M.J. Young
Ref: DG (SANCO)/ 7579/
2005 to South Africa

DG SANCO
Att: Mr Colm Gaynor
EUROPEAN COMMISSION
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Dear Sirs

RESPONSE: DRAFT REPORT ON MISSION
REFERENCE NUMBER: DG (SANCO)/ 7579/2005 TO SOUTH AFRICA

We refer to your report which was dated 2 August 2005, but which was received by us on 29 August 2005.

We have taken note of the contents and wish to offer some comments on the report, which will be reflected in Annex I to this correspondence.

The very detailed report is appreciated and most of the findings of your team are not disputed and were followed up and where possible, cleared as a matter of urgency. It is however, also true that some of the findings may take a longer time to clear and we would therefore also wish to highlight these.

1. **EU–report nr. 6.1.1(2) – Non-compliances and correction dates:**

   A meeting was held on 1 July 2005 with the executive management of all European Union listed factories and other industry stakeholders. A summary of the findings of the EU-Investigation team was discussed and a detailed report on the findings made, were issued to all attendants (similar to the report in your Annex). Findings were categorised and discussed in detail. The matter of industry not adhering to dates for closing out findings that were repeated from time-to-time, were discussed at this meeting and also with SABS – FAI – inspection team.

The following decisions were taken:

1.1 Every establishment had to submit a detailed corrective action plan for any outstanding finding pertaining to them, with a detailed explanation of the corrective actions that were implemented or the intended corrective action with the due date. These actions had to be submitted by 15 July 2005 to our lead auditor.

Result: Action plans were submitted and where necessary, were discussed with individual factories, or where problems were experienced with certain industry groupings, follow-up meetings were held with such groupings.

Some of the shortcomings at some of the larger plants can only be corrected with some major capital expenditure and for these, more time will have to be allowed. Frequent follow-up meetings are being held with these factories to verify progress to due dates. There are also certain issues which industry indicated they would require some clarification on from the EU-Commission. This relates to certain technology that was obtained from European equipment suppliers related to the transport of fish in ice water slurries. Written request from Industry is attached as Annex 2.

1.2 Finding reports furnished to EU-listed facilities in future will:

a) Have the due date for clearing such a finding next to the signature of the person acknowledging the finding at the establishment, or
b) Failing that, such a person must submit in writing the due dates for clearing such findings within 7 days of the finding being made.

1.3 Failure to attend to findings of the Competent authority (CA) will be appropriately dealt with and non-cooperation will lead to immediate suspension of establishments.

1.4 There will be changes to the SABS FAI audit system to ensure that corrective action loops are closed as required. More inspectors will be drawn into the audit system, while there will be a responsibility to ensure proper quality control of the audit function.

1.5 Finding reports presented to EU-listed factories will also highlight the paragraph in EU-Directives or Regulations in terms of which the finding is made, to ensure that individuals keep themselves updated with EU-legislation. (Directives and Regulations are made available to all establishments.)

2. **6.1.1(1).** The requirements of Council Directives 91/493 and 92/48EEC for fish products and fishing vessel are entrenched. We acknowledge that the special checks referred to under chapter V paragraph ii point 1 of Annex of 91/493EEC are not performed at the time of landing, but rather on every batch prior to being exported to the EU in its final form. In our country, it is not possible for us to be present at every landing site. However, it is required that every batch of fish exported to the EU, be subjected to complete inspection on representative samples drawn from the consignment prior to the issuing of health guarantees. We are of the opinion that this action can be considered to be equivalent to European systems, where samples are scored “at the time of landing or before first sale” (See also finding 6.1.1(4)). With our system, any deterioration of product due to

bad handling and processing techniques, will also be captured with compulsory inspection of final product.

3. 6.1.1(3) We have taken note of the findings that were made in this regard and corrective actions were instituted to ensure that (a) only approved substances are used at the correct quantities and (b) that no toxic chemicals (including approved cleaning chemicals) can come into contact with fishery products. These are also requirements legislated in terms of South African food laws.

4. 6.1.1(5) The maximum levels set for toxic metals in terms of Commission Regulation (EC) No 466/2001 are implemented for fishery products to be exported to the EU. Representative samples are taken and composite samples are tested and monitoring results will be submitted on a yearly basis (as in the past) to the EU-Commission. We are currently validating new test methods to ensure accuracy of tests for lead and cadmium at the low levels that were set.

5. 6.1.1(6) Although the South African standard for potable water (SANS 241) and the Compulsory Standards for fish products still refer to the coliform organisms, we have been implementing Council Directive 98/43/EC in terms of its requirements since 1999. The inspection team would have noticed that all records (for all factories, including the local market) would reflect test results for E.coli, Enterococci specifically (and not coliforms) and from time to time Clostridia (as well as total counts on autoclave cooling water). We are able to fax some examples if required.

6. 6.1.2. Fishing Vessels:
   The findings highlighted in this paragraph have been brought to the attention of industry and will be closely monitored for compliance with all future inspections.

7. 6.1.3 Establishments:
   Establishments have already implemented some of the corrective actions required as indicated in 1 above and inspectors will ensure that establishments heed their given due dates in this regard.

8. 6.2.1 Toxic metals:
   As stated in 4 above, the maximum levels for heavy (toxic) metals laid down by the EU will be implemented for the edible portion of the abalone (meat without entrails) should export of such product be authorised in future.

9. 6.2.2, 6.2.5(6), (13) and (15) The revision of the SAMSM & CP document and its implementation will be reviewed to be fully compliant with EU-requirements. The classification system will adopt EU health Status A and B as a reference, because these are the only classifications currently allowed. Although testing of the flesh and flesh fluids are currently implemented, it will be used for the full grading of farms, while the water is only used to classify the suitability of waters for intended aquaculture (where no animals are yet present – this would be made clearer and implemented as such).

10. 6.2.4 Abalone is in fact being verified at least on a monthly basis at dispatch centre level and results of such official verifications are available. We have taken

note of the fact that verifications were only on a microbiological basis and other verification tests will be included in future (metals, biotoxins, physical contaminants, etcetera).

11. 6.2.5(5) To clear this finding and those in 6.2.5(9) and (10), we have already held meetings with SANAS and are currently negotiating a memorandum of understanding with them which will give SABS access to certain detail of laboratory accreditation, as well as specific requirements that are laid down pertaining to SABS approval of certain accredited laboratories for use by SABS. Use of test standards and reference laboratories, to further supply guarantees to accuracy of testing, would also be investigated and introduced as relevant.

12. 6.2.5(7) Corrections pertaining to the number of abalone samples that are to be taken for microbiological examination, were already implemented and are now in line with the SAMSM & CP manual.

13. 6.2.5(8) Accreditation of all test methods is currently being discussed with laboratories. However, we consider incorporating the new intended EU tests, including E.coli for marine molluscs in the SAMSM & CP and would prefer to have that test method accredited as soon as possible.

14. 6.2.5(11) Time/ temperature records have already been included and are now kept.

15. 6.2.5(12), (18), (19) and (20) Attached please find the written report provided by Marine and Coastal Management pertaining to the referred sampling frequency and other issues. (Annex 3)

16. 6.2.5(14), (16) and (17) See attached comments received from CSIR and SABS pertaining to these requirements. (Annex 4 and 5)

We trust that the above information will give you an indication of what has been done, or is envisaged for the future, to implement all European Union requirements. Attached as Annex I, please find some further comments pertaining to the report.

Attached, please also find responses from the establishments mentioned in your report that require correction.

Yours Faithfully

Michael J Young
Manager
Food and Associated Industries
Regulatory Affairs and Consumer Protection
South African Bureau of Standards

Annex I

Comments on EU-Investigation Team Findings:

Referring to the draft report on Mission reference number: DG (SANCO)/ 7579/2005, we hereby wish to offer the following comments on certain sections of the report:

Paragraph 2.1.1:

We would recommend inserting one further bullet point between the second bullet (starting with "Local level…) and the third bullet (starting with "Airport level…). The bullet should read: "- Officers at the various export offices sample and verify each consignment of fishery products destined for Europe prior to the issuing of health guarantees".

The fourth paragraph should also be changed to read: "Specific and detailed manuals, procedures, check lists, certificates and reports, e.g. for inspection of vessels and establishments, sampling and for inspection of product prior to export are available and uniformly used".

It is our opinion that the fifth paragraph does not reflect the true situation accurately, for the following reasons:

1. South Africa exports products to various countries in the world and although Codex Standards and Codes of Practice are used extensively, they are still inadequate to reflect the varying requirements of the different countries with which the South African Industry is trading. To reflect most of the requirements of the various countries, manuals and procedures are implemented to reflect some of the most important requirements of certain trade blocks, so as to assist inspectors with their day-to-day task. These manuals and procedures are not aimed at replacing Community legislation and in some instances, may deviate for requirements stipulated by other countries. The intention is to review these manuals from time to time to adopt the most recent requirements. SABS inspectors are however furnished with the applicable EU-Directives and Regulations as they become available. Meetings are held regularly, as necessary, with inspection staff (as well as with industry) to discuss all changing EU-requirements, or highlight aspects which may be overlooked as per both internal and external audits. This is part of the review of our quality management system. Your advice to reflect the clauses of EU Regulations against the findings raised during our audits for EU-compliance, will be adopted, as it will ensure that both inspectors and industry personnel read up more frequently on EU-legislation.

   Pertaining to the requirements to have automatic recording devices on cold stores, it is not reflected in the manual because it is legislated as a requirement for landbased factories in our Compulsory Standard Specifications for frozen fishery products (e.g. Fish, Molluscs, Rock Lobsters and Crustaceans). It is true that it was not compulsory for freezer vessels because:
   a) Historically, it was seen to be impractical to have recording instruments that were not working well on vessels in rough seas (with the advent of

computerised systems, it is now possible and will be implemented in future – though indicating thermometers and manual records will still be required to force crew to become aware of temperature failure when it occurs).

b) Industry takes part in the standard writing process and committees and it was deemed to be adequate to keep manual records of cold store temperatures for the relatively short periods that most of the frozen product spent at sea.

We have taken note of EU-requirements in this regard, which will be implemented.

2.1.2 Paragraph 4

The use of ingredients and additives and potentially toxic substances such as detergents, disinfectants, rodenticides and insecticides are constantly monitored, as it is part of the regulatory and HACCP control. Only ingredients and additives approved in terms of the Foodstuffs Act, may be used at prescribed levels. This is constantly monitored as part of the process and product surveillance programme. Detergents and disinfectants have to be approved and may not be used in such a manner that it can contaminate the product or surfaces with which product comes into contact. We have taken note that a finding was raised at one factory where cleaning chemicals were not removed from utensils before being used on the process line, but that was not considered to be a normal practise and we acknowledge that it was highly unacceptable. Rodenticides and insecticides must be officially approved for specific use and may only be administered by persons that are trained and registered in terms of legislation. We would however, acknowledge the fact that a finding was raised in this instance, which is being taken up with industry to ensure that insect sprays cannot contaminate product or surfaces with which product comes into contact.

2.1.3.2 <u>Chemical checks (TVB-N and TMA-N)</u>

These chemical checks are only carried out at the request of industry (probably at the request of their buyers), as they are not considered to be as accurate and effective as sensory examinations carried out by trained inspectors to score fish freshness parameters. Except for its inaccuracy as indicators, chemical checks for freshness parameters can also access only a limited quantity of fish and therefore sensory freshness parameters will always take preference to chemical parameters. The tests are also expensive and can only be considered to confirm bad results obtained through the sensory examination of severely spoilt fish.

South African regulations for toxic metals as contained in the Foodstuffs Act, are only applied to local product, while we are well aware of stricter EC-requirements [(EC) No 466/2001 as amended] South African Health Regulations accept Codex Alimentarius Directives in this regard and will adjust legislation accordingly.

2.1.3.3 <u>Microbiological criteria:</u>

We are not sure whether EU-investigators have consulted the test records for water taken at establishments during the Mission. Such investigations would have revealed the fact that all potable and clean water tests include Enterococci (even for non-EU listed factories). The official Standard (SANS 241) for drinking water in South Africa, as well as requirements in Compulsory Standards, still reflect testing for coliforms and not Enterococci, but that may change in future. In the

mean time, we are testing Enterococci as per 98/83/EC, which was already implemented in 1999.

We trust that you will consider these comments and you are invited to contact us should you need further clarification on issues.

Yours Faithfully

M.J. Young

DEPARTMENT OF ENVIRONMENTAL AFFAIRS AND TOURISM
Branch: Marine & Coastal Management

South African Molluscan Shellfish Monitoring and Control Programme [SAMSMCP]: justification of the sampling frequency for biotoxin tests in the abalone [*Haliotis midae*]

Background

Harmful algal blooms [HABs] are common phenomenon on the South African coastline, which is influenced by two major boundary current systems – the cool Benguela on the west coast and the warm Agulhas on the east coast. The juxtaposition of these two systems creates a broad range of oceanographic conditions leading to regional disparity in problems relating to harmful algae [Probyn and Pitcher 2004]. A disproportionately high incidence of harmful events is recorded to the west of Cape Agulhas, which is generally acknowledged as the southern limit of the Benguela upwelling system. Blooms to the east of Cape Agulhas are seldom reported. A further biogeographic boundary is Cape Point, which appears to form a natural divide for species that dominate blooms of the west coast as opposed to those that dominate the south coast [Pitcher and Calder 2000].

HAB events on the South African coast can be broadly grouped into those that create problems owing to their high biomass and those that produce toxins [Pitcher and Calder 2000]. The harmful effects of high biomass blooms result typically from anoxia following the decay of dinoflagellate dominated blooms, whereas public health is impacted by a high incidence of Paralytic [PSP] and Diarrhetic Shellfish Poisoning [DSP].

PSP was confirmed in the region by Sapeika [1948] and is caused by the dinoflagellate *Alexandrium catenella,* which appears confined to the coast west of Cape Point. *A. catenella* typically occurs as a component of the plankton during the latter months of summer and the highest incidence of PSP is found in the Namaqua region. No records of PSP exist east of Cape Point [Pitcher et al. 2001]. Despite recent identification of another toxic *Alexandrium* species on the South Coast, PSP remains undetected in this region owing in all likelihood to the observed low concentrations of this species and to its low cell toxin quota [Ruiz Sebastian et al. 2005].

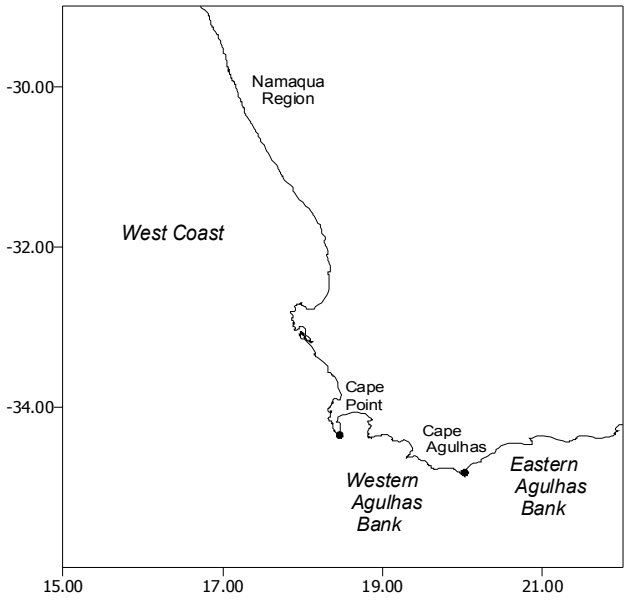

Figure 1: Although Cape Agulhas is considered the southern limit of the Benguela upwelling system, Cape Point is an acknowledged biogeographic divide, separating the cold-temperate west coast region from a warm-temperate south coast region, influenced by the warm Agulhas current.

DSP was identified on the South African coast in 1991 and attributed to *Dinophysis acuminata* [Pitcher et al. 1993]. Monitoring has revealed that DSP is common on both the west and south coasts and several other known DSP-causing species have been recorded in the region, e.g. *D. fortii, D. hastata, D. tripos and D. rotundata* [Pitcher and Calder 2000]. Determination of the specific toxicity of *D. acuminata* and *D. fortii* from the South African coast, has in both cases revealed moderate toxicity attributable to okadaic acid and the derivative DTX 2B [Pitcher et al. in prep]. Despite inter-annual variation *Dinophysis* cells tend to be observed throughout the upwelling season in relatively low concentrations, peaking during autumn months.

Amnesic Shellfish Poisoning [ASP] has not been reported on the South African coast. Although various species of *Pseudo-nitzschia* are frequently encountered, and extensive blooms of *Pseudo-nitzschia australis* have been recorded on the West Coast, domoic acid has not been detected in isolates of these blooms [Marangoni et al. 2001]. Neurotoxic Shellfish Poisoning [NSP] is also unknown on the South African coast, although fish-killing species have been reported, including the newly described dinoflagellate *Karenia cristata* [Botes et al. 2004], known to produce an aerosol toxin similar to that produced by *Karenia brevis* and *Karenia brevisulcata*.

Present requirements for biotoxin testing

The South African Molluscan Shellfish Monitoring and Control Programme specifies toxin levels in the edible portions of shellfish as the present basis for regulatory action [5.4.2 Biotoxin Management Plan]. It also specifies that sampling shall be conducted at differing levels of intensity as determined by the shellfish species of concern, the history of contamination with the biotoxin under consideration, and the geographical area under consideration.

During the routine phase of monitoring [5.4.2.1], shellfish samples for bioassay are collected in accordance with Table I. A composite sample of shellstock currently being harvested or intended for next harvest is taken. The sampling schedule given in Table I provides the minimum sampling requirements, although growing areas regarded as high risk may be required to test for biotoxins more frequently than specified.

Table I. Maximum allowable time between biotoxin test and shellfish harvesting.

	West of Cape Point		**East of Cape Point**	
	Filter feeders	Non-filter feeders	Filter feeders	Non-filter feeders
PSP	48h or twice a week for multiple harvesting	2 weeks	1 month	1 month
DSP	1 week	1 month	2 weeks	1 month
ASP	1 month	1 month	1 month	1 month

An intensive sampling phase [5.4.2.2] is initiated following detection of biotoxins in shellfish meats, although still below regulatory limits [4.6.2]. During this phase daily testing of filter-feeder shellfish meats and weekly testing of non-filter feeder meats for the relevant biotoxin(s) is required. A quarantine sampling phase [5.4.2.3] is brought into effect immediately following detection of biotoxin in shellfish meats at levels sufficient to cause a public health hazard [4.6.2]. The frequency of testing of shellfish meats during this phase is at the farm managers' discretion, although a maximum of one sample per day may be submitted for testing. A shellfish growing area closed due to biotoxins will proceed to a re-opening phase [5.4.2.4] when biotoxin levels are below the regulatory limit for 3 consecutive samples. Sampling intensity following re-opening to harvest will be dictated by toxic algal presence. This may involve intensive sampling in the continued presence of toxic species or biotoxins in the flesh even though the shellfish have attained sub-quarantine levels of biotoxins. Routine sampling will be re-instated once the biotoxin concentration has returned to non-detectable levels for 3 consecutive samples.

Justification of present requirements for biotoxin testing of abalone [*Haliotis midae*]

Weekly sampling frequencies are adopted by many monitoring programmes in areas where toxicity is prevalent and where harvesting is taking place or about to take place. However, rates of toxin accumulation by shellfish from toxic algae are both toxin and species-specific, owing both to the mode of uptake of the toxin and because mollusc species differ substantially in their retention capability for each of the toxin groups [Fernandez et al. 2003]. It therefore follows that decisions relating to sampling frequency may differ, but should be supported by historical baseline information specific to the shellfish and toxic algae of the area under consideration.

Bivalve molluscs [e.g. mussels, oysters, clams and scallops] are unquestionably the most serious vectors of shellfish toxins as their ability to filter large volumes of water enables them to effectively accumulate toxic phytoplankton [Shumway 1995]. Blooms that appear rapidly may therefore render bivalve molluscs toxic virtually overnight [Shumway 1990]. For this reason the required frequency of sampling of bivalve molluscs, in order to protect pubic health is high. Bivalve molluscs are nevertheless not the only vectors of shellfish toxins and various gastropods and crustaceans have also been shown to accumulate toxins. Of the gastropods, carnivores and scavengers are the most likely to accumulate toxins as some feed predominantly on filter-feeding bivalves. The toxins accumulated by these gastropods appear confined to the PSP toxins and tetrodotoxin [Shumway 1995]. Although grazing gastropods are less likely to accumulate toxins [Shumway 1995], Martinez et al. [1993] and Pitcher et al. [2001] have reported the detection of PSP toxins in abalone on the Spanish and South African coasts respectively, albeit at relatively low levels.

The abalone *Haliotis midae* forms the basis of an established fishery on the South African coast with present day operations including recreational, subsistence, and commercial activities. Abalone usually attach to rocky substrates and feeding is accomplished by browsing on drifting kelp and other seaweeds. This feeding behaviour and diet suggests that abalone are unlikely candidates for the ingestion and accumulation of toxins derived from micro-algae which primarily occur as a component of the plankton. This argument is supported by the absence of any report of shellfish poisoning associated with this fishery despite it being one of the oldest fisheries on the South African coast. Its perceived low risk is confirmed by its exclusion from the list of Backer et al. [2002] of shellfish that serve as vectors of human diseases associated with micro-algal toxins.

Land-based abalone farming was established in South Africa during the 1990s and incorporated into the SAMSMCP. Despite the alleged low risk of accumulation of biotoxins in abalone, PSP toxins were detected in animals on west coast farms in 1999. At this time, extension of sampling to the wild resource on the west coast also revealed the presence of PSP toxins in these populations. Initial detection of PSP toxins in abalone was coincident with blooms of *Alexandrium catenella* indicating that

this dinoflagellate was the probable cause of abalone toxicity. This link is further supported by the corresponding distribution of PSP toxins in abalone and the known distribution of *A. catenella* [Pitcher et al. 2001]. The mode of uptake of the toxins remains speculative.

Considering the above information, the following sampling frequencies are applied for each of the toxin groups:

Paralytic Shellfish Poisoning [PSP]: a 1-month sampling period is stipulated for abalone farmed to the east of Cape Point, and a 2-week sampling period for abalone farmed to the west of Cape Point. The reduced frequency of sampling to the east of Cape Point is applied owing to the fact that PSP toxins have not been detected in any form of shellfish in this region. Testing of abalone for PSP toxins has been a requirement of the SAMSMCP since 1999 and during this period 461 samples have been tested for PSP in abalone to the east of Cape Point without a positive result. The absence of PSP to the east of Cape Point is considered to reflect the distribution of *Alexandrium catenella* [Pitcher and Calder 2000]. A 2-week sampling frequency is stipulated for abalone farmed to the west of Cape Point as PSP is common in this area owing to the high incidence of blooms of *Alexandrium catenella*. This sampling frequency is lower than that stipulated for filter-feeding bivalves as abalone are considered to take up and retain PSP toxins less efficiently that filter-feeders. This is confirmed by the relatively low range of toxin concentrations in abalone. Since 1999, 356 abalone samples have been collected to the west of Cape Point of which 36 have tested positive for PSP [ranging from 80 – 325 $\mu g\ 100g^{-1}$].

Diarrhetic Shellfish Poisoning [DSP]: a 1-month sampling period is stipulated for abalone. Although DSP is common on the South African coast, abalone have not been reported as vectors of these toxins. Testing of abalone for DSP has been a requirement of the SAMSMCP since 1999 and during this period 561 abalone samples have been tested without a positive result.

Amnesic Shellfish Poisoning [ASP]: a 1-month sampling period is stipulated for abalone. This relatively infrequent sampling period is stipulated owing to the fact that abalone have not been identified as vectors of these toxins and ASP has not been reported on the South African coast. Although several *Pseudo-nitzschia* species are known to bloom regularly on the South African coast, no human diseases have been associated with these blooms and the consumption of shellfish. Testing of abalone for ASP has only been a requirement of the SAMSMCP since 2004 and during this period 80 abalone samples have been tested without a positive result.

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Marine & Coastal Management's Response to the European Union's Inspection Report

3.1 SAMSM&P

Concern was expressed over the Cd levels measured in cultivated whole abalone which were sometime in excess of the EU limit. To address these concerns a study will be initiated by M&CM with farmed abalone from three different regions (west, south and east) that aims to quantify the relative contribution of the viscera and the foot to total body burden of Cd. The ultimate goal is to establish whether evisceration can mitigate against elevated Cd levels.

Piet – will you add what is going to be done about the SA limits in the future, i.e. will follow Codex?

3.2 Classification of production areas .

The classification scheme has been amended to reflect three primary classes: approved (Class A), restricted (Class B) and prohibited. The microbiological standards for these categories are <300, <6000 and >6000 faecal coliforms/100g, respectively. The EU scheme of classes is included along with the US NSSP scheme. In addition, standards for *E. coli* are included (<230, <4600 and >4600/100g, respectively) with the intention of basing classifications on these indicators in the future, in accordance with Regulation (EC) 854/2004. Owing to the relatively unpolluted nature of the South African coastline and the stated objective of promoting aquaculture in areas of good water quality status, the accommodation of the Class C category is not regarded as necessary at this stage. The additional classification category of "conditional" remains but now as a separate entity. This refers to production areas that meet either the approved or restricted classification for a predictable and reasonable length of time.

In addition to flesh testing, the requirement for water testing (as per the US NSSP) is retained for non-filter-feeding molluscs such as abalone. The rationale being that non-filter-feeders would not provide as sensitive an indicator of water quality deterioration as bivalves. The issue here is less one of product quality but rather early detection of impending faecal contamination problems. However, classification will be based exclusively on flesh microbiological standards.

The misleading wording in Sections 4.1.5, 4.2.1.1 and 4.2.3.6 regarding water testing has been changed to unambiguously state that classification is based on flesh testing. (To date all microbiological classifications have been based on flesh faecal coliforms.).

3.3 Harvesting and transportation of aquacultured abalone.

Movement documents will be altered to reflect the additional information:

Address of harvester

Health status of production area (e.g. Approved (Class A)).

If purification facilities come on line a separate movement document will be issued that specifies additional information relating to address/location of the depuration plant/relaying area, duration of purification, and. in the case of depuration, the dates on which the batch entered and left the plant.

3.4 Dispath centres
No Manual issues

3.5 End product
No manual issues

3.6 Public health control and monitoring of production.
3.6.1 *General aspects*
Deadlines for receipt of results from the testing laboratories will be specified in the Manual
3.6.2 *Microbiology*
General
The number of animals to be sampled as specified in the Manual will be strictly adhered to by samplers and analysts.
Methods
Reference to the Donovan et al (1998) method for *E. coli* (on which ISO TS 16649-3 is based) has been included in the Manual.
Quality system
Appendix I of Manual– Sampling of shellfish and water.
An additional section on "Receipt of samples by laboratories" has been included. This requires that samples must be accompanied by an official laboratory submission form (collectors name, shellstock type, production area and position of sample station, time and date of collection, and intended analysis). Quality parameters such as condition, vitality, temperature and number of individuals shall be recorded by the laboratory. The laboratory shall provide records to show that microbiological samples were stored at the appropriate temperature prior to analyses and that analysis commenced within 24 hours of sample collection.

3.6.3 *Biotoxins*
Frequency of sampling – see accompanying document
Manual has been amended to reflect the methods used for analyses

3.6.4 *Phytoplankton*
M&CM are in the process of building up records of intoxication/depuration of shellfish and phytoplankton abundance correlates. At present we are not in a position to confidently set numerical phytoplankton thresholds as a trigger to instigate more intensive monitoring. Until such time, simple presence or absence of harmful species will be used to modify sampling intensity.
M&CM will initiate a study of epiphytic phytoplankton found on kelp fronds fed to cultivated abalone.