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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

INDIA

FROM 03 TO 14 MARCH 2014

IN ORDER TO EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE
PRODUCTION OF FISHERY PRODUCTS INTENDED FOR EXPORT TO THE EUROPEAN
UNION

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a Food and Veterinary Office audit in India carried out from 3 to 14 March 2014, as part of its programme of audits in third countries.

The primary objective of the audit was to evaluate the public health conditions for the production of fishery products intended for export to the European Union. The audit covered the relevant EU legislation for the public health sector.

The report concludes that the competent authority has implemented an official control system for fishery products intended for export to the EU which adequately covers processing activities.

However, official controls in relation to primary production, landing and first sale have only started very recently and are at a very early stage of implementation. To date, very few aquacultures farms and fishing vessels have been approved and only a small percentage of those approved have been subject to official inspection. Furthermore, the two recently approved landing and first sale facilities visited were not fully in line with EU requirements. Consequently, the situation has not significantly changed since the fish sector was first audited in 2005.

From a general point of view, processing establishments visited during the audit were found to be in good condition regarding structure, equipment, maintenance and hygiene. In general, own-check programmes reviewed during the audit were in line with EU requirements and were adequately implemented by food business operators at landing and first sale site.

Official controls of fishery products intended for EU export are implemented in line with EU requirements, except for organoleptic checks.

The laboratories responsible for official analyses on fishery products have put in place measures aimed at ensuring a satisfactory level of analytical performance. However, with regard to cadmium, dioxins and polychlorinated biphenyls, some shortcomings have been identified, which undermine the ability of the competent authority to ensure that fishery products with contaminant levels exceeding EU maximum levels are not exported to the EU.

Finally, the lack of official controls over primary production also undermines the ability of the competent authority to guarantee that non-eligible fishery products are excluded from export to the EU.

The report addresses to the Indian competent authority a number of recommendations aimed at rectifying identified shortcomings and enhancing the control system in place.

Table of Contents

1	<u>INTRODUCTION</u>	1
2	<u>OBJECTIVES AND SCOPE OF THE AUDIT</u>	1
3	<u>LEGAL BASIS FOR THE AUDIT</u>	2
4	<u>BACKGROUND</u>	2
4.1	<u>GENERAL BACKGROUND</u>	2
4.2	<u>PRODUCTION AND TRADE INFORMATION</u>	3
4.3	<u>RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS</u>	4
5	<u>FINDINGS AND CONCLUSIONS</u>	4
5.1	<u>LEGISLATION</u>	4
5.2	<u>COMPETENT AUTHORITY</u>	5
5.3	<u>NATIONAL PROVISIONS AND PROCEDURES FOR LISTING ESTABLISHMENTS EXPORTING TO THE EU</u>	5
5.4	<u>OFFICIAL CONTROLS</u>	5
5.4.1	<u>OFFICIAL CONTROLS OF PRODUCTION AND PLACING ON THE MARKET</u>	5
5.4.2	<u>OFFICIAL CONTROLS OF FISHERY PRODUCTS</u>	7
5.4.3	<u>OFFICIAL CONTROLS OF ADDITIVES</u>	7
5.5	<u>FOLLOW UP OF RASFF NOTIFICATIONS</u>	8
5.6	<u>LABORATORIES</u>	8
5.7	<u>OFFICIAL CERTIFICATION</u>	8
6	<u>OVERALL CONCLUSION</u>	9
7	<u>CLOSING MEETING</u>	9
8	<u>RECOMMENDATIONS</u>	9
	<u>ANNEX 1 - LEGAL REFERENCES</u>	10

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AAS	Atomic Absorption Spectrometry
APLAC	Asia Pacific Laboratory Accreditation Cooperation
AOAC	Association of Official Analytical Chemists
CA	Competent Authority
CCA	Central Competent Authority
DG SANCO	Health and Consumers Directorate General of the European Commission
EC	European Community
EIA	Export Inspection Agency
EIC	Export Inspection Council
ELISA	Enzyme-linked immunosorbent assay
EN	European Norm
EU	European Union
EU listed	Facility approved by the CA for EU fishery products export and listed on the internet site of DG SANCO
EUROSTAT	Statistical Services of the European Union
FAPAS	Food Analysis Performance Assessment Scheme - UK Department for Environment, Food and Rural Affairs
FBO	Food business operator
FVO	Food and Veterinary Office of the European Commission
HACCP	Hazard Analysis Critical Control Points
HPLC	High Performance Liquid Chromatography
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organisation for Standardisation
MPEDA	Marine Products Export Development Authority
ML	Minimum Level
NABL	The National Accreditation Board for Laboratories
NRCP	National Residues Control Plan
OJ	Official Journal of the European Union
PAH	Polycyclic Aromatic Hydrocarbons
PCBs	Polychlorinated Biphenyls
RASFF	Rapid Alert System for Food and Feed
SFD	State Fisheries Department
TVB-N	Total volatile basic-nitrogen

1 INTRODUCTION

The audit took place in India from 3 to 14 March 2014 and was undertaken as part of the Food and Veterinary Office's (FVO) audit programme. The audit team comprised five auditors from the FVO. The current audit was a joint audit covering two scopes regarding fishery and aquaculture products intended for export to the European Union (EU), one evaluating the control systems and operational standards in the residues sector and the other focusing on public health controls of the production system for fishery products. For each scope, an individual report is produced. This report covers the evaluation of the control systems in place governing the production of fishery products intended for export to the EU. The report dealing with residues monitoring aspects has the following reference: DG(SANCO)/2014-7029.

2 OBJECTIVES AND SCOPE OF THE AUDIT

The objectives of the audit were:-

- To evaluate whether the official controls put in place by the Competent Authority (CA) can guarantee that the conditions of production of fishery products in India destined to be imported into the EU are in line with the requirements laid down in EU legislation, and in particular with the health attestations contained in the health certificate laid down in Appendix IV to Annex VI to Commission Regulation (EC) No 2074/2005.
- To verify the extent to which the guarantees and the corrective actions submitted to Commission services in response to the recommendations of a previous FVO fishery products audit report of 2011 have been implemented and enforced by the CA.

In terms of scope the audit focused on the organisation and performance of the CA, the export certification procedure, the official control system in place covering production, processing and distribution chains applicable to fishery products to be exported to the EU. Accordingly, relevant aspects of the EU legislation referred to in Annex 1 were used as a technical basis for the audit.

In pursuit of this objective the audit team proceeded as follows:-

- an opening meeting was held in New Delhi on 3 March 2014 with the Central CA (CCA). At this meeting the audit team confirmed the objectives of, and itinerary for the audit, and requested additional information required for the satisfactory completion of the audit.
- the following sites were visited:

COMPETENT AUTHORITY ¹		
Central level	1	The Export Inspection Council (EIC): New Delhi
Regional level	2	The Export Inspection Agency (EIA) and the Marine Products Export Development Authority (MPEDA): Kerala
Local level	1	The National Centre for Sustainable Aquaculture(NACSA) under MPEDA: Andhra Pradesh
LABORATORY VISITS		
EIA laboratory	1	Kerala
EIC approved private laboratory	1	Kerala

¹ Competent Authority, including bodies to which the CA has delegated certain control tasks

PRIMARY PRODUCTION		
Aquaculture farms	1	Andhra Pradesh
Fishing vessels	5	Andhra Pradesh and Kerala
LANDING AND FIRST SALE		
Landing sites/ auction halls/ wholesale markets	2	Andhra Pradesh and Kerala
FACILITIES HANDLING FISHERY PRODUCTS		
Processing Plants	7	Andhra Pradesh and Kerala
Cold store	1	Andhra Pradesh

3 LEGAL BASIS FOR THE AUDIT

The audit was carried out under the general provisions of EU legislation and, in particular:

- Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare.

Full EU legal references are provided in Annex 1. EU legal acts quoted in this report refer, where applicable, to the last amended version.

4 BACKGROUND

4.1 GENERAL BACKGROUND

India is presently listed in Annex II to Commission Decision 2006/766/EC establishing the list of third countries and territories from which imports of fishery products in any form for human consumption are permitted. India is also included in the list of third countries (Annex to Commission Decision 2011/163/EU), which have an approved residue monitoring plan and therefore can export aquaculture fishery products to the EU.

The last FVO audit took place in 2011 (ref. DG(SANCO)/2011-8898), which highlighted a continuing lack of official controls of primary production in the fish sector; a recurring problem since the sector was first audited in 2005. The report – published on the Health and Consumers Directorate-General (SANCO) Internet site http://ec.europa.eu/food/fvo/ir_search_en.cfm – made a number of recommendations in respect of the action required from the CA. Written guarantees were received from the CA in relation to the implementation of actions aimed at addressing those recommendations.

4.2 PRODUCTION AND TRADE INFORMATION

In 2012 and 2013, according to information provided by Eurostat, respectively about 149,000 and 155,000 tonnes of fishery products were exported to the EU (Table 1). The main commodities were cephalopods (over 50%) and shrimps (30%). The main importing member states are United Kingdom, Spain, Italy, France and Belgium.

According to the list established by the CA and available on the DG SANCO website (list valid as

of 13/12/2013), imports of fishery products from India into the EU are authorised from a total of 285 processing establishments, including 215 establishments processing only or partially raw materials derived from aquaculture, and 43 cold stores. No freezer or factory vessels are listed.

This list is available on the SANCO web site at the following address:

http://ec.europa.eu/food/food/biosafety/establishments/third_country/index_en.htm

Table 1 summarises the exports from India of fishery products to the EU.

**Table 1 - Exports of fishery products from India to the EU (tonnes)
(source Eurostat)**

Commodity	2012	2013
Fish, chilled	603	705
Fish, frozen	4,695	4,534
Fish fillets, fish meat, fresh, chilled, frozen	4,774	5,158
Fish, smoked, dried, salted or in brine	15	0
Crustaceans (shrimp)	54,980	59,195
Cephalopods	72,272	73,039
Fats and oils	0	3
Prepared or preserved fish	7,515	6,262
Crustaceans, molluscs, prepared, preserved	4,157	6,176
Total export to the EU	149,011	155,072

4.3 RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS

From 01 January 2012 to 01 february 2014:-

- Regarding fish and fishery products exported to the EU, 17 RASFF notifications were issued, mainly concerning unauthorised use of additives, histamine and poor hygiene conditions.
- Regarding cephalopods and products thereof exported to the EU, nine RASFF notifications were issued, of which six were linked to the presence of cadmium exceeding the regulatory limits.
- Regarding crustaceans and products thereof exported to the EU, 20 RASFF notifications were issued, mainly concerning the presence of residues of veterinary medicinal products. More detailed information is provided in the report DG(SANCO)/2014-7029 – MR DRAFT.

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION

Legal requirements

Article 46(1)(a) of Regulation (EC) No 882/2004.

Article 11(4)(a) of Regulation (EC) No 854/2004.

Findings

With regard to fish and fishery products, the main applicable legislation remains the Government of India (GOI) Order N° SO 729 (E) and Notification N° SO 730 (E), dated 21.08.1995, laying down “General Food Law”, as last amended. Since coming into force, various amendments to the above mentioned legislation have been published.

The team noted that:-

- The following amendment: Notification SO 497 (E), from 10 March 2011, empowers the CA to have access to all parts of the production chain. It also enables the CA to carry out official controls (approval and official inspections) on primary production (aquaculture farms and fishing vessels), landing and first sale facilities that supply fishery products to EU approved processing establishments.
- However, no deadline has been set after which the non-approved primary producers could no longer supply EU export processing establishments.
- Moreover, the CA informed the team that official inspections on aquaculture farms and fishing vessels are restricted to those that request for and obtain approval.

Conclusions

A legal framework covering the production of fishery products intended for export to the EU is in place. However, even though there is a general obligation for the CA to carry out official controls over primary production, the lack of a clear deadline for implementing this obligation does not allow the CA to provide credible guarantees that primary producers involved in the production chain for EU export will be officially monitored either now or in the foreseeable future.

5.2 COMPETENT AUTHORITY

Legal requirements

Article 46 of Regulation (EC) No 882/2004, in particular points b) to (e), (g) and (h) of the aforementioned Article. Points g) and h) are covered in Section 5.4 of this report.

Findings

Structure and organisation

The Export Inspection Council of India (EIC) under the Ministry of Commerce and Industry is the CCA for the EU export fishery products production chain in India.

The Export Inspection Agencies (EIA), responsible for official controls at regional level, are under the administrative and technical control of EIC. There are five EIA in India, of which four deal with

fishery products (Mumbai, Kolkata, Chennai and Kochi). Sub-offices at local level operate under the control of regional EIA.

The team noted that EIA officials have the necessary means for performing their tasks, which include amongst others, vehicles, communication equipment/computers, material for sample collection, etc. They also have access to laboratories for the performance of official testing of fishery products.

The CA has delegated specific tasks related to official controls to the Marine Products Export Development Authority (MPEDA), which is also under the Ministry of Commerce and Industry.

The team noted that:-

- MPEDA has been delegated the responsibility to oversee the implementation of the National Residues Control Plan (NRCP), in accordance with the provisions laid down in GOI Notification N° SO 1034 (E) dated 09/09/2003.
- MPEDA is also responsible for pre-harvest sampling of aquaculture products for residue testing. This testing is performed in MPEDA testing laboratories using the ELISA method.

As regards the fish sector, the audit team also noted that many different players are involved for different purposes, in administrative tasks that are also relevant for the official controls carried out by EIC, in particular with regard to aquaculture farms and fishing:-

- MPEDA issues catch certificates for exports to the EU; for this purpose, fishing vessels which need to supply fishery products to EU approved processing establishments are allocated a unique ID number. According to MPEDA, to date, 40,844 fishing vessels have been issued with this unique ID number.
- MPEDA has, per order EIC/D(Q/C)/T-1/11-12 dated 2nd January 2012, been appointed as a designated agency for registration of farms supplying aquaculture products for export, as well as of hatcheries and feed mills supplying seed & feed to these farms.
- The Coastal Aquaculture Authority of India (CAA), is responsible, under the Aquaculture Act/2005, for the registration and monitoring (environment and sustainability) of coastal aquaculture farms, which are located within two kilometres from the coastline.
- The State Fisheries Departments (SFD) are responsible for the registration of fishing vessels for the purpose of issuing fishing licenses to fisherman. SFD is also responsible for the registration of fresh water aquaculture farms, which are located beyond two kilometres from the coastline.
- Food Safety & Standards Authority of India, under the Ministry of Health & Family Welfare is responsible for import controls and the domestic market.
- The seafood exporters association can also provide information relevant to Food Business operators (FBOs) in the fish sector.

Powers, Independence and Supervision

The powers and responsibilities of EIC are based upon provisions laid down in the Export (Quality Control and Inspection) Act, 1963 as last amended. EIC is empowered to enter and inspect

premises, check hygiene conditions and relevant documentation, collect samples for analysis and impose sanctions, such as issuing warnings, imposing fines, withdrawing authorisations or approval, restricting or prohibiting placing on the market. The team was provided with examples of actions taken in cases of non-compliance and sanctions imposed.

However the team was informed by the CA that currently EIC has no power to perform inspections on aquaculture farms or fishing vessels that are not approved. Furthermore, in one region visited, the team noted that, following an unsatisfactory assessment of 15 fishing vessels, which applied for approval (see chapter 5.4.1 below), no measures were taken by the CA to exclude these vessels from the EU production chain.

Regarding verification procedures, the team noted that supervision of the performance of official controls is carried out at different levels according to specific procedures:-

- Corporate audits are carried by EIC over EIA and sub-offices once a year.
- Supervisory audits are carried out by the senior officer of EIA to check the effectiveness of official controls implemented at establishment level, twice a year.
- In addition, monthly reports are regularly sent by sub-offices to EIA, which also report to EIC on a monthly basis.

Training

Regarding training of staff involved in official controls of fishery products, the team noted that:-

- Regular training programmes for officials have been organised to ensure uniform implementation of the procedures by EIA and the sub-offices.
- The knowledge of EU requirements by officials in charge of the controls was, in general, adequate.

Documented Control Procedures

The team noted that official document No EIC/F&FP/Ex. Inst./March / 2012/ Issue 4 (Executive instructions for approval and monitoring of fish and fishery products for export) has been issued by EIC. This document includes detailed procedures and instructions for staff performing official controls (approval and official inspections) of facilities including establishments involved in the export production chain.

Regarding reporting procedures, the team noted that inspection reports were available in all the establishments visited; examples of inspection reports reviewed by the team showed that reports included descriptions of deficiencies as well as requests for corrective actions, including deadlines for completion, where needed.

Regarding control activities, methods and techniques, the team noted that tasks related to official controls are, in general, carried out by EIA officials, using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.

Conclusions

The CA responsible for official controls on fishery products is clearly designated and has an adequate structure and organisation for the performance of its official control tasks. Official staff

knowledge of EU requirements was found satisfactory and adequately maintained by regular training. Updated documented procedures are in place to support official staff with their duties to guarantee the compliance of fishery products with EU equivalent standards. However gaps were identified in enforcement at primary production control level.

5.3 NATIONAL PROVISIONS AND PROCEDURES FOR LISTING ESTABLISHMENTS EXPORTING TO THE EU

Legal requirements

Article 12(1) and (2) of Regulation (EC) No 854/2004.

Part I.11. of the model health certificate for imports of fishery products intended for human consumption established in Appendix IV to Annex VI to Regulation (EC) No 2074/2005.

Findings

A list of EU approved establishments was available on the EIC website.

Regarding establishments that are EU listed (processing plants and cold stores), the approval procedure is as follow:-

- The FBO sends an application including supporting documents (lay-out, descriptions, HACCP manual, etc.) to concerned EIA for approval. Simultaneously FBO completes the procedure for getting the registration from MPEDA.
- If the file is judged satisfactory, a joint inspection group, (Assessment Panel of Experts), formed with representatives from EIA, MPEDA and the Central Institute of Fish Technology, visit the establishment to assess the infrastructure facilities and other requirements.
- Following a satisfactory assessment report, a conditional approval is granted for three months.
- After that, a second inspection by the panel takes place, mainly focusing on the implementation of the HACCP manual.
- If the report of this second visit is positive, a final approval is granted by EIC, which proposes the listing of the establishment to the EU Commission.
- Approvals are renewed every second year. An official notification of the attribution of approval for a specific activity was available in the establishments visited.

According to the list established by the CA and available on the DG SANCO website (list valid as of 13/12/2013), imports of fishery products from India into the EU are authorised from a total of 285 processing establishments, including 215 establishments processing only or partially raw materials derived from aquaculture, and 43 cold stores. No freezer or factory vessels are listed.

Conclusions

There is a system in place for approval and listing of establishments authorised to export to the EU in line with EU requirements. EIC keeps an up to-date list of approved establishments.

5.4 OFFICIAL CONTROLS

5.4.1 *Official controls of production and placing on the market*

Legal requirements

Article 12(2) and Article 11(4) of Regulation (EC) No 854/2004.

Requirements contained in point II.1 and point II.2 in case of aquaculture products of the model health certificate for imports of fishery products intended for human consumption established in Appendix IV to Annex VI to Regulation (EC) No 2074/2005, in particular official controls laid down in Annex III, Chapter I of Regulation (EC) No 854/2004.

Article 11(4) of Regulation (EC) No 854/2004 establishes that EU controls shall take particular account of the extent and operation of official controls on imports of animals and their products and the assurances which the third countries can give regarding equivalence to EU requirements (Article 46(1)(g) (h) of Regulation (EC) No 882/2004).

Findings

Official control system in place

Official controls are carried out by EIA officials, which are responsible for controlling the whole chain of production of fishery products, including aquaculture farms, fishing vessels, landing/first sale sites, processing establishments and cold stores.

The minimum frequency of official controls varies according to the type of establishment. For the primary production (aquaculture farms and fishing vessels), landing and first sale, official inspections are scheduled every six months. For processing establishments including cold stores, official inspections are carried out monthly; however, the inspection frequency may vary depending on the results of the previous year's inspections (every two or three months).

Standardised checklists have been developed to facilitate the performance and consistency of official controls in the fish sector.

A non-conformity report specifying deadlines for corrections where appropriate is prepared after each inspection and a request for corrective actions is sent to the establishment, which generally sends a reply within a month. Results of inspections of establishments are summarised in monthly reports prepared at local and regional levels.

Primary production

Under national legislation, aquaculture farms and fishing vessels that supply EU approved establishments can apply for approval. Facilities are only included in a programme of regular inspections once they have received approval.

With regard to this approval process, the team was informed by the CA that a letter dated 7 March 2013 was sent by EIC to the Seafood exporter association, requesting that the EU listed establishments provide a list of their suppliers to the relevant EIA. Following these instructions, a voluntary process of submission of applications from suppliers to EU listed establishments started.

Regarding primary production, landing and first sale facilities, the team noted that the approval procedure is as follow: the FBO sends an application including supporting documents (e.g. licence for fishing vessels). Then an on-site inspection is carried by an "Inter Assessment Panel" composed

of two EIA officials in order to assess the facilities. Following a satisfactory assessment, an approval is granted by EIC for three years.

A: Aquaculture farms

According to EIC, by March 2014, 108 aquaculture farms had been approved in India, out of approximately 48,000 registered by different authorities (MPEDA, CAA and SFD). The deadlines by which the approval of aquaculture farms will be completed have not been established.

In one region visited, the team noted the following:-

- The approval of aquaculture farms, which is legally possible since 2011, had only started to be implemented very recently (end of 2013); and at the time of the audit, 26 aquaculture farms had been officially approved by EIA out of 36,000 registered in this region.
- Only a few official inspections, scheduled every six months, of these approved farms had taken place very recently (February 2014), using a standardised checklist.
- In the same region, the team visited one aquaculture farm (*Litopenaeus Vannamei* - shrimp) and noted the following:-
 - Official approval for this aquaculture farm has been granted recently (end of 2013) by EIC for three years, in accordance with the instructions and procedures in place.
 - Own-checks records of the production pond by pond (growth, mortality, use of feeding stuffs, harvest and dispatch, etc.) were kept by the farmer in a standardised document. Own-checks also cover water quality (source, purification, salinity, temperature, pH, etc.), cleaning, sanitation, pest controls, biosecurity measures, etc.

B: Fishing vessels

According to EIC, 787 fishing vessels have been approved to date in India, out of 72,749 fishing vessels registered by SFD, of which 40,844 have been issued with a unique ID number by MPEDA (see chapter 5.2 above). The deadlines by which the approval of fishing vessels will be completed have not been established.

In one region, the team visited one fishing port and noted that:-

- 528 licenses for fishing have been granted by SFD, which informed the team that this figure corresponded to the number of fishing vessels currently in operation in the fishing harbour.
- At the time of the audit, 22 fishing vessels had been recently approved (end of 2013) by EIC in accordance with the instructions and procedures in place; and 25 applications for approval were still pending.
- No official inspection of these approved fishing vessels has been carried out so far.

In another region, the team visited also one fishing port and noted that:-

- 411 licenses for fishing had been granted by SFD.
- No fishing vessel had been approved by EIC. The team was informed by the CA that 78

applications for approval were received by EIA in August 2013, of which 42 were automatically rejected (no license for fishing), 15 were assessed and considered as non-compliant and 21 are pending. No measures had been taken by the CA to exclude the 15 vessels considered as non-compliant from the EU production chain.

Landing and first sale

In India, according to EIC, there are 23 landing sites, which have been officially listed to be approved for export to the EU. To date, five have been officially approved.

In one region, the team visited one approved landing and first sale site, which was not in operation, and noted the following:-

- The site, under the management of SFD was constructed by the Port Authority to accommodate 410 small fishing vessels (12m) and 15 shrimp trawlers. There were initially two auction halls; however, in 2005, one of the auction halls was converted into 28 compartments, designed to maintain fishery products landed in good hygienic conditions. The site has an ice producing unit, which was not in operation at the time of the visit. Auctions are performed as soon as the fish is landed.
- Official approval for this site has been granted recently (September 2013) by EIC for three years, in accordance with the instructions and procedures in place.
- An official inspection, scheduled every six months, took place very recently in November 2013, using a standardised checklist; however, no official controls of fishery products (organoleptic checks, histamine, contaminants, parasites, etc.) and no official control of the quality of water and ice used on site had been performed.
- Daily own-checks at the site (temperature of fishery products at landing, sanitation and hygiene requirements) are carried out by a hygiene officer of the Port Authority, using checklists. However, there were no checks on the freshness of the fishery products at landing, no sampling to check the quality of water and ice used on site, no pest controls, etc. These checks started in January 2014.

In another region, the team visited also one approved landing and first sale site, which was in operation and noted the following:-

- Among the positive points, the site had a restricted access to public and vehicles; the auction hall dedicated for export, together with the ice plant and the chilled rooms attached presented acceptable conditions, with an effective protection against the entry of birds; two wash-hand basins were available; pest controls were in place.
- However, the team noted significant shortcomings, such as: open-air storage of unclean plastic crates used for fishery products, not respecting the requirements of Points a) and b), section 1, Chapter V, Annex II, of Regulation (EC) No 852/2004; lack of changing rooms, insufficient number of toilets and showers as foreseen in section 9, Chapter I, Annex II, of Regulation (EC) No 852/2004; open air sewage discharge not providing full protection against accumulation of dirt and contact with toxic materials, as laid down in Points a) and b), section 2, Chapter I, Annex II, of Regulation (EC) No 852/2004.
- An official approval for this site has been granted recently on (October 2013) by EIC for three years, in accordance with the instructions and procedures in place.

- An official inspection, scheduled every six months, took place very recently at the beginning of 2014, using a standardised checklist; only organoleptic checks records, which were not carried out in line with EU requirements and results of swabs tests on surface were available. No official control of the quality of water and ice produced on site had been performed;
- Own-checks were poorly implemented, as they were generally favourable and therefore in contradiction with the findings of the team; water testing (tank level) had just started to be implemented, but ice testing was not yet carried out; results of swab tests on plastic crates and surfaces, pest controls, temperature records of fishery products and checks on the freshness of the fishery products at landing were available.

Facilities, including vessels, handling fishery products

The team visited seven processing plants including establishments dealing with aquaculture products and one cold store.

From a general point of view, these establishments presented good conditions regarding structure, equipment, maintenance and hygiene. The team noted minor deficiencies that can be easily corrected.

In the establishments visited, the team could verify the traceability system in place. End products could be traced back to the level of aquaculture farms or fishing vessels.

Official controls on the water supply

The team noted that:-

- In the landing sites/auctions visited, no official sampling and testing of the quality of water and ice used or produced on site had been performed.
- In the processing establishments visited, water and ice samples taken by EIA officials are regularly tested against the requirements of Council Directive 98/83/EC (*Escherichia coli*, *Enterococci*, *Clostridium perfringens*), once every two years (full set of microbiological and chemical analyses) and every six months (Annex I, part A of the said Directive) in an EIC approved laboratory.

HACCP-based procedures

The team noted that:-

- HACCP-based procedures, which generally describe and address the hazards related to the product, were available in all establishments visited. However, in one establishment, inconsistencies in the HACCP plan were identified, mainly concerning the identification of critical points or critical control points following a hazard analysis.
- HACCP plans reviewed during the audit were adequately implemented.
- HACCP plans implemented by the FBOs are assessed during the approval process and checked during official inspections and supervisory audits.
- Own-checks (training for staff, medical certificates, pest controls, swab tests, etc.) were found to be correctly implemented in the establishments visited.
- Own-checks analyses (microbiology and chemistry) of fishery products and water/ice are performed on a regular basis, either in in-house laboratories, private or official laboratories.

Checks on the EU eligibility of imported raw materials

The team was informed by the CA that there are no imports of fishery products as raw material used for processing and onward exported to the EU.

Conclusions

While nominally there is an official control system in place covering the production chain of fishery products intended for export for the EU, confidence in the system is undermined by the lack of implementation of these controls, notably at primary production level, landing and first sale sites, where such controls have only begun to be implemented. To date, very few aquacultures farms and fishing vessels have been approved by EIC and only a small percentage of those approved have been subject to official inspection. Moreover, the two recently approved landing and first sale facilities visited were not fully in line with EU requirements. Finally, the situation has not significantly improved since the last FVO audits and recommendations No 1, 2 and 3 of the preceding FVO report from 2011 cannot be considered as satisfactorily addressed.

With regard to processing activities, including cold stores, official controls are carried out in line with EU requirements. From a general point of view, establishments visited during the audit were found to be in good conditions regarding structure, equipment, maintenance and hygiene. In general, HACCP plans and own-check programmes reviewed during the audit were in line with EU requirements and were adequately implemented by FBOs. Although official controls on water and ice are carried out in line with EU requirements at processing level, they are not implemented at landing and first sale level.

5.4.2 Official controls of fishery products

Legal requirements

Point II.1 of the model health certificate for imports of fishery products intended for human consumption established in Appendix IV to Annex VI to Regulation (EC) No 2074/2005, in particular official controls laid down in Annex III, Chapter II of Regulation (EC) No 854/2004.

Findings

Organoleptic examinations

Requirements at least equivalent to those laid down in Regulation (EC) No 854/2004, Annex III, Chapter II, (point a).

The team noted that:-

- Written evidence of organoleptic checks carried out by EIA officers was available in one of the two landing sites visited and in all the processing establishments visited. These checks are performed on a certain number of samples during official inspections.
- However, the checklist used by EIA officials was not in line with the requirements laid down in Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products.

Freshness indicators: Total Volatile Basic-Nitrogen (TVB-N)

The team noted that TVB-N testing can be used in case of doubt by EIA officials during official inspections in the processing establishments.

Histamine

The team noted, in one establishment processing fish species associated with a high amount of histidine, that testing for histamine is regularly performed, during official monitoring (every six months) and prior to export (Pre-export testing). During official monitoring, nine samples of fishery products (if available) are taken by EIA officials and analysed in an EIA laboratory. Prior to export: nine samples of fishery products are taken by a laboratory sampler and analysed in an EIC approved laboratory.

Residues and contaminants

The team noted that testing for residues and contaminants is regularly performed in processing establishments, during official monitoring (every six months) and prior to export (Pre-export testing):-

- During official monitoring: samples of fishery products are taken by EIA officials and analysed for heavy metals (cadmium, lead, mercury), and antibiotic residues, in an EIA laboratory.
- Prior to export: samples of fishery products are taken by a laboratory sampler and analysed for cadmium for each cephalopod consignment and antibiotic residues for each shrimp consignment in an EIC approved laboratory.
- The official testing for Polychlorinated biphenyls (PCBs) and dioxins is carried out in the framework of the NRCP for aquaculture fishery products.

Microbiological checks

The team noted that in the processing establishments visited, samples of fishery products (raw material or final product) are taken during official inspections by EIA officials for microbiological analyses. Testing includes the following parameters, depending on the type of fishery products - e.g. Total Plate Count, coliforms, *Staphylococcus aureus*, *Salmonella*, *Vibrio Cholera* and *Vibrio Parahaemolyticus*.

Parasites

The team noted that visual checks are carried out and recorded by EIA officials during official inspections in the processing establishments.

Poisonous fishery products

According to the instructions and procedures in place, poisonous fishery products shall not be processed for export.

Conclusions

Official controls of fishery products intended for EU export are implemented in line with EU requirements, except for organoleptic checks, which are not carried out at landing and first sale site against requirements at least equivalent to those laid down in Council Regulation (EC) No 2406/96.

5.5 FOLLOW UP OF RASFF NOTIFICATIONS

Legal requirements

Article 11(4) of Regulation (EC) No 854/2004 establishes that EU controls carried out in the context of drawing up or updating lists of third countries from which imports of products of animal

origin are permitted, shall take particular account of amongst other factors: any experience of marketing of the product from the third country and the results of any import control carried out.

Findings

In one processing establishment involved in a RASFF notification for the presence of residues of veterinary medicinal products in frozen shrimp (*Litopenaeus Vannamei*) exported to the EU, the team could verify that the follow-up of this RASFF notification was performed by the CA, according to the instructions and procedures in place. The consignment was traced back to the original establishment and the root-cause investigated back to the farm level. However, the origin of the contamination was not found.

The residues team also examined six RASFF notifications relating to aquaculture products in two EIA offices and two EU approved processing establishments and noted some non-compliances (see report DG(SANCO)/2014-7029 – MR DRAFT).

Conclusion

From a review of one case carried out on the spot, internal procedures to try to identify and rectify the root cause of non-compliant consignments exported to the EU were followed.

However, taking into account the findings noted by the residues team, the procedures in place do not provide equivalent guarantees to those laid down in Articles 16-18 and 22-27 of Directive 96/23/EC (see report DG(SANCO)/2014-7029 – MR DRAFT).

5.6 LABORATORIES

Legal requirements

Article 46(1)(d) and (c) of Regulation (EC) No 882/2004.

Points 41 and 42 of Guidelines of Codex Alimentarius CAC/GL 26-1997 on the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.

Chapter 1 of Annex I to Regulation (EC) No 2073/2005 and Section II of Annex II to Regulation (EC) No 2074/2005.

Regulations (EC) No 333/2007 and Regulation (EU) No 252/2012.

Findings

Each EIA has its own laboratory to carry out official analyses on fishery products. Private laboratories also perform official analyses on fishery products. Both EIA and private laboratories are approved by EIC (EIC Laboratory Approval Scheme). Accreditation to ISO/IEC 17025 by the national accreditation body (the National Accreditation Board for Laboratories - NABL) is a pre-condition for the EIC approval.

Official samples are collected at processing level either by EIA officials or laboratory samplers (pre-export testing).

The FVO team dealing with public health aspects visited two EIC approved laboratories, one EIA laboratory in Kochi and one private laboratory in Aroor performing analyses of, inter alia, fishery products, water and ice.

The team noted that:-

- In both laboratories, microbiological and chemical analyses relevant for EU exports have been included in the scope of NABL accreditation. The latter body is a member of ILAC and APLAC.
- With regard to fishery products, the scope of accreditation includes the following analytical reference methods used: TVB-N, histamine, *Listeria monocytogenes* (ready to eat food) and *Salmonella* (cooked crustaceans) and heavy metals (lead, cadmium and mercury).
- As regards water and ice, the scope of accreditation includes the following analytical reference methods used: *Escherichia coli*, *Enterococci* and *Clostridium perfringens* (surface water).

The EIA laboratory uses:-

- AOAC instrumental methods for screening of *Salmonella* and *Listeria* in food samples, which were validated against EU reference methods.
- Atomic Absorption Spectroscopy (AAS) method for heavy metals.
- High Performance Liquid Chromatography (HPLC) method for histamine, using nine samples of fishery product.

In the private laboratory, internal methods (as in-house validated to reference methods) are indicated in the accreditation scope; in the standard operating procedure for histamine, reference was made to a method published in scientific literature (Journal of Chromatography, A, 1032, 2004, 79-85).

The EIA laboratory visited regularly participates in proficiency testing (FAPAS) and inter-laboratory comparative testing schemes (MPEDA) for various matrix/parameter combinations. Since 2011, fish matrix has been included in these schemes three times for heavy metals and once for microbiological parameters (*Vibrio cholerae*) and for histamine (canned fish).

The private laboratory participated in FAPAS proficiency tests for histamine in 2009 and 2011. The laboratory also participated in inter-laboratory comparative testing schemes for TVB-N, heavy metals, antibiotics and pesticides (overview provided since 2012).

The team noted that both laboratories had acceptable z scores for the tests described above.

The FVO team dealing with residues monitoring aspects also checked some analytical methods relevant to the public health side such as histamine, heavy metals, dioxins and polychlorinated biphenyls (PCBs).

Methods relevant for histamine and contaminants in fishery products were checked in four laboratories visited by the residues team: two EIA laboratories in Chennai and Kochi and two private laboratories approved by EIC.

The residues team noted that:-

- Accredited instrumental methods for testing histamine and heavy metals on fishery products were available in both the EIA and private laboratories visited. However, in case of methods for heavy metals operated in EIA Kochi, the accredited concentration range for cadmium²

² In their response to the draft report, the CA noted that, subsequent to the audit, EIA-Kochi laboratory has validated its analytical method for cadmium as per Regulation (EC) No 836/2011 and LOD established is 10ug/kg & LOQ

(0.15 mg/kg) was higher than the respective Maximum Level (ML) foreseen for muscle meat of fish (0.05 mg/kg) in Commission Regulation (EC) No 1881/2006 whilst for lead the accredited concentration range was equal to the ML.

- An accredited method for non-dioxin-like PCBs was available in EIA Chennai and a method for dioxins and dioxin-like PCBs was under development. There were neither methods in place for testing dioxins and PCBs on fishery products in the other EIA laboratories nor any formal agreement to process such samples in private laboratories.
- Method Standard Operating Procedures and validation files for histamine were checked in both EIA laboratories visited and were considered adequate as was the method of reporting laboratory results.
- Two validation files for cadmium were also examined in the EIA laboratories visited. In EIA Chennai the method in use was adequately validated for shrimp only, as wild caught fish is rarely tested. In EIA Kochi the method for cadmium³ was validated only at one concentration level of 0.5 mg/kg which is not sufficient to demonstrate adequate method performance for fish and fishery products destined for export to the EU. This shortcoming was not noted during previous audits carried out by the EIC.
- None of the laboratories visited had access to certified reference materials, control materials or in-house control samples. Only control samples spiked at the ML were used for quality control purposes.
- The laboratories visited have participated in proficiency tests and interlaboratory comparisons for heavy metals and histamine with satisfactory results.

Conclusions

The laboratories responsible for official analyses on fishery products have put in place measures aimed at ensuring a satisfactory level of analytical performance. However, with regard to cadmium, dioxins and PCBs, these measures have not been duly implemented. This undermines the ability of the CA to ensure that fishery products with contaminant levels exceeding EU MLs are not exported to the EU.

5.7 OFFICIAL CERTIFICATION

Legal requirements

Article 14 of Regulation (EC) No 854/2004.

Article 6 of Regulation (EC) No 2074/2005, in particular the model health certificate for imports of fishery products intended for human consumption established in its Appendix IV to Annex VI.

Article 6 of Directive 96/93/EC.

Findings

The team noted the following:-

being 18ug/kg.

3 See footnote no 2

- Health certificates for export of fishery products to the EU were signed by EIA officials.
- According to the instructions and procedures in place, the exporter has to send an application to EIA including MPEDA pre-harvest sampling results, pre-export testing results (antibiotic residues for aquaculture products, cadmium for cephalopods and histamine for fish), packing lists, invoices and attestations.
- Prior to export, identity checks to ascertain that the products correspond to the information given in the accompanying certificates, are not carried out by EIA officials. This task has been delegated to an EIA approved technologist from the exporting establishment, who verifies and certifies the data relevant for issuing the health certificate, using a specific form.
- The model of health certificate in use is the appropriate one, in line with the requirements laid down in Commission Regulation (EC) No 2074/2005. However, as official controls over primary production have only started very recently (see section 5.4.1 above), the CA is not, generally, in a position to certify that fishery products intended for export to the EU have been caught and handled on board vessels and landed in line with the requirements laid down in Section VIII, chapter I to III of Annex III to Regulation (EC) No 853/2004.

Conclusions

Procedures aimed at ensuring a proper certification of fishery products intended for export to the EU are in place. However, the lack of official controls over primary production undermines the ability of the CA to guarantee that non-eligible fishery products are not exported to the EU.

6 OVERALL CONCLUSION

The competent authority has implemented an official control system for fishery products intended for export to the EU which adequately covers processing activities.

However, official controls in relation to primary production, landing and first sale have only started very recently and are at a very early stage of implementation. To date, very few aquacultures farms and fishing vessels have been approved and only a small percentage of those approved have been subject to official inspection. Furthermore, the two recently approved landing and first sale facilities visited were not fully in line with EU requirements. Consequently, the situation has not significantly changed since the fish sector was first audited in 2005.

From a general point of view, processing establishments visited during the audit were found to be in good condition regarding structure, equipment, maintenance and hygiene. In general, own-check programmes reviewed during the audit were in line with EU requirements and were adequately implemented by the food business operators.

Official controls of fishery products intended for EU export are implemented in line with EU requirements, except for organoleptic checks at landing and first sale site.

The laboratories responsible for official analyses on fishery products have put in place measures aimed at ensuring a satisfactory level of analytical performance. However, with regard to cadmium, dioxins and polychlorinated biphenyls, some shortcomings have been identified, which undermine the ability of the competent authority to ensure that fishery products with contaminant levels exceeding EU maximum levels are not exported to the EU.

Finally, the lack of official controls over primary production also undermines the ability of the competent authority to guarantee that non-eligible fishery products are excluded from export to the EU.

7 CLOSING MEETING

At the closing meeting held in New Delhi on 14 March 2014, the team presented the main findings and preliminary conclusions of the audit to the CA.

During this meeting, the CAs acknowledged the findings and preliminary conclusions presented by the team.

8 RECOMMENDATIONS

The CA should provide Commission services with an action plan, including a timetable for its completion, within one month of receipt of the report, in order to address the following recommendations for fishery products exported to the EU.

N°.	Recommendation
1.	The CA should ensure that the necessary powers to adequately implement and enforce an official control system to monitor primary production within a realistic timeframe are put in place in line with the requirements laid down in point 1 (b), Article 46 of Regulation (EC) No 882/2004.
2.	The CA should ensure that aquaculture farms that supply fishery products to EU approved establishments are regularly inspected to verify whether they comply with requirements at least equivalent to the general hygiene provisions laid down in Part A of Annex I to Regulation (EC) No 852/2004.
3.	The CA should ensure that fishing vessels that supply fishery products to EU approved establishments comply with requirements at least equivalent to the the general hygiene provisions laid down in Part A of Annex I to Regulation (EC) No 852/2004 and the specific requirements laid down in Chapter I, section VIII of Annex III to Regulation (EC) No 853/2004.
4.	The CA should ensure that fishing vessels that supply fishery products to EU approved establishments are regularly inspected to verify whether the fishery products are handled correctly, the cleanliness of vessels and their equipment, staff hygiene and to check for compliance with the applicable hygiene and temperature requirements as laid down in point 1 (b), chapter I of Annex III to Regulation (EC) No 854/2004.
5.	The CA should ensure that landing and first sale sites supplying fishery products to EU approved establishments comply with requirements at least equivalent to the the general hygiene requirements laid down in Annex II to Regulation (EC) No 852/2004 and the specific requirements laid down in section VIII of Annex III to Regulation (EC) No 853/2004.
6.	The CA should ensure that official controls on the production of fishery products intended for export to the EU include regular checks on the hygiene conditions of landing as laid down Point 1 (a), Chapter I of Annex III to Regulation (EC) No

N°.	Recommendation
	853/2004.
7.	The CA should ensure that a regular monitoring of the quality of water and ice used in landing and first sale sites supplying fishery products to EU approved establishments is carried out to check that water and ice available meet parametric values equivalent to the requirements laid down in Council Directive 98/83/EC.
8.	The CA should ensure that organoleptic checks of fishery products intended for export to the EU are carried out in line with the requirements laid down in Council Regulation (EC) No 2406/96.
9.	The CA should ensure that analytical performance of laboratories involved in the testing of fishery products intended for export to the EU for dioxins, PCBs and cadmium, is sufficient to provide assurances that consignments exported to the EU do not contain those contaminants above the limits set down in Commission Regulation (EC) 1881/2006.
10.	The CA must ensure that only fishery products that comply with the requirements set for in Part II.1 of the model of health certificate laid down in Regulation (EC) No 2074/2005 are exported to the EU, in particular that any raw materials or products used to produce fishery products intended for export to the EU are EU eligible.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2014-7136

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
Dec. 2006/766/EC	OJ L 320, 18.11.2006, p. 53-57	2006/766/EC: Commission Decision of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
Reg. 2406/96	OJ L 334, 23.12.1996, p. 1-15	Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products

Legal Reference	Official Journal	Title
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Legal Reference	Official Journal	Title
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Reg. 1883/2006	OJ L 364, 20.12.2006, p. 32-43	Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Reg. 1333/2008	OJ L 354, 31.12.2008, p. 16-33	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives