SERNAPESCA comments to the draft Mission Report ref. DG(SANCO)/2013-6721-MR carried out from 17 April to 26 April 2013 in order to evaluate the control systems in place governing the production of live bivalve molluscs intended for export to the European Union

N°.	Recommendation	Action Proposed by the Competent Authority
1	In order to provide all the guarantees required by the Health Certificate for imports defined in Appendices IV and V of Annex VI to Regulation (EC) 2074/2005 the CA should ensure that standards at least equivalent to the EU ones are applied to dispatch centres approved for EU exports, in particular as regards the obligation for FBOs to implement and maintain HACCP based systems as required in Article 5 of Regulation (EC) No 852/2004.	In domestic dispatch centers, in accordance with the definition set in Annex I, item 2.7 of Regulation (EC) 853/2004, reception, preparation, cleaning, calibration, packing and assembly activities of live bivalve molluscs fit for human consumption are performed. Although these activities are considered primary production and related operations both in Article 3, item 17, of Regulation (EC) 178/2002 as in Annex I, part A, item I, paragraph I of Regulation (EC) 852/2004. Thus, and as per recital 11 of Regulation (CE) 852/2004, Sernapesca, as competent authority considers that the implementation of HACCP in dispatch centers is not necessary, so the application of good practices is sufficient. In this manner, sufficient guarantees are provided to comply with the statements included in the sanitary certificates, established in Appendixes IV and V of Annex VI of Regulation (EC) 2074/2005.
2	The CA should ensure that the standards applicable to live bivalve molluscs and fishery products derived therefrom intended for export to the EU are in line with Annex II, Chapter II, part A, points 4 and 5, to Regulation (EC) No 854/2004, in particular with regard to the requirements applicable to live bivalve mollusc samples to be analysed (i.e. flesh and intravalvular liquid).	The Fisheries Sanitary Manual documents were examined, specifically the reference to the analysis for E. *coli* in live bivalve molluscs, to include the requirements that the analysis must be performed in a sample of flesh and another comprised by flesh and intra valvular liquid. The following documents were modified: SMB/NT2 (item III, point1), SMB/NT3 (point 2.2) and LAB/NT7 (point 2), June 2013 version.
3	In order to provide the guarantees required by Article 12, point 1, of Regulation (EC) No 854/2004, the CA should ensure that the lists of live bivalve mollusc production areas are promptly updated as necessary.	The CA does not report the removal of the production areas immediately to the European Authority, because there are many companies that maintain a stock of product (for example canned products) which is produced from raw material extracted when the production area was authorized and therefore the product meet sanitary requirements.

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		Is required to know any alternative proposed by the European Authority to address these cases and not hinder the importation of these products to the EU, that comply with sanitary regulations. We propose that the shipments are accompanied with Special Certificate stating that at the time of raw material extraction, the production area was approved and incorporated in the list of EU Authority published in the following link: https://webgate.ec.europa.eu/sanco/traces/output/non_eu_listsPerCountry_en.htm# This certificate could be accompanied by a copy of the list in which the production area was incorporated.
4	The CA should ensure that, when a production area is modified (e.g. incorporation of new farms), the re-classification is performed following requirements at least equivalent to the ones indicated in point A of chapter II of Annex II to Regulation (EC) No 854/2204, in order to provide all the guarantees required by the Health Certificate for imports defined in Appendices IV and V of Annex VI to Regulation (EC) No 2074/2005.	Modification of production areas for example, the inclusion of a new farm is carried out on the basis of a study of the coastal line in the area, and in case of the absence of new contamination sources, the zone's classification remains as is. From hereon, in case of extending areas, document SMB/MP2 shall set forth that Sernapesca may require the re-classification of the zone if considered appropriate, mainly in those cases where the existence of new contamination sources is not considered in the initial assessment of the area. Time limit: January 2014
5	The CA should ensure that all classified production areas are periodically monitored for all the parameters defined in point B	The reduced monitoring procedure was modified and the analysis of Phytoplankton was replaced by a microbiologic analysis of resources according to the area classification. This was included in point 3 of

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	of chapter II of Annex II to Regulation (EC) No 854/2204, in order to provide all the guarantees required by the Health Certificate for imports defined in Appendices IV and V of Annex VI to Regulation (EC) No 2074/2005, in particular, when there is irregular harvesting from production areas, the CA should ensure that at the time of commencement of harvesting the microbiological quality of the live bivalve molluscs has been in line with the classification of the area during the previous month.	document SMB/MP2 (June 2013 version) and a start-up process is underway, while seeding takes place in those production areas presently without resources.
6	In order to provide all the guarantees required by the Health Certificate for imports defined in Appendices IV and V of Annex VI to Regulation (EC) No 2074/2005 the CA should ensure that Pectinidae and gastropods harvested from non-classified production areas comply with the health standards laid down in Annex III, Section VII, Chapter V, to Regulation (EC) No 853/2004 and with standards equivalent to the requirements laid down in Annex III, Section VII, Chapter IX, to Regulation (EC) No 853/2004.	The following actions have been determined to implement a better control of pectinidae and gasteropods exports from non-classified areas: 1. A survey of all non-classified natural Banks from which pectinidae or gasteropods are harvested for export to the UE, shall be made, in order to make up a list with their identification, geographical location, extension and existing resources. Deadline 31/11/2013 2. The available official documents that support the lots for such resources shall be examined, in order to determine the appropriate documentary control system similar to RET, thus complying with community legislation. Deadline 31/01/2014 3. Analysis requirements for raw material shall be established at the time of arrival at the plant and the finished product controls shall be examined. Deadline 31/01/2014 The above will be included in the Fisheries Health Manual documents (SMB/MP2, SMB/NT2 and CER/NT3) in the March 2014 version.

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7	In order to provide all the guarantees required by the Health Certificate for imports defined in Appendices IV and V of Annex VI to Regulation (EC) No 2074/2005 the CA should ensure that analyses performed on live bivalve molluscs are carried out in accordance with the requirements established in Regulation (EC) No 2073/2005 with regard to the number of individual animals to be used when forming the sample for analysis.	The manual that refers to E. *coli* analysis in live bivalve molluscs shall be revised to include the requirement that the analysis be performed in a simple comprised by 10 individuals. This was included in document LAB/NT7 (point 2) June 2013 version.
8	The CA should ensure that all laboratories performing official control analyses use EU reference methods (or alternative methods validated to the EU reference ones), have performance criteria for the methods used in line with EU rules, are assessed and that adequate quality controls are in place to provide for the reliability of test results (Codex Alimentarius, CAC/GL 26-1997), in particular for microbiology and lipophilic toxins testing (chemical method).	As to the microbiology essay, the Fisheries Health Manual was revised, specifically the part related to E. coli analysis in live and processed bivalve molluscs, to include that the analysis must be performed on the basis of NMP tables included in the ISO 7218 standard, taking due care of maintaining the Agar Triptona Bilis Glucuronide on slab up to 5 days, as per the relevant technical rule. This was included in document LAB/NT7 (point 2) June 2013 version. Additionally, Sernapesca notified the laboratories and inspectors in order to strengthen this provision. They were notified via fax N° 23476 and e-mail dated April, 23, 2013. As to lipophylic toxins analysis (chemical method), the laboratory answered the total number of findings, demonstrating the satisfactory compliance of international and European validation requirements. The following matters were dealt with: 1. Technical revalidation (robustness, calibration curb, detection limit, quantification limit, analysis of certified reference material).

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		2. Performance assessment essays: the U. de Chile Lab and Sernapesca have studied the participation of such University, but up to date, there are no offers available. We shall continue to consult the institutions that perform these essays, including the revision of the European Reference Laboratory page to include the (Rikilt Laboratory) method. 3. ISO 17025 Certification: In its Procedures Manual LAB/MP1 (point 6.2), Sernapesca sets forth the provisional authorization for a one year period, during which the lab must process its certification. As a result, the lab shall begin the certification process in September of 2013. 4. The laboratory has modified the reports format, in accordance with Sernapesca's requirements.