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& fisheries

Department: Environment, Forestry
and Fisheries
REPUBLIC OF SOUTH AFRICA

Standard Operating Procedure: Contingency Measures

Branch: Fisheries Management
Chief Directorate: Aquaculture & Economic Development
Directorate: Sustainable Aquaculture Management

Issue 2: March 2021

TITLE

Standard Operating Procedure: Contingency Measures

COMMENCEMENT

This Standard Operating Procedure comes into force on 1 March 2021.

REVOCAATION

This programme issue revokes and replaces Standard Operating Procedure (SOP): Closing & Reopening of Fish Farms Issue 5 and SOP: Contingency Measures Issue 1 and any previous issues of these documents.

STANDARD OPERATING PROCEDURES ISSUED

Issue	Date of issue
1	1 October 2020
2	1 March 2021

ISSUING AUTHORITY

This Standard Operating Procedure is issued by the Environmental Officer Specialised Production of the Directorate Sustainable Aquaculture Management of the Department of Environment, Forestry and Fisheries in terms of the South African Shellfish Monitoring (Issue 8) and Control Programme that was issued by the Deputy Director General of the Branch Fisheries Management.



Environmental Officer Specialised Production
DATE: 23/02/2021

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1. DOCUMENT CONTROL

The Standard Operating Procedure (SOP): Contingency Measures was compiled by Department of Environment, Forestry and Fisheries: Food Safety Office (FSO) of the Directorate Sustainable Aquaculture Management. The SOP is administered by the FSO and will be reviewed and updated as relevant new information becomes available.

A detailed record of all amendments shall be maintained, and the latest version will be made available at the FSO and will be loaded onto the DEFF website. Suggestions for alterations that would significantly improve the document are welcomed. These should be forwarded to the coordinator, Mr John Foord and enquiries can be directed to Mr Mayizole Majangaza (Appendix 1).

2. SCOPE

This document covers the procedures for the contingency measures required in terms of the South African Shellfish Monitoring and Control Programme (SASM&CP). The procedures include contingency measures associated with environmental and veterinary drug residues, biotoxins and microbiological contamination. The SOP covers finfish and shellfish production areas located between Port Nolloth in the Northern Cape and Haga Haga in the Eastern Cape, South Africa.

3. BACKGROUND

The Department of Environment, Forestry and Fisheries (DEFF) is the managing and regulatory authority for the undertaking of aquaculture activities that include farming, harvesting and transporting of fish for wholesale trading stipulated in the permit conditions issued in terms of the Marine Living Resources Act, 1998 (Act No. 18 of 1998) and associated regulations. The Directorate: Sustainable Aquaculture Management (D: SAM) of the Fisheries Branch of DEFF is responsible for the development, management and regulation of a sustainable aquaculture industry that contributes towards job creation, food security, rural development and economic growth. D: SAM aims to achieve the above mentioned strategic objectives through the development and implementation of relevant enabling legislation, policies and programmes as well as be responsive and compliant to international obligations and agreed standards. The Food Safety Office (FSO) within D: SAM is responsible for the development and management of food safety programmes stipulated in the permit conditions issued in terms of the Marine Living Resources Act, 1998 (Act No. 18 of 1998) including the SASM&CP, South African Aquacultured Marine Fish Monitoring and Control Programme (SAMFM&CP) and National Residue Control Programme (NRCP). The objectives of the food safety programmes include providing guarantees to domestic and international markets and consumers that South African cultured fish products are safe for human consumption.

The risks to food safety of cultured fish include environmental residues (heavy metals, pesticides, polychlorinated biphenyl, dioxins polycyclic aromatic hydrocarbons and radionuclides) and veterinary drug residues (hormones, antibiotics and anthelmintics), the accumulation of biotoxins (Paralytic Shellfish Toxins (PST), Lipophilic Shellfish Toxins (LST) and Amnesic Shellfish Toxins (AST)) and microbiological contamination in shellfish indicated by the presence of *E. coli*.

The DEFF has appointed National Regulator for Compulsory Specifications (NRCS) to officially sample fish from the marine aquaculture farms to monitor the food safety risks in the production areas. The samples are taken and transported to the relevant laboratories in accordance with the Standard Operating Procedure (SOP): The Sampling and Transport of Aquacultured Marine Fish. The samples are sent to laboratories approved by the Food Safety Office (FSO) for the testing of environmental and veterinary drug residues. The test results are submitted to the Food Safety Office (FSO) of the Directorate Sustainable Aquaculture Management for the monitoring and control of the product harvested.

If the contaminant concentration in the sample is below the regulatory limit stipulated in the relevant national legislation, national food safety programmes and/or the importing country requirements, the product may be considered for certification. However, should the residue concentration exceed the relevant regulatory limits, the procedures outlined in this SOP shall be implemented.

It must be noted that processes and procedures taken must be given priority so as the turnaround time is shortened.

4. ENVIRONMENTAL AND VETERINARY DRUG RESIDUE CONTINGENCY

In the case where non-compliant environmental or veterinary drug residue samples are detected at a laboratory the following procedures shall be followed:

1. The laboratory manager shall immediately inform the Environmental Officer Specialised Production (EOSP) telephonically and by email (Appendix 1) by providing an official sample report and all relevant information.
2. The EOSP shall inform the state vet when relevant and consider the test reports and take any remedial actions necessary to prevent non-compliances of this nature. The National Residue Control Programme may be amended if required.
3. The EOSP shall determine whether a retest or other confirmatory steps are advisable before the matter is accepted as a fact and the official follow-up procedure activated.
4. Where the EOSP determines that an environmental residue sample is non-compliant the EOSP informs the farm manager as well as NRCS and the relevant Fisheries Compliance Office (FCO) that the farm is closed for harvesting fish for direct human consumption until further notification and initiates the recall procedure.
5. The farm manager and relevant stakeholders are required to acknowledge receipt of the notification.
6. Should the cadmium concentration in the molluscan shellfish exceed the regulatory limits,
 - a. the shellfish may be placed into a depuration facility to reduce the cadmium levels to within the regulatory limits, and
 - b. each batch harvested shall be clearly marked and placed into its own tank. The farm shall ensure traceability of the batch until the product is marketed and/or returned to the production area.
 - c. Each batch shall be tested at the farmers discretion and may only be marketed once the cadmium concentration falls below the relevant regulatory limit.
 - d. Regarding production areas that are high risk i.e. cadmium concentrations within 10% of the regulatory limit, the farm manager shall submit the cadmium testing and traceability history to the Food Safety Office and the NRCS when requesting certification for export. The farm shall be sampled and tested for cadmium within 14 days of export under these conditions.
7. Where the EOSP determines that a veterinary drug residue samples is non-compliant the EOSP shall lodge an investigation into the reason for the non-compliant result(s).
8. The following must be included as part of the investigation for non-compliant veterinary drug residue samples:
 - Identify the farm of origin.
 - Identify any cohorts of the animal(s) from which the non-compliant sample(s) was (were) collected.
 - Identify any feed, feed additives, water sources, pastures or medication that were provided or administered to the animal or group of animals and it's cohorts from which the non-compliant sample(s) was(were) collected.
 - Collect samples from cohorts, other animals under the same production circumstances or related circumstances, feed, feed additives, water sources, pasture and any other samples indicated by the circumstances or findings.

- These samples must be sent to the relevant official laboratory for analysis. The normal sampling procedures and administrative procedures must be followed.
 - Particular consideration and further investigation must be given to the possible source of the residue or contaminant.
 - At the conclusion of the investigation consideration must be given to all findings, laboratory results and facts pertaining to the case.
 - A conclusion, where possible must be reached, which will fall in one of the following categories:
 - Application of illegal veterinary treatment to animals.
 - Failure to comply with instructions regarding administration of veterinary medicines to animals.
 - Indication of environmental contamination and possible source.
 - Inconclusive findings.
9. On conclusion of the investigation the Director: Sustainable Aquaculture Management shall complete the following actions:
- Institute penal action against offenders: Depending on the reason for the non-compliance, penal action can range from delisting as a registered export farm, to suspension of marketing animals at export approved establishments for a time period, or a warning letter.
 - Take steps to prevent any non-compliant animals of being harvested and marketed for export or the local market.
 - Take steps to recall any non-compliant fish products where applicable.

5. BIOTOXIN CONTAMINATION CONTINGENCY

In the case where non-compliant biotoxin samples are detected at a laboratory the following procedures shall be followed:

1. The laboratory manager shall immediately inform the Environmental Officer Production (EOP) telephonically and by email (Appendix 1) by providing an official sample report and all relevant information.
2. The EOP shall confirm whether the sample is non-compliant and activate official follow up procedures if required.
3. Where the sample is deemed by the EOP to be non-compliant the EOP informs the farm manager as well as NRCS and the relevant FCO that the farm is closed for harvesting fish for direct human consumption until further notification and initiates the recall procedure.
4. Should abalone in a production area exceed the regulatory limit for PST, the farm shall be closed for the marketing of abalone. The farm may, however, apply for an exemption from the Department to process the abalone for marketing. The processing shall include evisceration and scrubbing of epithelial layers to reduce the PST concentration to below the regulatory limit. Each batch of processed abalone shall be tested for PST to ensure that the PST concentration in the end-of-line product is below the regulatory limit.
5. A production area that is closed due to biotoxin concentrations exceeding the regulatory limit shall be reopened for marketing once the toxin concentration in two consecutive samples taken

- over a period of three days are below the regulatory limit and show a declining trend in the toxin concentration.
6. The intensive biotoxin monitoring is to be initiated following detection of biotoxins in shellfish in excess of the thresholds given in Appendix 5 of the SASM&CP, though still below regulatory limits.
 7. Intensive sampling may also be initiated when toxic phytoplankton are present in the absence of shellfish intoxication. The intensive sampling phase shall be carried out as described below:
 - a. Daily testing of filter-feeder shellfish and weekly testing of non-filter feeders for the relevant biotoxin(s) will be initiated - at an increased number of sampling points, as deemed necessary.
 - b. Should the presence of toxic algae be indicated in the water or in shellfish flesh, the individual daily phytoplankton samples around the event will be counted.
 - c. Supplementary phytoplankton samples may be collected from the implicated production area.
 8. Routine sampling will be re-instated in a specified production area once the biotoxin concentration in all official samples have returned to below the threshold limits stipulated in Appendix 5 of the SASM&CP.
 9. The Department must close an area immediately for emergency reasons if an investigation confirms that biotoxins from the growing area are responsible for an illness outbreak.
 10. The farm manager and relevant stakeholders are required to acknowledge receipt of the notification.

6. MICROBIOLOGICAL CONTAMINATION CONTINGENCY

In the case where non-compliant microbiological samples are detected at a laboratory the following procedures shall be followed:

1. Where a production area at any time does not comply with the sanitary requirements of its designated classification in terms of the *E. coli* standards stipulated in Appendix 4 of the SASM&CP, the following actions must be undertaken by the Department in collaboration with the NRCS and/or the relevant Health authorities:
 - a. Review all necessary documentation to trace and recall potentially contaminated shellfish products that are in the distribution system.
 - b. Where *E. coli* concentrations exceed the regulatory limit, effect an immediate temporary closure to harvest from the production area being monitored.
 - c. Conduct confirmatory *E. coli* tests on representative flesh samples taken from at least 5 sampling points (n=5) in the production area for farms in an open water system e.g. bays, spread out over the production area to be monitored or in the case of land-based tanks systems, from 5 baskets of the next batch to be marketed.
 - d. Re-open to harvest for direct consumption if the results are within regulatory limits (i.e. *E. coli* n=5, C=1, m=230/100g and M=700/100g (see CODEX STAN 292-2008), where 'n' = the number of sample units, 'c' = the number of sample units that may exceed the limit 'm', and 'M' is the limit which no sample unit may exceed on condition that the

requirements stipulated in Sections 8.3 or 8.4 of the SASM&CP, as applicable, are still complied with.

- e. If the confirmatory test results indicated in clause 1 (d) above are not within the regulatory limits, the farm is closed until at least 3 different batches of 5 samples each, taken over a minimum period of 3 consecutive days are within regulatory limits.
 - f. Where the *E. coli* regulatory limit, $n=5$, $C=1$, $m=230/100g$ and $M=700/100g$ has been exceeded but remains below the *E. coli* MPN value of 4 600/100g in all raw samples tested, approval may be granted to process product as indicated in Section 8.4, paragraphs 3 and 4 of the SASM&CP.
 - g. Furthermore the shellfish shall be tested for Salmonella and pathogenic Vibrio contamination in five samples taken on the same day within the implicated production area (see GNR 692 in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) as well as Compulsory Specifications administered by the NRCS).
 - h. Where Salmonella or Vibrio cholera (or other pathogenic Vibrio) positives are encountered, conduct confirmatory tests for that organism on representative flesh samples taken from at least 5 sampling points ($n=5$) for farms in an open water system e.g. bays, spread out over the production area to be monitored, or from 5 baskets in case of tanks systems of the next batch to be marketed.
 - i. Re-open to harvest if the results are within regulatory limits (absence of Salmonella or pathogenic Vibrio in all 5 samples (see CODEX STAN 292-2008)). If the confirmatory test results are not within the regulatory limits, the farm is closed until the test results of at least 3 different batches of 5 samples each, taken over a minimum period of 3 consecutive days are within regulatory limits.
 - j. Review the classification assigned to the production area when sampling indicates an area continues to exceed its current classification limits.
2. When an end of the line product fails to satisfy the microbiological criteria for human consumption, the following actions must be undertaken by the relevant Health authority, in consultation with the NRCS and the Department:
 - a. Investigate the possibility of a problem with handling, distribution and labelling and instigate appropriate corrective actions as required.
 - b. Instigate the course of actions given in Section 4, paragraph 1 for the implicated production area if the problem is not identified as related to handling, distribution and labelling.
 3. When an epidemiologically confirmed shellfish-borne illness is reported involving two or more persons and implicating a shellfish production area, the Health authority responsible for the particular area, in association with the Department and the NRCS, shall promptly:
 - a. Place a temporary ban on harvest from the implicated production area and classify the area as a prohibited zone.
 - b. Detain and recall any remaining shellfish that are in the distribution system.

- c. Investigate the possibility of a problem with handling, distribution and labelling and instigate appropriate corrective actions as required.
 - d. If it is determined that the production area is not the source of the outbreak, i.e. problem caused in handling or distribution, remove the ban on harvesting and re-instate the original classification category.
 - e. If it is determined that the production area is the source of the outbreak, review the classification of the production area and re-classify if necessary.
4. If an area is closed because an investigation confirms that pathogens in the area (other than those naturally occurring) are responsible for an illness outbreak, the Department must:
 - a. keep the area closed until:
 - i. a review of the classification using at least the last 3 years bacteriological results is completed;
 - ii. a field review of all actual or potential pollution sources is completed; and
 - iii. the Department determines that the event that caused the contamination no longer exists and that the pathogen is no longer present in the shellfish;
 - b. if the illness is consistent with viral etiology, keep the area closed for 28 days from the end of the contamination event (unless the Department determines that a greater or lesser time is required); and
 - c. implement an evaluation process for any implicated pollution sources until the pollution source has been eliminated or its effects adequately mitigated.
5. If the Department reasonably believes that an area has been impacted by a sewage event, the Department must keep the area closed for 28 days from the date of the end of the event, unless the Department determines that a greater or lesser time is required.
6. Microbiologically contaminated shellfish may be canned or cooked and frozen as per requirements in Section 8.4 of the SASM&CP, provided the microbial status meets the related Restricted classification criteria as a minimum. Such shellfish may also be harvested for relaying or depuration until the animals show compliance with Approved classification microbial limits (Section 8.3 of the SASM&CP). This option may only be exercised in accordance with special permit conditions issued by the Department.

7. RECALL PROCEDURES

The following procedure shall be carried for the recall of potentially contaminated product:

1. The FSO shall notify the affected farm manager(s), the NRCS, the FCOs and other relevant stakeholders of the need to recall product.
2. The FSO shall request the implicated FPEs to complete the recall datasheet (Appendix 2) of all products marketed and/or distributed since the last sample was analysed and the contaminant concentration in the sample was shown to exceed the regulatory limit and forward the form to the FSO.

3. The producer shall ensure that any stock marketed from the day that a representative sample of the stock was taken, and the contaminant concentration in the sample was shown to exceed the regulatory limit, is recalled.
4. Contaminated products shall be recalled, embargoed and destroyed under the supervision of the local Health authority or NRCS inspector responsible for the area.
5. The FSO official shall officially instruct the relevant farm managers to recall their product by email and request an acknowledgement of receipt; and
6. Should a product need to be destroyed the farm manager shall:
 - a) dump the product at a registered waste management site;
 - b) obtain a dumping certificate from the waste management site manager; and
 - c) submit a copy of the dumping certificate to the FSO.
7. Affected producers shall inform consignees that all potentially contaminated products in storage, distributed or already sold be withheld from further sale until shown to be safe for human consumption.
8. Should the shellfish still be alive, the farmer has the option to put the shellfish back into production area for natural depuration.
9. The FSO shall monitor the progress and success of the recall process and compile a report of the event.
10. Should product not have been marketed since the relevant date, the farm manager shall inform the FSO that product was not marketed and that recall is not required.

8. REOPENING OF A FARM

A farm that has been closed due to contaminant concentrations exceeding the regulatory limit shall be reopened once the farm meets the requirements stipulated in the relevant food safety programme implemented by the FSO by initiating the following steps:

1. The responsible FSO official emails an official Reopening Letter to the relevant farm manager informing the manager that the farm is open for harvesting shellfish for direct human consumption.
2. Relevant stakeholders viz. NRCS, FCO are copied on all correspondence.

9. REFERENCES

Department of Environment, Forestry and Fisheries. 2021 South African Shellfish Monitoring and Control Programme. Cape Town. Issue 8, 1-65.

National Regulator for Compulsory Specifications. 2018. Procedure: Sampling and Transport of Aquacultured Marine Fish. Cape Town. Issue 1, 1-14.

Appendix 1: Contact Information

Food Safety Office
Directorate: Sustainable Aquaculture Management
Chief Directorate: Aquaculture and Economic Development
Department of Environment, Forestry and Fisheries
Sea Point Research Facility
307 Beach Road
Sea Point
8001

Food Safety Office

Contact	Email	Office	Cell
Food Safety Office	SAMSanitation@environment.gov.za	021 430 7065	-
Ms Helen Ntoampe	HNtoampe@environment.gov.za	021 430 7065	-
Ms Portia Dwane	PDwane@environment.gov.za	012 319 6397	076 172 7305
Mr Mayizole Majangaza	MMajangaza@environment.gov.za	021 430 7076	061 5062328
Mr John Foord	JFoord@environment.gov.za	021 430 7003	082 343 8327

