

ANNEX

**Response of the Competent Authorities of South Korea to the recommendations of Report ref. DG(SANCO)/2012-6466-MR of an audit carried out from 19 to 30 November 2012 in order to evaluate the control systems in place governing the production of fishery products and bivalve molluscs intended for export to the European Union**

N°.	Recommendation	Action Proposed by the Competent Authority
1	The CA should ensure that EU listed freezer and factory vessels implement a HACCP plan in line with the requirements laid down in Article 5 of Regulation (EC) No 852/2004.	○ The CA has amended relevant notification to make it mandatory for the EU listed freezer and factory vessels to establish and implement HACCP plan (28 December 2012)
2	The CA should ensure that regular checks on the hygiene conditions of landing and first sale are carried out in line with the requirements laid down in Point 1 (a), Chapter I, Annex II of Regulation (EC) No 854/2004.	○ The CA will prepare sanitary management standards for landing and first sale and amend the relevant notification (end of October 2013), and conduct inspection at the site and establishment of concern (from November 2013)
3	The CA should ensure that the number of sample units of the sampling plan for histamine is in line with the requirements laid down in Point 1.26, Chapter 1, Annex I of Regulation (EC) No 2073/2005.	○ The CA will amend monitoring of fish and fishery products to be exported to enable sampling of histamine and analysis of results in accordance with the relevant EU regulations (end of September 2013).
4	The CA should ensure that live bivalve mollusc production areas are classified in line with the requirements laid down in Part A, Chapter II, Annex II of Regulation (EC) No 854/2004.	<ul style="list-style-type: none"> <li>○ Based on the E. coli test results of the shellfish in the production areas designated for EU exports, performed since 2006, the CA will reclassify the 7 production areas designated for EU exports (end of October 2013).</li> <li>○ The CA is planning to differentiate the current 7 production areas designated for EU exports into classes A, B and C in accordance with the EU criteria for classification of the waters (end of December 2013)</li> </ul>
5	The CA should ensure that water samples for the monitoring of	○ The CA will prepare and implement standard procedures in the case of

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	phytoplankton are representative of the water column in line with the requirements laid down in Point 7, Part B, Chapter II, Annex II of Regulation (EC) No 854/2004).	<p>sampling sea water for the monitoring and analysis of phytoplankton, and actions to take when toxic-producing planktons occur (end of October 2013).</p> <ul style="list-style-type: none"> <li>○ When sampling sea water, the CA will use method so that the samples are representative of the water column (such as using integrated hose-pipe sampler, etc.).</li> </ul>
6	The CA should ensure that, where several shellfish species are harvested, the one which has the highest toxin accumulation rate is sampled in line with the requirements laid down in Point 6, Part B, Chapter II, Annex II of Regulation (EC) No 854/2004.	<ul style="list-style-type: none"> <li>○ The CA will sample mussels, which has the highest toxin accumulation rate, as well as the major shellfish species produced in the production areas designated for EU exports in accordance with the EU recommendation (from March 2013).</li> </ul>
7	The CA should ensure that the sampling frequency for biotoxins monitoring is weekly during the harvesting season. The sampling frequency may be reduced if a risk assessment suggests a very low risk of toxic episodes, in line with the requirements laid down in Point 5, Part B, Chapter II, Annex II of Regulation (EC) No 854/2004.	<ul style="list-style-type: none"> <li>○ The CA will conduct weekly sampling of the shellfish for the export to the EU only during the harvesting season (from August 2013).</li> </ul>
8	The CA should ensure that, where there is an above the threshold result for E. coli, the production area concerned is closed or reclassified in line with the requirements laid down in Point 1,	<ul style="list-style-type: none"> <li>○ The CA will amend the relevant notification to reflect E. coli criteria on the shellfish produced in the production areas designated for EU exports (end of October 2013).</li> </ul>

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	Part C, Chapter II, Annex II of Regulation (EC) No 854/2004.	<ul style="list-style-type: none"> <li>○ If the level exceeds the limit, the CA will impose production restriction measures from the production areas designated for EU export in accordance with relevant regulation and procedure (end of October 2013).</li> </ul>
9	The CA should ensure that an action plan, which responds to varying levels of toxic-producing plankton species in water, is available in line with the requirements laid down in Point 7, Part B, Chapter II, Annex II of Regulation (EC) No 854/2004.	<ul style="list-style-type: none"> <li>○ The CA will prepare and implement standard procedure for the actions to take when toxic-producing plankton are present (end of October 2013).</li> <li>- When toxic-producing plankton are present, the CA will strengthen shellfish poison investigation on the shellfish produced in the production areas designated for EU exports .</li> </ul>
10	The CA should ensure that laboratories involved in official controls apply the principles of internationally recognised quality assurance techniques and are evaluated and/or accredited under officially recognised quality management and assurances programmes equivalent to international standards, such as ISO/IEC 17025, to ensure the reliability of analytical results.	<ul style="list-style-type: none"> <li>○ In order to ensure that only laboratories accredited with ISO/IEC 17025 would analyze the products to be exported to the EU, the analysis of the products of concern will be conducted by Busan District Office (formerly, Yeongnam Regional Office) (from April 2013)</li> <li>- The laboratories will regularly participate in the Ring test and Proficiency test on the analysis items.</li> </ul>