

(Please note that this report was written in 2005 when AISA was operating as MISA)

## **Report of visit to South Africa to provide assistance in obtaining EU approval for the export of South African aquaculture products, 7 – 12 February, 2005.**

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### **Introduction:**

This report is based on a visit to South Africa from 7<sup>th</sup> - 11<sup>th</sup> February 2005. The visit was at the invitation of the Department of Trade & Industry in collaboration with the Mariculture Institute of South Africa, the Department of Economic Development & Tourism and the Department of Environmental Affairs and Tourism

The aims of the visit were to:

1. assess the existing programme in South Africa
2. interview all stakeholders
3. point out the shortcomings within the programme and make suggestions for how the programme could be improved
4. recommend how best to formally incorporate the programme into the newly established Mariculture Institute of South Africa (Division: Industry Services)

### **Third Country Exports to the European Union**

Permission to export bivalve molluscs from third countries to the European Union is based on an inspection, or mission, to the country by officials from the EU –Food and Veterinary Office (FVO)

In broad terms the objective of an FVO Mission is to:

- assess the organisation of the Competent Authority (CA) and to evaluate whether the conditions of production of bivalve molluscs are equivalent to the requirements laid down in the European Community legislation.

As set out in Article 9 of Directive 91/492/EEC, in deciding whether the conditions of production and placing on the market of live bivalve molluscs in a third country can be deemed equivalent to those of the Community, particular account shall be taken of:

- (a) the legislation of the third country;
- (b) the organization of the Competent Authority of the third country and of its inspection services, the powers of such services and the supervision to which they are subject, as well as their facilities for monitoring the implementation of their legislation in force;
- (c) the actual health conditions during the production and placing on the market of live bivalve molluscs and in particular the monitoring of production areas in relation to

microbiological and environmental contamination, and to the presence of marine biotoxins;

(d) the regularity and the rapidity of the information provided by the third country on the presence of plankton containing toxin in the production areas and, in particular, of species not occurring in Community waters, and risks that such presence may signify for the Community;

(e) the assurances which a third country can give on the compliance with the standards laid down in Chapter V of the Annex to the Directive

A pre-Mission Questionnaire is typically sent to the Competent Authority, which sets out the information required by the FVO Mission team prior to visiting the country. An example of a pre –Mission Questionnaire is provided in Appendix 1. This may assist the Competent Authority in South Africa prepare for an FVO mission and help ensure that all the necessary documentation is assembled and available for inspection.

The Mission itself is based on the detailed response to questionnaire and typically involves visits to CA, laboratories, establishments and production areas. An example of the procedures followed during a recent FVO Mission to Ireland is given in Appendix II

## **Legislation and Monitoring Programme in South Africa**

The legislation and monitoring programme relevant to the control of bivalve molluscs are set out in the South African Molluscan Shellfish Monitoring and Control Programme prepared by the Marine & Coastal Management Branch of the Department of Environmental Affairs and Tourism.

This is a thorough and comprehensive document and sets out a detailed plan for the monitoring and management of bivalve mollusc production and placing on the market. The microbiological and biotoxin standards set down are equivalent to those required under current EU legislation.

The roles and responsibilities of SABS, M&CM as well as local Health Authorities are set out in Memorandum of Understanding.

The documents mentioned above form a sound legislative and administrative basis necessary to underpin the monitoring and management programme.

### **Sampling for biotoxin analysis**

The sampling programme set out in the South African Molluscan Shellfish Monitoring and Control Programme, includes details of the frequency of sampling, size of sample to be taken etc. While no set frequency of sampling is set out in current EU legislation it is important that the frequency of sampling matches the risk involved and is based on available data and can be scientifically justified. It was clear from discussion with M&CM senior scientists that a great degree of knowledge and expertise is available regarding the occurrence of potentially toxic phytoplankton and biotoxins in South

Africa. Given the apparent frequent detection of PSP toxins in abalone however, some detailed justification is required regarding the selection of the 2 week / 1 month sampling and testing frequency chosen.

**Recommendation:** It is recommended that a document be prepared detailing how the sampling and testing frequency for abalone was arrived at.

### **Laboratories**

The laboratories primarily involved in biotoxin (CSIR) and microbiological (SABS) analysis of molluscs were visited

### **Biotoxin Testing:**

All abalone samples taken for biotoxin testing are sent to the CSIR laboratory in Cape Town. The samples received in the laboratory are tested for the presence of lipophilic toxins (Okadaic acid, dinophysis toxins, azaspiracid toxins, yessotoxins and pectenotoxins) and Paralytic Shellfish Poisoning (PSP) toxins using mouse bioassays. The mouse bioassay used for lipophilic toxin detection involves an acetone extraction followed by liquid/liquid partitioning with dichloromethane/water. The mouse bioassay used for PSP toxin detection is the standard AOAC method. Standard Operating Procedures (SOP) for both assays are in place and both assays are included in the scope of the accreditation of the laboratory. With respect to these toxin groups, the procedures and techniques used correspond to the requirements of EU Decision 2002/225/EC and Directive 91/492/EEC.

Chapter V of the annex to EU Directive 91/492/EEC provides that *the total amnesic shellfish poison (ASP) content in the edible parts of molluscs (the entire body or any part edible separately) must not exceed 20 mg/kg Domoic acid using the high performance liquid chromatography (HPLC) method.* Samples of abalone have not, however, been tested for the presence of ASP toxins and at time of the visit the CSIR laboratory did not have the necessary laboratory equipment to perform this test. In the absence of routine ASP testing of abalone the requirements of EU Directive 91/492 are not being fulfilled.

**Recommendation:** It is recommended that routine testing of abalone for the presence of ASP toxins should be put in place as soon as possible in order to ensure compliance with the requirements of EU Directive 91/492/EEC.

### **Proficiency testing:**

Participation in internationally accepted proficiency testing schemes are important elements of laboratory quality assurance procedures and assist in ensuring comparability of test results between laboratories. While currently there are no international proficiency testing schemes in place involving PSP and lipophilic toxin analysis it would be useful for CSIR to make contact with other external laboratories e.g. EU Community Reference Laboratory in Vigo Spain, involved in similar analysis to arrange interlaboratory comparison studies. This is of particular relevance in the case of PSP analysis of abalone as few countries in Europe, with the exception of Spain have experience in the analysis of this toxin group in abalone.

An international proficiency scheme for ASP toxin analysis has been established by QUASIMEME (Quality Assurance of Information in Marine Environmental Monitoring) and following the setting up of routine ASP testing it is recommended that CSIR participate in this scheme. Details of the QUASIMEME proficiency testing schemes, how to participate, costs of participation etc, are available on the Web at <http://www.quasimeme.marlab.ac.uk/>

### **Microbiology Testing:**

The microbiology laboratory in SABS tests samples abalone for the presence of microbial contamination including *faecal coliforms* and *Salmonella*. The samples are taken by SABS staff and delivered to the laboratory on the day of collection. The testing procedures for faecal coliforms and *Salmonella* analyses are included in the scope of the accreditation of the laboratory. It is evident that a very good laboratory quality system is in place. The use of a 5- tube 3 -dilution MPN method for faecal coliforms corresponds to the requirements of EU Directive 91/492/EEC.

It should be noted, however, that with effect from 1<sup>st</sup> January 2006, the permitted microbiological criteria for classification of bivalve molluscs under EU legislation will be based solely on the levels of *E. coli* and classification based solely of levels of faecal coliforms will no longer be acceptable.

### **Phytoplankton analysis**

Water samples are collected in production areas on a frequent, often daily basis, and are sent to M&CM weekly for analysis. The samples collected in any one week are pooled and analysed microscopically. Specific toxic or potentially toxic species are targeted for identification and enumeration.

### **Turnaround time of samples**

In order to ensure that appropriate regulatory action can be taken in a timely manner and thus minimise the risk to human health through the consumption of unsafe product, it is important that the lag time between the collection of samples and the availability of test results is kept to a minimum. Documentary evidence was available which showed that, in many cases, the period between sample collection and the availability of results of toxin analysis exceeded 2 weeks. While acknowledging that there was documentary evidence showing considerable improvements in sample turnaround times in the recent past, a system is required to ensure a rapid turnaround time of all samples on a regular ongoing basis. This could involve the drafting of a Code of Practice setting out, *inter alia*, the frequency of sample collection, the required time of sample delivery to the testing laboratories in any week, procedures within the laboratories for dealing with samples that are not delivered on time or are delivered in poor condition and any regulatory actions needed on foot of the collection and delivery of samples outside the agreed times. Targets for turnaround time of samples following receipt in the testing laboratories should also be set. Given the number of samples being put through the system, a target of analysing and reporting 90% of samples within 3 working days of receipt is not unreasonable. The

collection and delivery of samples to the laboratories early in the week can greatly assist in this process.

**Recommendation:** It is recommended that the Competent Authority, Marine and Coastal Management and other agencies as appropriate, work with the testing laboratories to draft, agree and implement a system to ensure a rapid turnaround time of all samples on a regular and routine basis.

**Reporting of results:**

An important element of the monitoring and regulatory regime is the ability of the Competent Authority to act speedily and efficiently where and when appropriate. This relies on the reporting of the results of all analysis as soon as they become available. From discussions with laboratory staff and officials from M&CM as well as examination of some documentation it is evident that a system is in place but the present system could benefit from a review and revision.

In all cases the reports received from the testing laboratory must be clear and unambiguous. The reports should be signed and dated and should include details of the sample location, sample date, date the sample was received in the testing laboratory, species tested, test procedure and test result and date of issuing of the report. In some of the documentation reviewed some of the necessary information was absent.

Where necessary, it is appropriate for results to be communicated via telephone, particularly when the results obtained shows that the samples contains toxins or levels of bacteria above the regulatory limits. All telephone communication of results should be followed as soon as possible with the communication of results via e-mail, fax or post.

In some cases observed the documented reporting of test results via M&CM to producers and the regulatory decisions regarding the open / closed status of a production area based on the test results was unclear and ambiguous. The reports did not clearly state that an area was open / closed and in some cases the sample date was not included. A clear statement must be made in respect to the status of a production area. The reports should be on formal M&CM letterhead or template.

The results and regulatory decisions should be made available to all stakeholders. This is of particular importance where an establishment takes product from more than one production area. In these cases the results and regulatory status of each individual production area should be sent to the establishment and stored there to ensure full traceability

As stated above, a system of reporting is in place but the present system could benefit from a review and revision. This should also include a review of the staff required to run and maintain an efficient and effective system on an ongoing basis. The staff involved in regulatory decision-making and reporting should ideally be employed directly by the appropriate regulatory authority. This does not currently seem to be the case.

The costs involved in running a monitoring and management programme are not insignificant and internationally it has been found that these costs typically run at 3% - 6% of the value of the industry. The question of who bears the costs e.g. total cost borne by industry as in New Zealand, total cost borne by State as in Ireland, is a matter for each country to resolve. From an EU FVO perspective, however, the issue rests on the ability of the Competent Authority to demonstrate that sufficient staff and resources are available to implement the programme on a routine and ongoing basis regardless of who bears the cost.

### **Audits and Inspection reports**

Regular audits / inspections and subsequent reports are key elements in any regulatory programme. SABS inspectors carry out such a programme of audit and inspections at establishments and also at M&CM and reports of findings, including any non-conformances are prepared.

The reports should clearly identify any non-conformances and any actions that need to be taken to closeout the non-conformances. Reports of follow up audit /inspections should show if the recommended actions were taken and, if not, what regulatory actions /sanctions were applied. The reports should be signed and dated.

Reports of all audit /inspections carried out by the Competent Authority must be available centrally and in each of the individual locations audited. The report of an audit carried out by the Competent Authority of the M&CM monitoring programme in November 2003 was not immediately available at M&CM.

At the I & J establishment visited copies of all audit / inspection reports were available and it was clear that follow up inspections were carried out. In addition, copies of all test results as well as staff medical certificates, HACCP plan, etc were in place. It is important that a similar high standard of record keeping is in place in all establishments.

The I & J establishment visited was a “self contained” unit with abalone being taken through the entire growth cycle and dispatch. There are other establishments, however, that were not visited in which abalone from a number of different production areas are taken and packed for dispatch to the market. In such establishments it is important that systems that ensure full traceability of all product are in place and that the Competent Authority has audited and approved such systems.

### **Sanitation surveys and classification of production areas**

As set out in the South African Molluscan Shellfish Monitoring and Control Programme, sanitary surveys are of critical importance in distinguishing acceptable and unacceptable areas for shellfish production. The reports of these surveys and decisions regarding the classification of all production areas must be clear and signed and dated. One such report seen at M&CM was not signed or dated and this could lead to some confusion and possible errors.

### **Animal Health**

While not a public health concern the issue of animal health and the potential transfer of shellfish diseases needs to be addressed. Commission Decision 2003/804/EC sets down the animal health conditions and health certification requirements for imports into the EU of molluscs, their eggs and gametes for further growth, fattening, relaying or human consumption. With respect to abalone, health certification to guarantee that the animals are free of diseases including Perkinsiosis and withering syndrome is required. It was apparent from discussions with a shellfish health scientist and Veterinarians that currently no formal, official health certification procedure is in place specifically for abalone or other bivalve molluscs. In order to meet the requirements of Commission Decision 2003/804/EC such a system needs to be put in place. This should include dedicated staff and laboratory facilities of a standard required to carry out the necessary analysis to support certification

**Recommendation:** An officially approved health monitoring and certification system to ensure compliance with Commission Decision 2003/804/EC should be put in place.

### **Potential Role of Mariculture Institute of South Africa (MISA) Division: Industry Services, in programme.**

The Mariculture Institute of South Africa (MISA) is a newly formed entity. Based on discussions with current acting CEO and on the information provided in the Conceptual Business Plan in respect of MISA, dated 10 September 2004, the overall aim of MISA is to promote South African aquaculture nationally and internationally, identify research needs and priorities, and undertake the contracting and coordination of research activities aimed at stimulating and promoting development within all aspects of aquaculture for the benefit of the whole aquaculture sector in South Africa.

It is important, from the outset, to establish a clear and distinct separation between any development function and any regulatory function. For the purposes of the shellfish sanitation programme in South Africa the regulatory function should remain within SABS and M&CM. Similarly, at least in the short term, the co-ordination of laboratory testing activities should remain within the remit of SABS and M&CM and available resources should be put into developing the existing laboratory infrastructure and expertise. The role of MISA should be to assist and add value to the programme where possible. Depending on the availability of staff and resources this could be done by:

- Working with SABS, M&CM other agencies and industry as appropriate in the preparation of relevant Codes of Practice e.g. Code of Practice for biotoxin monitoring which sets out how shellfish and phytoplankton samples are to be collected, handled, transported, delivered to the laboratories, the methods of analysis, procedures for reporting of results, procedures for opening/closing production areas
- Working with SABS and M&CM on developing relevant databases and methods of making them accessible to all stakeholders

- Working with SABS and M&CM and other agencies as appropriate in the testing of novel phytoplankton and toxin detection methods that could be incorporated into routine monitoring programme.
- Working with SABS and other agencies as appropriate in the development and testing of novel molecular based bacterial and viral detection methods.
- Developing advisory and diagnostic service to the industry and Competent Authority on food and water quality related issues.
- Developing Web based sources of information in relation to shellfish safety and shellfish health

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**05/04/2005**

*Acknowledgements*

*I would like to thank sincerely all the people whom I met with during my visit to South Africa for their warm welcome, friendliness and willingness to discuss and share information. I would like in particular to thank Grant, Trevor and Fatima at M&CM, Mike and his team at SABS and especially Lizeth for her organisational, logistical and driving skills.*