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GOVERNMENT NOTICE

DEPARTMENT OF LABOUR

OCCUPATIONAL HEALTH AND SAFETY ACT, 1993 (ACT NO. 85 OF 1993)

## DRAFT REGULATIONS FOR HAZARDOUS BIOLOGICAL AGENTS

The Minister of Labour intends, in terms of section 43 of the Occupational Health and Safety Act, 1993 on the recommendation of the Advisory Council for Occupational Health and Safety, to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director General of Labour, Private Bag X117, Pretoria, 0001 (for the attention of the Chief Director: Occupational Health and Safety), within 90 days of the date of publication of this notice.

**M. M. S. MDLADLANA**  
Minister of Labour

### Definitions

1. In these regulations "**the Act**" means the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993), and any expression to which a meaning has been assigned in the Act shall have the meaning so assigned and, unless the context indicates otherwise -

"**biological agent**" means any micro-organism, cell culture or human endoparasite, including any which have been genetically modified, which may cause any infection, allergy or toxicity, or otherwise create a hazard to human health:

"**decontamination**" means to remove, as far as is reasonably practicable, all inanimate objects by way of sweeping, cleaning, washing, ventilating or any other process aimed at removing the contaminant;

"**diagnostic laboratory**" means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials;

"**disinfect**" means to render non-viable virtually all recognised pathogenic micro-organisms, but not necessarily all microbial forms;

"**engineering control measures**" means control measures that remove or reduce the exposure of persons at the workplace by means of engineering methods;

"**Facilities Regulations**" means the Facilities Regulations published under Government Notice No. R. 2362 of 5 October 1990 in terms of section 43 of the Act;

"**General Administrative Regulations**" means the General Administrative Regulations published under Government Notice No. R. [2206] of [5 October 1984] in terms of section 43 of the Act;

"**hazardous biological agents**" or "HBA" means micro-organisms, including those that have been genetically modified, pathogens, cells, cell cultures and human endoparasites that have the potential to

provoke an infection, allergy or toxic effects, subdivided into the following groups:

- i. Group 1 HBA, which means an HBA that is unlikely to cause human disease;
- ii. Group 2 HBA, which means an HBA that may cause human disease and be a hazard to exposed persons, which is unlikely to spread to the community and for which effective prophylaxis and/or treatment is usually available;
- iii. Group 3 HBA, which means an HBA that may cause severe human disease, which presents a serious hazard to exposed persons and which may present a risk of spreading to the community, but for which effective prophylaxis and/or treatment is available;
- iv. Group 4 HBA, which means an HBA that causes severe human disease and is a serious hazard to exposed persons and which may present a high risk of spreading to the community, but for which no effective prophylaxis and/or treatment is available.

"**micro-organisms**" means microbiological entities, cellular or non-cellular, capable of replication or of transferring genetic material;

"**monitoring**" means the planning, carrying out and recording of the results of a measurement programme;

"**respiratory protective equipment**" means a device which is worn over at least the mouth and nose to prevent the inhalation of airborne hazardous biological agents, and which is of a type, or conforms to a standard, approved by the chief inspector;

"**safety equipment**" means a contrivance or a device designed to prevent injury; and

"**standard precautions**" means a synthesis of the major features of Universal Precautions (UP) and Body Substance Isolation (BSI) and applies to all persons coming into contact with potentially infected persons or animals and/or animal products and potentially contaminated blood and other body fluids in health care facilities or elsewhere and

a. apply to:

- i. all blood;
- ii. all body fluids, secretions, and excretions except sweat, regardless of whether they contain visible blood;
- iii. non-intact skin;
- iv. mucous membranes; and
- v. tissues;

b. are designed to reduce the risk of transmission of HBA from recognised and unrecognised sources of infection in workplaces.

### Scope of application

2. (1) Subject to the provisions of subregulation (2), these regulations shall apply to every employer and self-employed person at a workplace where -
  - a. HBA is deliberately produced, processed, used, handled, stored or transported; or
  - b. an incident, for which an indicative list is given in Annexure II, occurs that does not involve a deliberate intention to work with a hazardous biological agent but may result in persons being exposed to a hazardous biological agent in the performance of work.

(2) The provisions of 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

3. (1) The chief inspector may publish in the Government Gazette for the purpose of these regulations a document, which may be revised or reissued from time to time, entitled "Categorisation of Biological Agents according to hazard and categories of containment" (Annexure V) containing a list of biological agents together with the classification of each agent.

(2) Where a biological agent has not been assigned a classification, 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 assign that agent to one of the groups according to its level of risk of infection and, if in doubt as to which of two alternative groups is the most appropriate, the HBA shall be assigned to the higher of the two.

### **Information and Gaining**

4. (1) Every employer shall, before any employee is exposed or may be exposed, after consultation with the health and safety committee established for that section of the workplace, ensure that the employee is adequately and comprehensively informed and trained, and is thereafter informed and trained at intervals as may be recommended by that health and safety committee 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 from exposure;
- d. the importance of good housekeeping at the workplace and personal hygiene requirements;
- e. the precautions to be taken by an employee to protect himself or herself against the health risks 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, storage and labelling of the HBA at the workplace;
- i. the procedure to be followed in the event of spillage, leakage, injury or any similar emergency situation; and
- j. the potential detrimental effect of exposure on the human reproductive process.

(2) An employer or a self-employed person shall give written instructions of the procedures contemplated in subregulation (1)(i) to the drivers of vehicles carrying the HBA.

(3) Every employer and every self-employed person shall ensure that he or she or any person who in any manner assists him or her in the carrying out or conducting of his or her business has the necessary information and has undergone sufficient training in order for him or her to identify the potential risks and the precautions that should be taken. ,

### **Duties of persons who may be exposed to hazardous biological agents**

5. (1) Every person who is or may be exposed to an 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 wearing of personal protective equipment and clothing as prescribed by these or any other regulations;
- d. the wearing of personal samplers, when necessary, to measure personal exposure to airborne hazardous biological substances;
- e. the disposal of materials containing HBA and the disinfection and decontamination of any site contaminated by an HBA;
- f. the reporting during normal working hours for such medical examination or test 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 exposure to an 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 of the General Administrative Regulations.

### **Risk Assessment by the employer or self-employed person**

6. (1) Every employer or self-employed person contemplated in regulation 2 shall, after consultation with the relevant health and safety representative or relevant health and safety committee, cause a risk assessment to be made and thereafter at intervals not exceeding two years, to determine if any person may be exposed to an HBA.
- (2) The employer shall inform the relevant health and safety representative or health and safety committee in writing of the arrangements made for the assessment contemplated in subregulation (1), give them reasonable time to comment thereon and ensure that the results of the assessment are made available to the relevant health and safety representative or health and safety committee, which may comment thereon.
- (3) When making the assessment, the employer or self-employed person shall keep a record of the assessment and take into account such matters as -
  - a. the HBA to which an employee may be exposed;
  - b. where the HBA may be present and in what physical form it is likely to be;
  - c. the nature of the work, process and any reasonable deterioration in, or failure of, any control measures;
  - d. what effects the HBA can have on an employee; and
  - e. the-period of exposure.
- (4) The employer or self-employed person shall cause the risk assessment to be conducted on the basis of all available information as far as is reasonably practicable, including -
  - a. classification of the HBA into the relevant risk group, according to its level of risk of infection;
  - b. recommendations from the manufacturer, supplier or a competent person regarding the control measures necessary in order to protect the health of persons against such agents as a result of their work;
  - 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 an employee may be suffering and which may be aggravated by conditions at the workplace.
- (5) An employer shall review the assessment required by subregulation (1) forthwith if -
  - a. there is a reason to suspect that the previous assessment is no longer valid; or
  - b. there has been a change in a process involving an HBA or in the methods, equipment or procedures in the use, handling, control or processing of the HBA, and the provisions of subregulations (2), (3) and (4) shall apply.

### **Monitoring exposure at the workplace**

7. The employer shall ensure that the exposure of employees to an HBA is monitored in accordance with a suitable procedure that is standardised, sufficiently sensitive and of proven effectiveness in any case which -
  - a. it is requisite for ensuring the maintenance of adequate control of the exposure of employees to HBA; or
  - b. it is otherwise requisite for protecting the health of employees.

### **Medical surveillance**

8. (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 may be exposed to an HBA; or
  - 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 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 on an occupational medicine practitioner to ratify the appropriateness of such recommendation.

(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 may exist, which comprises -
  - i. an evaluation of the employee's medical and occupational history;
  - ii. a physical examination; and
  - iii. any biological tests or any other essential examination that in the opinion of the occupational health practitioner is desirable in order to enable the practitioner to do a proper evaluation;
- b. periodic medical examinations and tests in cases where an HBA is known to be capable of causing persistent or latent infections which -
  - i. are, in the light of present knowledge, 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; or
  - 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.

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

## **Records**

9. (1) Every employer shall -

- a. keep records of the results of all assessments, monitoring results and medical surveillance reports required by regulations 6, 7 and 8, respectively: Provided that personal medical records shall be made available only to an occupational health practitioner;<sup>10</sup>
- b. subject to the provisions of paragraph (c), make the records contemplated in paragraph (a), excluding personal medical records, available for inspection by an inspector;
- c. allow any person subject to the formal written consent of an 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;
- e. keep all records of risk assessments and monitoring results for a minimum period of 30 years;
- f. keep all medical surveillance records for a minimum period of 30 years, and if the employer ceases activities all those records shall be handed over or forwarded by registered post to the relevant provincial director; and
- g. keep a record of the examinations and tests carried out in terms of regulation 12 and of any repairs resulting from these investigations and tests, and the records shall be kept for at least three years;

(2) A self-employed person shall keep records of all risk assessments for a minimum period of 30 years.

## **Control of exposure to HBA**

10. (1) Every employer and self-employed person shall ensure that -

- a. the exposure of persons to an HBA in the working environment is either prevented or, where this is not reasonably practicable, adequately controlled; and
- b. standard precautions as explained in Annexure VI are implemented to reduce the risk of transmission of HBA from recognised and unrecognised sources of infection in a workplace.

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

- a. Limit the amount of HBA used that may contaminate the working environment;
  - b. limit the number of employees who will be exposed or may be exposed;
  - c. introduce engineering control measures for the control of exposure, which may include the following:
    - i. Process separation, automation or enclosure;
    - ii. the installation of local extraction ventilation systems to processes, equipment and tools for the control of emissions of an airborne HBA; and
    - iii. separate workplaces for different processes;
  - d. introduce appropriate work procedures that employees must follow where materials are used, processes are carried out, or incidents may occur that could give rise to the exposure of an employee to an HBA, and such procedures shall include written instructions to ensure:
    - i. The safe handling, use and disposal of an HBA;
    - ii. the proper use and maintenance of process machinery, installations, equipment, tools and local extraction and general ventilation systems;
    - iii. the regular cleaning of machinery and work areas by vacuum cleaners fitted with a suitable filter that prevents contamination of the environment; and
    - iv. that a system whereby changes in work procedures and processes that indicate the need for early corrective action can be readily identified;
- a. ensure that emissions to the atmosphere comply with the provisions of the Atmospheric Pollution Prevention Act, 1965 ( Act No. 45 of 1965);
  - b. display the biohazard sign shown in Annexure 1 and other relevant warning signs; and
  - c. specify procedures for taking, handling and processing samples that may contain HBA.

### **Personal protective equipment and facilities**

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

- a. in the case of an airborne HBA, provide the employee with suitable respiratory protective equipment and protective clothing; and
- b. in the case of an 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 -

- a. that the relevant equipment is capable of preventing the exposure to the relevant HBA;
- b. that the relevant equipment is correctly selected and properly used;
- c. that information, instructions, training and supervision that is necessary with regard to the use of the equipment is known to the employees; and
- d. that the equipment is kept in good condition and efficient working order.

(3) An employer shall -

- a. not issue used personal protective equipment to an employee unless it is capable of being decontaminated and sterilised prior to use;
- b. provide separate containers or storage facilities for personal 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 is stored only in the place provided therefor.

(4) 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 the clothing is sent off the premises to a contractor for cleaning purposes, the clothing shall be placed in impermeable, tightly sealed containers, and such containers shall be clearly identified as contaminated with a biohazard label as depicted in Annexure 1; and
- c. 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 for the handling of the contaminated clothing.

(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 provide employees using personal protective equipment and clothing as contemplated in subregulation (1) with -

- a. adequate washing facilities that 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 an HBA;
- b. two separate lockers labelled "Protective clothing" and "personal clothing", respectively, and ensure that the clothing is kept separately in the locker concerned; and
- c. separate "clean" and "dirty" change rooms if the employer uses or processes a HBA to the extent that the HBA could endanger the health of persons outside the workplace.

#### **Maintenance of control measures**

12. An employer shall ensure that -

- a. all control equipment and facilities provided in terms of regulations 10 and 1 are maintained in good working order; and
- b. thorough examinations and tests of engineering control measures are carried out at intervals not exceeding 24 months by an approved inspection authority or by a person whose ability to do the measurements and tests is verified by an approved inspection authority.

#### **Prohibitions**

13. No person shall -

- a. use compressed air to remove HBA from any surface or person; or
- b. eat, drink, keep food or beverages or apply cosmetics in an HBA workplace or require or permit any other person to eat, drink, keep food or beverages or apply cosmetics in such a workplace; or
- c. leave a controlled area without prior removal of protective or contaminated clothing.

#### **Labelling, packaging, transporting and storage**

14. Every 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, in transit or being distributed are properly contained and are controlled to prevent the spread of contamination from the workplace; and
- b. the containers in which HBA are transported are clearly marked with a biohazard sign as depicted in Annexure 1 and other relevant warning signs that identify the contents.

#### **Special measures for health and veterinary isolation facilities**



15. (1) Subject to the provisions of regulation 6, every employer and self-employed person shall, in the case of health and veterinary isolation facilities, take into account -
- a. uncertainties about the presence of HBA in a patient or animal and the materials and specimens taken from them;
  - b. the hazard represented by an HBA known or suspected to be present in a patient or animal and materials and specimens taken from them; and
  - c. the risks posed by the nature of the work.
- (2) The employer or self-employed person as contemplated in subregulation (1) shall ensure that the correct containment measures as indicated in Annexure III and VI are selected for persons and animals in isolation facilities that are suspected of being infected with Group 3 or Group 4 HBA in order to minimise the risk of infecting others.

#### **Special measures for laboratories, animal rooms and Industrial processes**

16. In the case of laboratories, animal rooms and industrial processes the employer or self-employed person contemplated in regulation 2 shall ensure that -
- a. the containment measures required in Annexure III and VI are implemented in laboratories and in rooms for laboratory animals, including diagnostic laboratories, and in rooms for laboratory animals that have been deliberately infected with Group 2, 3 and 4 HBA or where laboratory animals are suspected of carrying such agents;
  - b. the containment measures required in Annexure III and VI are implemented in laboratories handling materials in respect of which uncertainty prevails about the presence of HBA that may cause human disease, but that do not have as their aim working with HBA as such: Provided that the containment measures that are required for Group 3 or 4 are implemented where it is known or suspected that it is necessary; and
  - c. the containment measures required in Annexure IV and VI, are implemented where Group 2, 3 or 4 HBA are used in industrial processes: Provided that where H has not been possible to carry out a conclusive assessment of an HBA, but where the use envisaged might involve a serious health risk for persons, such activities may be carried out only in workplaces where the containment measures correspond to requirement for a Group 3 HBA.

#### **Disposal of HBA**

17. (1) 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 vehicles, reusable containers and covers that have been in contact with HBA waste are disinfected and decontaminated after use in such a way that it does not cause a hazard inside or outside the premises concerned;
  - d. ensure that all HBA waste that can cause exposure is disposed off only on sites specifically designated for this purpose in terms of the Environmental Conservation Act, 1989 (Act No. 73 of 1989), in such a manner that it does not cause a hazard inside or outside the site concerned;
  - e. ensure that all employees engaged in the collection, transport and disposal of HBA waste 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 regulations.

#### **Offences and penalties**

18. Any person who contravenes or fails to comply with any provision of regulation 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 or 17 shall be guilty of an offence and liable on conviction to a fine or to imprisonment for a period not exceeding 12 months and, in the case of a continuous offence, to an additional fine of R200 for each day on which the offence continues or additional imprisonment of one day for each day on which the offence continues: Provided that the period of such additional imprisonment shall in no case exceed 90 days.



**Short title**

19. These regulations shall be called the Draft Regulations for Hazardous Biological Agents, 1999.

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[Annexures 2, 3 & 4](#) | [Annexure 5](#) | [Annexure 6](#)