BRANCH: INSPECTION AND ENFORCEMENT SERVICES
CHIEF DIRECTORATE: OCCUPATIONAL HEALTH AND SAFETY
DIRECTORATE: OCCUPATIONAL HEALTH AND HYGIENE

Draft Hazardous Biological Agents Regulations

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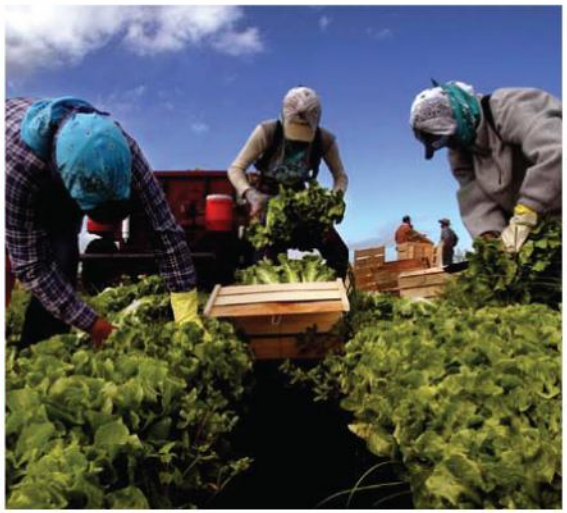
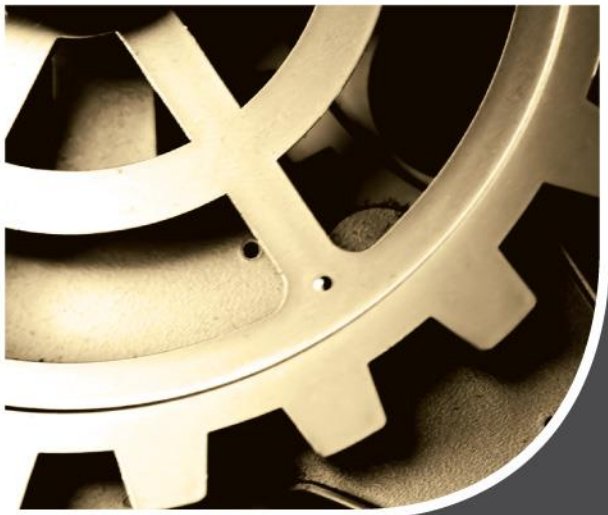

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REPUBLIC OF SOUTH AFRICA

NATIONAL DEVELOPMENT PLAN 2030

Introduction

- Biological agents are living organisms or products of living organisms
- They include viruses, bacteria and fungi and their metabolites, as well as parasitic worms and plants.
- Many microbes reproduce rapidly, require minimal resources for survival, they are a potential danger in a wide variety of occupational settings.
- HBAs are infectious and toxic, but they can also cause allergic reactions, some types of asthma and organic dust toxic syndrome.

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Definitions

- "biozard" means potential source of harm caused by biological agent or toxin;
- "biological agent" means any micro-organism, cell or organic material with plant, animal or human origin, including any which have been genetically modified;
- "control measures" means measures that remove or reduce the exposure of persons at the workplace;
- "decontamination" means the procedure that eliminates or reduce biological agents to a level that does not cause harm with respect to the transmission of infection or other adverse effects;
- "diagnostic laboratory" means a workplace where all diagnostic or other screening procedures are performed on any biological agent or material;
- "equipment" means a device designed to process HBA;
- "HBA" means a hazardous biological agent which may cause an infection, allergy or toxicity, or otherwise create a hazard to human health, subdivided into the following groups:

Definitions

- "laboratory" means a room or part of a building equipped for experimentation, research, testing or manufacture of drugs or chemicals or which may manipulate microbiological agents;
- "safety equipment" means equipment which is designed to prevent exposure;
- "standard precautions" means a synthesis of the major features of Universal Precautions (UP) and Body Substances Isolation (BSI) and applies to all persons coming into contact with potentially infected persons, animals or animal products and potentially contaminated blood and other fluids in the workplace and –

Apply to -

i. all blood

ii. All body fluids, etc

Scope of application

(1) Subject to subregulation (2), these Regulations shall apply to every employer and self-employed person at a workplace where –

(a) HBA is produced, processed, used, handled, stored or transported; or

(b) an incident, for which an indicative list is given in Annexure A to these Regulation occurs that does not involve a deliberate intention to work with a HBA but may result in persons being exposed to HBA in the performance of his or her work.

(2) Regulations 8, 14, 15, 16 and 17 shall not apply to an employer or self-employed person at a workplace where the exposure is restricted to a Group I HBA.

Classification of biological agents

1. The Biological Agents shall be assigned a classification of Group 1, Group 2, Group 3 or Group 4 according to hazard and categories of contaminant.
2. Where a biological agent has not been assigned a classification as contemplated in subregulation 1, the employer and self-employed person shall provisionally classify that agent in accordance with subregulation (3) below, having regard to the nature of the agent and the properties of which he or she may reasonably be expected to be aware.
3. When provisionally classifying a biological agent, the employer and self-employed person shall conduct a risk assessment and assign that agent to one of the groups and if there is doubt according to its level of risk of infection and as to which of two alternative groups would be most appropriate, the HBA shall be assigned to the higher of the two.

Information and training

1. An employer, after consultation with the health and safety committee established for that section of the workplace, shall ensure that any employee at risk of being exposed or exposing others to HBA is comprehensively informed and trained, on both practical aspects and theoretical knowledge with regard to –

(a) the contents and scope of these regulations;

(b) the potential risks to health caused by the exposure;

(c) the measures to be taken by the employer to protect an employee against any risk of being exposed;

(d) the importance of good housekeeping at the workplace and personal hygiene requirements;

Information and training

(e) the precautions to be taken by an employee to protect him- or herself against the health associated with the exposure, including the wearing and use of protective clothing and respiratory protective equipment;

(f) the necessity, correct use, maintenance and potential of safety equipment, facilities and engineering control measures provided;

(g) the necessity of medical surveillance;

(h) the safe working procedures regarding the use, handling, labelling, and disposal of HBA at the workplace;

(i) the procedures to be followed in the event of exposure, spillage, leakage, injury or any similar emergency situation, and decontaminating or disinfecting contaminated areas; and

(j).the potential detrimental effect of exposure on the human reproductive process.

Duties of persons who might be exposed

(1) Any person who is or might be exposed to HBA, shall obey any lawful instruction given by or on behalf of the employer or a self-employed person regarding –

(a) the prevention of an uncontrolled release of an HBA;

(b) the adherence to instructions regarding environmental and health practices, personal hygiene and good housekeeping;

(c) the appropriate use of personal protective equipment and clothing as prescribed by these Regulations;

(d) The appropriate use of personal samplers, when necessary, to measure personal exposure to airborne hazardous biological agents;

(e) the disposal of materials containing HBA and the disinfection and decontamination of any site contaminated by an HBA;

Duties of persons who might be exposed

(f) the reporting during normal working hours for such medical examination or tests as contemplated in regulation 8(1); and

(g) information and training as contemplated in regulation 4.

(2) Any person shall immediately report to the employer, the health and safety representative or self-employed person any possible accidental exposure to a HBA at the workplace, and the employer or self-employed person shall ensure that such incident is investigated and recorded in accordance with regulation 8 9 of the General Administrative Regulations.

Risk assessment by employer or self-employed person

(1) An employer or a self-employed person contemplated in regulation 2 shall, after consultation with the relevant health and safety representative or relevant health and safety committee, conduct a risk assessment to determine if any exposure to HBA has occurred.

(2) When making the risk assessment, as contemplated in subregulation 1, the employer or self-employed person shall take into account as a minimum the following matters –

(a) the nature and of the HBA to which an employee may be exposed and the possible route of exposure;

(b) where the HBA might be present and in what physical form it is likely to be;

(c) the nature of the work and work processes;

Risk assessment by employer or self-employed person

(d)current control measures in place, effectiveness of control measures, and any reasonable deterioration in, or failure thereof; and

(e) what effects the HBA can have on an employee including pregnant and immunocompromised employee;

(3) An employer or a self-employed person shall conduct the risk assessment on the basis of all available information, as far as is reasonably practical, including –

(a) Classification of the HBA into the relevant risk group, according to its level of risk of infection as contained in Annexure B

(b) Recommendations from the manufacturer, supplier or a competent person regarding additional control measures necessary in order to protect the health of persons against such agents as a result of their work;

Risk assessment by employer or self-employed person

(c) Information on diseases that may be contracted as a result of the activities at the workplace;

(d) Potential allergenic or toxic effects that may result from the activities at the workplace; and

(e) Knowledge of diseases from which employees might be suffering and which may be aggravated by conditions at the workplace.

(4) An employer shall review the assessment required by subregulation 1

(a) at intervals not exceeding two years;

(b) forthwith, if there –

i. Is a reason to suspect that the previous assessment is no longer valid; or

ii. has been a change in a process involving a HBA; or

Risk assessment by employer or self-employed person

iii. Has been a change n the methods, equipment or procedures in the use, handling, control or processing of HBA

(5) The employer shall ensure that all employees, and the relevant health and safety committee are informed of the results of the risk assessment and may comment thereon.

Monitoring exposure at workplace

(1) An employer shall ensure that the exposure of employees to a HBA is monitored in accordance with a validated procedure, sufficiently sensitive and of proven effectiveness in any case, which is –

(a) requisite for ensuring the maintenance of adequate control of the exposure of employees to HBA as per risk assessment; or

(b) otherwise requisite for protecting the health of employees.

(2) The monitoring referred to in paragraph (1) shall take place -

(a) at regular intervals; and

(b) when any change occurs which may affect the exposure.

Monitoring exposure at workplace

(3) The employer shall ensure that a suitable record of monitoring carried out for the purpose of this regulation is made and maintained and that record or a suitable summary thereof is kept -

(a) where the record is a representative of the personal exposures of identifiable employees, must be kept for at least 40 years; or

(b) where an employee is required by regulation 8 to be under medical surveillance, an individual record of any monitoring carried out in accordance with this regulation shall be made, maintained and kept in respect of that employee.

Medical surveillance

(1) An employer shall ensure that an employee is under medical surveillance if –

(a) the results of the assessment referred to in regulation 6 indicate that an employee might have been exposed to HBA;

(b) the exposure of the employee to any HBA hazardous to his or her health is such that an identifiable disease or adverse effect to his or her health may be related to the exposure, there is a reasonable likelihood that the disease or effect may occur under the particular conditions of his or her work and there are techniques such as pre-clinical biomarkers, where appropriate, for detecting sensitisation to allergens or an inflammatory response associated with exposure to diagnose indications of the disease or the effect as far as is reasonably practicable; or

(c) an occupational health practitioner recommends that the relevant employee should be under medical surveillance, in which case the employer may call upon an occupational medicine practitioner to ratify the appropriateness of such recommendation

Medical surveillance

(2) In order to comply with the provisions of subregulation (1), the employer shall after extensive counselling and education offer the employee the opportunity to have –

(a) An initial health evaluation, which should be carried out by an occupational health practitioner immediately before or within 14 days after a person commences employment, where any exposure exists or might exist, which comprises –

i. an evaluation of the employee's medical and occupational history;

ii. a physical examination: and

iii. any biological tests and other appropriate medical tests or any other essential examination that is the opinion of the occupational health practitioner is desirable in order to enable the practitioner to do a proper evaluation.

Medical surveillance

(b) Periodic medical examinations and tests in cases where a HBA is known to be capable of causing persistent or latent infections which –

i. in the light of present knowledge, are undiagnosable, until signs or symptoms develop;

ii. can have particularly long incubation periods;

iii. can result in an illness which is recurrent in spite of treatment; and

iv. are known to have serious long-term effects;

(c) All tests and examinations as contemplated in paragraphs (a) and (b) shall be conducted according to a written medical protocol following current best practices/guidelines national or international.

Medical surveillance

(3) The employer shall, in accordance with regulation 8 of the General Administrative Regulations, investigate and record all incidents that result or might result in infections or the death of an employee.

(4) All occupational health practitioners shall submit to the health and safety committee for approval a written protocol for procedures to be followed when dealing with abnormal results.

Records

(1) An employer shall –

(a) keep records of all training, assessments, monitoring results and medical surveillance reports required by regulations 4, 6, 7 and 8 respectively: Provided that personal medical records shall be made available only to an occupational health practitioner;

(b) keep a record of the examinations and tests carried out in terms of regulation 12(b) and of any repairs resulting from these investigations and tests, which records shall be kept for at least three five years.

(c) subject to the formal written consent of an employee, allow the representative of the employee to peruse the records with respect to that particular employee;

(d) make the records of all risk assessments and monitoring results available for perusal by the health and safety representative or health and safety committee;

Records

(e) keep all records of risk assessments and monitoring results for a minimum period of 40 years;

(f) keep all medical surveillance records for a minimum period of 40 years, and if the employer ceases activities, all those records shall be handed over to the relevant Chief Director: Provincial Operations (HPCSA guidelines); and

(g) keep a record of the examinations and tests carried out in terms of regulation 12(b) and of any repairs resulting from these investigations and tests, which records shall be kept for at least five years.

(2) A self-employed person shall keep records of all risk assessments for a minimum period of 40 years, and if the self-employed person ceases activities, all those records shall be handed over or forwarded by registered post to the relevant provincial director Chief Director: Provincial Operations.

Control of exposure to HBA

(1) An employer and self-employed person shall ensure that–

(a) As a result of their activities, exposure of persons to HBA in the working environment is either prevented or, where this is not reasonably practicable, controlled such that exposure is highly improbable; and

(b) The following standard precautions are implemented to reduce the risk of transmission of HBA from recognised and unrecognised sources of infection in a workplace:

i. Hand washing
ii. Gloves
iii. Face or eye protection
iv. Protective clothing
v. Safety equipment
vi. Environmental controls

Control of exposure to HBA

(2) Where reasonably practicable, the employer or self-employed person shall control the exposure of persons to a HBA in the working environment by applying the following measures where appropriate:

(a) limiting the amount of HBA used which might contaminate the working environment;

(b) limiting the number of employees who might be exposed;

(c) introducing measures for the control of exposure, which shall include any combination of the following contamination control concepts:

i. Separation of different infectious processes from each other and from people;

ii. barrier isolation of process or agent;

iii. local exhaust ventilation;

iv. environmental air dilution or disinfection;

Control of exposure to HBA

v. positive static air pressure differential from infectious process to human occupied zones;

vi. suppression of emissions of an airborne HBA;

vii. access control to prevent unauthorised access; and

viii. immediately accessible emergency personal or environmental disinfection.

(d) Introducing appropriate work procedures that employees must follow where materials are handled, used, processes are carried out, or incidents might occur that could give rise to the exposure of an employee to HBA, and such procedures shall include documented instructions to ensure –

i. the safe handling, use and disposal of HBA;

ii. the proper use and maintenance of process machinery, installations, equipment, tools and local exhaust and general ventilation systems;

iii. the regular cleaning of machinery and work areas by vacuum cleaners fitted with a suitable filtration that prevents contamination of the environment;

Control of exposure to HBA

iv. that a system is in place that identifies the need for early corrective action from changes to work procedures and practices.

(e) displaying the biohazard sign shown in Annexure C to these Regulations and other relevant warning signs; and

(f) specifying procedures for taking, handling and processing samples that might contain HBA.

Personal protective equipment and facilities

(1) If it is not reasonably practicable to ensure that the exposure of an employee is controlled as contemplated in regulation 10, the employer shall in the case of –

(a) airborne HBA, provide the employee with suitable respiratory protective equipment and protective clothing; and

(b) HBA that can be absorbed through the skin, provide the employee with suitable impermeable personal protective equipment.

(2) Where respiratory protective equipment is provided, the employer shall ensure that –

(a) the relevant equipment is correctly selected, fitted and properly used;

(b) the reusable equipment is kept in good condition and efficient working order.

Personal protective equipment and facilities

(c) information, instructions, training and supervision which would be necessary with regard to the use of the equipment are known to the employees; and

(d) the reusable equipment is kept in good condition and efficient working order.

(3) An employer shall as far as is reasonably practicable –

(a) Not issue personal protective equipment which has been used to an employee unless it is capable of being decontaminated and sterilised prior to use;

(b) Provide separate containers or storage facilities for protective equipment and protective clothing when not in use; and

(c) Take steps to ensure that all protective equipment and protective clothing not in use are stored in a demarcated area with proper access control;

(d) Provide sufficient hazardous waste containers for disposal of used personal protective equipment.

Personal protective equipment and facilities

(1) An employer shall as far as is reasonably practicable, ensure that all contaminated personal protective clothing issued is cleaned and handled in accordance with the following procedures -

(a) where such clothing is cleaned on the premises of the employer, care shall be taken to prevent contamination during handling, transporting and cleaning;

(b) where clothing is sent off the premises to a contractor for cleaning purposes, the clothing shall be placed in impermeable, tightly sealed colour coded containers and such containers shall be clearly identified with a biohazard label as depicted in Annexure C to these Regulations as contaminated;

(c) where clothing from facilities, handling HBA Risk Group 3 and Risk Group 4 agents is sent off the premises for any purposes these must first be decontaminated

(d) ensure that the contractor as contemplated in subregulation (4)(b) is fully informed of the requirements of these Regulations and the precautions to be taken regarding the handling of contaminated clothing.

Personal protective equipment and facilities

(5) Subject to the provisions of subregulation (4)(b), an employer shall ensure that no person removes dirty or contaminated personal protective equipment and personal protective clothing from the premises: Provided that where contaminated personal protective equipment has to be disposed of, it shall be treated as HBA waste as contemplated in regulation 17.

(6) Subject to the provisions of the Facilities Regulations an employer shall, where reasonably practicable, provide employees using personal protective equipment and clothing as contemplated in subregulation (1) with –

(a) Adequate washing facilities which are readily accessible and located in an area where the facilities will not become contaminated, in order to enable the employees to meet the standard of personal hygiene consistent with the adequate control of exposure, and to avoid the spread of HBA;

Personal protective equipment and facilities

(b) Two separate lockers labelled “protective clothing” and “personal general clothing” respectively, and ensure that the general and protective clothing is kept separately in the lockers concerned; and

(c) Separate “clean” and “dirty contaminated” change rooms if the employer uses or processes HBA to the extent that the HBA could endanger the health of persons outside the workplace.

Maintenance of control measures and facilities

- The employer shall ensure that -

a. documented risk-based protocols are developed, maintained and available at the workplace for all control measures, equipment and facilities provided in terms of regulations 6, 10 and 11, which include -

i. performance parameters and minimum acceptance criteria;

ii. performance monitoring methodology and intervals;

iii. routine maintenance requirements, specifications and intervals;

iv. relevant standards, regulations and manufacturer's requirements; and

v. minimum competency and training required to perform monitoring and maintenance activities.

Maintenance of control measures and facilities

(b) all control measures, equipment and facilities provided in terms of regulations 6, 10 and 11 are maintained in good working order and in accordance with the protocols referred to in (a) above;

(c) thorough examination and tests of control measures, equipment and facilities provided in terms of regulations 6, 10 and 11 are carried out in accordance with the protocols referred to in (a) above, but at intervals not exceeding 24 months;

(d) the protocols referred to in (a) above comply with any applicable guideline issued by the Chief Inspector.

Labelling, packaging, transporting and storage

An employer or self employed person shall, as far as is reasonably practicable, take steps to ensure that –

(a) all HBA under his or her control in storage, transit or being distributed, are properly contained and controlled to prevent the spread of contamination from the workplace;

(b) Transport of HBA are performed with due consideration of the National Road Traffic Act, Chapter VIII, Transport of Dangerous Goods and Substances (Act 93 of 1996), and/or the International Air Transport Association (IATA) Infectious Substances Shipping Regulations;

Labelling, packaging, transporting and storage

(C) Authorizations for the transport and storage of biological agents as required by the National Health Act (Act No 61 of 2003), Regulations relating to the Registration of Microbiological Laboratories and the Acquisition, Importation, Handling, Maintenance and Supply of Human Pathogens (Regulation 178), The Non-Proliferation of Weapons of Mass Destruction Act (Act 87 of 1993), Declaration of Certain Biological Goods and Technologies as Controlled Goods and Control Measures Applicable to Such Goods (Regulation no 19), The Animal Diseases Act (Act 35 of 1984), and the Genetically Modified Organisms Act (Act 15 of 1997), where applicable.

Disposal of HBA

An employer or self-employed person as contemplated in regulation 2 shall –

(a) lay down written procedures for appropriate decontamination and disinfection;

(b) implement written procedures enabling infectious waste to be handled and disposed of without risk;

(c) ensure that all fixtures and equipment including vehicles, re-usable containers and covers which have been in contact with HBA waste are disinfected and decontaminated after use in such a manner that it does not cause a hazard inside or outside the premises concerne

(d) ensure that all HBA waste that can cause exposure is disposed of only on sites specifically designated for this purpose in terms of the National Environmental Management Waste Act, 2008 (Act No. 59 of 2008), in such a manner that it does not cause a hazard inside or outside the site concerned;

Disposal of HBA

(e) ensure that all employees involved in the collection, transport and disposal of HBA waste and who may be exposed to that waste are provided with suitable personal protective equipment; and

(f) ensure that if the services of a waste disposal contractor is used, a provision is incorporated into the contract stating that the contractor shall comply with the provisions of these Regulation.

Hazardous Biological Agents Health and Safety Technical Committee

1) The Chief Inspector must establish a HBA health and safety technical committee which must consist of-

a) a person who is to be the chairperson;

b) two persons designated by the Chief Inspector from the employees of the Department of Labour;

c) three persons designated by employer's organisations to represent employers;

d) three persons designated by employee's organisations representing the federation of unions;

e) one representative of each of the professional bodies, recognised by the Chief Inspector;

f) one person from the field of HBA representing a higher educational institution; and

2) The Chief Inspector must appoint members of the HBA health and safety technical committee for a period that he or she may determine at the time of appointment: Provided that the Chief Inspector may after having afforded a member a reasonable opportunity to respond, discharge him or her at any time, for reasons that are fair and just, and appoint a new member in his or her place.

Hazardous Biological Agents Health and Safety Technical Committee

3)The HBA health and safety Technical Committee must –

a) advise the Chief Inspector on HBA related matters, including but not limited to codes, standards and training requirements;

b) make recommendations and submit reports to the Chief Inspector regarding any matter to which these regulations relate;

c) advise the Chief Inspector regarding any matter referred to the HBA health and safety technical committee by the Chief Inspector;

d) perform any other function for the administration of a provision of these Regulations that may be requested by the Chief Inspector; and

e) conduct its work in accordance with the instructions and rules of the conduct framed by the Chief Inspector.

Categorization of biological agents according to risk groups

Annexure B

1.The attached list must be read in conjunction with the Hazardous Biological Agents Regulation, and in particular regulation 3.

2.Biological agents listed are categorised in risk groups on the basis of their ability to cause human disease by infection, allergy and/or toxicity, potential to cause epidemics or pandemics, endemicity in South Africa and availability of curative or prophylactic treatment:

- **Risk group 1:** A microorganism known not to or unlikely to cause human disease

- **Risk group 2**: A pathogen that may cause human disease but unlikely to pose serious hazard to laboratory workers, the community and the environment. Specific treatment or vaccines may be available to manage or prevent infection with these pathogens.

- **Risk group 3**: A pathogen that may cause serious human disease but does not typically spread from human-to-human. Treatment and vaccines may be available to manage or prevent infection with these pathogens.

Categorization of biological agents according to risk groups

- **Risk group 4**: A pathogen that may cause serious human disease and may be readily transmissible from human-to-human. Specific treatment and preventative measures are typically not available for the diseases caused by these pathogens.

3. In allocating biological agents to a risk group, account is not taken of effects on those whose susceptibility may be affected for one or other reason such as pre-existing disease, medication, compromised immunity, pregnancy or breastfeeding. Workplace specific risk to such workers should be considered as per risk assessment as in regulation 6.

4. Biological agents that have not been classified for inclusion into group 2 to 4 in the list are not implicitly classified as Group 1. All viruses that have been isolated in humans and that have not been assessed and allocated to a group in the list are to be classified in group 2 as a minimum, except where there is evidence that they are unlikely to cause disease in humans.

Categorization of biological agents according to risk groups

5. If more than one species of any particular agent is known to be pathogenic to humans, the most prominent of these is generally named, together with the wider reference “Species” (spp) to indicate the fact that the other species of the same genus may be hazardous. If a whole genus is mentioned in this way, it is implicit that species and strains that are non-pathogenic to humans are excluded.
6. When a strain is attenuated or has lost known virulence genes, then the containment required by the classification of its parent strain need not necessarily apply, subject to risk assessment as per Regulation 6. For example, when such strain is used as a product or as part of a product for prophylactic or therapeutic purposes (see point 2).
7. The requirements as to containment consequent upon the classification of parasites apply only to stages in the life cycle of the parasite in which it is liable to be infectious, allergic or toxic to humans.

Categorization of biological agents according to risk groups

8. The list also gives a separate indication where biological agents are capable of causing allergic or toxic reactions, and where registered vaccine is available for use in the Republic of South Africa.

The indications are identified by the following notations:

- A: Possible allergic effects
- T: Toxin production
- V: Vaccine available

9. The selection of control measures for biological agents should take into account the fact that there are no exposure limits for them. Their ability to replicate and to infect, cause allergic or toxic effects, at very low doses, means that exposure may have to be reduced to levels that are diminishingly low.

Categorization of biological agents according to risk groups

Not all the listed measures will be required in every case. The assessment may indicate, for example, that a specific mode of transmission and route of infection, allergy or toxic effect is required, a susceptible host is needed, there is low prevalence of the infection, allergy or toxic effect in that particular activity, and that illness is easily treatable, leading to rapid and complete recovery.

Table 1: Prescribed risk groups for parasitic agents (in alphabetic order)

Table 2: Prescribed risk groups for fungal agents (in alphabetic order)

Table 3: Prescribed risk groups for bacteria, rickettsiae and mycoplasmas (in alphabetic order)

Categorization of biological agents according to risk groups

Table 4: Prescribed risk groups for viruses. This list pertains primarily to human pathogens, but also includes other viruses that may be frequently used in experimentation (for example baculovirus for protein expression) or veterinary pathogens that will be likely processed in medical laboratories (for example BSL 4 agents) (*unassigned species refer to species not specifically listed here) (in alphabetic order per family).

Indications concerning containment measures and containment levels for laboratories and industrial processes

Annexure D

- For group 1 biological agents, including life-attenuated vaccines, no physical containment measures are prescribed below. For work with group 1 biological agents the principles of good occupational safety and hygiene should be observed.
- Where hazardous biological agents can be transmitted through suspended aerosols over long distances they are classified as airborne spread in the table below. Mechanism of transmission including contact, droplet and vector spread are considered as non-airborne spread below.
- For group 2, 3 and 4 agents, it may be appropriate to select and combine containment requirements from different categories below on the basis of a risk assessment related to any particular process or part of process.

Indications concerning containment measures and containment levels for laboratories and industrial processes

	Containment measures	Containment levels ✚ Mandatory for animal containment facilities ► Mandatory for industrial processes ⊙ Mandatory for Suite Laboratories			
		2	3 (HBA Not Airborne Spread)	3 (HBA Airborne Spread)	4
1.	Viable microorganisms should be contained in a system which physically separates the process from the environment (closed system).	►Yes	►Yes		►Yes

WAYFORWARD

Step 1	Approval and establishment of Technical Committee
Step 2	Review/drafting of regulations
Step 3	Obtaining ACOHS approval
Step 4	Ministerial approval for public comments
Step 5	Publication of draft regulations for 90 for public comments
Step 6	Consolidation and consideration of public comments by TC
Step 7	Resubmit draft regulations to ACOHS
Step 8	Obtain legal opinion from State Law Advisors
Step 9	Draft to undergo language check and editing
Step 10	Socio-economic Impact Assessment System (SEIAS)
Step 11	Final ACOHS approval
Step 12	Promulgation by the Minister

Thank you