An approach to hazardous biological agents in the workplace -

legal provisions and practical considerations

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The recent promulgation of the Regulations for Hazardous Biological Agents in December 2001, brings South African health and safety legislation on hazardous biological agents (HBA) more in line with international standards. The lack of specific guidance in relation to HBA under the Occupational Health and Safety Act (OHSA) in the past has been responsible for the lack of adequate preventive strategies to protect the health of workers exposed to these agents. This article will present an approach to manage HBA in the workplace setting, taking cognisance of international standards and specific local considerations in eliminating, controlling or minimising exposure to HBA.

What constitutes a hazardous biological agent (HBA)?

A biological agent may be defined as any micro-organism, cell of plant (vegetable), animal, human origin, cell culture, human endoparasite, including those that have been genetically modified, which may cause an infection, allergy, inflammation, toxic reaction, malignancy or otherwise create a hazard to human health.[1,2,3,4]

Major biological agents and their active constituents

The three main sources of biological agents arise from microbes, animal and plant tissue (Table 1).[1,4] The biologically active agents of microbial origin may include the organism itself (eg. viruses, bacteria, fungi), toxins (eg. endotoxins produced by gram negative bacteria, mycotoxins produced by fungi), cell wall constituents such as β(1→3)-glucans produced by moulds, or enzymes produced by genetic modification of microorganisms.[2]

CATEGORY	Examples
Micro-organisms	
• Viruses	Hepatitis, HIV, Influenza, Rubella, Herpes
• Bacteria	Legionella, Mycobacteria, Leptospira, Thermophilic bacteria
• Fungi	Aspergillus, Alternaria
Plants	
• Lower plants	Lichens, liverwarts, ferns
• Higher plants	Wood, grain, cotton, coffee, tobacco, spices
Animals	
• Invertebrates	Amoebae, Shistosoma, Plasmodium, Anisakis, Sponges, Sea-squirts
• Arthropods	Crustaceans, Arachnids (spiders, storage mites, ticks), Insects (cockroaches, weevils, moths, bees)
• Vertebrates	Fish, Amphibians, Reptiles, Birds, Mammals

Table I. *Major categories of biological agents of natural origin*

Among *plant* tissue, processed plant proteins (eg. grain, coffee, soya), vegetable gums or resins (eg. latex, guar), toxins, wood compounds (eg. plicatic acid, tannins, colophony), proteolytic enzymes and organic dust from processing have been shown to be biologically active.[5,6,8] In the *animal* group, exposure to arthropods such as crustaceans, arachnids (eg. storage mites) and insects (eg. weevil) have been commonly associated with adverse health effects.[5,6] Furthermore, invertebrates other than arthropods eg. endoparasites (eg. *Shistosoma, Anisakis*) and proteins present in urine, hair, dander, feathers, saliva and feces of vertebrate animals are also a common source of infectious agents or protein allergens.[5,7]

Biological agents are ubiquitous in ambient air, contaminated water supplies and diseased animals. They enter the human body by inhalation (airborne, droplet spread), ingestion

SECTOR	Examples
Agriculture	Cultivating, harvesting, forestry Breeding and tending animals, fishing
Agricultural products	Abattoirs, food processing plants Storage facilities: grain silos, tobacco Processing animal hair, leather, silk Textile plants, sawmills, paper-mills
Animal care	Veterinary facilities, pet shops
Biotechnology/research labs	Production of enzymes, microbiology, animal units
Mining	Gold and coal mining
Health care	Patient care in hospitals, clinics, nursing homes
Pharmaceutical	Production of drugs, herbal products
Sewage and waste disposal	Waste removal, treatment plants

Table II. Common occupational settings with exposure to hazardous biological agents

PATHOLOGICAL MECHANISM	Examples of causative agents
Microbial infection	
• Infectious material	*Hepatitis (A/B/C), Leptospira, Mycobacterium TB*
• Opportunist pathogens	*Legionella Pneumophilla*
• Zoonoses	*B. Anthracis, C.Psittaci*
Allergic response	
• Micro-organisms	*Actinomycetes, Aspergillus*
• Proteinaceous material	Pollen, dust, animal secretions
• Chemical compounds	Plicatic acid, gums, resins
Toxic/inflammatory response	
• Endotoxins (gram neg. bacteria)	Stored grain, hay, cotton, swine and poultry confinement units
• Mycotoxins (fungi) and β(1→3)-glucans	Stored fodder, grain, nuts
Carcinogenic	
• Wood dust	Hardwood (Beech, oak), Softwood
• Mycotoxins (aflatoxin)	Stored nuts

Table III. Major pathological mechenisms for health effects associated with hazardous biological agents

or through faecal-oral route, percutaneous innoculation and by direct contact with plants or animals (eg. zoonosis).[5] The extent to which they become hazardous to human health will depend on the occupational context, the circumstances surrounding exposure and the health status of the host (worker).

Common occupational settings with exposure to HBA

Although biological agents are commonly found in most domestic and workplace environments, there are certain high-risk occupational settings that constitute hazardous exposure since they result in adverse health outcomes (Table II). These settings include health care and laboratory workers threatened by human pathogens causing infection and among agricultural workers who are at risk from organic dust-borne biological allergens, toxins and parasitic worm infestations especially in warm climates.[5,10,11,12] In South Africa, mining activities which are associated with tuberculous infection are an added high-risk setting.

Health effects associated with exposure to HBA

HBA mediate their adverse health effects through four main pathological mechanisms. These include infection, allergic, toxic/inflammatory and carcinogenic mechanisms (Table III). The most common non-infectious diseases affect the lungs and skin, with a large proportion of these diseases or syndromes being on a general inflammatory or immune basis (Table IV).[2,3,5]

Laws and standards governing HBA in the workplace

Although the traditional emphasis of health and safety regulations and occupational health activities have been on microbes causing infection in occupational settings, the toxic/inflammatory, allergic and carcinogenic potential of HBA is becoming increasingly important.

Some of the well known regulatory initiatives include the comprehensive European directive No. 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work.[13] Other well-cited standards include the US OSHA Regulations (Hepatitis B vaccination, blood-borne pathogens, TB) and the NIOSH criteria documents for animal handlers and health care workers exposed to latex.[14,15,11,5]

In the South African context there are various laws that deal with or have a bearing on HBA (Table V).[15]

Occupational health and safety legislation

The preventive laws dealing with HBA are primarily the OHSA and to a certain extent the MHSA (Table V). Under the former law, the Hazardous Chemical Substances Regulations deals indirectly with substances due to plant/vegetable origin such as grain, cotton, wood and rubber (possibly latex). However, it does not provide adequate and appropriate guidelines for evaluating exposure to specific allergens causing allergenic and inflammatory effects.[5,17] Furthermore, the exposure standards stipulated for these agents are not sufficiently protective in preventing sensitisation to these allergens. Of more direct relevance is the recently promulgated Regulations for Hazardous Biological Agents (HBA) which deals specifically with eliminating, controlling or minimising exposure to HBA.[15]

PATHOLOGICAL MECHANISM	Examples of occupational syndromes or disease entities
General constitutional symptoms	Inhalation fever (fever, myalgia, fatigue)
Infection of any body organ/system	Infections (including zoonosis) eg. TB, Brucelloisis
Allergic/Toxic inflammatory *lung* reactions	• Toxic pneumonitis • Organic dust toxic syndrome (fever, myalgia, headache, respiratory symptoms) • Rhinitis, conjuctivitis, urtcaria • Asthma • Asthma-like syndrome (acute functional response) • Hypersensitivity pneumonitis (extrinsic allergic alveolitis) • Chronic bronchitis • Chronic obstructive lung disease
Allergic/Toxic inflammatory *skin* reactions	• Contact irritant dermatitis • Contact allergic dermatitis • Protein contact dermatitis
Cancer	Carcinoma (eg. nasopharynx, liver, lung)

Table IV. *Occupational syndromes or disease entities associated with hazardous biological agents*

South African Regulations for Hazardous Biological Agents

These Regulations which became enforceable on the 27th December 2001, apply to every employer and self-employed person where:

- HBA is deliberately produced, processed, used, handled, stored or transported
- Incident or high risk exposure to a HBA in the following work situations (Annexure A):
  - food production plants
  - where there is contact with animals and/or products of animal origin
  - health care, including isolation and post mortem units
  - clinical, veterinary and diagnostic laboratories
  - sewage purification installations
  - general workplace

The Regulations define HBA as "micro-organisms, including those that have been genetically modified, pathogens, cells, cell cultures and human endoparasites that have the potential to provoke an infection or toxic effects." (Annexure B)

The HBA Regulations have specific and direct relevance to the following:

a) Information, Education and Risk Assessment

- Every employer is to provide information and training to employees on potential risks of HBA and risk reduction measures.
- Employees are to follow safe procedures for HBA disposal and decontamination and to report all incidents of accidental exposure to a HBA, whereupon such incident should be investigated by the employer.
- A risk assessment should be done every 2 years and a record kept thereof. Biological risks are to be categorised (Grades 1-4) according to specified guidelines (Table VI)

In conducting a risk assessment due consideration needs to be given to:

- Name of the HBA and its biological properties
- Where HBA might be present and its physical form
- Nature of the work process and effectiveness of existing controls to minimise exposure
- Route of exposure (some routes eg. respiratory and skin are more important than others)
- Dose/level and period of exposure
- Potential health effects (eg. infection, toxic, allergenic, carcinogenic)

b) Exposure monitoring and/or medical surveillance

- Regular exposure monitoring is to be conducted using sensitive and effective procedures.
- Medical surveillance of employees should be based on risk assessment or presence of an occupational disease directly related to exposure. Initial (within 14 days) and periodical health evaluations should be done according to a written medical protocol.
- Occupational health practitioners should submit a protocol containing procedures dealing with abnormal results to the health and safety committee for approval.
- All incidents resulting in infections or death should be investigated.
- All risk assessment, exposure monitoring and medical surveillance records to be kept for 40 years

c) Risk Management and control measures

- Sets out a hierarchy of control measures using standard and transmission-based precautions (Annexure C).
- Personal protective equipment should be appropriate to the route of transmission eg. respirators, impermeable gloves, supply, selection, training, separate storage, decontamination or sterilisation.
- Testing of engineering control measures should be conducted every 24 months by an approved HBA inspection authority (retaining records for at least 3 years).
- Labeling, packaging, transporting and storage in special containers marked with the biohazard sign (Figure 1)

Figure 1. *Bio-Hazard sign*

- Written procedures for disposal of HBA to designated site in terms of the Environmental Conservation Act and decontamination or disinfection of all containers.
- Special control measures are indicated for HBA in category 2-4 for:
  - health and veterinary isolation facilities, labs, animal rooms for human/animal materials to use control measures in Annexure E (containment levels) and Annexure C (precautions)
  - industrial processes to use control measures in Annexure F (containment levels) and Annexure C (precautions)

The major deficiency of HBA Regulations relates to the very narrow definition of HBA. The primary focus appears to be on preventing and controlling microbial infections since it excludes the primary allergic, inflammatory and malignant health effects associated with cells of plant and animal origin in its definition. It also omits special mention of incidents or exposure involving work in agriculture and the processing of plant products in its scope of application. Most of the following major biological categories (and their species) such as fungi/moulds, arthropods, vertebrates, vegetable/plant proteins and invertebrates therefore do not appear in its classification system for biological agents (Annexure B). The lack of emphasis on protein allergens causing allergic diseases in the absence of microbial infections may point to the need for the development of specific regulations in the future that deal adequately and effectively with allergens of biological (protein) origin.

In more recent years industrial hygiene and analytical capabilities have been refined for evaluation of bioaerosols and their protein allergens making surveillance technically feasible. Clear evidence is also emerging in the current literature for exposure intensity response relationships for occupational allergens of plant, animal or microbial origin, illustrating the renewed emphasis on this group of agents. Allergen exposure levels below determined exposure limit values have been associated with a decreased risk of sensitisation and allergic health outcomes such as asthma. Some examples include wheat flour (1-2.4 mg/m^3), fungal alpha-amylase (0.25 ng/m^3), natural rubber latex (0.6 ng/m^3), western red cedar (0.4 mg/m^3) and rat allergens (0.7 ug/m^3) and wood dust (2 mg/m^3). Stipulating legally binding occupational exposure limits is therefore an essential strategy in preventing exposure to allergens and should be the focus of future local legislation.[17,19]

SCOPE	ACT (and specific Regulation)	Examples of HBA covered
Occupational Health and Safety	1. Occupational Health and Safety Act (OHSA) • Hazardous Chemical Substances Regulations • Regulations for Hazardous Biological Agents	Grain, cotton, wood, rubber (?latex) Micro-organisms, cells pathogens, cell cultures human endoparasites
	2. Mine Health and Safety Act (MHSA)	TB
Workers Compensation	1. Compensation for Occupational Injuries and Diseases Act (COIDA)	*Infections* TB, Brucella, Anthrax, Q-fever, Bovine TB, Rift Valley Fever, (HIV, Hepatitis) *Lung diseases* Occupational asthma, lung fibrosis, extrinsic allergic alveolitis (organic dust, moulds, proteins/enzymes, animals/insects) *Skin diseases* Allergic contact dermatitis (dust, liquids)
	2. Occupational Diseases in Mines and Works Act (ODMWA)	TB associated with risk work in mines and quarries
Other	1. Labour Relations Act (LRA)	Deals with unfair discrimination in relation to disability
	2. Food-related (consumer-oriented) • Foodstuffs, Cosmetics & Disinfectants Act, Abattoir Hygiene Act, Health Act • Standards Act	Deals with food hygiene and safety Deals with medical surveillance of workers in order to protect food safety
	3. Environmental Conservation Act	Deals with disposal of biological waste
	4. Health Act	Deals with compulsory notification of infectious diseases

Table V. Major South African laws relating to hazardous biological agents

Compensation-related legislation

These include laws dealing with compensation of occupational diseases in the general workplace (Compensation for Occupational Injuries and Diseases Act - COIDA) and in the mines (Occupational Diseases in Mines and Works Act) (Table V). In its expanded schedule of occupational diseases (schedule 3) under COIDA, all compensable diseases, including those due to HBA are listed. Tuberculosis (associated with silica exposure in gold/coal mines and foundries, among health care workers) and occupational asthma (due to grain cereals and latex) are commonly reported under COIDA and the voluntary Surveillance of Occupational Respiratory Diseases in South Africa (SORDSA) programme.[20,21] Although HIV/AIDS and Hepatitis are not specifically listed under Schedule 3 of COIDA, the Compensation Commissioner is known to accept liability for these diseases should they shown to be occupationally acquired.[22]

Other related legislation

Other legislation having a bearing on HBA relate to the various legislative requirements for food hygiene and safety enforced unevenly by a multitude of different governments departments (Table V).[23] These laws are geared primarily towards fulfilling consumer needs, while none deal explicitly with the occupational health concerns of workers exposed to these foods. This is confirmed by our research into the seafood processing industry that revealed inadequate surveillance programs and preventive strategies for workers in the industry.[24]

Principles in the management of occupational health risks and diseases due to HBA

1. Remove from exposure and/or isolate individual

After discussion with the patient, the medical practitioner should write a motivating letter to have the person moved to a job that has no or minimal exposure, or declare the person temporarily unfit to work in the presence of acute infection. The various options should be discussed with the worker and due consideration needs to be given to the worker's rights under the LRA code of good practise.

2. Institute appropriate treatment where possible

Institute appropriate treatment of infection/allergy and preventive measures such as post-exposure prophylactic treatment or vaccination for as yet unaffected workers. The treatment of occupational diseases from HBA is no different from treatment of these conditions from non-occupational causes.

3. Submit a claim for worker's compensation

Submission of a claim under the COIDA requires First, Progress and Final Medical reports (specific for occupational diseases) with supporting documentation. Few published criteria currently exist that outline the basis for the Compensation Commissioner's decisions.[19,21,22,25] For mineworkers with TB, different procedures need to be followed under ODMWA for submission to the Medical Bureau for Occupational Diseases (MBOD).

4. Notify the case to the Chief Inspector in the Department of Labour and/or the Department of Health

Medical practitioners are required by the OHSA to notify all cases of suspected occupational disease to the Chief Inspector, Department of Labour (Fax: 012-309 4382). This should also be done on form WCI 22 (see section 3 above). If the worker has a notifiable disease, the case should also be notified to the Department of Health as required under the Health Act.

5. Investigate and treat the workplace

The diagnosis of an occupational disease in a worker implies that measures at the workplace are inadequate and pose a potential health risk

CATEGORY	DEFINITION	Examples
Group 1	- unlikely to cause human disease	*E Coli K10, yeast*
Group 2	- can cause severe human disease - might be a hazard to workers - unlikely to spread to community - effective prophylaxis/treatment	*Legionella pneumoniae, Leptospira, Neisseria meningitidis* (V), *Rubella, Influenza A/B* (V), *Hepatitis A* (V), *Herpes simplex, Ascaris* (A)
Group 3	- can cause severe human disease - serious hazard to workers - may spread to community - effective prophylaxis/treatment	*Mycobacterium TB* (V), *Bacillus anthracis* (V), *Shigella dysenteriae Type I* (T), *Plasmodium falciparum, Rabies* (V), *Hepatitis B* (V), *Human Immunodeficiency virus*
Group 4	- causes severe human disease - serious hazard to workers - high risk of spread to community - no effective prophylaxis/treatment	*Congo haemorrhagic Fever, Ebola pox*

Symbols: A-allergenic, T-toxic effects, V-vaccine available

Table VI. Risk group categories according to the South African Regulations for Hazardous Biological Agents, 2001

to co-workers similarly exposed. The incident requires investigation and prompt action. The exposure should be evaluated by an approved inspection authority (AIA) for HBA, (list obtainable from the Department of Labour). This evaluation will identify sources of high-risk exposure and provide recommendations for controlling the hazards either through substitution, body substance isolation, engineering controls (e.g. exhaust ventilation) and/or administrative controls (e.g. universal infection control precautions). Special care should be taken when instituting preventive measures that one hazard is not replaced by another hazard (e.g. using latex containing rubber gloves in preventing skin transmission of blood-borne pathogens). Exposure monitoring using industrial hygiene surveillance programmes can evaluate the effectiveness of control measures in decreasing the risk of infection and/or allergic sensitisation of other, as yet unaffected, workers.

The employer should also make use of the expertise of an occupational medical practitioner in designing appropriate medical surveillance programmes for the workforce as an adjunct to industrial hygiene evaluation and control measures. Various early sub-clinical biomarkers (eg. skin prick testing, serum antibodies, target organ tests) can be used to identify signs of early infection, inflammation or allergic sensitisation before overt symptoms and clinical disease manifest. These tests can also be used to assess the effectiveness of control measures instituted. Finally, education and training programmes are essential in informing and educating workers about the health effects of hazardous agents they are exposed to so that they may take the necessary precautions when working with these agents.

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