



**THE PRESIDENCY
REPUBLIC OF SOUTH AFRICA**



SOCIO-ECONOMIC IMPACT ASSESSMENT SYSTEM (SEIAS)

REVISED (2020): FINAL IMPACT ASSESSMENT TEMPLATE –PHASE 2

NAME OF THE PROPOSAL: HAZARDOUS BIOLOGICAL AGENTS REGULATIONS, 2021

1. Please DO NOT ALTER the template and questionnaire
2. Date must be clearly indicated
3. Draft SEIAS report should have a watermark word DRAFT indicating the version and should be accompanied by the supporting documents (draft proposal, M&E plan and pieces of research work)
4. FINAL report will be in PDF format and will be inclusive of the sign-off
5. FINAL report will have the approval stamp of the Presidency on the front cover and will include the signoff
6. Sign off forms are only valid for a period of six months.

PART ONE: ANALYSIS FOR FINAL SEIAS REPORT

Please keep your answers as short as possible. Do not copy directly from any other document.

1. Conceptual Framework, Problem Statement, Aims and Theory of Change

1.1. What socio-economic problem does the proposal aim to resolve?

Exposure to hazardous biological agents (HBAs) in the workplace is governed by the Regulations for Hazardous Biological Agents, 2001. In terms of these regulations, employers must ensure that they:

- a. Conduct a risk assessment every two years.
- b. Carry out monitoring in accordance with a suitable procedure that is standardized, sufficiently sensitive and of proven effectiveness.
- c. Implement engineering control measures, administrative control measures and / or use of personal protective equipment and facilities to prevent or, where this is not reasonably practicable, adequately control the exposure risk presented to employees.
- d. Provide medical surveillance for exposed employees.

The workplace provides an ideal place for the proliferation of microorganisms and the spread of diseases as workers spend approximately 90% of their time indoors. Congregate settings, poor personal hygiene habits (e.g. hand hygiene and inadequate best practices of coughing and sneezing), and the quick spread of disease through international travel all lead to the increased likelihood of disease being introduced into the work environment.

Biological agents include bacteria, viruses, fungi, other microorganisms and their associated toxins. They have the ability to adversely affect human health in a variety of ways, ranging from relatively mild, allergic reactions to serious medical conditions—even death.

Biological agents are usually invisible; it is often difficult to appreciate the risks they present. As they are living microorganisms, they have the ability to replicate rapidly, require minimal resources to survive and can infect at very small doses.

The emerging of SARS CoV-2 has necessitated the acceleration in the review of this regulations because new measures had to be implemented by the employers in the workplace to curb the spread of the virus.

In the workplace, exposure to biological agents can be:

- a. intentional, whereby the employee works directly with them, for example, in a laboratory or research facility, or
- b. unintentional, whereby the employee is exposed to the biological agent due to the work they do, for example, a healthcare worker who is exposed to a blood borne virus, a laundry worker who receives a needle stick injury or a farmer who is exposed to an animal disease that can also affect humans (a zoonoses).

Occupational exposure among the workers, more specifically among health care personnel, can be attributed to several direct or indirect factors, such as integral and direct care to patients, administering medication and dressing wounds, cleaning and sterilization of surgical materials and diverse instruments, excessive workload and inappropriate conditions for carrying out the work process.

During the enforcement of the current regulation, the following shortcomings were identified that necessitated the review of the regulations:

- a. no reference is made to fungi that cause infection, except in its definition of a biological agent;
- b. the hazard group classification of the Regulation does not allow for additional risks like pre-existing disease, the effects of medication, co-exposure in the workplace, immune-compromised persons or pregnant or breastfeeding females.
- c. the very narrow definition of HBA whereby the primary focus appears on preventing and controlling microbial infections because it excludes the primary allergic, inflammatory and malignant health effects associated with cells of plant and animal origin;
- d. It also omits special mention of incidents or exposure involving work in agriculture and the processing of plant products in its scope of application.
- e. Most of the following major biological categories (and their species) such as fungi/moulds, arthropods, vertebrates, vegetable/plant proteins and invertebrates, including Severe Acute Respiratory Syndrome (SARS) do not appear in the classification system for biological agents.

Workers exposed to hazardous biological agents do suffer ill-health, even death whilst performing their duties. This cause a huge burden to the family if the worker was a bread winner. This also affects the industry and economy because a skill is being lost. When workers suffer ill- health, some do not fully recover and thus they become a burden to the state in that they must be compensated in terms of the Occupational Injuries and Diseases Act, 1993 and also the Unemployment Insurance Fund.

The Compensation Fund exist to provide social protection to workers who sustain occupational injuries or who contract occupational diseases during the course of their employment. As of 16 February 2021, a total of 17 185 claims have been lodged for exposure to COVID-19 at work. Out of that number, regrettably, 32 claims relate to fatalities.

Of these, 12 257 have been lodged directly with the Compensation Fund (CF) while 4434 were lodged with Rand Mutual and 494 with Federated Employees, the two mutual funds that operate under licence from the Minister of Employment and Labour. To date, an amount of R35, 152, 044.17 has since been paid towards benefits. The distribution of payments is as follows;

- R 2, 975, 631.50 paid for temporary total disablement and this constitutes 9% of the total amount paid.
- R 10, 702, 338.70 paid out in medical aid costs and constitutes just above 29% of the total amount paid.

- R 160, 908.00 paid out in funeral costs and constitutes below 1% of the total amount paid.
- R 119, 433.81 paid out in PD Pension and constitutes below 1% of the total amount paid.
- R 21, 193, 732.16 paid out in dependents benefits costs and constitutes 62% of the total amount paid.

The draft hazardous biological agent’s regulations is the legal tool that provide legal responsibilities on any employer or self-employed person to provide a safe working environment by implementing control measures that will protect employees’ exposure to hazardous biological agents. Annexure A, which is the categorization of biological agents and their risk groups contains the updated list which includes the “Severe Acute Respiratory Syndrome” (SARS) of which SARS Cov-2, falls under. The current HBA regulations’ list of categorization, excludes SARS.

1.2. What are the main root causes of the problem identified above?

What socio-economic problem does the proposal aim to resolve	What are the main roots or causes of the problem
<p>The exposure of employees to hazardous biological agents in the course of performing their duties at the workplace. Workers exposed to hazardous biological agents do suffer ill-health, even death whilst performing their duties. This cause a huge burden to the family if the worker was a bread winner. As of 16 February 2021, a total of 17 185 claims have been lodged for exposure to COVID-19 at work. Out of that number, regrettably, 32 claims relate to fatalities. (South African Government News Agency, NEWS, 16 February 2021)</p>	<p>Failure of employers to put in place effective control measures to prevent the exposure of employees to HBAs and failure to maintain engineering equipment.</p>
	<p>Failure of employers to conduct baseline medical surveillance to establish the health status of employees who might be exposed to HBAs in the workplace</p>
	<p>The failure of employers to provide effective personal protective equipment (PPE) against HBAs in the workplace. Failure to inform, instruct and train the employees on the correct use of PPE</p>
	<p>Failure of employees to follow lawful instructions given by the employer to minimize their exposure to HBAs</p>
	<p>Failure by employers to vaccinate employees where the vaccine is available, e.g. Hepatitis B vaccine</p>
	<p>a. Limitation of the current regulations e.g. most of the following major biological categories (and their species) such as fungi/moulds, arthropods, vertebrates, vegetable/plant proteins and invertebrates, including Severe Acute Respiratory Syndrome (SARS) do not appear in the classification system for biological agents.</p>

1.3. Summarise the **aims** of the proposal and **how** it will address the problem in no more than five sentences.

The aim of the proposal is to address the shortcomings already mentioned above in the current regulation and including the following:

- Encourage the employer to vaccinate employees who might be exposed to HBAs as will be indicated in the risk assessment.
- To include primary allergic, inflammatory and malignant health effects associated with cells of plant and animal origin. Additional risks like pre-existing disease, the effects of medication, co-exposure in the workplace, immune-compromised persons or pregnant or breastfeeding females.
- To extend the scope of application of the regulations to include workplaces where HBAs are not deliberately produced, processed, used, stored or transported as realized by the appearance of COVID-19 strain.

1.4. How is this proposal contributing to the following national priorities?

National Priority	Impact
1. Economic transformation and job creation	When employees suffer ill-health, the production and efficient service is affected thus affecting the productivity that the economy requires for growth and job creation.
2. Education, skills and health	<p>The proposal makes it the duty of the employer to train and instruct the employees at the workplace. The training offered is relevant to the sector and the duties carried out by the employees. Therefore, after the training, the employees will have developed the skills required to conduct their duties effectively. The knowledge gained through training will enable the employees to save and protect their own lives too.</p> <p>Example: Safety of workers will ensure that much needed skills and experience are not lost due to injuries and fatalities.</p>
3. Consolidating the social wage through reliable and quality basic services	N/A
4. Spatial integration, human settlements and local government	N/A

National Priority	Impact
5. Social cohesion and safe communities	N/A
6. Building a capable, ethical and developmental state	Routine inspections will be carried out as per the work plan to ensure compliance with these regulations. Non-complying employers will be served with notices, giving them a specific period to rectify the non-compliance. If they fail to comply after the period of the notice, they will be sent for prosecution.
7. A better Africa and world	South Africa is the member of the Africa Centres for Disease Control (CDC) on the Biosafety and Biosecurity Initiative (BBI) aimed at strengthening the biosafety and biosecurity systems of African Union (AU) Member States in order build their capacity to comply with international requirements and regulations. On an annual basis a report is sent to Africa CDC regarding the legislative framework that South Africa has in place to ensure biosecurity and biosafety systems in the country

1.5. Please describe how the problem identified could be addressed if this proposal is not adopted. At least one of the options should involve no legal or policy changes, but rather rely on changes in existing programmes or resource allocation.

Option 1.	<p>Continue to enforce the current Regulations for Hazardous Biological Agents, 2001 with its shortcomings, namely;</p> <ul style="list-style-type: none"> • Exclusion of the primary allergic, inflammatory and malignant health effects associated with cells of plant and animal origin. • Omission of incidents or exposure involving work in agriculture and the processing of plant products. • Hazard group classification of the Regulation does not allow for additional risks like pre-existing disease, the effects of medication, co-exposure in the workplace, immune-compromised persons or pregnant or breastfeeding females. • No reference is made to fungi that cause infection.
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Option 2.	Advocacy and awareness raising through workshops and seminars. The challenge with this option is that, previous workshops and seminars were conducted and limited changes happened in industries. With the invent of COVID-19 as an example, advocacy and awareness is not enough to drive the message home.
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PART TWO: IMPACT ASSESSMENT

2. Policy/Legislative alignment with other departments, behaviours, consultations with stakeholders, social/economic groups affected, assessment of costs and benefits and monitoring and evaluation.

2.1. Are other government laws or regulations linked to this proposal? If so, who are the custodian departments? Add more rows if required.

Government legislative prescripts	Custodian Department	Areas of Linkages	Areas of contradiction and how will the contradictions be resolved
National Health Laboratory Service Act, 200	Department of Health	It provides for the establishment of National Health Laboratory Service;	There are no areas of conflict. This legislation applies to researchers.
Animal Diseases Act, 36 of 1984 and Animal Health Act, 2002	Department of Agriculture, Forestry and Fisheries	Employees working with animals that could contract zoonotic diseases	There are no areas of conflict but their legislation is specific to employees working with animals
The Military Health Services Act	South African National Defence Force	The provision of medical care for employees of SANDF	There are no areas of conflict but Department of Employment and Labour has no jurisdiction
OHS Act, 85 of 1993	Department of Employment and Labour	It provides for the health and safety of persons at work and for the health and safety of persons in connection with the	There are no areas of contradiction

		use of plant and machinery; the protection of persons' other than persons at work against hazards to health and safety arising out of or in connection with the activities of persons at work.	
Compensation for Occupational Injuries and Diseases Act, 130 of 1993	Department of Employment and Labour	It provides for compensation for disablement caused by occupational injuries or diseases sustained or contracted by employees in the course of their employment, or for death resulting from such injuries or diseases.	There are no areas of contradiction

2.2. Proposals inevitably seek to change behaviour in order to achieve a desired outcome. Describe (a) the behaviour that must be changed, and (b) the main mechanisms to bring about those changes. These mechanisms may include modifications in decision-making systems; changes in procedures; educational work; sanctions; and/or incentives.

a) What and whose behaviour does the proposal seek to change? How does the behaviour contribute to the socio-economic problem addressed?

- Failure of employers to put in place effective control measures to prevent the exposure of employees to HBAs and non-maintenance of engineering control equipment. Employers failing to provide effective personal protective equipment (PPE) and failure to instruct, inform and train employees on the correct use of PPE. Currently, the emergence of SARS CoV-2 has indicated the need for new control measures to be put in place. For an example, office space in the current regulations is not considered as a workplace that could expose employees to HBAs, but employers had to provide hand sanitizers and cloth masks to all workplaces where there are employees. Failure of employees to follow lawful instructions given by the employer to minimize their exposure to HBAs and to utilize the PPE issued to them by the employer.

b) How does the proposal aim to bring about the desired behavioural change?

The proposal instructs the employers to take into considerations the recommendations identified in the exposure monitoring reports and to develop a documented action plan to implement the recommendations. The current regulations do not have such a clause, as a result, employers conduct exposure monitoring for the sake of compliance with the law, but they never implement the recommendations given by experts in the reports.

- The current regulations states that the maintenance of control measures, equipment and facilities must be carried out by an approved HBA inspection authority. When the Department conducted audits of HBA AIAs, it was found that very few AIAs have the necessary equipment and expert knowledge to maintain some of the engineering control measures, for an example, the biosafety cabinets. Instead, the importers and manufacturers of biosafety cabinets are the ones with expert knowledge and necessary equipment to maintain those cabinets and the importers and manufacturers do not fall under the HBA AIAs. Therefore, the approach with this proposal is that a competent person must conduct the maintenance.
- The draft regulations states clearly the risk assessment must be conducted by a competent person and the definition of a competent person has been included in the definitions. The current regulations are not specific on who must conduct a risk assessment and there is no definition of a competent person.
- The HBA Technical Committee will be established and will consist of specialists from the different fields, related to hazardous biological agents and it will advise the Chief Inspector on matters related to HBA. The current regulations do not have a technical committee to advice the Chief Inspector.

2.3. Consultations

- a) Who has been consulted inside of government and outside of it? Please identify major functional groups (e.g. business; labour; specific government departments or provinces; etc.); you can provide a list of individual entities and individuals as an annexure if you want.

The proposed Hazardous Biological Agents Regulations were reviewed by the Technical Committee which comprised of representatives from the South African Society of Occupational Medicine, South African Society of Occupational Health Nurses, Specialists in Hazardous Biological Agents, Department of Health, Organized Labour and Organized Business after approval was granted by the Minister's Advisory Council for Occupational Health and Safety. The draft regulations were published for public comments on 31 July 2020 to 31 October 2020 for 90 days to allow the stakeholders to comment thereon. The Department also conducted 2 virtual workshops for the stakeholders to present the draft HBA Regulations. The dates for the workshops were 25 and 28 August 2020, respectively.

Consulted Government Departments, Agencies and Other Organs of State

Department's name	What do they see as main <u>benefits, Implementation/ Compliance costs and risks?</u>	Do they <u>support or oppose</u> the proposal?	What <u>amendments</u> do they propose?	Have these amendments been <u>incorporated</u> in your proposal? If yes, under which section?
National Institute for Occupational Health (Department of Health)	They employ researchers who work with HBAs in laboratories. Therefore, this regulation will provide maximum protection for such employees.	They support the proposal	To include the exposure of employees to HBAs when travelling on official duties. Proposed fitted in this context means putting on properly, propose fit testing element as part of an effective respiratory protective programme to be included.	No. The matter will be included in the explanatory notes. Fit testing is expensive and the SMME's will not afford the service.

Consulted stakeholders outside government

Name of Stakeholder	What do they see as main <u>benefits, Implementation/ Compliance costs and risks?</u>	Do they <u>support or oppose</u> the proposal?	What <u>amendments</u> do they propose?	Have these amendments been <u>incorporated</u> in your proposal?
Transnet SOC Ltd	The protection of their employees against HBAs at the harbours	They support the proposal	<ul style="list-style-type: none"> •Addition of competency to a person who must conduct a risk assessment. •The control measures to include 	<p>Yes, Regulation 6(2)(b).</p> <p>Yes, Regulation 10(4)(g)</p>

Name of Stakeholder	What do they see as main <u>benefits</u> , <u>Implementation/</u> <u>Compliance costs</u> and <u>risks</u> ?	Do they <u>support</u> or <u>oppose</u> the proposal?	What <u>amendments</u> do they propose?	Have these amendments been <u>incorporated</u> in your proposal?
			preventative immunization. •To include guidance on how to deal with emergencies	Yes, Regulation 10(4)(e)(ix)
South Africa Petroleum Industry Association (SAPIA)	The Protection of their employees in the Petroleum industry	They support the proposal	Change wording back to original. By changing it to “conduct a risk assessment” this means that the employer or self-employed person has to do the risk assessment themselves and if some body else did the risk assessment on their behalf it would mean that the employer was legally non-compliant. The original wording “cause a risk assessment to be made”, meant that even if the employer got somebody else (a competent person) to do the risk assessment then they would still	No. Regulation 6(2)(b) indicates that the employer must endure that the risk assessment is conducted by a competent person, which implies the risk assessment might be conducted by another person other than an employer.

Name of Stakeholder	What do they see as main <u>benefits</u> , <u>Implementation/</u> <u>Compliance costs</u> and <u>risks</u> ?	Do they <u>support</u> or <u>oppose</u> the proposal?	What <u>amendments</u> do they propose?	Have these amendments been <u>incorporated</u> in your proposal?
			be legally compliant).	
			<p>On first reading of Regulation 2(1)(b) it is not evident that the HBA regulations are applicable to exposure to HBA in general workplaces (it says only incident and not exposure in the regulation). Only on examination of Annexure A is this clear. This needs to be changed to make the application clear. This is one of the most significant changes needed to these regulations</p>	<p>Yes. Under scope of application it is mentioned that the Regulations shall apply to every employer or self-employed person at a workplace where –</p> <p>(b) an exposure to HBA may occur. Annexure A has been removed.</p>
			<p>The new definition of biological agent includes organic material of plant origin. When read with</p>	<p>No. The other HBAs that are of plant origin. Therefore, there is no overlap with the RHCS as it focuses on chemicals and not microorganisms.</p>

Name of Stakeholder	What do they see as main <u>benefits</u> , <u>Implementation/</u> <u>Compliance costs</u> and <u>risks</u> ?	Do they <u>support</u> or <u>oppose</u> the proposal?	What <u>amendments</u> do they propose?	Have these amendments been <u>incorporated</u> in your proposal?
			<p>Regulations 8(1)(b) this means that an immune response caused by cotton dust (which both contains organic material of plant origin (cellulose) and bacteria are covered in both the HBA regulations as well as in the Regulations for Hazardous Chemical Substances. This creates overlap between the two sets of regulations.</p>	
			<p>During the COVID-19 pandemic the understanding of science in the HBA arena has progressed dramatically. It is evident that transmission / exposure routes are complex and in line with this it is appropriate</p>	<p>Yes. Regulation 6(2)(b)</p>

Name of Stakeholder	What do they see as main <u>benefits</u> , <u>Implementation/</u> <u>Compliance costs</u> and <u>risks</u> ?	Do they <u>support</u> or <u>oppose</u> the proposal?	What <u>amendments</u> do they propose?	Have these amendments been <u>incorporated</u> in your proposal?
			that a competent person conducts the risk assessment.	
			The fundamentals of HBA risk assessment by scientific necessity reference dose. By removing reference to dose (which includes by definition both concentration and duration), it renders the entire risk assessment ineffective.	No. Dose is not applicable to all HBAs and as HBAs are living organisms, they replicate at all times
			Put back the requirement for an AIA to do the maintenance and monitoring of facilities and equipment.	No. The word monitoring was changed to verification to accommodate the competent persons who are not AIAs.
University of KwaZulu-Natal	For the protection of their employees and researchers	They support the proposal	To define immunocompromised employee	No, because immunocompromised can be temporary or permanent depending on why your immune system is compromised

Name of Stakeholder	What do they see as main <u>benefits</u> , <u>Implementation/</u> <u>Compliance costs</u> and <u>risks</u> ?	Do they <u>support</u> or <u>oppose</u> the proposal?	What <u>amendments</u> do they propose?	Have these amendments been <u>incorporated</u> in your proposal?
			The list of biological agents categorised according to their risk group (Annexure B) should be read in conjunction with this regulation. To include the word “risks” in reference to the health risks associated with exposure	Yes, regulation 4(1)(e)
			The parts of the sentence after the word “potential” are not clear in sub-regulation 4(1)(f)	Yes, included the word potential “limitation” in the text
			The reference to storage to be returned in the regulations	Yes, regulation 4(1)(h)
			Sub-regulations 5(2) needs to reflect the reporting, recording and investigation of incidents and occupational diseases. Propose the	No. investigation of incidents is already covered in the General Administrative Regulations.

Name of Stakeholder	What do they see as main <u>benefits</u> , <u>Implementation/ Compliance costs</u> and <u>risks</u> ?	Do they <u>support</u> or <u>oppose</u> the proposal?	What <u>amendments</u> do they propose?	Have these amendments been <u>incorporated</u> in your proposal?
			inclusion of regulation 8 and 9	
			With regard to the frequency of monitoring, regular intervals should be defined.	Yes, regulation 7(2)(c)
			Include fit testing of RPE	No. To be included in the explanatory notes as most of the employers won't afford the costs attached to fit testing
			"Coronaviridae risk group classification needs to be amended, in Table 4. Specifically SARS-CoV-2 (causing COVID-19), needs to be added and included as risk group 4 HBA.	NO. The WHO has classified the virus under risk group 2.
			Return Annexure C to the regulations	No. The content of Annexure C were included in the body of the regulations.
South African Institute of Occupational Health and	It will benefit their members who conduct the monitoring of HBAs	They support the proposal	To define toxin	Yes, included toxin in definition of biohazard

Name of Stakeholder	What do they see as main <u>benefits</u> , <u>Implementation/ Compliance costs</u> and <u>risks</u> ?	Do they <u>support</u> or <u>oppose</u> the proposal?	What <u>amendments</u> do they propose?	Have these amendments been <u>incorporated</u> in your proposal?
Safety and Southern African Institute for Occupational Hygiene	in different workplaces			
			To define competent person	Yes, under the definitions.
			Specify a recognised international standard such as such as CE or NIOSH as well as fulfilling the requirements of the SANS 10338 Homologation of Respiratory Equipment;	The standards acceptable to the CI will be included in the explanatory notes
			Include the requirement for an “emergency response plan”	Emergency response plan will be included in the explanatory notes
			Remove 4(2). 4(2) is redundant as the intro to 4(1) already covers this.	Yes, reworded sub-regulation 4(1) and 4(2)
			change back to the wearing of personal samplers	Yes. Regulation 5(d)

Name of Stakeholder	What do they see as main <u>benefits</u> , <u>Implementation/</u> <u>Compliance costs</u> and <u>risks</u> ?	Do they <u>support</u> or <u>oppose</u> the proposal?	What <u>amendments</u> do they propose?	Have these amendments been <u>incorporated</u> in your proposal?
			Change the work "site" to "workplace"	Yes. Regulation 5(e)
			Include the requirement for the risk assessment to be carried out by a competent person.	Yes. Regulation 6(2)(b)
			In regulation 7(1) change the word "procedure" to method.	Yes
			New recommendation include the requirement for monitoring to be carried out by an AIA in Regulation 7	No. Monitoring cannot be prescribed to AIAs only, because not all of them are knowledgeable in HBAs. Further clarity will be given in the explanatory notes
			Remove the approval and submission to the H&S committee	Yes. Regulation 8(1)(3)
			Use of the word monitoring is not aligned to the definition of monitoring in the regulations.	Yes. Changed monitoring to verification in regulation 12.

Name of Stakeholder	What do they see as main <u>benefits</u> , <u>Implementation/ Compliance costs</u> and <u>risks</u> ?	Do they <u>support</u> or <u>oppose</u> the proposal?	What <u>amendments</u> do they propose?	Have these amendments been <u>incorporated</u> in your proposal?
			One representative from each of the SAQA recognised professional bodies, identified by the Chief Inspector, Regulation 16.	Not all professional bodies are required to be SAQA recognized
Private persons	They conduct surveys in workplaces where HBAs might be present	They support the proposal	To include body substance isolation (BSI)	No, because it is not referred to in the regulations
			To include definition of Universal precautions (UP) and Ventilation	Yes, under definitions
			To include "accidental release" in regulation 4(1)(i)	Yes
			To include...to determine potential exposure to HBA in regulations 6(1)	Yes, concept included in the rewording of the paragraph
			the results of the assessment referred to in	Yes, regulation 8(1)(a)

Name of Stakeholder	What do they see as main <u>benefits</u> , <u>Implementation/</u> <u>Compliance costs</u> and <u>risks</u> ?	Do they <u>support</u> or <u>oppose</u> the proposal?	What <u>amendments</u> do they propose?	Have these amendments been <u>incorporated</u> in your proposal?
			regulation 6 indicate that an employee is at risk of exposure have been exposed to HBA;	
			Reword the sentence of Regulation 8(2)(c) to “shall be conducted according to a written medical protocol; and as advised by the occupational health practitioner..”	No. Original sentence to be retained as it covers the proposal.
			Replace the word “good” with “hygienic” in regulation 11(2)(d)	Yes.

- b) Summarise and evaluate the main disagreements about the proposal arising out of discussions with stakeholders and experts inside and outside of government. Do not give details on each input, but rather group them into key points, indicating the main areas of contestation and the strength of support or opposition for each position

- (i) The maintenance of control measures, equipment and facilities must be done by an Approved Inspection Authority (AIA). The reason being that AIA have a technical knowledge of the control measures. The technical committee opposed the proposal because the persons who do maintenance on the biosafety cabinets with all the necessary equipment are not AIAs. The AIAs on the other hand do not have the necessary equipment to maintain some of the engineering control measures put in place by the employers.
- (ii) The employers when making risk assessments should take into consideration the dose of an HBA to which an employee might be exposed. The argument in this case was that the microorganisms are living and they replicate at all times, therefore, the dose of infection may not apply for all microorganisms. The infection dose might not apply to other employees because of the genetically make up of individuals. Therefore, employers must take the worst case scenario when conducting the risk assessment so that all employees are protected.
- (iii) To keep **Annexure C** in the regulations because it clearly specifies the precautionary measures to be in the workplace. The Technical Committee incorporated the measures contained in Annexure C in the body of the regulations and in the explanatory notes.

2.4. Describe the groups that will benefit from the proposal, and the groups that will face a cost. These groups could be described by their role in the economy or in society. Note: No law or regulation will benefit everyone equally so do not claim that it will. Rather indicate which groups will be expected to bear some cost as well as which will benefit. Please be as precise as possible in identifying who will win and who will lose from your proposal. Think of the vulnerable groups (disabled, youth women, SMME), but not limited to other groups.

List of beneficiaries (groups that will benefit)	How will they benefit?
Employees	Their exposure to risks posed by the HBA will be mitigated and they will be protected from occupational diseases caused by the exposure to HBA
Employers	Employees will not be absent from work because of ill health thus saving the loss in production and medical costs to be incurred to treat ill employees.
Compensation Fund	Less claims for occupational diseases
Unemployment Insurance Fund	Less claims for unemployed employees due to ill health.

List of cost bearers (groups that will bear the cost)	How will they incur / bear the cost
Employers	<ol style="list-style-type: none"> 1. The provision of personal protective equipment for all employees. 2. Provision of hand hygiene measures for all employees and visitors to their premises 3. Provision of vaccines to employees identified in the risk assessment 4. Provision of social distance measures between employees and visitors 5. Provision of engineering control measures to minimize exposure to HBA 6. Provision of training, instruction and information to all employees who might be exposed to HBAs
Department of Employment and Labour	Training of inspectors to implement the new regulations
Compensation Fund, UIF, Hospitals	<ol style="list-style-type: none"> 1. Compensation in the case of disablement caused by occupational diseases through COIDA and Unemployment Insurance Act 2. Compensation Fund will save on costs for compensating claims, for medical treatment and rehabilitation of affected workers 3. UIF paying for illness benefits when workers are laid-off due to ill health 4. Burden to hospitals and clinics will be reduced when hazardous biological related illnesses are reduced.

- a. Describe the costs and benefits of implementing the proposal to each of the groups identified above, using the following chart. Please do not leave out any of the groups mentioned, but you may add more groups if desirable. Quantify the costs and benefits as far as possible and appropriate. Add more lines to the chart if required.

Note: "Implementation costs" refer to the burden of setting up new systems or other actions to comply with new legal requirements, for instance new registration or reporting requirements or by initiating changed behaviour. "Compliance costs" refers to on-going costs that may arise thereafter, for instance providing annual reports or other administrative actions. The costs and benefits from achieving the desired outcomes relate to whether the particular group is expected to gain or lose from the solution of the problem.

For instance, when the UIF was extended to domestic workers:

- The implementation costs were that employers and the UIF had to set up new systems to register domestic workers.*
- The compliance costs were that employers had to pay regularly through the defined systems, and the UIF had to register the payments.*
- To understand the inherent costs requires understanding the problem being resolved. In the case of UIF for domestic workers, the main problem is that retrenchment by employers imposes costs on domestic workers and their families and on the state. The costs and benefits from the desired outcome are therefore: (a) domestic workers benefit from payments if they are retrenched, but pay part of the cost through levies; (b) employers pay for levies but benefit from greater social cohesion and reduced resistance to retrenchment since workers have a cushion; and (c) the state benefits because it does not have to pay itself for a safety net for retrenched workers and their families.*

Group	Implementation costs	Compliance costs	Costs/benefits from achieving desired outcome	Comments
<p>Employers</p>	<p>To provide personal protective equipment for employees who might be exposed to HBAs.</p> <p>To provide hand hygiene measures for employees and visitors</p> <p>To provide engineering controls to minimize exposure to HBAs.</p> <p>To provide for the disinfection of workplaces on a regularly basis</p>	<p>To maintain the systems put in place for an example the calibration of thermometers and the regular maintenance of engineering control measures.</p> <p>To have systems in place for symptoms screening for both employees and visitors before entering the premises</p> <p>Replacing the worn out personal protective clothing</p> <p>Ensuring that hand hygiene measures and disinfectants are always available</p> <p>On-going training of employees</p>	<p>The employer benefits because employees will be protected from acquiring occupational diseases and no medical claims will be made against the employer. The production will also not be affected by the absent employees because of ill-health.</p>	<p>The initial costs of putting systems in place might be expensive, but the benefits outweigh those costs.</p>

Group	Implementation costs	Compliance costs	Costs/benefits from achieving desired outcome	Comments
Department of Employment and Labour	Conduct advocacy sessions for all stakeholders through workshops and seminars on the new regulations Training of inspectors in the enforcement of the new regulations		The initial costs will include travelling and accommodation for inspectors. Booking of venues for stakeholders including meals.	The initial costs might be expensive, but if stakeholders understand the legislation, it will promote the concept of self-regulation which will ease the burden of costs for inspectors travelling to conduct inspections.

2.6. Cost to government: Describe changes that the proposal will require and identify where the affected agencies will need additional resources

- a) Budgets, has it been included in the relevant Medium Term Expenditure Framework (MTEF)
 - Training cost for Department of Employment and Labour Inspectors and advocacy sessions for stakeholders is already included in the budget of the Department. We might even expect costs to be less than what has been budgeted for because due to the COVID-19 pandemic, training will be conducted on virtual platforms. The platforms are already available to conduct training virtually. Personal protective equipment that Inspectorate may need is already provided for in the Provincial budgets and PPE is already procured as inspections in terms of the COVID-19 Consolidated Direction for Occupational Health and Safety in other workplaces are already taking place.

- b) Staffing and organisation in the government agencies that have to implement it (including the courts and police, where relevant). Has it been included in the relevant Human Resource Plan (HRP)

- No additional staffing will be required with the promulgation of the proposed regulations because we are not introducing something new, but the revised version. Inspectors are already conducting inspections based on the current regulations for Hazardous Biological Agents. Also, there will be no additional job created for government agencies that have to implement the proposed regulations.

Note: You MUST provide some estimate of the immediate fiscal and personnel implications of the proposal, although you can note where it might be offset by reduced costs in other areas or absorbed by existing budgets. It is assumed that existing staff are fully employed and cannot simply absorb extra work without relinquishing other tasks.

2.7 Describe how the proposal minimises implementation and compliance costs for the affected groups both inside and outside of government.

For groups outside of government (add more lines if required)

Group	Nature of cost (from question 2.6)	What has been done to minimise the cost?
Employers outside government	Provision of systems for symptoms screening, personal protective equipment for employees, hand hygiene measures for employees and clients, engineering controls measures as the effective measure for the control of exposure to hazardous biological agents and disinfection of workplaces on a regular basis.	The initial costs of keeping workplaces safe might be expensive, but it is better to have employees who are healthy than employees who will acquire occupational diseases and be unable to perform their tasks. The organization will suffer losses due to the loss in profits and also pay increased premiums for insurance when claiming from the insurance fund for medical expenses. If engineering control measures are provided as the first line of defence in the hierarchy of control, their maintenance period is usually 24 months, then the employer will have sustainable safe working environments. This type of control measure is better than the provision of PPE because employees do not always wear PPE correctly, and the life span is very short. For an example, masks must be changed every day, which in the long it becomes very expensive for the employer.

For government agencies and institutions:

Agency/institution	Nature of cost (from question 2.6)	What has been done to minimise the cost?
Department of Employment and Labour	Training of inspectors and advocacy sessions for stakeholders	Training for inspectors and advocacy sessions for stakeholders will be done virtually thus no costs will be incurred for travelling, accommodation, venues and meals.

2.8 Managing Risk and Potential Dispute

- a) Describe the main risks to the achievement of the desired outcomes of the proposal and/or to national aims that could arise from implementation of the proposal. Add more lines if required.

Note: It is inevitable that change will always come with risks. Risks may arise from (a) unanticipated costs; (b) opposition from stakeholders; and/or (c) ineffective implementation co-ordination between state agencies. Please consider each area of risk to identify potential challenges.

- There are no anticipated risks to the achievement of the desired outcomes because the proposed control measures are already being implemented by the employers at all workplaces. Employers might have experienced unanticipated costs for providing cloth masks, hand hygiene measures and the frequent disinfectants of workplaces, but have also realized that it is important to protect the lives of employees.

- b) Describe measures taken to manage the identified risks. Add more rows if necessary.

Mitigation measures means interventions designed to reduce the likelihood that the risk actually takes place.

Identified risk	Mitigation measures
Employers, especially from the SMME's who might find it expensive to purchase hand sanitizers for both the employees and clients. Ongoing provision of cloth masks for employees.	The Department of Employment and Labour has developed the COVID -19 Consolidated Direction on Occupational Health and Safety for workplaces to guide employers on the control measures they need to put in place to protect their employees. The inspectors will always be available to assist employers and guide them on the best possible options to keep their workplaces safe.

Employees failing to wear the PPE at all times and not complying with hand hygiene measures	Employers were instructed to develop Occupational Health and Safety policy for their employees to ensure that all employees are aware of the risks of HBA and the measures that will be taken by the employer if they fail to adhere to the policy requirements.
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- c) What kinds of dispute might arise in the course of implementing the proposal, whether (a) between government departments and government agencies/parastatals, (b) between government agencies/parastatals and non-state actors, or (c) between non-state actors? Please provide as complete a list as possible. What dispute-resolution mechanisms are expected to resolve the disputes? Please include all of the possible areas of dispute identified above. Add more lines if required.

Note: Disputes arising from regulations and legislation represent a risk to both government and non-state actors in terms of delays, capacity requirements and expenses. It is therefore important to anticipate the nature of disputes and, where possible, identify fast and low-cost mechanisms to address them.

Nature of possible dispute (from sub-section above)	Stakeholders involved	Proposed Dispute-resolution mechanism
Disputes are not anticipated in terms of these regulations because they are already being implemented and all employers have seen the importance of keeping the lives of employees safe to avoid loss in production and service delivery to the clients.	All stakeholders	None

2.9 Monitoring and Evaluation

Note: Sound implementation of policy and legislation is due to seamless monitoring and evaluation integration during the policy development phase. Policies and legislation that are proficiently written yet unable to report on implementation outcomes are often a result of the absence of an M&E framework at the policy and legislative planning phase. It is therefore imperative to state what guides your policy or legislation implementation monitoring.

2.9.1 Develop a detailed Monitoring and Evaluation Plan, in collaboration with your departmental M&E unit which should include among others the following:

2.9.1.1 Provide clear and measurable policy or legislative objectives

2.9.1.2 Provide a Theory of Change clearly describing the following components:

- Impact: the organisational, community, social and systemic changes that result from the policy or legislation;
- Outcomes: the specific changes in participants (i.e. beneficiaries) behaviour, knowledge, skills, status and capacity;
- Outputs: the amount, type of degree of service(s) the policy or legislation provides to its beneficiaries;
- Activities: the identified actions to be implemented
- Input: departmental resources used in order to achieve policy or legislative goals i.e. personnel, time, funds, etc.
- External conditions: the current environment in which there's an aspiration to achieve impact. This includes the factors beyond control of the policy or legislation (economic, political, social, cultural, etc.) that will influence results and outcomes.
- Assumptions: the facts, state of affairs and situations that are assumed and will be necessary considerations in achieving success

2.9.1.3 Provide a comprehensive Logical Framework (LogFrame) aligned to the policy or legislative objectives and the Theory of Change. The LogFrame should contain the following components:

- Results (Impact, Outcomes and Output)
- Activities and Input
- Indicators (A measure designed to assess the performance of an intervention. It is a quantitative or qualitative factor or variable that provides a simple and reliable means to measure achievement, to reflect the changes connected to an intervention, or to help assess the performance of a development actor)
- Baseline (the situation before the policy or legislation is implemented)
- Targets (a specified objective that indicates the number, timing and location of that which is to be realised)

2.9.1.4 Provide an overview of the planned Evaluation, briefly describing the following:

- Timeframe: when it the evaluation be conducted
- Type: What type of evaluation is planned (formative, implementation or summative) – the selection of evaluation type is informed by the policy owners objective (what it is you want to know about your policy or legislation).

2.9.1.5 Provide a straightforward Communication Plan (Note: a common assumption is that the target group will be aware of, and understand how to comply with a policy or legislation come implementation. However, increases in the complexity and volume of new or amendment policy or legislation render this assumption false. Hence, the need for a communication plan to guide information and awareness campaigns to ensure that all stakeholders (including beneficiaries) are informed.

2.10 Please identify areas where additional research would improve understanding of then costs, benefit and/or of the legislation.

- Additional research will be needed on non-alcohol based hand sanitizers as other employees develop allergic reactions to alcohol based to sanitizers
- Provision of less costly engineering control measures especially for the SMMEs because they are effective in controlling exposures to HBAs in terms of the hierarchy of controls.
- Less costly vaccine that will be affordable and be accessible to all employees and employers who might be exposed to HBAs.

PART THREE: SUMMARY AND CONCLUSIONS

1. Briefly summarise the proposal in terms of (a) the problem being addressed and its main causes and (b) the measures proposed to resolve the problem.
 - a) The exposure of employees to hazardous biological agents in the workplace and being at risk of developing occupational diseases. The main cause being lack of effective control measures being provided, lack of proper personal protective equipment and lack of training in terms of hazardous biological agents.
 - b) The provision of effective control measures in place, provision of proper personal protective equipment, information, training and instruction of employees about hazardous biological agents.
2. Identify the social groups that would benefit and those that would bear a cost, and describe how they would be affected. Add rows if required.

Groups	How they would be affected
<i>Beneficiaries</i>	
1. Employees	They will not suffer from occupational diseases that might lead to disablement or early retirement from work due to ill-health.
2. Employers	They will not lose employees due to ill-health thus affecting production of service delivery. They will also save costs in terms of medical claims insurance
3. Compensation Fund	There will be no claims to be paid out for employees claiming for occupational diseases
<i>Cost bearers</i>	
1. Employers	To provide control measures in the workplace, provide personal protective clothing and training, informing and instructing employees in terms of hazardous biological agents. Vaccinate employees who might be exposed to HBAs.

3. What are the main risks from the proposal in terms of (a) undesired costs, (b) opposition by specified social groups, and (c) inadequate coordination between state agencies?
 - a) Undesired costs might emanate from the ongoing provision of hand hygiene measures, personal protective equipment ongoing training and vaccination of employees who might be exposed to HBAs.
 - b) No opposition is foreseen because the regulations were reviewed by the Technical Committee which has representatives from Organized Labour, Organized Business, Department of Health and specialist from Professional Bodies. Two workshops were held for all stakeholders whereby they were informed about the review of the regulations and they were given 90 days to comment.
4. Summarise the cost to government in terms of (a) budgetary outlays and (b) institutional capacity.
 - Department of Employment and Labour will have to budget for the training of inspectors on the new Hazardous Biological Agents. Budget for the advocacy for all stakeholders. Must also provide resources to inspectors to enable them to conduct inspections at all workplaces where there might be exposure to HBAs. There will be no need to employ more inspectors as the Department has already employed 500 inspectors in the year 2020.
5. Given the assessment of the costs, benefits and risks in the proposal, why should it be adopted?
 - This proposal will assist employers to ensure that employees and clients are safe and healthy at the workplace. We have seen the impact of fatalities related to the exposure to hazardous biological agent in the form COVID-19 virus on the economy of the country, job losses and loss of lives. Therefore, the costs of providing protective measures and risks are less important when we look at the benefits of adopting this proposal. Human lives will be saved, the economy of the country will improve and there would be no job losses.
6. Please provide two other options for resolving the problems identified if this proposal were not adopted.

Option 1.	To continue to enforce the current Regulations for Hazardous Biological Agents, 2001 with its shortcomings.
Option 2.	To conduct advocacy and awareness raising through workshops and seminars. The challenge with this option is that, previous workshops and seminars were conducted and limited changes happened in industries. With the invent of COVID-19 as an example, advocacy and awareness is not enough to drive the message home.

7. What measures are proposed to reduce the costs, maximise the benefits, and mitigate the risks associated with the legislation?
 - Government to assist the SMMEs financially, so as to continue to provide protective measures for employees at their workplaces.

- Inspectors to continue to advise the employers on the cost effective measures they can implement at their workplaces.

8. Is the proposal (mark one; answer all questions)

	Yes	No
a. Constitutional?	√	
b. Necessary to achieve the priorities of the state?	√	
c. As cost-effective as possible?	√	
d. Agreed and supported by the affected departments?	√	

9. What is the impact of the Proposal to the following National Priorities?

National Priority	Impact
1. Economic transformation and job creation	When employees do not suffer ill-health, the health system is not burdened therefore, money will be spent on creating more job opportunities especially for the youth to enter the job market. When the youth enter the job market, there will be economic growth in the country. This also contribute to the decent employment program of the country.
2. Education, skills and health	The proposal makes it the duty of the employer to train and instruct the employees at the workplace. The training offered is relevant to the sector and the duties carried out by the employees. Therefore, after the training, the employees will have developed the skills required to conduct their duties effectively. The knowledge gained through training will enable the employees to save patients' lives and protect their own lives too.
3. Consolidating the social wage through reliable and quality basic services	N/A
4. Spatial integration, human settlements and local government	N/A
5. Social cohesion and safe communities	N/A
6. Building a capable, ethical and developmental state	N/A

National Priority	Impact
7. A better Africa and world.	N/A

For the purpose of building a SEIAS body of knowledge please complete the following:

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