

Hazardous Biological Agents Regulations, 2022

DISCLAIMER: This summary is provided for informational purposes only and does not constitute legal advice. While efforts have been made to ensure accuracy, this summary may not be comprehensive or reflect all amendments. The official published legislation remains the authoritative source. Readers should consult the complete, official text of the legislation and seek qualified legal advice for specific matters. The author and SHEQ Warehouse (Pty) Ltd accept no liability for any errors, omissions, or consequences arising from reliance on this summary.

1. Definitions

Key definitions include:

- "biohazard sign" - symbol and sign complying with SANS 1186-1 for safety signs
- "biological agent" - micro-organism, cell culture, endoparasite or other agent that can cause infection, allergy, toxic effects or otherwise create a hazard to human health
- "biosafety" - containment principles, technologies and practices implemented to prevent unintentional exposure to biological agents
- "biosafety level" - facilities and procedures for managing biological agents according to their risk assessment
- "biosafety manual" - document describing risk control measures and emergency procedures
- "blood-borne pathogen" - pathogenic microorganism present in human blood that can cause disease
- "cell culture" - in vitro growth of cells derived from multicellular organisms
- "competent person" - person with knowledge, training, experience and qualifications specific to hazardous biological agents
- "containment" - physical and procedural measures to restrict biological agents or toxins
- "decontamination" - removal or neutralization of hazardous biological agents
- "disinfection" - procedure eliminating or reducing viable biological agents on materials, equipment or surfaces
- "engineering control measures" - physical control measures to reduce hazard exposure
- "exposed" - exposure during work to a biological agent due to inhalation, ingestion, percutaneous inoculation, direct contact, etc.
- "exposure control plan" - written control plan minimizing employee exposure to hazardous biological agents
- "health and safety committee" - committee established under section 19 of the Act

Reviewed Date	Next Review Date	Document Owner	Responsible Person
01 Feb 2024	28 Feb 2026	SHEQ Warehouse (Pty) Ltd	Neville
This document is active, and any copy made from the electronic version shall be considered an uncontrolled copy. Individuals with uncontrolled copies are responsible for ensuring the use of the current version. Revision levels are electronically controlled.			

- "health and safety representative" - person designated under section 17(1) of the Act
- "health care worker" - person in a health facility who has contact with patients, blood or tissue
- "HBA" - hazardous biological agent that can cause infection, allergy, toxic effects or hazard to human health
- "incident" - event resulting in release of an HBA outside established barriers
- "medical surveillance" - program of medical examinations by occupational health practitioner
- "micro-organism" - microbial, viral, or parasitic entity capable of replication
- "monitoring" - planning, carrying out and recording of measurement program for risk assessment
- "occupational health practitioner" - person with statutory health care qualifications
- "reasonably practicable" - practicable having regard to: (a) Severity and scope of hazard (b) State of knowledge reasonably available about the hazard and removal (c) Availability and suitability of means to remove or mitigate the hazard (d) Cost of removal or mitigation in relation to benefits
- "recombinant genetic material" - genetic material formed by combining pieces of DNA
- "regulation" or "these Regulations" - Hazardous Biological Agents Regulations, 2022
- "respiratory protective equipment" - device worn over breathing zone to prevent inhalation of air that is not safe
- "sterilization" - process to destroy or remove all forms of microbial life
- "the Act" - Occupational Health and Safety Act, 1993 (Act No. 85 of 1993)
- "toxin" - substance released by or present in a biological agent that harms humans
- "zoonotic disease" - disease transmissible from animals to humans

2. Scope of application

(1) Subject to subsection (2), these Regulations apply to: (a) Employers or self-employed persons exposing persons to HBAs (b) Exposure to HBAs

(2) Regulations do not apply to: (a) Legally defined organisms modified by genetic manipulation (b) Mining industry (c) Public places where members of the public may be exposed (d) Private households

3. Classification of biological agents

(1) Biological agents shall be classified according to their level of hazard into 4 risk groups based on: (a) Level of risk of infection (b) Likelihood of causing disease (c) Likelihood of spreading to community (d) Availability of preventive measures or treatment

(2) (a) For Group 1 biological agents: (i) Unlikely to cause human disease (ii) If listed in risk group 1 in Annexure A, classified accordingly (iii) If not listed, shall be provisionally classified by employer based on international data



Reviewed Date	Next Review Date	Document Owner	Responsible Person
01 Feb 2024	28 Feb 2026	SHEQ Warehouse (Pty) Ltd	Neville
This document is active, and any copy made from the electronic version shall be considered an uncontrolled copy. Individuals with uncontrolled copies are responsible for ensuring the use of the current version. Revision levels are electronically controlled.			

(b) For Group 2 biological agents: (i) Can cause human disease, is a hazard to employees, unlikely to spread to community, effective prevention or treatment usually available (ii) If listed in risk group 2 in Annexure A, classified accordingly (iii) If not listed, shall be provisionally classified by employer based on international data

(c) For Group 3 biological agents: (i) Can cause severe human disease, is a serious hazard to employees, may spread to community, effective prevention or treatment usually available (ii) If listed in risk group 3 in Annexure A, classified accordingly (iii) If not listed, shall be provisionally classified by employer based on international data

(d) For Group 4 biological agents: (i) Causes severe human disease, is a serious hazard to employees, high risk of spreading to community, usually no effective prevention or treatment (ii) If listed in risk group 4 in Annexure A, classified accordingly (iii) If not listed, shall be provisionally classified by employer based on international data

(3) If there is doubt about classification or provisional classification of a biological agent that can cause infectious disease in humans, the higher risk group shall apply.

(4) If new biological agents emerge, they shall be classified according to this regulation.

4. Information and training

(1) Employers or self-employed persons exposing themselves or others to HBAs shall, after consultation with health and safety committee or representatives: (a) Provide information and training to exposed persons about: (i) Contents and scope of these Regulations (ii) Potential risks to health (iii) Precautions to prevent exposure (iv) Importance of reporting incidents (v) Safe working procedures (vi) Use of protective equipment and clothing (vii) Steps to be taken in case of incidents (viii) Medical surveillance requirements

(b) Issue written instructions on procedures to employees who transport, handle, store, remove or process HBAs (c) Ensure education and training are provided by a competent person (d) Keep training records (e) Review training when necessary or at least annually

5. Duties of persons who might be exposed to HBAs

(1) Any person exposed to HBAs shall obey all instructions regarding: (a) Prevention of HBA release or spread (b) Procedures and precautions regarding exposure (c) Wearing and use of personal protective equipment and clothing (d) Wearing of monitoring equipment to measure personal exposure (e) Reporting of incidents or emergencies (f) Information and training received (g) Reporting for medical surveillance

6. Risk assessment by employer or self-employed person

(1) Employers or self-employed persons shall: (a) Make risk assessment of potential exposure within 6 months from commencement of these Regulations



Reviewed Date	Next Review Date	Document Owner	Responsible Person
01 Feb 2024	28 Feb 2026	SHEQ Warehouse (Pty) Ltd	Neville
This document is active, and any copy made from the electronic version shall be considered an uncontrolled copy. Individuals with uncontrolled copies are responsible for ensuring the use of the current version. Revision levels are electronically controlled.			

(b) Consider in making assessment: (i) Classification of HBAs (ii) Diseases that may result (iii) Potential for transmission (iv) Work procedures that may result in exposure (v) Likelihood of exposure (vi) Nature, degree and duration of exposure (vii) Volume of HBAs to be handled (viii) Presence of vectors (ix) Potentially infected material (x) Infected humans or animals (xi) Activities of work involving HBA exposure (xii) Endemic local disease presence that may be present as result of work (xiii) Proposed methods of treatment and disposal of HBAs (xiv) Emergency procedures (xv) Measures to protect susceptible employees

(c) Obtain additional information needed for assessment

(d) Keep record of assessment and make it available to: (i) Inspector on request (ii) Any person subject to assessment (iii) Health and safety representatives or committee

(e) Review assessment at least every 2 years and reassess if: (i) Assessment no longer valid (ii) Processes, methods, HBA or procedures change (iii) Monitoring or medical surveillance indicates necessity

7. Monitoring exposure at workplace

(1) Where exposure to HBAs occurs, employer shall ensure exposure measurement program is: (a) Carried out according to these Regulations (b) Carried out after health and safety committee or representatives have been informed and given reasonable opportunity to comment (c) Carried out by approved HBA inspection authority or person whose capability is verified by inspection authority (d) Representative of exposure (e) Verified by inspection authority if done by person in (c) (f) Done by following a structured approach using documented sampling strategy (g) Done with instruments calibrated as required by manufacturer (h) Documented as required by regulation 9 (i) Done according to a suitable procedure

(2) Monitoring may be conducted by in-house competent person if: (a) Qualifications and experience meet requirements (b) HBA control measures are currently in place (c) Subject to verification process as in (1)(e)

(3) Air monitoring for viable airborne organisms must be done as specified in regulation 17(a)

8. Medical surveillance

(1) Employer shall ensure employees are under medical surveillance if: (a) Results of assessment indicate it's necessary (b) Employee may have been exposed to HBA

(2) Medical surveillance shall be carried out according to a protocol designed by occupational health practitioner based on the assessment and specific HBAs to which employees may be exposed, including at least: (a) Evaluation of employee's health by occupational health



Reviewed Date	Next Review Date	Document Owner	Responsible Person
01 Feb 2024	28 Feb 2026	SHEQ Warehouse (Pty) Ltd	Neville
This document is active, and any copy made from the electronic version shall be considered an uncontrolled copy. Individuals with uncontrolled copies are responsible for ensuring the use of the current version. Revision levels are electronically controlled.			

practitioner (b) Relevant laboratory tests if recommended (c) Other necessary examinations (d) Screening tests if recommended (e) Biological monitoring if recommended

(3) Employer shall ensure that for employees engaged in work with risk of exposure to Group 3 or 4 HBAs: (a) Each employee has immediate access to their appointed occupational health practitioner (b) Practitioner has access to information about work conditions (c) Practitioner must have successfully completed training in clinical assessment management of patients with diseases from Group 3 and 4 HBAs (d) Immediate medical evaluation and necessary treatment is available 24/7 (e) First aid treatment plans and procedures are established

(4) Medical surveillance program shall include: (a) Initial health evaluation within 30 days after employment (b) Periodic health evaluations at intervals determined by occupational health practitioner but at least every 2 years (c) Exit health evaluation within 30 days after termination of employment

(5) Personal medical records shall: (a) Be kept for 40 years after employment termination (b) Not be disclosed except: (i) To an inspector (ii) With formal consent (iii) In accordance with regulation 15

9. Records

(1) Employer or self-employed person shall: (a) Keep records of assessment, risk assessments, monitoring and medical surveillance reports (b) Keep records at least 40 years (c) If ceasing activities, give records to provincial director (d) Make non-personal records available to health and safety representatives or committee (e) Allow persons to examine their own records (f) Keep record of everyone who handles, stores, transports or uses HBAs

10. Control of exposure to HBAs

(1) Employer or self-employed person shall ensure: (a) Exposure to HBAs is prevented or, if not practicable, adequately controlled (b) Control measures comply with these Regulations (c) Control measures are: (i) Appropriate to risk (ii) Applied at point of exposure (iii) Effective in preventing or controlling exposure (iv) Not creating health hazard

(2) For adequate control, employers shall implement in the following order: (a) Engineering control measures to prevent/minimize release (b) Procedural and administrative controls to eliminate/minimize risk of contamination (c) Provision of personal protective equipment

(3) Where respiratory protective equipment is provided, employers shall ensure: (a) It's capable of preventing exposure (b) It's correctly selected for the type of exposure (c) Users are trained in its effective use (d) Equipment is kept in good condition and efficient working order (e) When not in use, it's kept in clean, dust-free place

(4) For Group 3 or 4 HBAs, employers shall: (a) Control airborne concentrations (b) Control exposure through engineering controls according to biosafety level (c) Institute combination



Reviewed Date	Next Review Date	Document Owner	Responsible Person
01 Feb 2024	28 Feb 2026	SHEQ Warehouse (Pty) Ltd	Neville
This document is active, and any copy made from the electronic version shall be considered an uncontrolled copy. Individuals with uncontrolled copies are responsible for ensuring the use of the current version. Revision levels are electronically controlled.			

of engineering controls, respiratory protection, good housekeeping and personal hygiene as evaluated by occupational hygienist

(5) If employee is exposed to more than one HBA, control measures shall be adequate to control risks of all HBAs

11. Personal protective equipment and facilities

(1) Employer or self-employed person shall: (a) Provide sufficient and suitable personal protective equipment and facilities free of charge (b) Ensure personal protective equipment is: (i) Properly used (ii) In good condition (iii) Inspected before use (iv) Cleaned after use (v) Repaired if necessary (vi) Stored in a clean, dust-free place (c) Take steps to ensure only those given protective clothing use it (d) Provide separate containers or storage for protective equipment (e) Ensure contaminated personal protective equipment is decontaminated (f) Ensure only cleaned, decontaminated, serviced, maintained, or repaired equipment is taken from workplace with precautions (g) Dispose of or repair damaged or defective personal protective equipment

12. Prohibitions

(1) No employer shall allow HBA work if: (a) Assessment not done (b) Not able to implement control measures

(2) No employer shall allow reproductive work with: (a) Rubella virus, excepting if employee proven immune (b) HIV work by HIV antibody-positive employees (c) HBV work by HBV antigen-positive employees (d) Biological agents causing prolonged or latent infections, or: (i) Are undiagnosable until disease develops (ii) Have particularly effective treatments (iii) Carry serious risk of spreading to community (e) Group 3 or 4 HBAs in Annexure A that cause disease via action on embryo or fetus (f) Group 3 or 4 HBAs in Annexure A that cause genetic defects

(3) No person shall: (a) Use mouth pipetting (b) Eat, drink, smoke, keep food/beverages or apply cosmetics where risk of contamination with HBAs exists

13. Labelling, packaging, transporting, storing, and disposal of HBAs

(1) Employer or self-employed person shall, as far as reasonably practicable, ensure: (a) All HBAs under their control are labeled and packaged in accordance with regulations (b) Laboratory samples are transported according to regulations (c) Storage facilities for HBAs: (i) Are lockable (ii) Are designed to prevent HBA escape (iii) Are maintained according to regulations (iv) Have inventory of all HBAs stored (d) Material containing HBAs is disposed of only at licensed disposal sites (e) All vehicles transporting HBAs are identified with biohazard signs (f) All HBAs being transported are packaged and labeled according to regulations



Reviewed Date	Next Review Date	Document Owner	Responsible Person
01 Feb 2024	28 Feb 2026	SHEQ Warehouse (Pty) Ltd	Neville
This document is active, and any copy made from the electronic version shall be considered an uncontrolled copy. Individuals with uncontrolled copies are responsible for ensuring the use of the current version. Revision levels are electronically controlled.			

14. Special measures for health facilities

(1) In health facilities where patients infected with Group 3 or 4 HBAs are treated, employer shall ensure additional measures are taken, including: (a) Appropriate training for all employees potentially exposed (b) Prevention of sharps injuries (c) Instructions on precautions for specific infectious diseases with special emphasis for employees with direct patient contact (d) Prevention of percutaneous injury with contaminated sharps (e) Protection against splash or spray contamination

(2) Every health facility shall: (a) Have a documented exposure control plan (b) Include special measures for employees who practice midwifery where exposure to blood may occur

15. Implementation of regulations by employer or self-employed person

(1) Employer or self-employed person shall ensure: (a) Processing, use, handling or storage of HBAs is conducted in approved facilities (b) Access to facilities is limited to authorized persons (c) Facilities permit safe storage, receipt, handling, packaging, shipping, disposal (d) Processes exist to: (i) Appropriately validate/certify facilities (ii) Conduct annual inspections (iii) Implement engineering, procedural and administrative controls (iv) Have necessary equipment and materials for all activities (v) Have emergency response plan (vi) Implement procedures for receipt/transport of HBAs in/out of facility (vii) Implement security procedures (viii) Apply disinfection procedures (ix) Ensure workers trained and have demonstrated proficiency (x) Specify personal protective equipment requirements (xi) Have safety manual available (xii) Implement program to prevent/detect release of HBAs

(2) No person shall enter HBA work area unless: (a) That person is an employee undergoing training/apprenticeship (b) That person's duties require presence in that area (c) That person's presence is authorized by person in charge (d) That person is a health and safety representative

16. Keeping of registers, records and incidence register

Every employer shall: (a) Keep registers of employees exposed to Group 3 or 4 HBAs (b) Keep register of incidents which may result in infection (c) Keep all records for minimum of 40 years

17. Miscellaneous regulations

Every employer shall: (a) For air monitoring for viable airborne organisms, document procedures for: (i) Taking air samples (ii) Handling air samples (iii) Identifying viable microorganisms (b) For health facilities: (i) Ensure rooms with suspected/confirmed Group 3 or 4 HBA patients have engineering controls to reduce exposure (negative pressure rooms, HEPA filtered exhaust, UV lights) (ii) Apply Standard Precautions to all patients regardless of diagnosis (iii) Implement Transmission-Based Precautions for known/suspected infections

	Reviewed Date	Next Review Date	Document Owner	Responsible Person
	01 Feb 2024	28 Feb 2026	SHEQ Warehouse (Pty) Ltd	Neville
	This document is active, and any copy made from the electronic version shall be considered an uncontrolled copy. Individuals with uncontrolled copies are responsible for ensuring the use of the current version. Revision levels are electronically controlled.			

(iv) Provide personal protective equipment (c) Prohibit use of compressed air to remove HBAs from surfaces (d) Maintain equipment for detecting, alarming, preventing release of HBAs (e) Certify biosafety equipment annually (f) Use Class II or higher biological safety cabinets for Group 3 and 4 HBAs (g) Have procedures to minimize contact with blood (h) Routinely decontaminate work surfaces, equipment (i) Use impervious materials for cleaning blood/body fluid spills (j) Decontaminate protective equipment before washing, reusing or disposing (k) Place potentially infectious materials in labeled containers (l) Establish written procedures for exposure incidents (m) Document employee training (n) Update exposure control plans annually

18. Approved hazardous biological agents inspection authority

(1) The chief inspector may approve any organization that meets criteria to be an inspection authority. (2) HBA inspection authorities may apply for chief inspector's approval. (3) Chief inspector shall furnish approved inspection authorities with certificates. (4) Certificates remain valid for 3 years, as determined by chief inspector. (5) Approved inspection authorities shall perform functions as prescribed.

19. Offences and penalties

Any person who contravenes or fails to comply with regulations may be guilty of an offense and liable to fine or imprisonment for up to 12 months or both.

20. Short title

These Regulations shall be called the Hazardous Biological Agents Regulations, 2022, and shall come into effect on the date of publication.