 14644-2 or NF EN 12469 Standards)
Is there a programme for verifying the integrity of the piping and treatment system for contaminated effluent if it was not treated before exiting the building containing the technical facility?	yes ☐ no ☐ NA ☐ Comments

2.2 Personal protective measures

Building number: XX

Protection	If "yes", specify the type of protection
Head	yes ☐
Eyes	yes ☐
Respiratory	yes ☐
Face	yes ☐
Hands	yes ☐
Forearms	yes ☐
Ankles	yes ☐
Legs	yes ☐
Feet	yes ☐
Other (specify):	yes ☐

2.3. Work practices

Are there safety instructions prohibiting the introduction of the following, by workers and for their own use, in work areas where there is risk of contamination? - food and drink; - items for smokers; - cosmetics and tissues other than paper tissues, which should be disposed of as contaminated waste. - jewellery and objects that are difficult to decontaminate Does there is safety instructions concerning specific dress requirements ?	yes ☐ no ☐ Comments If yes, what are they?
Are there written instructions in the workplace and, if applicable, posters showing the procedure to be followed when handling any biological agent, and especially the list of operations to be performed in a BSC or requiring specific means of protection?	yes ☐ no ☐ Comments List quality documents
Are there written instructions on the worksite and, if applicable, posters showing the procedure to be followed when handling any biological agent, especially during its disposal, with appropriate cleaning and disinfection methods?	yes ☐ no ☐ Comments (required for group 4 MOTs)
Are there specific provisions, included in the internal regulations if necessary, reminding workers of their duty to immediately report any accident or incident involving a biological pathogen?	yes ☐ no ☐ Comments

2.4. Management of decontamination of facilities, materials and equipment

Is there a system for decontaminating facilities?	yes ☐ no ☐
	Comments:
Is there a system for decontaminating materials?	yes ☐ no ☐
	Comments
Is there a system for decontaminating equipment?	yes ☐ no ☐ Comments
Is there a programme for validating decontamination techniques?	yes ☐ no ☐
	Comments (Describe the qualification methods for each decontamination procedure used)
Is there a programme for verifying the effectiveness of decontamination processes?	yes ☐ no ☐
	Comments (provide Document)
Is a document certifying the decontamination of materials and equipment likely to be contaminated given to maintenance workers before any other maintenance operations?	yes ☐ no ☐
	Comments

2.5. Waste management

Solid waste, including single-use material	yes ☐ no ☐ *Decontamination method:* chemical ☐ autoclaving ☐ incineration ☐ other ☐ (specify)
	Comment: refer to current procedures
Liquid waste	yes ☐ no ☐ *Decontamination method:* chemical ☐ autoclaving ☐ incineration ☐ other ☐ (specify)
	Comments refer to current procedures

Reusable material	yes ☐ no ☐ *Decontamination method:* chemical ☐ autoclaving ☐ other ☐ (specify)
	Comments refer to current procedures
Is there a programme for validating decontamination techniques?	yes ☐ no ☐
	Comments (Describe the qualification methods for each decontamination procedure used)
Is there a programme for verifying the effectiveness of decontamination processes?	yes ☐ no ☐
	Comments (provide Document)

2.6. MOT transport

Measures or appropriate containment system used for the risk-free transport of MOTs inside the establishment	yes ☐ no ☐
	Comments

2.7. Staff training

Is training on biological safety provided before staff perform an activity involving contact with MOTs?	yes ☐ no ☐
	Comments
Is the safety training repeated on a regular basis?	yes ☐ no ☐
	Comments (frequency)
Is the safety training adapted as risks evolve and when work procedures change significantly?	yes ☐ no ☐
	Comments
Is access prohibited to anyone not trained in biological safety?	yes ☐ no ☐
	Comments
Is there specific training on use of the MOT?	yes ☐ no ☐
	Comments
Is there a specific accreditation process for use of the MOT as defined in the 17025 Standard?	yes ☐ no ☐
	Comments

2.8. Medical supervision

Is the list, drawn up by the employer, of people likely to be exposed to an MOT given to the physician of the preventive medical services?	yes ☐ no ☐ Comments
Have the people likely to be exposed to an MOT undergone a medical examination to draw up a medical fitness certificate?	yes ☐ no ☐ Comments
Is the medical fitness certificate renewed at least yearly?	yes ☐ no ☐ Comments
Is there a specific medical surveillance plan for the MOT?	yes ☐ no ☐ Comments

2.9. Other risk control measures

Lister tout autre moyen de maîtrise du risque non pris en compte dans les chapitres précédents	yes ☐ no ☐ Comments

3. Risk analysis

This section should be completed for each operation, taking into account the hazards identified in Section A.

The risk rating scales are presented in Chapter 5

Si: Intrinsic severity of the MOT

Se: Extrinsic severity: related to the concentration of the MOT

L: Likelihood: of the incident occurring

D: Detectability: likelihood of detecting the incident

RPI: Si x Se x L x D: risk priority index or criticality index

No.	Identified hazards	Control measures used	Si	Se	L	D	Justification	RPI

Example No. 1: *Animal testing with handling of mice inoculated with* Brucella

No.	Identified hazards	Control measures used	Si	Se	L	D	Justification	RPI
1	Risk of cut, sting	Restraint tubes, replacement of scalpels with thin blunt-tipped scissors, no use of glass	**4**	**2**	**3**	**5**	Impossible to predict this risk in advance - highly dependent on the animal-tester pair	**120**
2	Risk of bite, scratch	Wearing 2 pairs of gloves	**3**	**1**	**3**	**5**	Same as 1	**45**
3	Risk of unintentional release of an animal infected with the MOT	Cages with fixed lids Animals placed in an isolator Counting the animals in the cage whenever it is opened	**3**	**2**	**2**	**3**	Check that the cage lids are securely in place Count the animals every day	**36**
4	Risk of the MOT being excreted by an animal	Animals placed in an isolator Type A3 animal facility Wearing very high-coverage PPE	**5**	**2**	**5**	**5**	Culturing ground dirty bedding to test for *Brucella*	**250**
5	Risk of contact with the body fluids or tissues of the contaminated animal	Wearing PPE with high skin coverage	**5**	**2**	**1**	**2**	Splashing when handling Stains on the workstation's absorbent paper	**20**
6	Risk related to MOT multiplication by the animal	Animals placed in an isolator Type A3 animal facility Wearing very high-coverage PPE	**5**	**2**	**5**	**4**	Testing for MO multiplication in the animal Bibliographic data?	**200**
7	Risk of there being an animate vector	Animals placed in an isolator Type A3 animal facility Installation of traps for flying insects	**5**	**3**	**2**	**2**	Occasional verification of the traps	**60**

8	Risk of animal exchange	Electronic identification by RFID chips	**5**	**1**	**2**	**3**	List of the nos. of animals in the cage Verification of the list when the cage is opened	**30**

Example no. 2: *implementation of the animal phase as part of Biotox water tests for ricin*

	Identified hazards	**Control measures used**	**Si**	**Se**	**L**	**D**	**Justification**	**RPI**
	Risk of sting During intraperitoneal (IP) injection of the sample	Wearing PPE Accreditation of staff practising IP	**5**	**3**	**2**	**3**	To justify D, accredited staff know from experience whether a mouse is poorly attached and might move during injection, and know to wait for it to calm down	**90**
	Risk of unintentional release of an animal infected with the MOT After injection, mice are no longer handled unless they need to be euthanised because they did not die from the injection	Ventilated rack identified and number of mice known Sealed secondary containment.	**5**	**1**	**2**	**3**	For D, accredited staff know how the lid and box should be positioned to limit risks of leaks. Moreover, if a mouse is handled after injection, it is for euthanasia and so the injection contains few or no pathogens.	**30**
	Risk of contact with the body fluids or tissues of the contaminated animal When the mouse is euthanised, if applicable	No handling animals after injection except for euthanasia and wearing PPE Mice isolated in sealed racks marked "Biotox in progress"	**5**	**1**	**3**	**4**	For D, the mouse's position in the hand can keep the hand from being splashed if urine is released. Otherwise, same comment as to euthanasia for Biotox mice, adding that a mouse contaminated by ricin does not excrete it	**60**
	Risk of eye damage During IP injection of mice	During injection but work conducted in a BSC and	**5**	**1**	**3**	**4**	Prior detection is difficult but moments of inattention would really need to be combined	**60**

		visors worn					to bring about such a scenario	
	Risk of the MOT coming into contact with a body part During IP injection of mice	PPE	**5**	**1**	**3**	**5**	No comment	**75**
	Risk related to the water supply	Backflow preventer	**5**	**1**	**2**	**4**	Preventive maintenance and visible backflow preventer	**40**
	Risk of breach of the primary containment = cages and ventilated racks	Appropriate, verified cages	**5**	**1**	**2**	**5**	Maintenance should only be conducted on the filters of the ventilated racks	**50**
	Risk of breach of the secondary containment = P3 laboratory	P3 maintenance	**5**	**1**	**1**	**2**	Secondary containment = P3 which is maintained and enough parameters are alarmed (Pressure, Air handling units, AHUs)	**10**
	Risk of the MOT splashing in the air	If the tube falls but work conducted in a BSC during handling	**5**	**1**	**2**	**3**	Various materials and stoppered tubes stored in a BSC	**30**
	Risk of the MOT splashing on a surface (spillage, etc.) During IP injection of mice	In the BSC	**5**	**1**	**4**	**3**	Various materials and stoppered tubes stored in a BSC	**60**

4. Acceptability of residual risk

4.1. Calculating residual risk

This table only shows operations whose **RPI value is equal to or greater than 180**

Operation no.	RPI	Proposed corrective action	Residual RPI	Deadline for application	Person responsible for implementing the measure

4.2. Approval of risk management and acceptability of residual risk

Name	Position	Date	Signature

Comments

5. Rating scales for the assessment of biological safety risk

Degree	Intrinsic severity	
Very high	quantity unknown	**5**
High	quantity of MOT handled much higher than the infectious/toxic dose for humans	**4**
Average	quantity of MOT handled equal to the infectious/toxic dose for humans	**3**
Low	quantity of MOT handled poses a negligible risk to humans	**1**

Degree	Extrinsic severity	
Serious	can cause very serious or irreversible injuries to humans or mass exposure/dissemination	**3**
Average	can cause significant injuries for humans or very likely exposure/dissemination	**2**
Benign	can cause mild injuries for humans or a very limited risk of exposure/dissemination	**1**

Degree	Likelihood	
Frequent	certainty that the failure will frequently occur	**5**
Likely	frequent failure	**4**
Occasional	failure occurred occasionally with a similar process	**3**
Rare	could occur and has been observed once	**2**
Unlikely	could occur, but has never been observed	**1**

Degree	Detectability	
Impossible	Detection is not possible	**5**
Difficult	An experienced person needs to verify several parameters and interpret a complex situation to highlight the possible occurrence of the event.	**4**
Moderate	An experienced person or a measurement/test can detect that the event could occur	**3**
Easy	There are multiple factors that could alert the personnel before the event occurs	**2**
Obvious	A novice could easily detect the event before it occurred.	**1**

Calculating the criticality index for the assessment of biological safety risk

RPI: Si x Se x L x D

IPR	≤ 90	90 à 180	≥ 180
Risk	**Low**	**Middle**	**Not acceptable**
Recommandations	The analysed processus could be applied	Supplementary measures are necessary	The analysed processus could NOT be applied

BOOKLET 2

Analysis of biological security risks

*The management of risks related to **biological security** is intended to identify, analyse and control hazardous phenomena likely to lead to the theft of pathogenic micro-organisms or toxins or their misuse.*

1. Hazard identification

Possession of MOTs	yes ☐ no ☐
	Comments
Use of biological material likely to contain an MOT	yes ☐ no ☐
	Comments
Use of non-infectious MOTs	yes ☐ no ☐
	Comments
Possession of genetic material	yes ☐ no ☐
	Comments
GMO handling	yes ☐ no ☐
	Comments
Use of animal testing	yes ☐ no ☐
	Comments
Possession of equipment for culturing biological agents (including fermenter, incubator, freeze-dryer, centrifuge, aerosolisation device, etc.)	yes ☐ no ☐
	Comments

O *If all answers are negative, it is not necessary to continue further before the risk identification process.*

Risk of **one or more external parties** breaking and entering into the **site**	yes ☐ no ☐
	Comments and history from the last 5 years
Risk of one or more external parties breaking and entering into the MOT storage **building**	yes ☐ no ☐
	Comments and history from the last 5 years
Risk of breaking and entering into the MOT storage **room** or handling by one or more external parties	yes ☐ no ☐
	Comments and history from the last 5 years
Risk of breaking and entering into the MOT storage **building** or handling by an unauthorised employee	yes ☐ no ☐
	Comments and history from the last 5 years

Risk of breaking and entering into the MOT storage **room** or handling by an unauthorised employee	yes ☐ no ☐ Comments and history from the last 5 years
Risk of electronic intrusion into the computer network	yes ☐ no ☐ Comments and history from the last 5 years
Risk of access to the site or building being blocked	yes ☐ no ☐ Comments and history from the last 5 years
Risk of staff being assaulted to retrieve MOTs	yes ☐ no ☐ Comments and history from the last 5 years
Other	yes ☐ no ☐ Comments and history from the last 5 years

2. Description of risk control measures

2.1. Perimeter protection and site access

Protected enclosure - fence	yes ☐ no ☐
	Comments (specify the composition, location on the site and height)
If the building's walls are also the enclosure, protection of all openings located less than 5.50m above ground level	yes ☐ no ☐
	Comments
Detection system for perimeter intrusion	yes ☐ no ☐
	Comments (specify the type of detection system, location on the site and management of alarms)
CCTV system	yes ☐ no ☐
	Comments (specify the type of system, location on the site and management of alarms)
Is there a security post/guardhouse/security guard?	yes ☐ no ☐
	Comments Description of the security system (mission, workforce, subcontracting, continuous or occasional duty, days/nights/weekends, rounds)
Onsite perimeter lighting system	yes ☐ no ☐
	Comments
Description of crossing points (gate):	yes ☐ no ☐
	Comments
Other arrangement (specify):	yes ☐ no ☐
	Comments

2.2. Building perimeter protection

Break-in resistance of windows, primary and secondary exits and low-resistance wall panels	yes ☐ no ☐
	Comments: describe the system
Description of the intrusion detection system for required entry and exit points, valuable areas and the zones leading up to these areas	yes ☐ no ☐
	Comments and description
Other arrangement (specify):	yes ☐ no ☐
	Comments

2.3. Physical Protection of Storage Units

Units intended for storing MOTs including a locking system (traditional or electronic) that cannot be opened fraudulently without forcing.	yes ☐ no ☐ Comments
Units intended for storing information or information media are secure	yes ☐ no ☐ Comments Description of security systems
Other arrangement (specify):	yes ☐ no ☐ Comments

2.4. Information system security

Computer protection system used	yes ☐ no ☐ Comments Description of the system
Is a password required to access the establishment's internal and/or external network?	yes ☐ no ☐ Comments
Is a password required to access the computer system?	yes ☐ no ☐ Comments
Other (specify)	yes ☐ no ☐ Comments

2.6. Inventory

Scheduled MOT inventories	yes ☐ no ☐ Comments
Is there a traceability system for incoming/outgoing MOTs, products containing them and infected animals between the site's various buildings and on the site?	yes ☐ no ☐ Comments

2.7. Access controls for permanent and temporary employees

Is there an access control system for the site? deployment level	yes ☐ no ☐ Comments
Is there an access control system for the areas where MOTs are	yes ☐ no ☐ Comments

stored/handled? methods	
Procedure for assigning access codes and keys	yes ☐ no ☐ Comments
Procedure for withdrawing access codes and keys	yes ☐ no ☐ Comments
Verification of entrances/exits in the various areas under control	yes ☐ no ☐ Comments
Badge permanently worn	yes ☐ no ☐ Comments
Procedure for checking vehicles accessing the site	yes ☐ no ☐ Comments

2.8. Upkeep, maintenance and repairs

Specific procedure for companies in charge of upkeep, maintenance and repairs in areas with MOTs or sensitive data	yes ☐ no ☐ Comments
Establishment of preventive maintenance for facilities with MOTs	yes ☐ no ☐ Comments
Establishment of preventive maintenance for critical equipment	yes ☐ no ☐ Comments

2.9. Site access - Visitors

Control procedure for visitors	yes ☐ no ☐ Comments
Are visitors accompanied?	
Do visitors have access to controlled areas?	yes ☐ no ☐ Which ones?
Is there a register of visitors linked to the access control system?	yes ☐ no ☐ Comments
Authorisation procedure for visiting facilities	yes ☐ no ☐ Comments
Procedure for checking visitor vehicles accessing the site	yes ☐ no ☐ Comments

2.10. Staff training and awareness-raising

Is training/awareness-raising on security provided before staff perform an activity involving contact with MOTs?	yes ☐ no ☐
	Comments
Is the security training/awareness-raising repeated on a regular basis?	yes ☐ no ☐
	Comments

2.11. Internal transport

Is there a specific procedure for transporting biological materials between various controlled areas?	yes ☐ no ☐
	Comments

2.12. Other Risk Control Measures

	yes ☐ no ☐
	Comments

3. Risk analysis

This section should be completed for each operation, taking into account the hazards identified in Section A.

The risk rating scales are presented in Chapter 5

No.	**Potential risks**	**Control measures used**	**Severity (S)**	**Likelihood (L)**	**RPI (SxL)**

4. Acceptability of residual risk

This table only shows operations whose **RPI value is equal to or greater than 12**

Operation no.	RPI	Proposed corrective action	Residual RPI	Deadline for application	Person responsible for implementing the measure

Approval of risk management and acceptability of residual risk

Name	Position	Date	Signature

5. Rating scales for risks related to biological security

Degree	Severity: nature of the MOT/sensitive goods	Value
Catastrophic	Presence on the site of a vector infected with an MO or Annex I micro-organisms or toxins	**5**
Critical	Annex II micro-organisms or toxins	**4**
Significant	Nucleic acid greater than 500 bp or whole genome from Annex I or II or deactivated MOT, plasmid	**3**
Minor	Antigenic material or incomplete genome less than 500 bp	**1**

Degree	Likelihood that the scenario will occur	Value
Frequent	certainty that the scenario will occur	**5**
Likely	frequent failure	**4**
Occasional	failure occurred occasionally with a similar process	**3**
Rare	could occur and has been observed once in the establishment	**2**
Unlikely	could occur, but has never been observed	**1**

Criticality index: RPI = S x L

RPI	Risk	Action
RPI < 10	Low	The analysed process can be applied
10 < RPI < 14	Average	Additional measures are necessary
RPI > 14	Unacceptable	The analysed process cannot be applied

S / L	1	2	3	4	5
1	1	2	3	4	5
3	3	6	9	12	15
4	4	8	12	16	20
5	5	10	15	20	25