



DG Health and
Food Safety

Health and Food Audits and Analysis Programme July to December 2016

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1. Introduction

The European Commission's Directorate-General for Health and Food Safety (DG SANTE), and, in particular, its Directorate on Health and Food Audits and Analysis, carries out audits to ensure that EU legislation on food safety, animal health, animal welfare, plant health and some areas of human health is properly implemented and enforced.

DG SANTE published its detailed work programme of audits and analysis for 2016 at the beginning of the year on the European Commission's website:

http://ec.europa.eu/food/audits_analysis/audit_programmes/docs/fvo_inspect_prog_audit_en_2016.pdf

The detailed work programme provides

- an overview on key Commission priorities and objectives to which the audit and analysis work contributes;
- a detailed description of its multi-annual programme of audits and assessments in the areas of food and feed safety, food quality, animal health, animal welfare and plant health;
- an outline of the programme of audits and assessments in the human health area;
- an overview of desk-based control activities and activities to further promote sound regulatory practices in the implementation of controls and
- a short report on the execution of the audit programme in 2014.

This present document updates the detailed work programme for the second half of 2016, taking account of changes that have become necessary as the year progressed, mainly due to new emerging circumstances (such as, for example, animal health or plant pest outbreaks), necessitating modifications to the programme including the postponement of already planned audits. The document focusses on audit activities.

The audit reports with findings and recommendations are published together with the responses of competent authorities at the website of DG SANTE:

http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

In addition to the individual audit reports, DG SANTE produces overview reports which are discussed with stakeholders to help with implementation, or may help in the production or review of legislation. These reports may also be used in training sessions, mainly in the framework of the Better Training for Safer Food (BTSF).

http://ec.europa.eu/food/audits-analysis/overview_reports/index.cfm

The audit and analysis work carried out by DG SANTE contributes to the development of evidence based policies, in particular, through the increased country knowledge available. The knowledge built is presented in "country profiles" on each Member State outlining the state-of-play of their performance and providing in-depth country-specific knowledge.

The country profiles can be found at:

http://ec.europa.eu/food/audits-analysis/country_profiles/index.cfm

2. Audits and analysis in the area of food safety and quality, animal health and welfare, and plant health

2.1. Number and distribution of audits in the second half of 2016

As shown in table 1, a total of 94 audits, study visits and fact-finding missions are planned for July to December 2016.

Table 1. Breakdown of audits in the second half of 2016 by main areas:

Area	No. of Audits	%
Horizontal and Cross-Sectoral Priorities ¹	16	17%
Food of Animal Origin ²	30	32%
Food of Non-Animal Origin ³	12	13%
Food Quality	5	5%
Plant Health	9	10%
Feed/Animal-by Products	6	7%
Animal Health	5	5%
Animal Welfare	2	2%
Import Controls ⁴	4	4%
General Follow-Up Audits	5	5%
Total	94	100%

The horizontal and cross-sectoral projects make up 17% of the programme. Audits on food safety (food of both animal and plant origin) amount to 45%, while 5% of audits will be carried out in relation to food quality. 10% of audits are planned in the area of plant health. Audits on feed and animal by-products account for 7% of the programme; also 7% of audits will focus on animal health and welfare. 4% of audits are targeted at Member States' import control systems. Finally, 5% of audits deal with follow-up.

Table 2 provides an overview of the geographical breakdown of audits.

In the second half of 2016, 68% of the audits will take place in the European Union. Two percent of audits are planned in candidate countries and 30% in other non-EU countries.

Taking into account the audits in the EU dealing with Member States' import control systems, overall, controls on candidate and non-EU countries' exports of feed, food, plants and animals to the EU amount to 36% of the programme.

¹ excluding food quality

² including veterinary residues

³ including pesticides and GMOs

⁴ controls on products of animal and non-animal origin, live animals

Table 2. Geographical breakdown of audits in the second half of 2016:

Country	No. of Audits	%
EU-28	64	68%
Candidate countries	2	2%
Other non-EU countries	28	30%
Total	94	100%

2.2. Audits in Member States

In the second half of 2016, work will continue on key Commission and DG SANTE priorities. Amongst those are:

- **Antimicrobial resistance (AMR)**

The two projects on AMR monitoring in food and animals as well as on the prudent use of antimicrobials in food producing animals will be carried on.

- **Crisis preparedness and prevention**

In the area of animal health, two study visits are planned on the prevention of animal diseases ("worst case scenario"). In the plant health area, follow-up work on a number of serious outbreaks of harmful organisms incl. *Xylella fastidiosa*, *Popillia japonica* and *Trioza erytreae* is ongoing.

- **Animal welfare**

The new audit series dealing with welfare at dairy farms, in the light of the end of the milk quota regime and likely changes to the structure of dairy farming, is also continuing.

- **Import controls**

Audits of Member States import controls systems, in addition to main exporting non-EU countries, are an essential and regular element of the work programmes.

- **Pesticides**

The work on plant protection products (authorisation and marketing and use of plant protection products / sustainable use of pesticides) and on pesticide residue testing in organic farming will be finalised.

- **Other priorities for the remainder of the year**

Other work priorities include food of animal origin (slaughter hygiene, milk/milk products, eggs/egg products and fishery products), composite products (food containing both products of plant origin and processed products of animal origin), primary production (in particular of seeds for sprouting), contaminants, food additives, feed safety, GMOs, EU funded animal disease eradication programmes as well as Member State systems of internal or external audits of their official controls systems.

In addition, the Commission continues its audit programme on organic production and on geographical indications such as "protected designations of origin".

Finally, general follow-up audits are intended to ensure that progress made by Member States in addressing recommendations of previous audits is systematically followed up and to encourage Member States' commitment to continuous improvement. The results of the general follow-up audits will also be used to update country profiles. This work will be complemented by desk-based follow-up of a number of Member State files.

A full overview of audits, fact-finding missions and study visits planned in Member States in the second half of 2016 is provided in table 3.

Table 3. Audits in Member States in the second half of 2016

CROSS-SECTORAL PRIORITIES		COUNTRY
Antimicrobial resistance (AMR) monitoring		Hungary, Netherlands, Romania, Spain
AMR – Prudent use of antimicrobials (<i>fact-finding</i>)		Cyprus, Netherlands, Romania, Spain
Organic farming		Ireland
Geographical Indications (PDO, PGI, TSG)		Greece, Portugal
Composite products (<i>fact-finding</i>)		Belgium
Food Improvement Agents Package: Food additives		France
Biocides		(<i>desk study/ survey</i>)
High Pressure Processing (Pascalisation)		(<i>overview report</i>)
National Audit Systems		Austria, Denmark, France, Ireland, Slovenia
GENERAL FOLLOW-UP		COUNTRY
General follow-up (audits) ⁵		Greece, Hungary, Italy, Netherlands, Poland
FOOD OF ANIMAL ORIGIN		COUNTRY
Food of Animal Origin - Mammals	Slaughter hygiene (bovine and ovine) (<i>study visits</i>)	Austria, France, Greece, Spain
	Milk and milk products	Croatia, Estonia, Germany
Food of Animal Origin - Birds	Eggs and egg products	Germany, Italy

⁵ In addition, desk based follow-up is planned for a number of Member States, including Luxembourg, Lithuania and Romania.

Food of Animal Origin – Fish	Fishery products		Italy
	Traceability and labelling of fishery products (fact-finding)		France, Germany, Latvia
FOOD OF PLANT ORIGIN			COUNTRY
Pesticides	Authorisation of plant protection products (PPP)		France, Lithuania
Contaminants	Contaminants		United Kingdom
GMOs	Traceability, labelling and field trials		Denmark
Primary production	Microbiological contamination		Germany, Hungary, Poland, Slovenia
FEED AND ANIMAL NUTRITION			COUNTRY
Feed Safety	Feed importers (fact-finding)		Poland, Spain, United Kingdom
ANIMAL HEALTH AND ANIMAL WELFARE			COUNTRY
Animal Health	EU funded eradication programmes	African swine fever	Italy, Latvia
	Traceability of horses		Bulgaria
	Prevention of animal diseases – contingency planning (study visits)		Denmark, Germany ("worst case scenario")
Animal Welfare	Welfare at dairy farms		Austria, United Kingdom
PLANT HEALTH			COUNTRY
Plant Health	Plant pest outbreaks	Japanese beetle <i>Popilia japonica</i>	Italy (combined with Thousand canker disease)
		Thousand canker disease	Italy (combined with <i>Popilia japonica</i>)
		<i>Trioza erytrae</i>	Portugal, Spain (combined with Pinewood nematode)
		Pinewood nematode	Spain (combined with <i>Trioza erytrae</i>)
		<i>Xylella fastidiosa</i>	Italy
IMPORT CONTROLS			COUNTRY
Import Controls	Enhanced import controls (products of animal origin and live animals / products of non-animal origin)		Belgium, Italy, Sweden, United Kingdom

Some of the above audits will be combined into one mission as shown in the alphabetical list of audits in Member States ([Annex 1](#)).

2.3. Audits in Candidate Countries

In the second half of 2016, the Commission plans two audits to Turkey, all targeted at exports of products (compare table 4).

Table 4. Audits in Candidate Countries in the second half of 2016

AREA/SECTOR		COUNTRY
Food of Animal Origin	Fishery products	Turkey
Food of Non-Animal Origin	Microbiological contamination – primary production	Turkey

2.4. Audits in non-EU Countries

In non-EU countries, the Commission verifies that competent authorities correctly apply relevant EU standards or their equivalent with respect to animals, plants and products intended for export to the European Union.

As usual, most of the audits planned in non-EU countries in the area of *live animals and food of animal origin* are targeted at a review of existing approvals of major trade partners. Regular controls on the implementation of *residue control programmes* are a key element for the listing of non-EU countries for export.

The programme in the area of *food of plant origin* covers primary production of vegetables as well as pesticides and contaminants.

In the *food quality* area, the series of audits on organic farming, in relation to recognised control bodies operating in non-EU countries will also be continued.

Audits in the area of *plant health* are crucial to prevent the spread of plant pests through imports of fruit and vegetables, including citrus or cut flowers and plants for planting.

The readiness of application files (such as timely replies by competent authorities to pre-audit questionnaires) and also certain specific regional circumstances (e.g. security considerations) are always major conditions for the completion of the audit programme. Therefore, a number of non-EU country audits can only be programmed provisionally.

Finally, antimicrobial resistance (AMR) is a major European and global challenge. In addition to the ongoing projects in Member States, DG SANTE will start a desk study in the second half of 2016 to collect information on AMR in non-EU countries.

Table 5. Audits in non-EU Countries in the second half of 2016

AREA/SECTOR	COUNTRY	
Antimicrobial resistance (AMR)	AMR – Collection of information in non-EU countries	<i>(desk study)</i>
Food of Animal Origin – Mammals	Fresh meat (from bovidae and wild leparidae)	Argentina
Animal By-Products	Animal by-products (ABP) and derived products	Chile, Morocco
Food of Animal Origin – Birds	Poultry meat and related products	United States
Food of Animal Origin – Fish	Fishery products	Colombia, , Ecuador, Honduras <i>(combined with residues)</i> , Mauritania, Myanmar, Panama, Philippines, United States
	Small exporters of fishery products (> 5,000 t/year)	Two non-EU countries to be confirmed following the desk study
	Tuna exporting non-EU countries	Morocco
Veterinary Medicines and Residues	Residues in food of animal origin	Argentina, Chile, Honduras <i>(combined with fishery products)</i> , Ukraine
Feed Safety	Feed additives and premixtures	India
Food of Non – Animal Origin	Microbiological contamination – Primary production of vegetables	Thailand
	Pesticides	Malaysia, Sri Lanka
Food Quality	Organic farming – recognised control bodies	Two control bodies
Plant Health	Fruit and vegetables	Lao People's Democratic Republic, Uganda, Ghana

[Annex 3](#) lists all audits categorised by country in alphabetical order.

3. Assessments and audits in the human health area in the second half of 2016

In the area of human health, the Commission will continue to carry out joint assessments together with designating authorities from Member States, EFTA and EEA countries on the performance and designation of Notified Bodies in the medical devices sector. Six of such assessments are planned for the second half of 2016.

In addition, the Commission will perform one audit of a non-EU country exporting active pharmaceutical ingredients for medicinal products for human use to the EU.

Annex 1: Audits in Member States in the second half of 2016, by country in alphabetical order

<u>MEMBER STATE</u>	<u>THEME</u>	<u>REFERENCE NUMBER</u>
<u>Belgique/België (Belgium)</u>	Import controls - Enhanced checks Composite products (<i>fact-finding</i>)	2016-8872 2016-8879
<u>България (Bulgaria)</u>	Traceability – horses	2016-8754
<u>Česká republika (Czech Republic)</u>	-	
<u>Danmark (Denmark)</u>	Animal health - contingency planning (<i>study visit "worst case scenario"</i>) Genetically Modified Organisms National audit systems	2016-8758 2016-8802 2016-8828
<u>Deutschland (Germany)</u>	Eggs and egg products Labelling of fishery products (<i>fact-finding</i>) Microbiological contamination - Primary production Animal health - contingency planning (<i>study visit "worst case scenario"</i>) Milk and milk products	2016-8682 2016-8711 2016-8730 2016-8757 2016-8842
<u>Eesti (Estonia)</u>	Milk and milk products	2016-8851
<u>Éire/Ireland</u>	Food quality – Organic Farming National audit systems	2016-8746 2016-8834
<u>Ελλάδα (Greece)</u>	Geographical indications (PDO, PGI, TSG) Slaughter hygiene (<i>study visit</i>) General follow-up	2016-8748 2016-8818 2016-8850
<u>España (Spain)</u>	AMR monitoring Plant pest outbreaks (<i>Trioza erytreae</i>) – (<i>combined with Pinewood nematode</i>) Plant pest outbreaks (<i>Pinewood nematode</i>)- (<i>combined with Trioza erytreae</i>) AMR - prudent use of veterinary medicines (<i>fact-finding</i>) Feed importers (<i>fact-finding</i>) Slaughter hygiene (<i>study visit</i>)	2016-8678 2016-8797 2016-8803 2016-8887 2016-8906 2016-8992
<u>France</u>	Labelling of fishery products (<i>fact-finding</i>) Plant Protection Products - Authorisation Slaughter hygiene (<i>study visit</i>) National audit systems Food additives	2016-8710 2016-8781 2016-8819 2016-8831 2016-8861
<u>Hrvatska (Croatia)</u>	Milk and milk products	2016-8845

<u>MEMBER STATE</u>	<u>THEME</u>	<u>REFERENCE NUMBER</u>
<u>Italia (Italy)</u>	Eggs and egg products	2016-8683
	Fishery products	2016-8686
	African swine fever	2016-8764
	Plant pest outbreaks (<i>Xylella fastidiosa</i>)	2016-8794
	Plant pest outbreaks (<i>Popilia japonica</i>) – (combined with Thousand canker disease)	2016-8795
	Plant pest outbreaks (<i>Thousand canker disease</i>) – (combined with <i>Popilia japonica</i>)	2016-8796
	General follow-up	2016-8849
	Import controls - Enhanced checks	2016-8874
<u>Kύπρος (Kypros)/Kıbrıs (Cyprus)</u>	AMR - prudent use of veterinary medicines (<i>fact-finding</i>)	2016-8884
<u>Latvija (Latvia)</u>	African swine fever	2016-8766
	Labelling of fishery products (<i>fact-finding</i>)	2016-8914
<u>Lietuva (Lithuania)</u>	Plant Protection Products - Authorisation	2016-8782
<u>Luxembourg</u>	-	
<u>Malta</u>	-	
<u>Magyarország (Hungary)</u>	AMR monitoring	2016-8676
	Microbiological contamination - Primary production	2016-8727
	General follow-up	2016-8843
<u>Nederland (Netherlands)</u>	General follow-up	2016-8839
	AMR - prudent use of veterinary medicines (<i>fact-finding</i>)	2016-8889
	AMR monitoring	2016-8919
<u>Österreich (Austria)</u>	Animal welfare - dairy farms	2016-8765
	Slaughter hygiene (<i>study visit</i>)	2016-8821
	National audit systems	2016-8826
<u>Polska (Poland)</u>	Microbiological contamination - Primary production	2016-8732
	General follow-up	2016-8846
	Feed importers (<i>fact-finding</i>)	2016-8905
<u>Portugal</u>	Geographical indications (PDO, PGI, TSG)	2016-8749
	Plant pest outbreaks (<i>Trioza erytrae</i>)	2016-8798
<u>România (Romania)</u>	AMR monitoring	2016-8677
	AMR - prudent use of veterinary medicines (<i>fact-finding</i>)	2016-8888
<u>Slovenija (Slovenia)</u>	Microbiological contamination - Primary production	2016-8733
	National audit systems	2016-8830
<u>Slovensko (Slovakia)</u>	-	
<u>Suomi/Finland</u>	-	

<u>MEMBER STATE</u>	<u>THEME</u>	<u>REFERENCE NUMBER</u>
<u>Sverige (Sweden)</u>	Import controls – Enhanced checks	2016-8868
<u>United Kingdom</u>	Contaminants	2016-8737
	Animal welfare - dairy farms	2016-8767
	Import controls - Enhanced checks	2016-8873
	Feed importers (<i>fact-finding</i>)	2016-8907

Annex 2: Audits in Candidate Countries in the second half of 2016, by country in alphabetical order

<u>CANDIDATE COUNTRY</u>	<u>THEME</u>	<u>REFERENCE NUMBER</u>
<u>Türkiye (Turkey)</u>	Fishery products	2016-8679
	Microbiological contamination - Primary production	2016-8728

Annex 3: Audits in non-EU Countries in the second half of 2016, by country in alphabetical order

<u>NON-EU COUNTRY</u>	<u>THEME</u>	<u>REFERENCE NUMBER</u>
<u>AR – Argentina</u>	Fresh meat	2016-8854
	Residues in food of animal origin	2016-8894
<u>CL – Chile</u>	Residues in food of animal origin	2016-8893
	Animal by-products	2016-8916
<u>CO – Colombia</u>	Fishery products	2016-8690
<u>EC - Ecuador</u>	Fishery products	2016-8691
<u>GH - Ghana</u>	Plant health – Fruit and vegetables	2016-8983
<u>HN - Honduras</u>	Residues in food of animal origin – (<i>combined with fishery prod.</i>)	2016-8898
	Fishery products – (<i>combined with residues</i>)	2016-8947
<u>IN - India</u>	Feed additives and premixtures	2016-8949
<u>LA – Lao People's Democratic Republic</u>	Plant health - Fruit and vegetables	2016-8807
<u>LK – Sri Lanka</u>	Pesticides	2016-8787

<u>NON-EU COUNTRY</u>	<u>THEME</u>	<u>REFERENCE NUMBER</u>
<u>MA – Morocco</u>	Tuna exporting non-EU countries Animal by-products	2016-8693 2016-8915
<u>MR – Mauritania</u>	Fishery products	2016-8692
<u>MM - Myanmar</u>	Fishery products	2016-8864
<u>MY – Malaysia</u>	Pesticides	2016-8785
<u>PA - Panama</u>	Fishery products	2016-8998
<u>PH – Philippines</u>	Fishery products	2016-8696
<u>TH – Thailand</u>	Microbiological contamination - Primary production	2016-8735
<u>UA – Ukraine</u>	Residues in food of animal origin	2016-8897
<u>UG - Uganda</u>	Plant health - Fruit and vegetables	2016-8806
<u>US – United States</u>	Fishery products Poultry meat and related products	2016-8700 2016-8706

N.B. In addition, two audits are planned of recognised control bodies operating in non-EU countries in the area of organic farming.

Two audits will be performed to non-EU countries exporting small amounts of fishery products (the countries will be decided following the desk study).

