

**T.C.**  
**DIŐIŐLERİ BAKANLIĐI**  
AVBİR Daimi TemsilciliĐi

Faks ile  
29.05.2015

**Sayı** : 70946263-450.00-2015/7918245  
**Konu** : Türkiye'den AB'ye ihraç edilen çift kabuklu yumuŐakçalar ve balıkçılık ürünlerinin üretimini kontrolü

**EKONOMİ BAKANLIĐINA**

Avrupa Komisyonu SaĐlık ve Tüketiciler Genel MüdürlüĐü'ne (DG SANCO) baĐlı Gıda ve Veterinerlik Ofisi'nden (FVO) alınan ekteki mektupta Türkiye'den AB'ye ihraç edilen çift kabuklu yumuŐakçalar ve balıkçılık ürünlerinin üretimini kontrol amacıyla 8-17 Eylül 2015 tarihlerinde Türkiye'ye bir çalıŐma ziyareti gerçekleŐtirmek istendiĐi ifade edilmiŐtir. Sözkonusu ziyarete iliŐkin planlama ekte takdim kılınmıŐtır.

Bilgi ve gereĐini müsaadelerine saygılarımla arz ederim.

  
Selim YENEL  
Büyükelçi  
Daimi Temsilci

Ekler:2

**DaĐıtım:**

**GereĐi:**

Ekonomi Bakanlığı  
Gıda Tarım ve Hayvancılık Bakanlığı

**Bilgi:**

ABGY Avrupa BirliĐi Genel Müdür YardımcılıĐı

■ Ref. Ares(2015)2182956 - 26/05/2015



**EUROPEAN COMMISSION**  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Food and Veterinary Office  
Food of animal origin: birds and fish

DG(SANTE)/2015-7481

**ANNEX I**

# **PLAN FOR THE AUDIT TO BE CARRIED OUT IN**

## **TURKEY**

### **FROM 8 TO 17 SEPTEMBER 2015**

**IN ORDER TO EVALUATE THE CONTROL SYSTEMS IN PLACE  
GOVERNING THE PRODUCTION OF BIVALVE MOLLUSCS AND FISHERY  
PRODUCTS DERIVED THEREFROM INTENDED FOR EXPORT TO THE  
EUROPEAN UNION**

### **Note to the Competent Authority**

The audit plan is designed to provide information on the scope and depth of the audit. It indicates the main areas that the audit team will wish to examine, and is intended to assist both national authorities and the Food and Veterinary Office in its planning and preparation.

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THIS AUDIT PLAN

<b>CA</b>	Competent Authority
<b>EC</b>	European Community
<b>EU</b>	European Union
<b>FVO</b>	Food and Veterinary Office
<b>HACCP</b>	Hazard Analyses Critical Control Point

## 1. GENERAL INFORMATION

➤ **Dates of the audit:** 8 to 17 September 2015

The audit will be undertaken as part of the Food and Veterinary Office's (FVO) planned audit programme.

A representative of the Competent Authority (CA) should accompany the audit team throughout the audit.

➤ **Composition of the team(s)<sup>1</sup>:**

- Mrs Julia URIOL (Team leader – FVO),
- Mr Miguel MENDES (FVO),
- Two Member State national experts on laboratories.

## 2. OBJECTIVES OF THE AUDIT

The objectives of the audit are:

- To evaluate whether the official controls put in place by the CA can guarantee that the conditions of production of bivalve molluscs in Turkey destined for export to the European Union (EU) are in line with the requirements laid down in EU legislation, and in particular with the health attestations contained in the certificate of Appendix IV to Annex VI to Regulation (EC) No 2074/2005.
- To verify the extent to which the guarantees and corrective actions submitted to the Commission services in response to the recommendations of the previous FVO audit report of 2012<sup>2</sup> have been implemented and enforced by the CA.

## 3. LEGAL BASIS FOR THE AUDIT

The audit will be carried out under the general provisions of EU legislation<sup>3,4</sup> 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 rules.

## 4. AUDIT SCOPE AND DEPTH

The audit will focus 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 bivalve molluscs<sup>5</sup> to be exported to the EU. Accordingly, certain aspects of the EU legislation mentioned in the Appendix will be used as a technical basis for the audit. The audit team will pay particular attention to the ability of the CA to deliver the required standards and its implementation of national provisions, against which the CA controls those bivalve molluscs.

<sup>1</sup> Any change to the composition of the audit team will be provided at a later stage to the CA.

<sup>2</sup> ref. DG(SANCO)/2012-6544 - MR - FINAL, published on SANCO's website at [http://ec.europa.eu/food/fvo/audit\\_reports/details.cfm?rep\\_id=3031](http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=3031).

<sup>3</sup> All legal references, which can be found in the Appendix, refer, where applicable, to the latest amended version.

<sup>4</sup> EU legislation (Internet): <http://eur-lex.europa.eu/en/index.htm>

<sup>5</sup> The term bivalve molluscs means both live bivalve molluscs and fishery products derived from live bivalve molluscs.

The audit will cover the whole EU export bivalve molluscs' chain, in particular: live bivalve molluscs production areas, establishments handling bivalve molluscs, including cold stores, and laboratories.

#### 5. PRELIMINARY INFORMATION REQUIRED FOR THE AUDIT

In order to assist in the effective preparation and execution of the audit, the information requested in the Pre-Audit Questionnaire that will follow this audit plan should be made available as soon as possible and no later than **10 August 2015**. The information provided will be discussed during both the opening meeting and in the course of the audit. Copies of the national legislation should equally be made available before the start of the audit. To the extent where this was already done in the course of an earlier FVO audit, only amendments to the legislation need to be provided.

#### 6. PROCEDURES

The audit will consist of the following steps:

- Opening meeting on 8 September 2015:
  - Presentation of the objectives of the audit by the FVO audit team.
  - Presentation of any additional information required of the CA by the FVO team.
  - Review of the proposed itinerary for the audit.
- Meetings with official services involved in the areas of the audit:
- Visit to laboratories where analyses are carried out for official purposes on bivalve molluscs, toxin-producing plankton and drinking water/ice
- On-site verification: provisions should be made to allow visits to the sites in operation.

**NOTE: The audit programme will be discussed during the opening meeting. However the right of the audit team to modify the on-the-spot visits during the course of the audit is reserved, where logistically appropriate.**

**Provisions should be made in order to ensure that all locations to be visited should be in operation at the time of the visit and to provide adequate protective clothing at each site for the team.**

- Closing meeting on 17 September 2015:
  - Presentation of the main findings and preliminary conclusions by the audit team.
  - Initial response from the CA.

#### 7. DOCUMENTS TO BE AVAILABLE FOR THE AUDIT TEAM

During the opening meeting:

- Organisational charts of all services involved, staff numbers and their status/background, training, etc.

- All other relevant documentation (*e.g.* maps with the location of production areas, establishments, laboratories, etc.) and written procedures (*e.g.* approval/registration of establishments, production areas, inspection, health exports certification, etc.).

#### Official services:

- Organisational charts, number of staff performing official controls and their status/background.
- Written procedures (*e.g.* approval/registration of establishments/vessels, inspection, exports certificates).
- Files of registration/approval and official inspection reports of establishments.

#### Laboratories:

- Information on the quality system, *e.g.* scope of accreditation, standard operating procedures, inter-laboratories testing, etc.
- List of the methods used for microbiological and chemical analyses on bivalve molluscs and drinking water/ice, and methods used for detection/ analyses of toxin-producing plankton.
- Summary of results of analyses (for 2012, 2013 and 2014).

#### Establishments handling bivalve molluscs:

- Official registration/approval documents, reports of official inspections, HACCP/own-check plans and records, analysis' results, etc.

#### Classified live bivalve molluscs production areas

- Official classification documents, areas maps, sampling points maps, sanitary surveys, monitoring analysis' results, etc.

### **8. LANGUAGE TO BE USED DURING THE AUDIT**

The language to be used during the course of the audit will be English.

### **9. CONFIDENTIALITY REQUIREMENTS**

Subject to the provisions of Article 339 of the Treaty on the functioning of the EU, the final report of this specific audit will be made available to the European Parliament, EU Member States and consumers, according to the provisions of the FVO's Manual of Procedures.

### **10. PROCESSING AND DISTRIBUTION OF AUDIT REPORT**

The draft report will be produced within 10 working days (where the findings indicated that urgent action is needed) or 20 working days (in all other cases) of completion of the Audit. The CA will receive a copy of the draft report for comment. Comments should be provided within 10 working days (where the findings indicated that urgent action is needed) or one month (in all other cases) of receipt of the draft report. The report will be finalised after receipt of the CA's comments.

The report, together with any CA comments on the draft report, will be distributed to all EU Member States and the European Parliament for their information and published on the Commission's website.

**11. FEEDBACK**

Once the final report of this audit has been sent to you, the FVO Unit responsible for Operational and Administrative Services will contact you in order to obtain your feedback on the performance of this audit.

### APPENDIX: EU LEGAL REFERENCES

LEGAL REFERENCE	TITLE	OFFICIAL JOURNAL
Directive 98/83/EC	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption	L 330, 5.12.1998, p. 32
Regulation (EC) No 852/2004	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.	L 139, 30.4.2004, p. 1
Regulation (EC) No 853/2004	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	L 139, 30.4.2004, p. 55
Regulation (EC) No 854/2004	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	L 139, 30.4.2004, p. 206
Regulation (EC) No 882/2004	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	L 165, 30.4.2004, p. 1
Regulation (EC) No 2073/2005	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs	L 338, 22.12.2005, p. 1
Regulation (EC) No 2074/2005	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	L 338, 22.12.2005, p. 27
Regulation (EC) No 1881/2006	Commission Regulation (EC) No 1881/2006 of 19 December setting maximum levels for certain contaminants in foodstuffs.	L 364, 20.12.2006, p. 5
Regulation (EC) No 333/2007	Commission Regulation (EC) No 333/2007 of 28 March laying down 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.	L 88, 29.3.2007, p. 29
Regulation (EC) No 1333/2008	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December on food additives	L 354, 31.12.2008, p. 16
Regulation (EC) No 589/2014	Commission Regulation (EC) No 589/2014 of 2 June laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012.	L 164, 03.06.2014, p. 18



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**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office  
Director

Grange,  
SANTE.F3 JU/cd

**Subject: Reference number: DG(SANTE)/2015-7481**  
**Proposed FVO audit in Turkey from 8 to 17 September 2015 in order to evaluate the control systems in place governing the production of bivalve molluscs and fishery products derived therefrom intended for export to the European Union**

Dear E. Tayfun,

I would like to advise you that the Commission proposes to carry out an audit in your country in order to evaluate the control systems in place governing the production of bivalve molluscs and fishery products derived therefrom intended for export to the European Union from 8 to 17 September 2015.

The audit team will comprise two auditors from the Food and Veterinary Office and two National Experts from Member States. The team leader will be Julia Uriol (telephone: +353 46 9061 924, fax: + 353 46 9061 705, e-mail: [Sante-fvo-inspections@ec.europa.eu](mailto:Sante-fvo-inspections@ec.europa.eu)).

The team leader will be in contact with you in the near future to propose a tentative itinerary for the audit.

It would be appreciated if suitable accommodation could be arranged for the members of the team. Please contact the lead auditor *before* reserving the accommodation so that any limits on these costs which may apply under existing Commission rules can be taken into account.

I would also be grateful if you could confirm that cars and drivers will be made available to assist the team in carrying out the audit. In order to facilitate its operation, a representative of your central competent authority should accompany the team throughout the audit.

Attached in annex to this letter is an audit plan, which is designed to assist further in the planning of the audit. The plan describes the objectives, legal basis, scope and depth of the audit and is provided for your information.

E. Derya Tayfun  
Head of the Department  
Ministry of Food, Agriculture and Livestock (MARA)  
Eskisehir Yolu 9. km  
Lodumlu / Çankaya  
Ankara  
Turkey

A pre-audit questionnaire which requests information necessary for the in-depth preparation of this audit will follow in due course.

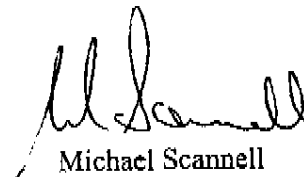
A copy of the report on the audit's findings will be sent to you in due course. You will be given the opportunity to comment upon the audit's findings and recommendations, before these are made publicly available.

Details of the proposed accommodation and eventually completed questionnaire should be forwarded to the Food and Veterinary Office, (fax: +353 46 9061 705 or by e-mail: [Sante-fvo-inspections@ec.europa.eu](mailto:Sante-fvo-inspections@ec.europa.eu)) as soon as possible. Julia Uriol will be in touch with you to confirm the final arrangements for the audit, including flight times and travel details.

Should you require any further information or assistance, please do not hesitate to contact the team leader. I would be grateful if you could use the audit reference number in all future correspondence.

I look forward to hearing from you shortly.

Yours sincerely,



Michael Scannell

Encl: Annex I: Audit Plan

c.c.: H.E. Mr Izzet Selim Yenel Mission of Turkey to the EU  
Head of Delegation, Delegation of the EU to Turkey