Western Cape Department of Agriculture: Auditing of export facilities

A risk assessment and service delivery strategy during the Covid-19 outbreak and beyond

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Background.
Since the outbreak of the Covid-19 pandemic in South Africa, disease control measures such as the strict lock-down that was put in effect on 26 March 2020 under Government Notice no. 318 of 18 March 2020, have had a major impact on Food Business Operators (FBO’s) as well as the service delivery from Regulatory Authorities. One of the key functions of the Export Control section that was severely affected under the strict travel- and physical distancing restrictions was the performance of audits at approved export facilities in order to renew annual registration with the Department of Agriculture, Land Reform and Rural Development (DALRRD). All site visits were immediately suspended upon implementation of the National Lockdown, in support of the call for physical distancing. Many FBO’s gave notice that they would not be able to receive any visitors to their factories under the current outbreak situation. As the restrictions came to force shortly after the start of the 2020 audit cycle, this immediately posed a problem with regards to the expiry of registration certificates and how to ensure renewal of export approval without compromising food safety or ethical certification. The Western Cape Department of Agriculture (WC DoA), in line with the action taken by international Food Safety Certification Bodies requested a 6 month extension of expiry dates for currently approved export Food Business Operators (FBO’s) for whom certificates were due to expire imminently. After the companies for whom expiry was most urgent received an extension for 6 months, a blanket extension until 15 July was issued by DALRRD for all ZA registered facilities.
Purpose

The purpose of this document is to:

• Outline the health risks posed by traditional auditing methods under the current disease outbreak situation.
• Provide guidelines for the resumption of the audit program.
• Provide a framework for risk analysis of individual FBO’s.
• Recommend a strategy for interim audit methodology until traditional audit methods may be resumed in a safe and responsible manner.

The health risks posed by traditional auditing methods under the current disease outbreak situation.

Traditional auditing methods consists of a 1-2 day visit to the factory. Documents are reviewed at the company- and under guidance of various representatives of the company. Audits typically starts with an opening meeting where the scope and audit procedures are outlined to as many representatives of the company wishing to attend. A physical inspection of the entire premises and production activities is considered a compulsory part of a traditional audit. The proceedings are concluded with a closing meeting where feedback is provided, usually to the same group of people who attended the opening meeting.

The health risks for traditional auditing methods under the current disease outbreak situation should take the following aspects into consideration:

• Health risks to auditors as well as individual employees of the FBO.
• The effect of an infection outbreak amongst employees on the productivity of the FBO.
• Risk to maintenance of the food safety system and the concurrent risk to ethical certification in the absence of traditional regulatory verification of compliance with export requirements.

Health risks should be considered through risk assessment to ultimately satisfy the requirements of the Occupational Health and Safety Act of 1993 (OHSA) – for employers to provide and maintain, as far as is reasonably practicable, a work environment which is safe and without risk to the health of his employees OHSA 8(1). Comprehensive risk assessments usually consider three factors when determining risk, and in the context of the Covid-19 outbreak these are:

• Exposure.
• Likelihood of disease given exposure.
• Severity of the outcome of infection (Managing risk of Covid-19 in potentially exposed health workers, 2020)

Exposure

In a food factory a large number of people, out of necessity, work in relative close proximity. Workers use communal amenities and cafeteria areas. Due to the lay-out of factories and the nature of food processes it is not always possible to rearrange workstations to ensure physical distancing of 1,5m between workers (R.480 of 29 April 2020 under the Disaster Management Act of 2002). Many workers use the public transport system to travel between their homes and place of work, which increases the likelihood of
exposure to the virus.

Current statistics from the National Institute for Communicable Diseases points to the Western Cape as the epicenter of disease in the country. As the pandemic progresses, cases of community transmission will rise and as lockdown restrictions ease this will result in more people returning to their place of work, the likelihood of exposure for anybody working in a factory environment or coming into contact with people working in a factory environment, also rises.

The long backlog in the audit program will inevitably result in an increased workload on auditors, which will necessitate an increase in the frequency of inspections performed during any given period per individual. Auditors travelling between different factories may become infected, unbeknownst to themselves, and act as a vehicle of disease transmission. Research has shown that infected persons may spread disease for approximately 2 weeks prior to showing symptoms of disease (WHO, Covid-19 Situation Report 73).

**Likelihood of an individual contracting the disease post exposure**

There is no individual with immunity against this novel virus. Therefore, it can be expected that individuals exposed to the virus will be infected. The use of Personal Protective Equipment (PPE) such as facemasks, may reduce the chances of transmitting the disease, but is by no measure a guarantee against infection and is considered the last line of defense. The OHSA requires the employer to, as far as practicable, eliminate or reduce exposure to a hazard before resorting to PPE (OHSA, 8(2)(b)).

**Severity of the outcome**

This can be calculated on various levels. Firstly, there is the severity of the outcome for the individual being infected and secondly the severity of the outcome to the FBO when a spread of infection is detected within the employee corpse of the factory.

Statistical data shows that based on co-morbidities which may exist in any given individual, the disease symptoms may vary from mild to rapidly progressive and fatal. A health survey performed by the WC DoA amongst auditors indicated four members who either falls within the vulnerable age group for severe disease development upon infection and/or present with co-morbidities known to predispose an individual to the development of severe disease upon exposure. Six of the auditors have immediate family that either falls within the vulnerable age group for severe disease development upon infection and/or present with co-morbidities known to predispose an individual to the development of severe disease upon exposure. Two of the auditors has immediate family that is a health care worker.

The advised route of action when disease transmission is identified within a factory environment, is temporary closure of such a facility with testing of all employees, quarantine of ‘in contact’ employees and full disinfection of the premises before re-opening. This will result in a loss of jobs, loss of revenue and increased costs to the FBO.

The WC DoA audit team consists of 15 auditors of which five are Veterinary public health officers that are limited to auditing distribution centers and abattoirs and two are CCS vets limited to auditing distribution centers and dairies. All of the auditors have other
essential function such as export certification, and inspections for export certification. Auditors contracting disease and being unable to provide services for extended periods will significantly hamper the service delivery ability of the entire audit team. Three of the auditors are located more than 250km away from factories and would need accommodation and food to be available for them to be effective.

The continuation of traditional auditing methods during the rising phase of the infection curve presents significant risks with potentially severe effects to all involved. Traditional audit methods cannot be resumed until Level 1 of lockdown has been reached in the municipal area where the FBO is situated. It is unlikely that, even with all lockdown measures lifted, the threat of disease will be eliminated within the next year.

The extension of expiry deadlines, for an initial period of at least 6 months, are the international practice in terms of food safety certification under the global pandemic (GFSI). Factors contributing to the viability of this option include:

- FBO’s with established food safety systems implement an internal auditing program.
- Many FBO’s have a proven history of compliance.
- South African food safety regulations places the onus for the implementation of a food safety system on the FBO, regardless of whether a certified system is implemented.
- Preliminary survey results have indicated that very few factories in the Western Cape have made changes to the inherent nature of their production processes.

However, the complete cessation of all auditing activities indefinitely is not a sustainable option. The main aim of export registration audits is to verify that an exporting company meets all applicable national and international standards as well as any specific export requirements from the importing country, which would allow for the ethical export certification of products from approved FBO’s. Remote audits have been experimentally implemented by a number of certifying bodies over the past few years and in more earnest in response to the current outbreak situation. The challenges and shortcomings of such a procedure is well documented, also by the audit team of the WC DoA (A Parker). The Global Food Safety Initiative (GFSI) which is the benchmarking body for widely implemented food safety systems like FSSC 22000 and BRC have rejected the plausibility of remote audits as a singular alternative to traditional audits (though extension of expiry deadlines is accepted).

A long term approach towards the resumption of audit functions, which will respect human welfare whilst demonstrating due diligence in terms of food safety and certification requirements, is therefore urgently called for.

Guidelines for the resumption of the audit program.

- Extension of expiry deadlines by DALRRD should be continued throughout phase 4 of lockdown (on a municipal level) for all FBO’s for whom registration expiry is imminent.
- Extension of expiry deadlines by DALRRD should be continued during phase 3 of lockdown (on a municipal level) for all low and medium risk FBO’s for whom registration is imminent to an extent which will allow the export audit team to audit ‘high risk’ FBO’s according to priority and within their capacity.
- The resumption of traditional audits should only be considered once level 1 of lockdown is implemented at the municipal area where the FBO is situated.
An interim audit methodology, which satisfies the requirements of ISO 19011, shall be consistently implemented. This will minimize (not avoid) human contact whilst adequately verifying areas of concern (both documentary as well as structural and procedural) and specific export requirements by means of a limited physical inspection. This will be implemented during level 3 and level 2 lockdown within municipal areas.

The audit program shall be restructured to resume audits, not in a chronological sequence, as is the tradition, but in a risk hierarchy with perceived high risk factories to receive priority in the program. Individual FBO’s shall be risk profiled according to a documented methodology. This risk profiling will determine the sequence of individual audits within the audit program.

Audit reports shall be compiled and submitted to DALRRD in the traditional manner. An audit report shall indicate the audit methodology followed.

Factors which reduces the audit capacity of the audit team

- Auditors shall not perform site visits less than 2 weeks apart. This is the quarantine period recommended by the Department of Health post exposure and will reduce the chances of spreading disease between multiple factories. In addition it will facilitate fast and easy traceability in the unfortunate event of an auditor contracting Covid-19. This practice will align with the requirement of the OHSA; 9(1) for employers to conduct their undertaking in such a manner as to ensure, as far as is reasonably practicable, that persons other than those in his employment who may be directly affected by his activities are not thereby exposed to hazards to their health or safety.
- Auditors shall not travel between municipal areas with a markedly varied disease outbreak status as this will increase the potential of spreading disease from an area of higher prevalence to an area of lower prevalence.
- Auditors, who personally fall within a high vulnerability patient group due to age and/or co-morbidities shall not be required to perform site visits. This is in line with requirement R.480 of 29 April 2020 under the Disaster Management Act of 2002, 5(5)(d,e) that special measures be implemented for employees within high vulnerability groups.

Framework for risk analysis of individual FBO’s.

All individual FBO’s and other approved export facilities shall be subjected to a risk analysis and shall be scored according to a predetermined set of criteria. The sequence in which audits will be assigned shall be determined by the combined score assigned to individual facilities.

### Risk analysis criteria and scoring system.

<table>
<thead>
<tr>
<th>Criteria:</th>
<th>Score</th>
<th>1 = low risk</th>
<th>6 = high risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Processed meat products</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Cooked</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Uncooked</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unprocessed meat products</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Fresh</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Frozen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raw dairy products including raw milk</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pasteurized dairy products including pasteurized milk</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Egg for human consumption</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Casings</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pet food</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Animal feed containing animal byproducts.
Animal byproducts for uses other than feed
Animal feed
Enzymes
Semen and Ova
Salted hides and skins
Trophies
Fully processed leather

<table>
<thead>
<tr>
<th>Amount of export consignments certified during past 3 months</th>
</tr>
</thead>
</table>
| Top 80-100% of total amount of export certificates issued during the past 3 months | 5  
| Middle 20-80% of total amount of export certificates issued during the past 3 months | 3  
| Less than 20% of total amount of export certificates issued during the past 3 months | 1  

<table>
<thead>
<tr>
<th>Uninterrupted duration of registration</th>
</tr>
</thead>
</table>
| 5 years or more | 1  
| 2-4 years | 2  
| 1 year or less | 3  

<table>
<thead>
<tr>
<th>Compliance history as rated by previous auditors</th>
</tr>
</thead>
</table>
| Poor compliance history | 6  
| Intermediate compliance history | 3  
| Good compliance history | 1  

**Strategy for interim audit methodology.**

The risks presented by traditional auditing methods as detailed in the initial section of this document indicates that traditional auditing methods can only reasonably be resumed once level one of lockdown has been declared in a municipal area. The WC DoA: Export Control therefore proposes an interim audit method which aim to:

- minimise physical contact
- satisfy the requirements of ISO 19011 concerning sample based auditing.
- provide reasonable confidence that food safety and export requirements are met.

In the design of this audit method the approaches of international benchmarked food safety systems like BRC and FSSC 22000 has been taken into account. The priority of this sample based audit method is to sample and verify aspects of concern of a FBO’s production system whilst minimizing the time an auditor has to spent on site as well as minimizing the amount of people an auditor comes into contact with when on site.

**Audit method**

- Every registered company applying for renewal of export approval shall be required to
complete a self-assessment’ according to a standardized format supplied by the WC DoA. The self-assessment will resemble a comprehensive internal audit.

- Auditors shall evaluate the information obtained from the self-assessment tool in conjunction with the records of previously identified non-conformances and their respective corrective actions to determine specific areas of concern. Auditors shall focus particularly on key procedures within a specific production process.
- Auditors shall identify the particular area in a factory, which may be considered highest risk, taking into account the nature of the production processes carried out as well as the records of previously identified non-conformance. Auditors shall eventually physically inspect only this area during the site visit.
- Auditors shall prepare an audit plan, focusing on the aspects of concern which were identified from the self-assessment. This shall include the section of the factory which was identified to be inspected during the site visit as well as a detailed list of documents and records which will be verified in the presence of an audit guide during the site visit. It shall include the requirement for a traceability exercise during the site visit.
- Auditors shall share the audit plan with the FBO upon determining a date for the site visit.
- During the site visit, no more than 3 people (including the auditor) shall be present during the opening meeting or document review. The auditor shall only inspect the predetermined section of the factory during the site visit.
- An audit report detailing all findings and outlining the sample selection used will be compiled by the auditor and submitted to DALRRD for renewal of export approval.
- Corrective actions shall be handled in the traditional manner, but shall be verified remotely as opposed to a repeat site visit.

Where a company holds valid certification from a Certifying Body for one of the following food safety systems:
- BRC Global Standard
- ISO 22000
- FSSC 22000
- SANS 10330

and has received a site visit from a Certifying Body during the previous 6 months, such a company may be exempted from a site visit provided the audit report form the Certifying Body is made available to the WC DoA and reveals no critical operational non-conformances. This shall not exempt a company from completing the self-assessment.

Guidelines to auditors.

Audits will be re-assigned for the 2020 audit year taking into account individual auditor’s health risk profiles, locations and availability. Auditors will receive notice of audits assigned to them as well as an indication of the risk rating for the facility. Auditors will receive an invite to a Microsoft Teams team, which will provide them with access to audit documents for the facilities they have been assigned to assist with. The self-assessment documents will already be available to the facility in Microsoft Teams. The facility will alert the auditor with an email when the self-assessment has been completed and all requested documents have been uploaded to Microsoft Teams.

For ‘Low risk’ facilities:

1. The auditor review the outcome of the self-assessment.
2. Based on the outcome of the review and taking into account previous non-conformances and the availability of third party audit reports, the auditor may:
   - Deem certain aspects of the self-assessment results of minor concern and recommend extension of the expiry date for 6 months.
• Deem certain aspects of the self-assessment results of major concern and recommend an audit.

• Deem the self-assessment results to provide enough confidence in the facility’s compliance with requirements to recommend annual renewal of the facility’s approval for export.

3. Administrative process:

<table>
<thead>
<tr>
<th>EXTENSION RECOMMENDED</th>
<th>AUDIT RECOMMENDED</th>
<th>ANNUAL RENEWAL RECOMMENDED</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Auditor shall indicate his/her recommendation in the comments section of the Self-Assessment (Version 2).</td>
<td>The auditor will inform both the client and the DD: Export Control of the intention to perform an audit.</td>
<td>The Auditor shall indicate his/her recommendation in the comments section of the Self-Assessment (Version 2).</td>
</tr>
<tr>
<td>No formal audit report is required.</td>
<td>The audit method described under ‘Strategy for interim audit methodology’ in this document is to be followed</td>
<td>The auditor prepares an audit report and present findings to the facility for corrective actions within a specified time frame. The report shall include a description of the method of auditing followed.</td>
</tr>
<tr>
<td>No formal corrective actions are required.</td>
<td>The audit may continue electronically OR may include a site visit depending on the discretion of the auditor.</td>
<td>The auditor uploads the audit report under the appropriate audit reference to Sharepoint and alerts the DD: Export Control that the report has been uploaded.</td>
</tr>
<tr>
<td>No fee shall be charged.</td>
<td>The auditor prepares an audit report and present findings to the facility for corrective actions within a specified time frame. The report shall include a description of the method of auditing followed.</td>
<td>Fees shall be charged according to the fee structure described under the section “Renumeration” in this report.</td>
</tr>
<tr>
<td>The auditor informs the auditee and the Deputy Director: Export Control of the recommendation per email.</td>
<td>The auditor recommends the facility for annual renewal based on the audit report.</td>
<td></td>
</tr>
<tr>
<td>The auditor uploads the self-assessment results under the appropriate audit reference to sharepoint.</td>
<td>The auditor uploads the audit report under the appropriate audit reference to Sharepoint and alerts the DD: Export Control that the report has been uploaded.</td>
<td></td>
</tr>
</tbody>
</table>
For ‘High risk’ facilities:

- An audit is always required as per the audit methodology described under ‘Strategy for interim audit methodology’ in this document. The auditor may continue with an electronic audit and/or a site visit as per his/her discretion based on the evidence provided by the self-assessment, previous audit findings and available third party audit reports (A site visit is not compulsory).
- The auditor shall always prepare an audit report including a description of the audit methodology followed, the audit findings and the recommendation for renewal of approval.
- The auditor shall upload all relevant documentation to Sharepoint as per normal audit procedure and alert the DD: Export Control once the documents have been uploaded.
- Fees shall be charged according to the fee structure described under the section “Remuneration” in this report.

Remuneration for audits.

<table>
<thead>
<tr>
<th>Service</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review of a self-assessment</td>
<td>No fee charged.</td>
</tr>
<tr>
<td>Recommendation for an extension</td>
<td>No fee charged.</td>
</tr>
<tr>
<td>Electronic assessment for renewal</td>
<td>A standard fee as determined by the DD: Export Control shall be charged.</td>
</tr>
<tr>
<td>Site visit</td>
<td>The duration of the site visit shall be charged per hour, as per normal audit procedure.</td>
</tr>
</tbody>
</table>

References.

Department of Health, Guidelines for quarantine and isolation in relation to Covid-19 exposure and infection.
Department of Health, Managing risk of Covid-19 in potentially exposed health workers, 2020
ISO 19011, Guidelines for auditing management systems.
World Health Organization, Coronavirus Disease 2019, Situation report 73.
World health Organization, Covid-19 and food safety.