EU in the SPS field

THE EUROPEAN COMMISSION IN THE SPS FIELDS: STRUCTURE AND DECISIONS

Tokyo 12-15 June 2018

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European Commission
DG Health & Food Safety
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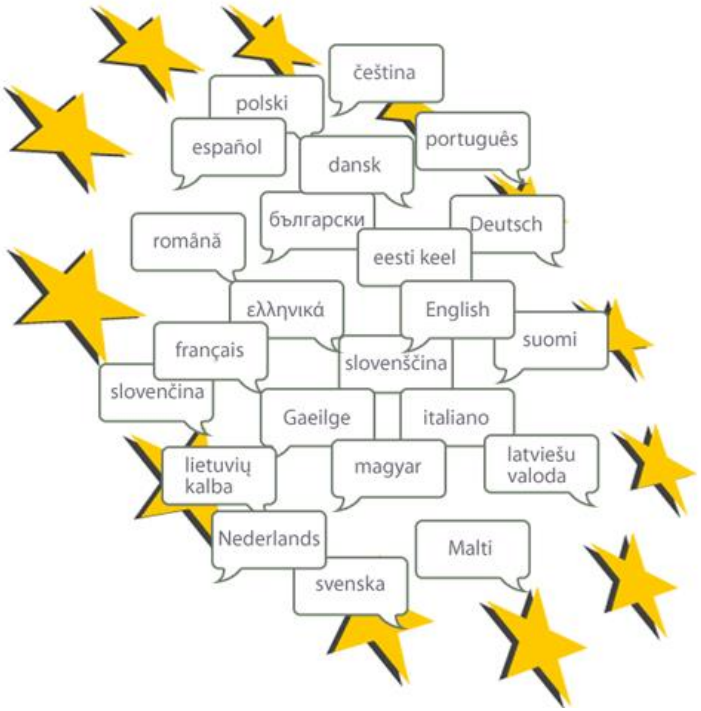
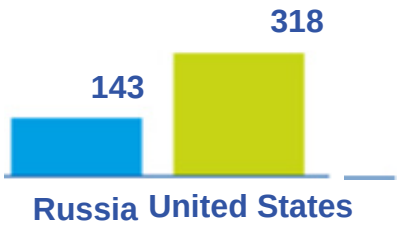
The European Union

- ***28 Countries***
- ***Different structures and and organization of controls***
- ***One policy***
- ***One set of animal health and food safety rules***

The European Union

24 official languages →500 million consumers





EU Institutions and bodies

- *European Council*
- *European Commission*
- *European Parliament*
- *Council of Ministers*
- *Court of Justice and Court of Auditors*
- *European External Action Services*

European Commission

- *Proposes legislation*
- *Enforces European Union Law*
- *Sets objectives and priorities for action*
- *Makes proposals*
- *Manages and implements policies and budget*
- *Trade agreements with non-EU countries*

European Commission

EU Commission - General Directorates

- ***7 Directorates: A, B, C, D, E , F and G***

European Commission

The European Union

EU's main economic engine. It enables goods, services, money and people to move freely across "EU internal borders".

European Commission

The European Union

- *An economic and political partnership between 28 European countries.*
- *Based on the rule of law. Founded on Treaties voluntarily and democratically agreed by Member countries: binding agreements.*
- *Member States ceded part of their sovereignty which empowers the EU institutions to adopt laws.*
- *These laws take precedence over national laws and are binding on national Authorities.*

European Commission

The EU legislation

The Treaties (Primary legislation): sets out EU objectives, rules for EU institutions, rules for decision-making, relationships between the EU and its member countries.

European Commission

1952 *The European Coal and Steel Community*

1958 *The treaties of Rome:*
- *The European Economic Community*
- *The European Atomic Energy Community (EURATOM)*

1987 *The European Single Act: the Single Market*

1993 *Treaty on European Union - Maastricht*

1999 *Treaty of Amsterdam*

2003 *Treaty of Nice*

2009 *Treaty of Lisbon*

European Commission

The EU legislation

- *Regulations and Decisions are binding and directly applicable in all Member States. This means that once in force, the text becomes part of the national law in all Member States and supersede the national provisions.*

- *Directives are binding but need "National implementing measures" incorporating EU provisions (under EU scrutiny).*

This traduces under the terms: "Member States shall ensure that … "

European Commission

The EU legislation

- *European Parliament and Council Regulations and Directives are primary legislation (directly based on the Treaty).*

- *Primary legislation may provide the Commission with implementing or delegated acts and quasi-legislative powers to be adopted in "Comitology". These procedures involve consultation with Member States and scrutiny by the European Parliament and the Council depending on the type of procedure.*

European Commission

Responsibilities and obligations

- *Member States: implement and enforce EU legislation within their territory according to national administrative structures.*
- *Notify direct or indirect risks.*
- *Lay down the rules and sanctions applicable to infringement of EU law and implement them.*

European Commission

Responsibilities and obligations

The Commission promotes the common interest of the EU: four key roles.

- *Right of initiative: propose new legislation*
- *Executive organ: apply EU policies*
- *Guardian of the treaties: control the application of the law*
- *Representation of the EU on the international stage*

European Commission

Responsibilities and obligations

- *The Commission ensures that the EU law is properly applied.*
- *The Commission is responsible for overall coordination, inspection and audits of inspection systems and the necessary legislative action to ensure uniform application of standards and requirements within the Union's internal market.*
- *The Commission can bring a matter to the European Court of Justice (possibility of penalties) for MS incompliances*

Responsibilities and obligations

- *DG SANTE proposes policies on animal health, food safety, plant health, etc. (5 Directorates policies).*
- *DG SANTE carries out general and specific audits in Member States (and in non-EU countries): annual inspection programme / reports / recommendations / action plans / follow ups.*

- *The Commission takes emergency measures necessary to contain a risk (i.e. failure in a control system, possible risk for human, plant or animal health).*

European Commission

Responsibilities: exports to non-EU countries

- *EU legislation requires that products exported from the EU for placing on the market of a third country shall comply with the relevant requirements of the EU legislation (unless otherwise requested by the importing Party).*

- *The Member States are responsible for the control of the production conditions and requirements, including statutory inspections and issuing health and animal welfare certifications attesting to compliance with Japan's standards and requirements.*

European Commission

Responsibilities: imports from non-EU countries

- *EU import conditions are equivalent or identical to EU internal market requirements.*

- *The Member States are responsible for controlling compliance of imports with the Union's import conditions.*

European Commission

Exporting to the EU: what does it mean?

28 EU Member States

*Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom**

24 languages – 500 millions citizens

+ EFTA States

Iceland, Liechtenstein, Norway, Switzerland

+ Candidate countries

Albania, Montenegro, Serbia, The former Yugoslav Republic of Macedonia, Turkey

* 29 March 2019 = BREXIT

European Commission

DG Health and Food Safety (SANTE)

- *Where to place it?*
- *Amongst different Institutions*
- *Different competencies in comparison to MSs*

European Commission

European Court of Justice

EU

Member States

Parliament

Council

Commission

DG TRADE

DG SANTE

Audits

Advisory group of the food chain

EFSA

National Government

Regulatory authorities

Control authorities

Evaluation bodies

European Commission

DG Health and Food Safety

- *1997: Reorganisation of Commission Services: SANCO and creation of the Food and Veterinary Office*

- *2002: Creation of the EFSA (European Food Safety Authority)*

- *New regulatory framework: the Food Law (Regulation 178/2002) + Recasting + Simplification*

- *2014: DG SANCO becomes DG SANTE*

Health and Food Safety

European Commission

DG Health and Food Safety

- **Role**: *to promote and protect health and food safety and contribute to a well-functioning and fair internal market in food, feed, agricultural and medical products.*

- **Objective**: *to make the EU a healthier, safer place, where citizens can be confident that their interests are protected. A zero-risk society may not be possible but we are doing as much as we can to reduce and manage risks for our citizens.*

European Commission

DG Health and Food Safety

We aim to:

- protect and improve public health
- ensure Europe's food is safe and wholesome
- protect the health and welfare of farm animals
- protect the health of crops and forests

FOOD

Every European citizen has the right to know how the food he eats is produced, processed, packaged, labelled and sold.

The central goal of the European Commission's Food Safety policy is to ensure a high level of protection of human health regarding the food industry — Europe’s largest manufacturing and employment sector.

The Commission's guiding principle - primarily set out in its White Paper on Food Safety - is to apply an integrated approach from farm to fork covering all sectors of the food chain.

ANIMALS

The objective of the Animal Health policy is to raise the health status and improve the conditions of the animals in the EU, in particular food-producing animals, whilst permitting intra-Community trade and imports of animals and animal products in accordance with the appropriate health standards and international obligations.

The general aim of the Animal Welfare policy is to ensure that animals don’t need to endure avoidable pain or suffering and obliges the owner/keeper of animals to respect minimum welfare requirements.

The EU zootechnical legislation aims at the promotion of free trade in breeding animals and their genetic material considering the sustainability of breeding programs and preservation of genetic resources.

PLANTS

The European Commission takes actively part in the setting of international phytosanitary and quality standards for plants and plant products.

EU legislation has, over the years, provided for the harmonised protection of our 'green resources' pesticides, plant variety rights or Genetically Modified Organisms

European Commission

DG Health and Food Safety

Leadership and organisation

COMMISSIONER
Vytenis Andriukaitis

DIRECTOR-GENERAL
Xavier Prats Monné

DEPUTY DIRECTOR-GENERAL
Martin Seychell

DEPUTY DIRECTOR-GENERAL
Celine GAUER

Around 960 staff.

About 660 of us are in Brussels;

About 120 work in Luxembourg and

Another 180 in Grange, near Dublin.

DG Health and Food Safety

- *7 Directorates (A, B ,C, D, E, F, and G)*
- ***Dir. D** Food Chain: stakeholders and International relations*
- ***Dir. E** Food and Feed safety, innovation*
- ***Dir. F** Health and Food Audits and Analysis*
- ***Dir. G** Crisis management in food, animals and plants*
- *Staff: +/-960*

Directorate D –Food Chain: stakeholders and international relationships

- *Unit D1 Stakeholders, enforcement,* ***BTSF***
- *Unit D2 Multilateral international relationships*
- *Unit D3 Bilateral international relationships*
- *Unit D4 Food Safety programme, emergency funding*

Directorate D –Crisis management in food, animals, and plants

- *Unit G1 Plant health*
- *Unit G2 Animal health and welfare*
- *Unit G3 Officials controls and eradication of diseases in animals*
- *Unit G4 Food hygiene*
- *Unit G5 Alerts, traceability*

DG Health and Food Safety

- General principles: *risk analysis and scientific basis, precautionary principle, transparency*

- *Right of consumers to safe food and to accurate and honest information*

- *EU commitment to follow international obligations*

- *« Food and feed exported (or re-exported) from the EU for placing on the market of a non-EU country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country … »*

DG Health and Food Safety

- *There are too many policies and activities dealt by DG SANTE.*

The major pillars are:

1. *Animal health law*
2. *Food law (hygiene package and official controls, traceability)*
3. *Plant health law*
4. *IT systems (TRACES, RASFF)*

More details could follow during workshop or on request

The General Food Law

- *Members States enforce Food Law, lay down rules and sanctions, monitor and verify implementation, communicate on food safety and risk, assess guides to good practices for hygiene in agreement with FBOs*

- *Commission test the performance of Member States' control capacities and capabilities through audits and inspections*

European Commission

Health and Food Safety

The EU approach and policies on animal health

Prevention, Surveillance, Control and Eradication

June 2018, Japan

Better training for safer food

DG SANTE - European Commission, Brussels

This presentation does not necessarily represent the views of the European Commission

Table of contents

European Commission

The basic principles of EU Animal health legislation

Food Safety

The basics of the EU animal health policy

- Progressively developed within the framework of the Common Agricultural Policy
- Supported by comprehensive fully harmonised legislation, which is binding for all EU Member States
- Main objective: reaching an maintaining a high status of animal health throughout the EU

Why is animal health important for the EU?

- Food safety (farm to table approach)
- Public health (zoonoses)
- Sustainable development and productivity of agriculture
- Establishment and functioning of the EU single market
- Safe trade and imports in animals and their products (including food of animal origin)

The international context of EU legislation

- It follows WTO rules and its SPS (Sanitary and Phytosanitary) Agreement which follows OIE & CODEX standards
- It is scientifically based: the European Food Safety Authority (in Parma, Italy) gives scientific advice to the Commission and to Member States

Principles of EU response to animal diseases

-Harmonised Legislation

-Animal Disease Notification System (ADNS)

-Standing Committee on Plants Animals, Food and Feed (SCoPAFF)

-Clear definition of roles of Member States and Commission

EU Veterinary Control System

Prevention	Detection	Control	Transparency
Biosecurity Animal identification Veterinary certification and movement control for intra-EU trade of livestock Veterinary certification and border controls for animals and products imported.	Surveillance Reference laboratories Health monitoring in high risk areas Animal Disease Notification System.	Contingency planning Animal Disease Notification System Isolation of infected holdings Eradication EU support: Emergeny team, vaccine banks, compensation, training.	EU audits of Member State veterinary services Public information systems (RASFF, ADNS) Scientific consultations Notification.

Surveillance

- ***Owners/keepers surveillance***
- ***veterinarians' surveillance:*** *detecting threats (with priorities depending on categorisation) training and laboratories challenge*
- ***competent authorities****:*
  - *surveillance organisation and rapid alert*
  - *(ADNS et WAHIS OIE notifications)*
- ***laboratories, research****:*

Borders biosecurity

- *Protect community without disrupting the cross-border movement of people and agricultural goods*
- *Collaboration veterinary services – customs*
- *Borders inspection (documents and/or products)*
- *Illegal trade control*
- *Improve cooperation with non-EU countries (technical assistance, exotic diseases control)*

Surveillance and preparedness

- ***Preparedness with partners*** *(responsabilities, costs)*
- ***Regular exercices*** *of implementation (expertise, slaughter equipments, communication tools)*
- ***Reduce the risk to a negligible or acceptable level***
- ***Reduce the costs due animals culling***

EU main tools for diseases control (1)

- EU-fully harmonised veterinary legislation
- Specific disease control Directives
- Regionalisation policy
- Contingency plans
- The EU Reference Laboratory network (EURLs)– diagnostic manuals
- The EU co-financed eradication programmes
- Enforcement – audits

EU main tools for diseases control (2)

- Enforcement – audits
- Financial support in case of outbreaks
- The Community Veterinary Emergency Team - CVET
- Better training for safer food – BTSF
- The European Food Safety Authority - EFSA
- International cooperation – OIE/FAO GF-TADSs
- EU research projects – Horizon 2020

Tools for control

- **TRACES**
- **EU Network of Laboratories**
- **Animal Disease Notification System (ADNS)**
- **Country listing for third countries**

TRACES

Trade Control and Expert System of the EU

- Online tool for health certification in 35 languages
- **Trade of live** poultry/hatching eggs **between Member States**
- **Imports** to the EU of **poultry and poultry products**
- Standardised **animal health certificate** accompanying consignments
- **Traceability** tool in case of outbreaks
- **Pre-notification**, allows official animal health controls at destination or in Border control posts at import
- **Official controls -** sampling and results

Laboratory network

EU Reference Laboratory (EURL) and national laboratories (AI and ASF)

- Confirmation, virus characterisation and storage
- Standards, training
- Ensure quick diagnosis due to location in all Member States
- EURL assistance to **national laboratories** in outbreak situations
- **Inter-laboratory tests**
- Data collection and analysis
- Annual meetings with national reference laboratories

Cooperation and verification

Rapid exchange of information

Animal Disease Notification System (ADNS)

Primary outbreaks

- **Member States must notify** the Commission and other Member States **within 24 hours**
- Immediate, automatic e-mail sent to all Member States
- **Specific information must be** provided in e.g. number of birds, measures taken

Secondary outbreaks

- Notification/update at least once per week

Weekly e-mail updates to all ADNS members and on website

- Member States and non-EU countries receive information provided by affected Member States **at the same time**
- Information on Decisions on protection measures

Imports from Third countries

Only from countries listed in Commission Regulation (EC) No 798/2008

- Health status of poultry
- Regular & rapid information to EU and OIE
- Legislation on animal disease prevention and control
  - Monitoring, surveillance, early detection
  - AI/ND control measures at least equivalent to those in EU
  - Reliable laboratory test results – EU or OIE standards
- Structure of veterinary services and their powers
- Organisation and implementation of controls and measures
- **Reliable export certification**

Country pre-listing audits carried out by Commission services
Safeguard measures in case of outbreaks (e.g. HPAI USA, UA..)

How we keep the EU system alert?

The Commission role:

- Contingency planning
- Directorate SANTE F audits for MS preparedness
- BTSF – training of EU and non EU officials on technical aspects

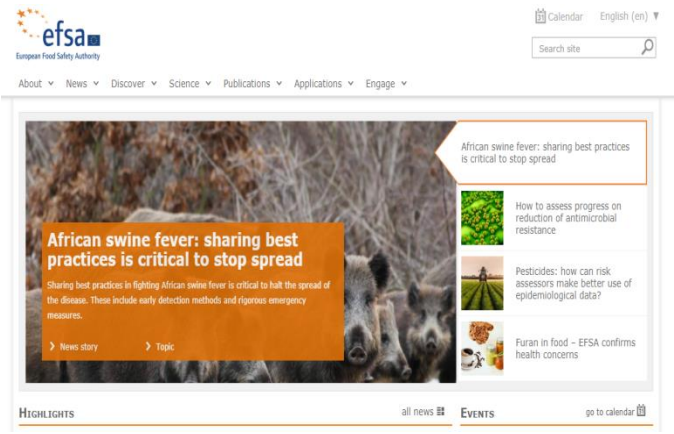
TRANSPARENCY

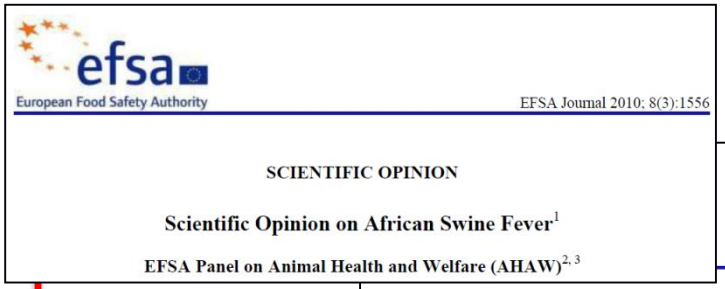
EFSA ASSESSMENTS

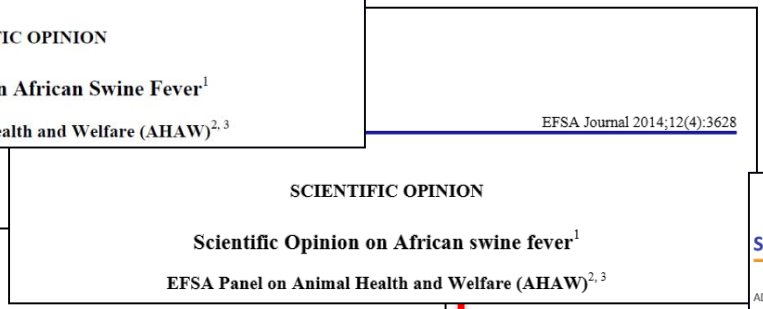
AN EXAMPLE -ASF

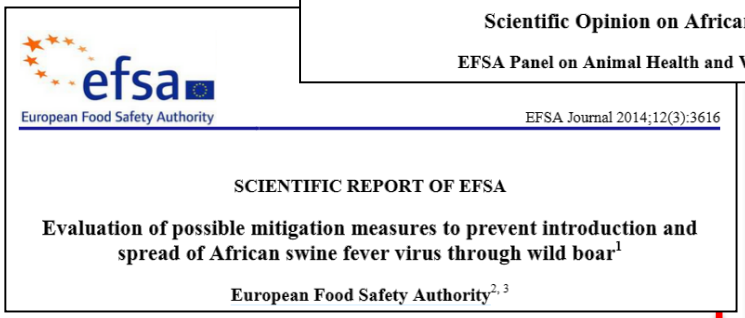
European Commission

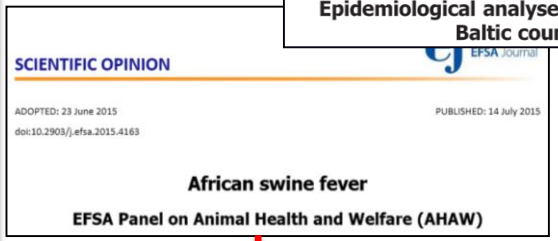
http://www.efsa.europa.eu/en/topics/topic/african-swine-fever







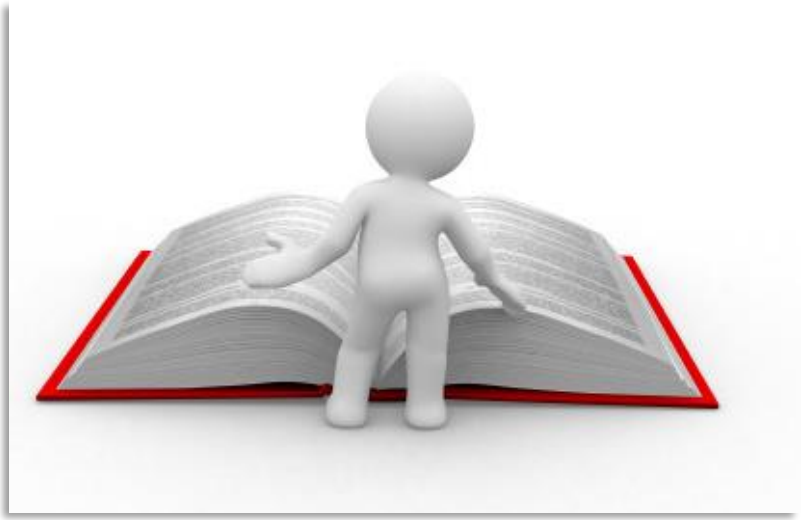




Scientific opinion Scientific report

2010	2011	2012	2013	2014	2015	2016	2017	2018	2019

European Commission



Animal Health law

Food Safety

European Commission

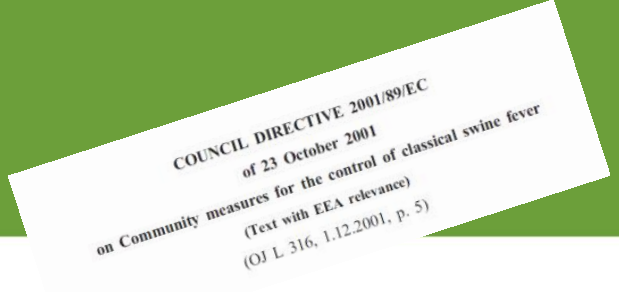
Adopted March 2016

Applicable from 2021

EU Animal Health Law

Regulation 2016/429

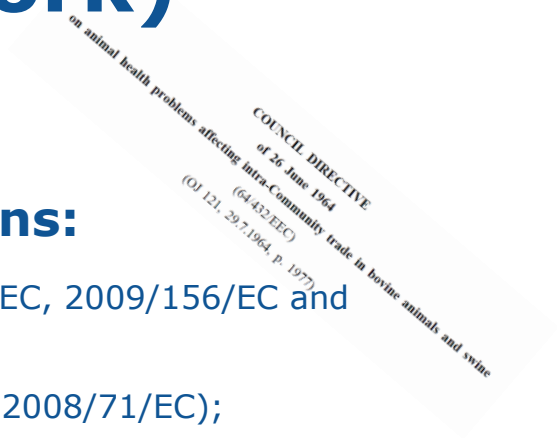
- **A single, robust legal framework** for animal health to simplify existing rules:
  - from 40 Directives and Regulations **to one framework**!
  - binding legislative act, directly applicable in all Member States
- More **risk based, proactive, preventive behaviour**
- It improves **response to emerging diseases** by allowing the Commission to act rapidly and effectively

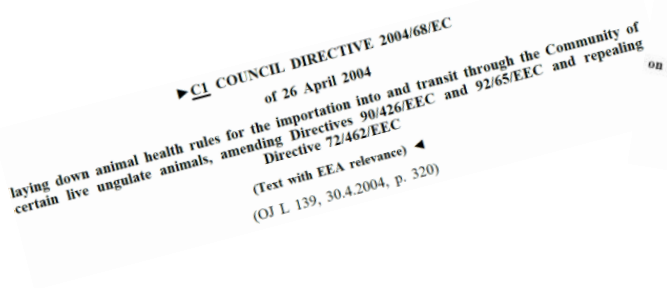


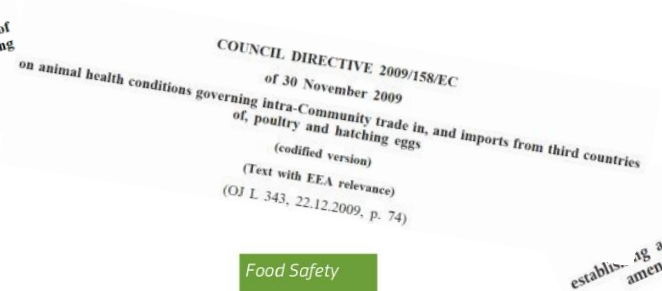
European Commission

Animal Health Law (from existing to the future legal framework)

- A legal framework for animal health
  - **taking over 39 Directives and Regulations:**
    - "Trade" directives (e.g. Dir 64/432/EEC, 91/68/EEC, 92/65/EEC, 2009/156/EC and 2009/158/EC),
    - I&R of animals (e.g. Reg (EU) No. 1760/2000, 21/2004, Dir 2008/71/EC);
    - Import into the EU (e.g. Dir 2004/68/EC, 2002/99),
    - Disease control directives (e.g. Dir 2003/85/EC, 2001/98/EC, 2005/94/EC, etc…)
  - **provides a basis for a single EU animal health policy**







Important new elements

- **Responsibilities** of keepers, operators, veterinarians, competent authorities, etc.
  "**animal health: everyone is responsible!"**

- More **prevention** (biosecurity, surveillance, improved knowledge on animal health, use of vaccines & reduction of AMR, emerging diseases,)

- **Easy and safe** trade

Responsibilities for animal health

- Economic Operators (farmers, transporters, slaughterhouses, meat-processors, retailers):
  - **health of their animals, biosecurity, etc.**
  - **knowledge on animal health**
    Animal diseases, biosecurity, interaction with animal welfare, good husbandry practices and antimicrobial resistance
  - **more preventive behaviour ➔ better biosecurity**
    - Contribute to better overall husbandry
    - Result with healthier animals and possible lower use of veterinary medicines

- Veterinarians to play a more active role in:
  - **raising awareness on how animal health & welfare is interlinked with human health (resistance to treatments, AMR)**

- Competent Authorities to ensure resources, personnel, laboratories.

More prevention in animal health law:

- **Biosecurity at farms, in transport, assembly, and official controls at EU borders**
- **enhanced and more structured surveillance, disease notification and reporting to the Commission**
- **improved knowledge, disease awareness & preparedness** (contingency plans)
- **clearer policy for vaccines**
  (for disease prevention and control measures)
- **more tools to control emerging diseases**

Conclusion: easy and safe trade

- Enhanced **convergence with international standards** on animal health (OIE)
- Added **flexibility for animal** (or product) **movements**: by fostering good practices (e.g. surveillance and biosecurity)
- More **modern and harmonised import rules** at EU Border Inspection Posts

European Commission

More at:
https://ec.europa.eu/info/departments/health-and-food-safety_en

Food Safety

Regional Workshop on Animal Disease Preparedness

Better Training For Safer Food

Marius Masiulis

Official controls on products of animal origin

Food safety

Tokyo, Japan
12-15 June 2018

Regulation 854/2004 of European Parliament and of the Council - Scope

Regulation lays down specific rules for the organization of official controls on products of animal origin.

Performance of official controls shall be without prejudice to FBO primary legal responsibility for ensuring food safety as laid down in Regulation 178/2002 laying down general principles and requirements of food law, establishing EFSA and laying down procedures in matters of food safety.

Regulation 854/2004

- Official controls in relation to Community establishments:
  - **Approval of establishments;**
  - **General principles for official controls in respect of all products of animal origin;**
  - **Fresh meat;**
  - **Live bivalve molluscs;**
  - **Fishery products;**
  - **Raw milk and dairy products;**
- Procedures concerning imports:
  - **Lists of third countries and parts of third countries from which imports of specified products of animal origin are permitted;**
  - **List of establishments from which imports of specified products of animal origin are permitted;**
  - **Live bivalve molluscs, echinoderms, tunicates and marine gastropods;**
  - **Special provisions for fishery products.**

Regulation 854/2004 – Approval of establishments

Approval is granted after one-site visit by Competent Authority.

Establishment will be approved for particular activities after full compliance to structural and hygiene requirements is confirmed.

Conditional approval can be granted up to 3 months. When there is clear progress but still not full compliance another 3 months prolongation (only once).

12 months for factory vessels.

Regulation 854/2004 – Approval of establishments

CA gives every approved establishment unique approval number.

Code may be added to specify type of production.

When serious deficiencies are identified or production is stopped repeatedly CA may withdraw establishments approval.

For wholesale markets the approval can be suspended for certain groups of products.

Regulation 854/2004 – General principles

FBOs offer all assistance needed to ensure that official controls by Competent Authority can be performed effectively

In particular

- give access to all buildings, premises, installations or other infrastructures
- make available any documentation and record required under present regulation or considered necessary by the CA for judging the situation

Regulation 854/2004 General principles

The official controls include audits of good hygiene practices and HACCP based procedures verifying

- checks on food chain information
- design and maintenance of premises and equipment
- pre-operational, operational and post-operational hygiene
- personal hygiene
- training in hygiene and work procedures
- pest control
- water quality
- temperature control
- controls on food entering and leaving the establishment

Regulation 854/2004 General principles

During audits CA will take special care:

- to determine whether staff and staff activities at all stages of production process comply with requirements;

- to verify the FBOs relevant records;

- to take samples for laboratory analyses whenever necessary;

- to document elements taken into account and findings of the audit.

Regulation 854/2004 General principles

Nature and intensity of auditing tasks in respect of individual establishments shall depend upon assessed risk.

CA shall regularly assess :

- public and animal health risks;
- in case of slaughterhouses animal welfare aspects;
- type and throughput of processes carried out;
- FBOs past record as compliance with food law.

Regulation 854/2004 - Fresh meat

OV shall carry out inspections in slaughterhouses, game handling establishments and cutting plants in particular as regards:

- food chain information;
- ante-mortem inspection;
- animal welfare;
- post-mortem inspection;
- specified risk material and other animal by-products;
- laboratory testing.

Health marks shall be applied by or under the responsibility of OV.

Regulation 854/2004 Fresh meat

After carrying out the controls OV shall take following measures:

-The communication of inspection results;
-Decisions concerning food chain information;
-Decisions concerning live animals;
-Decisions concerning animal welfare;
-Decisions concerning meat.

Member States ensure that official veterinarians and auxiliaries are qualified and undergo special training.

Regulation 854/2004 Food chain information

OV is to check and analyze information from the records of the holding of origin of animals intended for slaughter and take account of the documented check and analysis during ante- and postmortem inspection.

- Certificate
- Owners declaration
- ID – database
- Passport

Regulation 854/2004 Ante-mortem inspection

OV is to carry out ante-mortem inspection of all animals to be slaughtered.

The inspection must take place within 24 hours of arrival and less than 24 before slaughter.

Inspection must exclude

- that welfare has been compromised

- any condition that might adversely affect human or animal health (zoonotic diseases, OIE listed diseases).

Regulation 854/2004 Post-mortem inspection

Carcasses and offal are inspected without a delay after slaughter.

Particular attention to detection of zoonoses and/or OIE listed diseases.

The speed of slaughter line and number of inspection staff present must enable proper inspection.

Precautions must be taken to ensure that meat is not contaminated by palpation, cutting or incision.

Regulation 854/2004 Decisions concerning meat

Meat is declared unfit for human consumption :

- derives from animals without ante-mortem inspection;
- derives from animals the offal of which has not undergone post-mortem inspection;
- derives from animals dead before slaughter, stillborn, unborn or slaughtered under age of 7 days;
- derives from animals affected by OIE listed diseases;
- derives from animals affected by a generalised disease (septicaemia, pyaemia, toxaemia);
- is not in conformity with microbiological criteria.

Regulation 854/2004 Decisions on meat

- exhibits parasitic infestation;
- contains residues or contaminants in excess of permitted levels;
- derives from animals treated with forbidden substances;
- has been treated illegally with decontaminating substances;
- has been treated illegally with ionizing UV-rays;
- contains foreign bodies;
- exceeds the maximum permitted radioactivity levels;
- indicates patho-physiological changes, abnormalities in consistency, insufficient bleeding, organoleptic anomalies (sexual odour).

Regulation 854/2004 Actions in the case of non-compliance

- imposition of sanitation procedure or other corrective action;
- restriction of the placing on the market, export or import;
- recall and/or destruction of products;
- authorization to use products for different purposes;
- suspension of operations or closure of all or part of FBO;
- suspension or withdrawal FBO approval;
-consignments from third countries – seizure followed by destruction or re-dispatch;
-any other measure CA deems appropriate.

Regulation 854/2004 - PROCEDURES CONCERNING IMPORTS

- Lists of third countries and parts of third countries from which imports of specified products of animal origin are permitted;
- List of establishments from which imports of specified products of animal origin are permitted.

- It does not matter whether or not a country is part of the EU!
- No discrimination – legislation applies directly or must be complied with or equivalent and applicable for internal market within EU, for export and for import.

Regulation 854/2004 - PROCEDURES CONCERNING IMPORTS

- Lists of third countries and parts of third countries from which imports of specified products of animal origin are permitted

- **A third country shall appear on such lists only if:**

- a Community control in that country has taken place;
- demonstrates that the competent authority provides appropriate guarantees;

Regulation 854/2004 - IMPORT

Criteria for listing:

- the legislation of the country on:
  - products of animal origin;
  - the use of veterinary medicinal products;
  - the preparation and use of feedingstuff.
- the hygiene conditions - production, manufacture, handling, storage and dispatch applied to products of animal origin;
- any experience of marketing and import controls;
- the results of Community controls carried out in the country;
- existence, implementation and communication of an:
  - approved zoonoses control programme,
  - approved residue control programme.

Regulation 854/2004 - IMPORT

- List of establishments from which imports of specified products of animal origin are permitted

- Products of animal origin may be imported into the Community only if they have been dispatched from, and obtained or prepared in, establishments that appear on lists;
- Fresh meat, minced meat, meat preparations, meat products and mechanically separated meat may be imported into the Community only if they have been manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists.

Regulation 854/2004 - IMPORT

Placing on the list:

- Only if the competent authority of the country of origin guarantees:

- establishment complies with relevant Community requirements - Regulation (EC) No 853/2004 or equivalent to such requirements and country is included in the list of countries from which imports of specified products of animal origin are permitted;
- official inspection in place;
- all relevant information available to the Commission;
- real power exist to stop the export in the case of failure of meeting the requirements.

THANK YOU !!!

The contents of this presentation are the views of the author and do not necessarily represent an official position of the European Commission.

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Better Training for Safer Food
BTSF

European Commission
Consumers, Health, Agriculture and Food Executive Agency
DRB A3/042
L-2920 Luxembourg

Food safety

The EU Audit approach

Implementation and Enforcement of EU laws

Tokyo 12-15 June 2018

Andrea DIONISI
European Commission
DG Health & Food Safety
Bilateral International Relations

Health and Food Safety

The EU Audit approach

Implementation and Enforcement of EU laws

1. The former F.V.O.

Directorate F

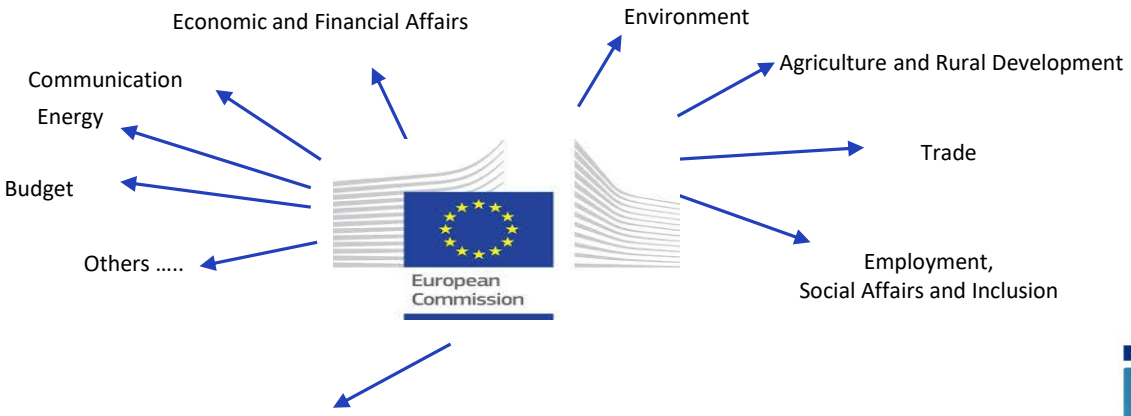
2. Audit process

European Commission

The EU Audit approach
Implementation and Enforcement of EU laws

Food Safety

The former Food and Veterinary Office (FVO)



European Union civil service

Health and Food Safety

DG SANTE

- Directorate A
- Directorate B
- Directorate C
- Directorate D
- Directorate E
- Directorate F
- Directorate G

European Commission

Directorate F

- Staff ± 180 staff
  ± 80 auditors -

+/- 250 audits per year :

- EU Member States,
- Candidate Countries
- Non-EU countries

Audits - SYSTEMS APPROACH

http://ec.europa.eu/food/food_veterinary_office/index_en.htm

Health and Food Safety

Areas of activity

- Food and feed safety
- Food quality
- Animal health and welfare
- Plant health

Farm to Fork

In EU Member States, Candidate Countries and Third Countries

since 2013:
Medical devices
active pharmaceutical ingredients
Organics

Role of the Dir. F

- Key responsibility of the Commission is to act as a "guardian of the treaties"
- Ensure EU legislation is properly implemented and enforced
  - increased trust between Member States
  - …and with Trade Partners
  - Health and safety EU citizens

Role of the Dir. F

- Ensures **trade partners can provide equivalent guarantees** that commodities intended for export to the EU meet the EU requirements
- Assesses specific issues, the controls taken, and the need for additional EU legislation as appropriate
  - Task force
  - Work groups
- Defined in Regulation 882/2004 for Food and Feed or Directive 2000/29 for plant health, as recently amended.

How does the Dir. F do it?

- Carries out **audits** in Member States, candidate countries and trade partners.
- **Reports** on its findings (publicly).
- Makes **recommendations** to Competent Authorities (CA) to address identified shortcomings.
- **Follow-up** on the implementation of corrective actions proposed by CAs.

How does the Dir.F do it?

- Carries out extensive **non-audit work**
  - Desk studies, mandatory reporting
- Contribute to **policy development** within the Commission
  - Overview reports
- Active in BTSF

Previous audit reports

- Individual audit reports
- Overview audit reports

- Publicly available on Directorate F web page

  http://ec.europa.eu/food/fvo/audit_reports/index.cfm

Country Profile

- **provide** a horizontal, integrated, country-based overview which:
  - **Helps** to identify the main strengths and weaknesses of the control systems audited
  - **Assists** the overall prioritisation of DG SANTE audits and other monitoring activities
  - **Supports** the systematic follow up of recommendations in DG SANTE activities and reports
  - **Documents** progress made by MS on implementing DG SANTE recommendations
  - **Serves** as a basic source of background information for stakeholders

Annual Reports

- Article 44 of Regulation 882/2004
- Member States submit to the Commission. Comprises the results of the official controls carried out under their MANCP
- Commission Annual report on the overall operation of controls in the MS:

  http://ec.europa.eu/food/audits_analysis/annual_reports/index_en.htm
- Reports available to the public

Multi-Annual national control plans

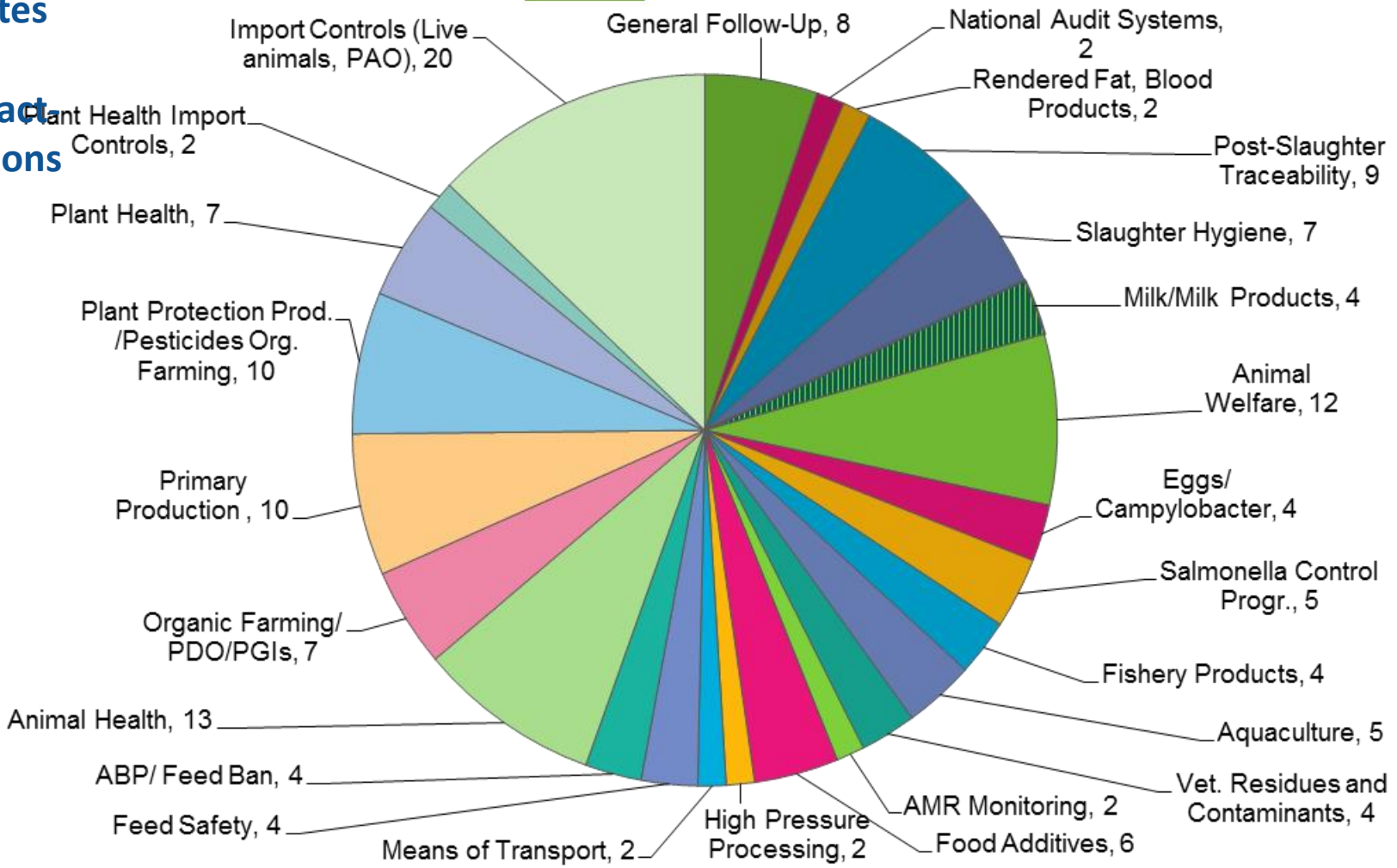
- Art 41 of Regulation (EC) No 882/2004
- Each Member State has a multi-annual national control plan (MANCP) to ensure effective implementation of food/feed safety, animal health and animal welfare rules
- Updated regularly
- MANCP to take account of guidelines of the EU Commission

Dir. F audits

- 250 audits each year
  - Food safety - 150
  - Food quality - 14
  - Animal health – 15
  - Animal welfare – 11
  - Plant health and seeds – 22
  - General follow-up - 9

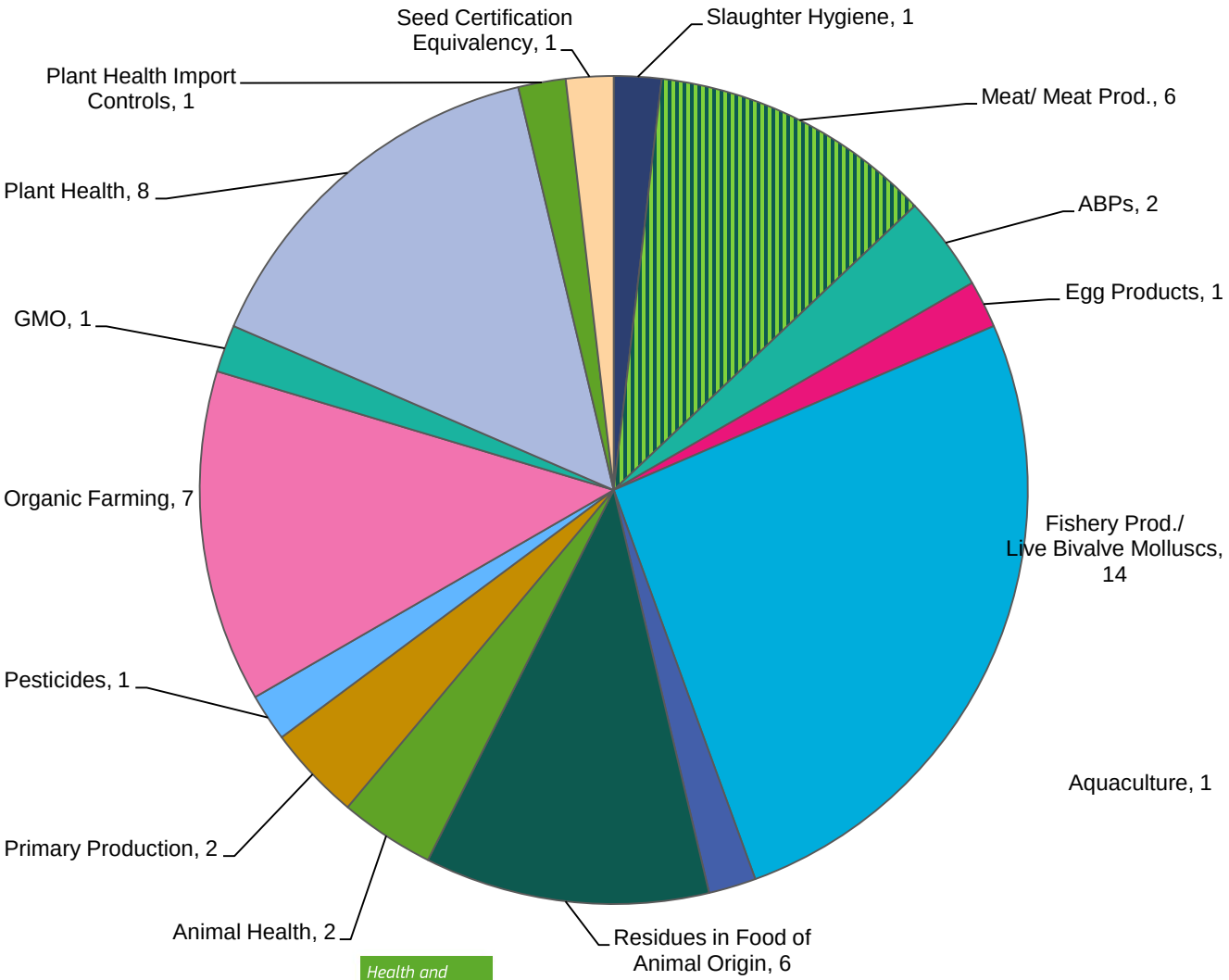
Member States

155 audits, fact-finding missions and study-visits completed



Trade partners incl. cand. countries

54 audits, fact-finding missions and study-visits completed



Dir. F audits

- 250 audits each year
  - 60% EU Member States
  - 40% in Candidate Countries and other Trade partners

European Commission

The EU Audit approach

Implementation and Enforcement of EU laws

European Commission

Audit cycle

Planning

Pre-audit activities

Audit

Post-audit activities

END

Dir.F Programme

Project planning

Technical and administrative preparation

Audit Performance

B T O

Draft Report

Final Report

Intra-Unit Follow-up

F7 Follow-up

END

F7 Input

European Commission

The objectives of the audits are to:

1. Ensure satisfactory levels of compliance to EU requirements (import requirements)
2. Produce report and recommendations
3. Follow up and output for Country Profiles
4. Inform in full transparency the Council (MSs), the European Parliament and other stakeholders

Dir. F audit process

- Based on standard auditing practice
- Agreement with CA
- Audit plan and questionnaire
- Opening meeting
- Site visits
- Closing meeting

European Commission

Audit on the spot

- To assess the Competent Authority supervision power
- CA performance
- Capability of ensuring that food business operators comply with Union legislation or
- Provide guarantees equivalent to said legislation

European Commission

Audit

- *To assess the fulfilment of EU import conditions*
- *To inspect the establishments, randomly*
- *To assess the general sanitary conditions*
- *Carry out "ad hoc" audits in specific fileds (AH, PH, Residues, etc.)*

Pre-audit activities

Audit plan

Report template – ready before start of series

Information gathering

- **Pre-audit questionnaire**
- **Other sources of information**

Itinerary

Audit plan

- *Provides information on:*
  - **Objectives, scope and depth**
  - **Background**
  - **Audit procedures**
  - **Main areas of examination**
  - **Language to be used**
  - **Reporting procedure**

European Commission

Information gathering

- Audit questionnaire
- Country profiles
- Multi-annual national control plans (MANCP)
- Previous audit reports
- RASFF
- TRACES
- Trade data

Audit questionnaire

- *To gather necessary information, for example:*
  - **Updates of legislation/procedures**
  - **Update of actions taken**
  - **Sampling programmes**
  - **Data on exports to EU**

Itinerary

- *Opening meeting*
- *On-site visits*
  - **Documentary review**
  - **Interview**
  - **Observation**
- *Closing meeting*

Audit

A number of establishments in the trade partners to check:

- If the CA are seen to be competent and capable of maintaining a credible system of official controls on the production of food of animal origin
  - the country may then benefit 'pre-list'
- Once accepted
  - establishments would be free to export the respective foodstuff to the EU

Listing of food establishments is handled by SANTE/F

Listing of establishment for animal by-product are listed by SANTE/G.

Reporting and follow-up

- Back-to office note
- Draft report
- Comments from the Competent Authority
- Final Report
- Competent Authorities Action Plan
- Follow-up of report recommendations
- Close-out Note (Unit level)
- Overview report of series of audits

Post Audit Follow-up

DG Health and Food Safety Follow-Up process – General

- "Standard" follow-up
  - Administrative follow up of each individual **Non-EU** Audit
  - General Follow-up Audits, Desk Audits and Administrative Updates to the **Country Profile** for **Member States**

- "Extraordinary" follow-up
  - Verification on-the-spot by means of a follow-up audit

- The system is flexible in dealing with specific situations

Post Audit Follow-up

Actions *can* be taken immediately at the end of an audit and before the normal follow-up procedures of F7

When an audit identifies an **immediate threat to consumer, animal or plant health**, the Commission may take emergency ("safeguard") measures

Post Audit Follow-up

- All recommendations contained in audit reports are uniquely identified in the workflow/information system **"MisDoc"**

- Following assessment by the audit unit (F1, 2, 3, 4 and 5) of the Competent Authority's **Action Plan**, a Closeout Note (CN) is prepared and sent to unit F7

- The Close out Note assesses the "adequacy" of the response for each recommendation and includes advice to F7 on which specific follow-up actions are required.

- **All recommendations stay open until closed by F7**

General Follow-up in Member States

- Assessments of corrective actions are based on verifiable assurances, documentary evidence and dialogue with the competent authorities.

- Recommendations are then classified as
  - **Action taken** **(Closed)**
  - **Action in progress** **(Open)**
  - **Action still required** **(Open)**

- Recommendations still open after GFA **remain the subject of monitoring** by the Commission to assess progress

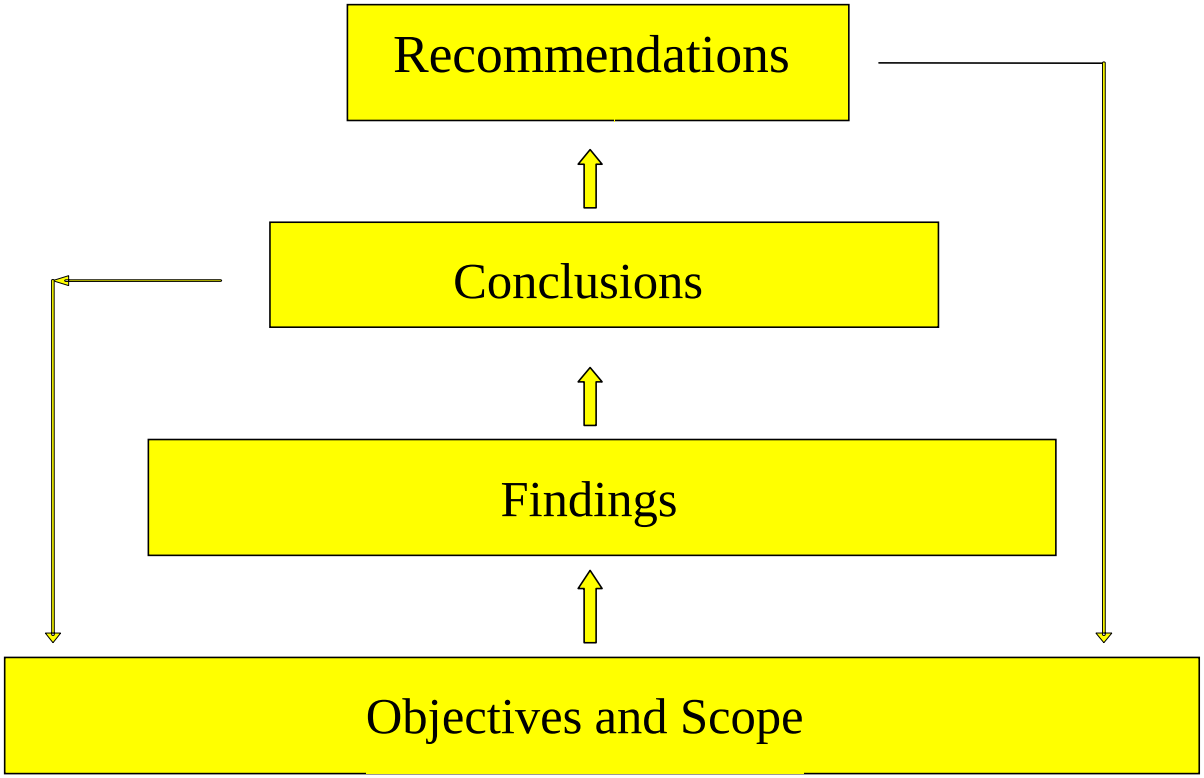
- MS are invited to provide DG Health and Food Safety with an Action Plan on any cases of **"Action still required"** within one month of receiving the final **Country Profile** (CP)

Follow up measures "Action still required"

- **SANTE Management Committee on follow-up**
  - *Meeting every quarter to discuss further DG SANTE follow up measures including on "Action still required" cases and other issues (e.g. safeguard measures)*
- **All these actions may lead to additional measures:**
  - *Forwarding file for further enforcement,*
  - *Pressure on MS (at PAFF* meetings),*
  - *High-level discussions with counterparts in the MS.*
- **As a last resort, legal action under EU law may be taken by the Commission to ensure that Member States meet their obligations under Community law.**

*** Standing Committee on Plants, Animals, Food and Feed – a regulatory committee of the Commission to which EU Parliament and Council have delegated their power**

Coherence


Recommendations
Conclusions
Findings
Objectives and Scope

Useful links

Dir F main page

http://ec.europa.eu/food/food_veterinary_office/index_en.htm

Dir F reports

http://ec.europa.eu/food/fvo/audit_reports/index.cfm

Videos

Dir F introduction

https://www.youtube.com/watch?feature=player_embedded&v=c0J_3wIz6Qg

Food, 500 Million Reasons to keep it safe" (video)

http://www.youtube.com/watch?v=MYt_FRwNu7w

European Commission

Prof. Andrea DIONISI
European Commission
DG Health & Food Safety
Bilateral International Relations

Health and Food Safety

Regional Workshop on Animal Disease Preparedness

Thierry van den Berg

Better Training For Safer Food

The EU analytical support system: the role of the EU and National reference laboratories

Tokyo, Japan
12-15 June 2018

Food Safety

EU Veterinary Control System

Prevention	Detection	Control	Transparency
Biosecurity Animal identification Veterinary certification and movement control for intra-EU trade of livestock Veterinary certification and border controls for animals and products imported.	Surveillance Reference laboratories Health monitoring in high risk areas Animal Disease Notification System.	Contingency planning Animal Disease Notification System Isolation of infected holdings Eradication EU support: Emergency team, vaccine banks, compensation, trainings.	EU audits of Member State veterinary services Public information systems (RASFF, ADNS) Scientific consultations Notification.

DG SANTE priorities on animal health policy

The new Animal Health Law:

1. **Puts emphasis on increased effort to anticipate possible outbreaks of new or exotic diseases in the EU**
2. **Provides even more solid foundation to ensure that the high levels of protection in the EU**
3. **EC to deliver on the objectives of this Law:**
   - simpler and clearer rules focus on key priorities: preventing and eradicating disease with **prioritization by listing** and **categorizing** diseases
   - modern **technologies:** for surveillance and early detection, **electronic identification** and it is even more aligned with international standards
   - **more flexibility**: to adjust rules to local circumstances, and to emerging issues such as climate and social change

Reference organization

Official laboratories **network** at EU and national level (OIE/WHO)

+

official method with known and **shared performance criteria**

+

Competences

Reference activities and outbreaks

=

confidence

The key-role of the EURLs

A) General role

Coordination of high quality methods employed for diagnosing diseases in EU

B) Specific role in crisis management

Assist actively in diagnosis of disease outbreaks in MS

Current role under 882/2004,
Future role under 2017/625

Regulation (EC) No 882/2004 ---> Regulation (EC) No 625/2017

KEY: Activities of EURLs/NRLs should cover all areas of food and feed law and animal health.

Responsibilities and requirements described for

882/2004: EURLs in Article 32, NRLs in Article 33

625/2017: EURLs in Article 94, NRLs in Article 101

EU reference centre for Animal Welfare, Article 96

Distribution of responsibilities among Commission, Member States, EURLs and NRLs; more specific and more precise

EURL network 2017

46 EURLs

28 Food and Feed safety

18 Animal Health

2 new EURLs animal health designated in 2016

PPR and LSD

New EURL selected in 2017

Viruses in food

Brexit: UK EURLs moving to other EU countries (2019)

- EURL - Animal health and live animals
- Avian Influenza and Newcastle Disease
- Bluetongue
- African Horses sickness
- Foot and Mouth Disease
- African Swine Fever
- Classical Swine Fever
- Molluscs diseases
- Zootechnics (bovine breeding)
- Brucellosis
- Fish diseases
- Bovine Tuberculosis
- Crustacean Diseases
- Equine diseases
- Rabies
- Bee Health
- Peste des Petits ruminants
- Capripoxes

Regulation (EU) No 2017/625

The new legislation concerning the designation and tasks of the **European Union Reference Laboratories** and the European Union Reference Centres is in Regulation (EU) No 2017/625 on import and export of animals and goods starting 29 April 2018.

1. European Union reference laboratories shall contribute to the improvement and harmonisation of methods of analysis, test or diagnosis to be used by official laboratories designated in accordance with Article 37(1) and of the analytical, testing and diagnostic data generated by them.

2. European Union reference laboratories designated in accordance with Article 93(1) shall be responsible for the following tasks

3. European Union reference laboratories shall publish the list of the national reference laboratories designated by the Member States in accordance with Article 100(1).

TASKS

(a) guidance on the laboratory methods;

(b) providing reference materials to NRLs;

(c) coordinating the methods and in particular, by organising regular inter-laboratory comparative testing or proficiency tests (PTs);

(d) coordinating practical arrangements necessary to apply new methods;

(e) conducting training courses;

(f) providing scientific and technical assistance to the Commission;

(g) providing info on relevant research activities to Com & NRLs;

(h) collaborating within the scope of their mission with laboratories in third countries and with the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC);

(i) assisting actively in the diagnosis of outbreaks by carrying out confirmatory diagnosis, characterisation and taxonomic or epizootic studies on pathogen isolates;

(j) coordinating or performing tests for the verification of the quality of reagents and lots of reagents (certification and batch control);

(k) where relevant for their area of competence, establishing and maintaining reference collections of pathogenic agents and provide samples thereof to national reference laboratories; up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents;

(l) where relevant for their area of competence, cooperate among themselves and with the Commission, as appropriate, to develop methods of analysis, testing or diagnosis of high standards.

As regards point (i) of point (k), the European Union reference laboratory may establish and maintain those reference collections and reference strains by contractual outsourcing to other official laboratories and to scientific organisations.

EXAMPLE: PROPOSED WORK PROGRAMME FOR THE EUROPEAN UNION REFERENCE LABORATORY FOR FOOT-AND-MOUTH DISEASE

Activity 1: Distribution of high quality ELISA kits and reagents

Activity 2: Review and evaluate new analytical methods that have been developed

Activity 3: Promotion of EU-RLs collaboration with laboratories in third countries

Activity 4: Perform vaccine matching and European Pharmacopeia potency tests on vaccine antigens held in the European Union FMD vaccine bank

Activity 5: Identify new emerging threats to Europe

Activity 6: Carry out Proficiency Testing Scheme (PTS) for the National Reference Laboratories in EU member states in 2016 and 2017

Activity 7: EU-RL to carry out an annual workshop for the NRLs

Activity 8: Share information between the EU-RL and NRLs

Activity 9: Administrative Activities to ensure sound and efficient management

Main requirements for NRLs in the Reg. 625/2017

- **Competent Authorities responsible for designating a NRL for each EURL (Total network in EU >1300) (art 100)**
- **Assist Competent Authorities in outbreaks! (art 101)**
- **Ensure the dissemination to the competent authorities and official laboratories of information that the European Union reference laboratory supplies**
- **NRLs to comply with:**
  - ISO 17025 (art.100 and 37)
  - obligations to participate successful in trainings & proficiency tests with EURLs (art. 101);
  - Coordinate activities of official laboratories (art 101)
- **NRLs to be equipped with biosecurity standards (art 100)**
- **Conduct training courses for Official Labs**
- **NRLs subjects to audits by Competent Authorities in the Member States (art. 39)**

Notifiable animal diseases - an EU approach

What? Animal infectious agents with higher impact on economy, public safety, **zoonotic threats**

Who? Everyone, including suspicions of outbreaks

<u>Two exemples</u>:

<u>Diagnosis</u>: constant evolution of NAI

<u>Vaccination</u>: evaluation of LSD vaccines

Concepts of AI diagnosis

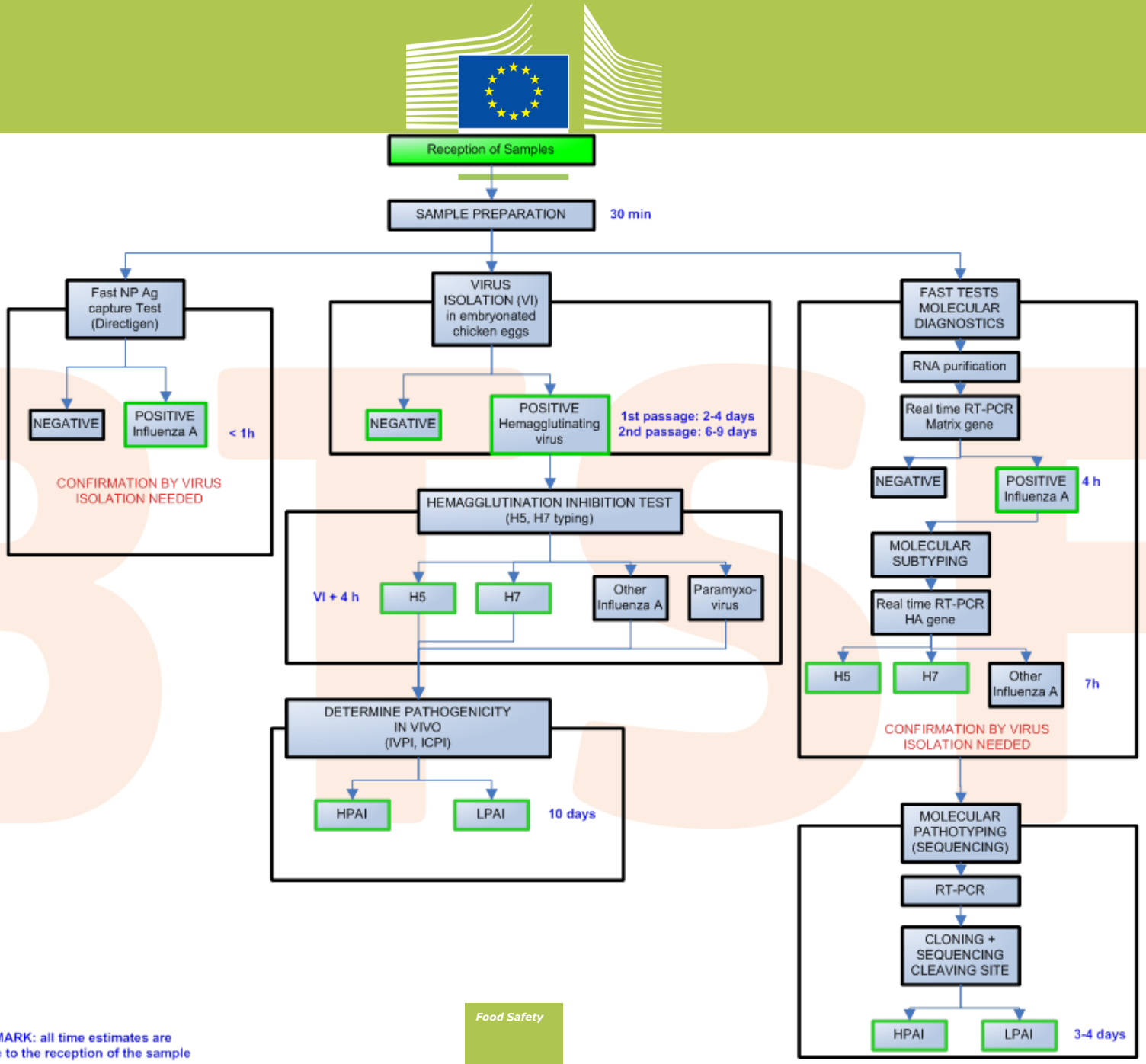
Must be:

- - Rapid, sensitive, specific
- - Harmonized (recommended & validated protocols)
- - Quality controled (QMS, ISO certification, PT)
- Hierarchically organized (international/national/regional, private/public…)

Legal bases and legal bindings

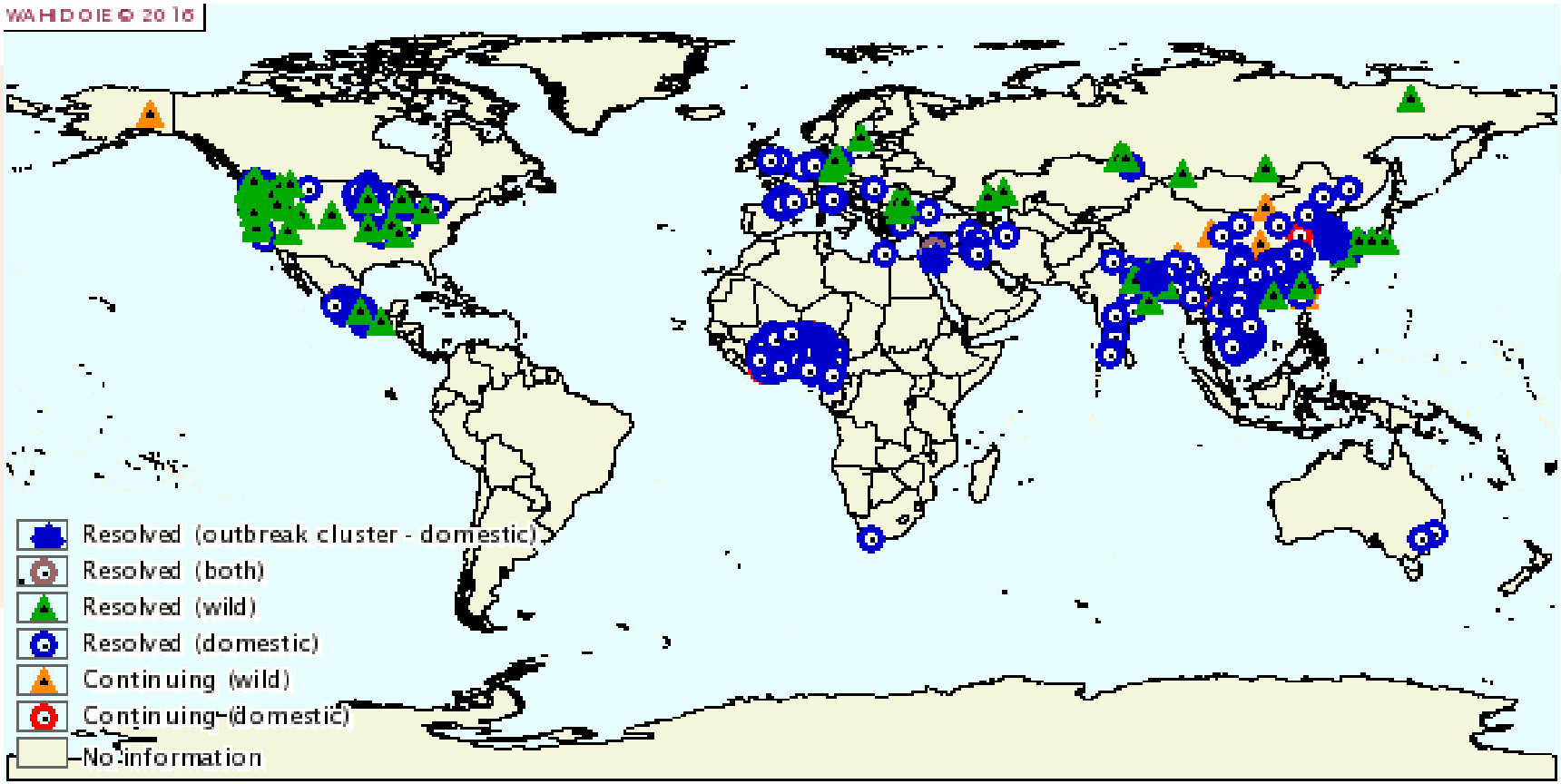
Directive 2005/94/EC

Decision 2006/437/EC (Diagnostic Manual)



REMARK: all time estimates are relative to the reception of the sample

World situation 2016



The current European AI status: sporadic and isolated cases

- Sporadic occurrence of clinically suspicious flocks
- Sporadic serological evidence of presence of NAI in single flocks
- No (or low) sustained chains of transmission

Immediate detection allows containing virus at index case and minimize restrictions

- Early warning systems
- Syndromic, active and passive surveillances
- Rapid reporting
- Good and informative sampling
- Rapid diagnosis

Endemic situation: stamping out alone not an option anymore…

- Ubiquitous virus presence and circulation (evolution)
- Recycling waves of virus (e.g. H5Nx)
- Reservoirs of virus (LBM, retailers, Wils Birds…)
- Public Health concern if zoonotic potential…

Adapt diagnosis in order to detect the broadest scope and minimize time to diagnostic

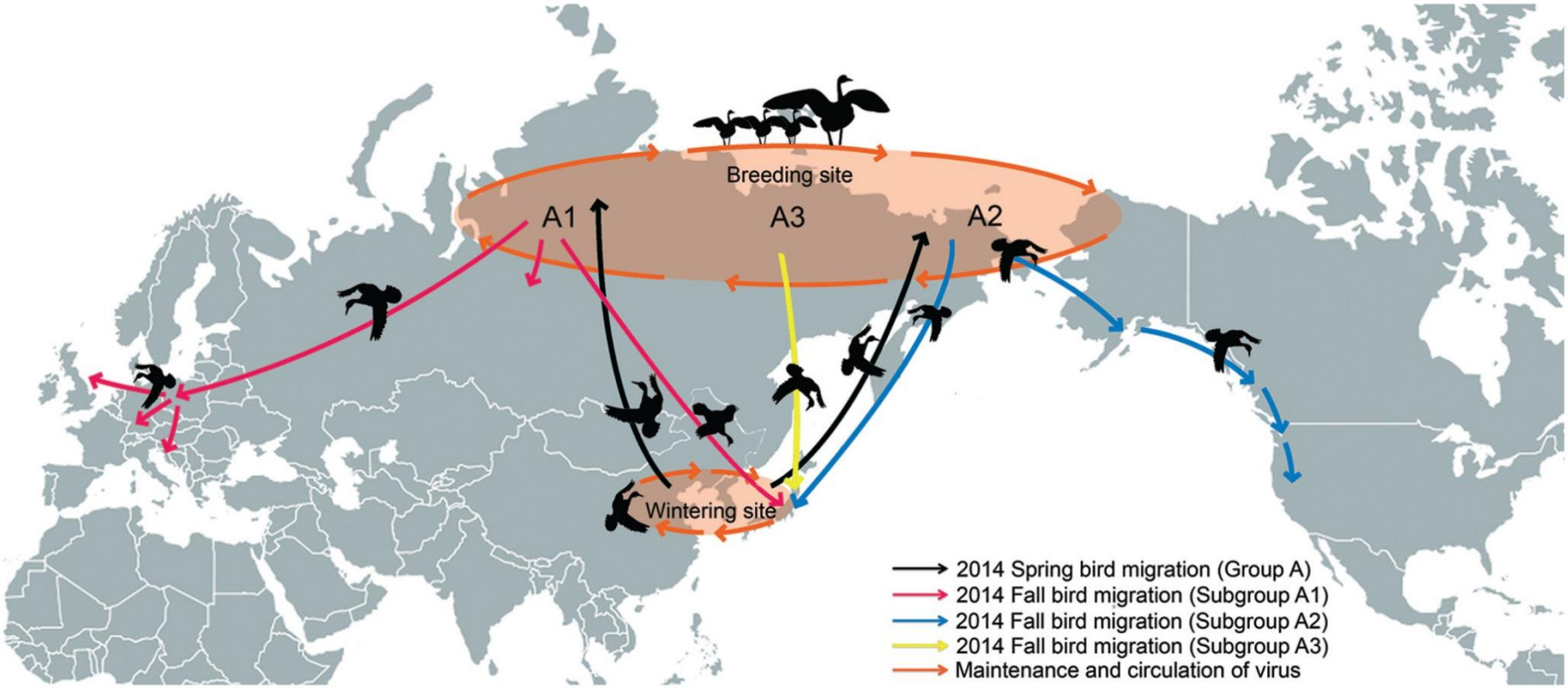
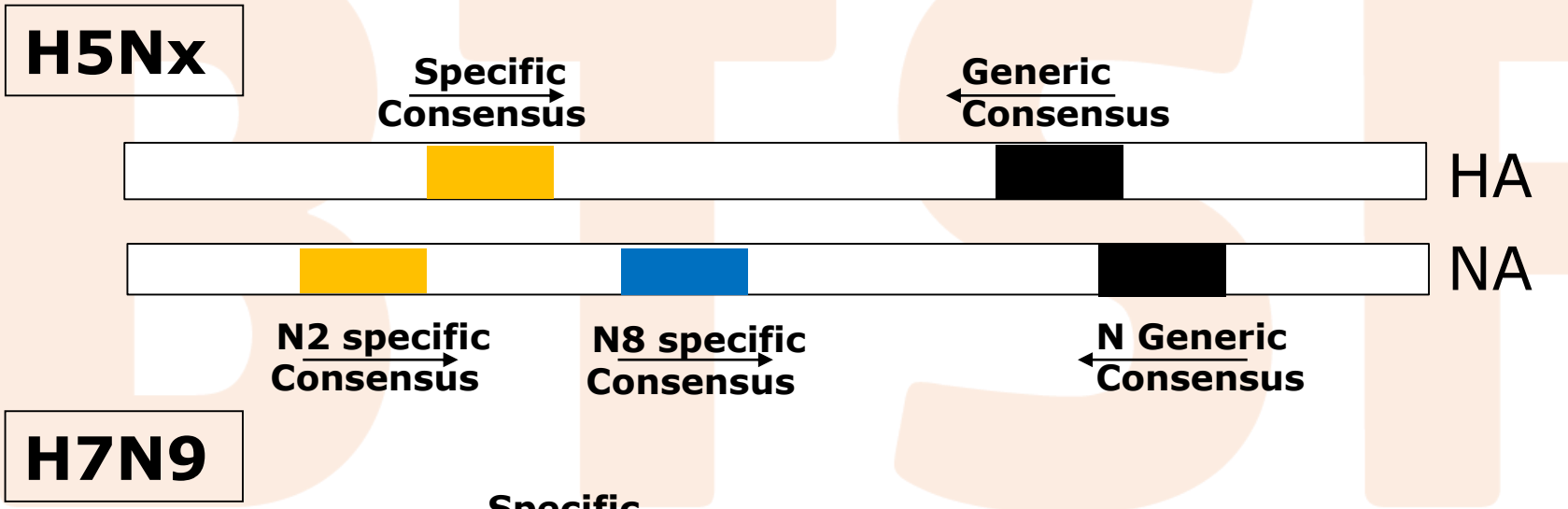


FIG 2 Geographic map showing the movement of H5N8 HPAIV in Asia, Europe, and North America in relation to regional waterfowl migration routes. The map, by Dmthoth, is from Wikipedia Commons (http://commons.wikimedia.org/wiki/File:Blank_Map_Pacific_World.svg).

Adapt methods to minimize time-to-diagnostic



T. Harder et al., FLI, Germany

FLU-LAB-NET An EU funded Avian Influenza programme

Welcome to FLU-LAB-NET - Enhancing Global Avian Influenza Networks

FLU-LAB-NET was founded through funding from a European Framework 6 programme to deliver new opportunities for the enhancement and reinforcement of the European Union Reference Laboratory (Animal and Plant Health Agency – Weybridge, UK) and the National Reference Laboratory network for Avian Influenza within the European Union.

This facility provides an interactive forum for laboratory specialists and other scientific professionals working in the area of veterinary public health with specific interest in animal influenza. It also provides a rapid way of disseminating some of the latest information at a global level.

This site is currently under review. Further content will be available shortly.

10th International Symposium on Avian Influenza (ISAI 2018)

The symposium will take place 15 - 18 April 2018 at the Grand Hotel in Brighton. It provides an opportunity for scientists, biologists, medics, veterinarians and government regulators from all over the world to exchange and discuss current scientific information on avian influenza.

Find out more about the ISAI 2018. Full conference programme now available.

EU Reference Laboratory contributes to Avian influenza articles

The EU Reference Laboratory for Avian Influenza has contributed to the following publications:

- Avian influenza overview November 2017 - February 2018
- Avian influenza overview September - November 2017
- Avian influenza overview October 2016 - August 2017

Situation assessment following detection and spread of H5N8 HPAI in EU Member States

The International Reference Laboratory (IRL) at APHA Weybridge is keeping the ongoing epizootic with H5N8 HPAI in Europe and beyond under constant review. See the situation assessment reports below.

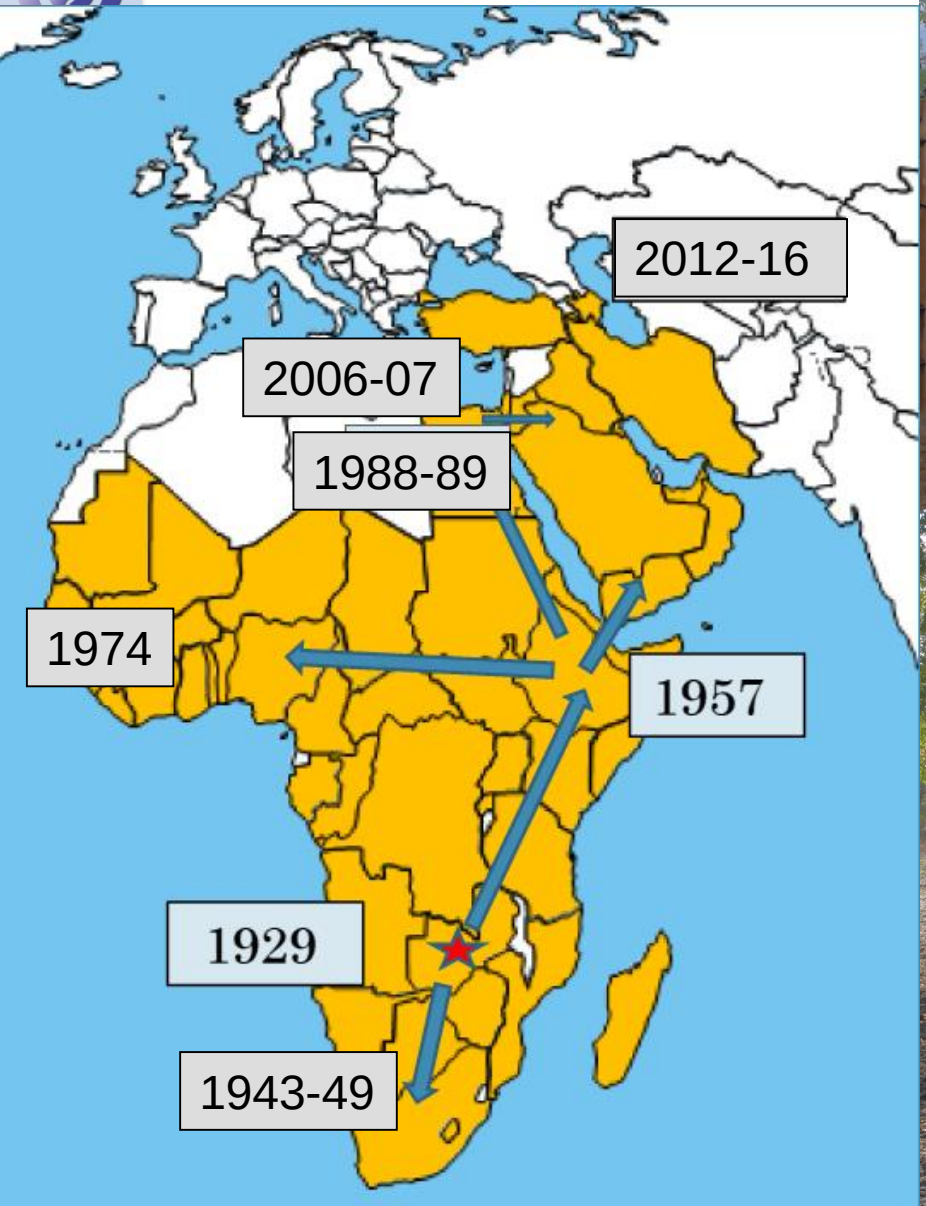
- Updated situation assessment report (published February 2018)
- Phylogenetic tree from February 2018 situation report

- Previous situation assessment report (published November 2017)
- Phylogenetic tree from November 2017 situation report

In vivo evaluation of Lumpy Skin Disease vaccine efficacy in controlled environment

Kris De Clercq, Andy Haegeman, Ilse De Leeuw, Annebel De Vleeschauwer, Laurent Mostin, Willem Van Campe, Maria Vastag, Claude Saegerman, Eeva Tuppurainen, Thierry van den Berg

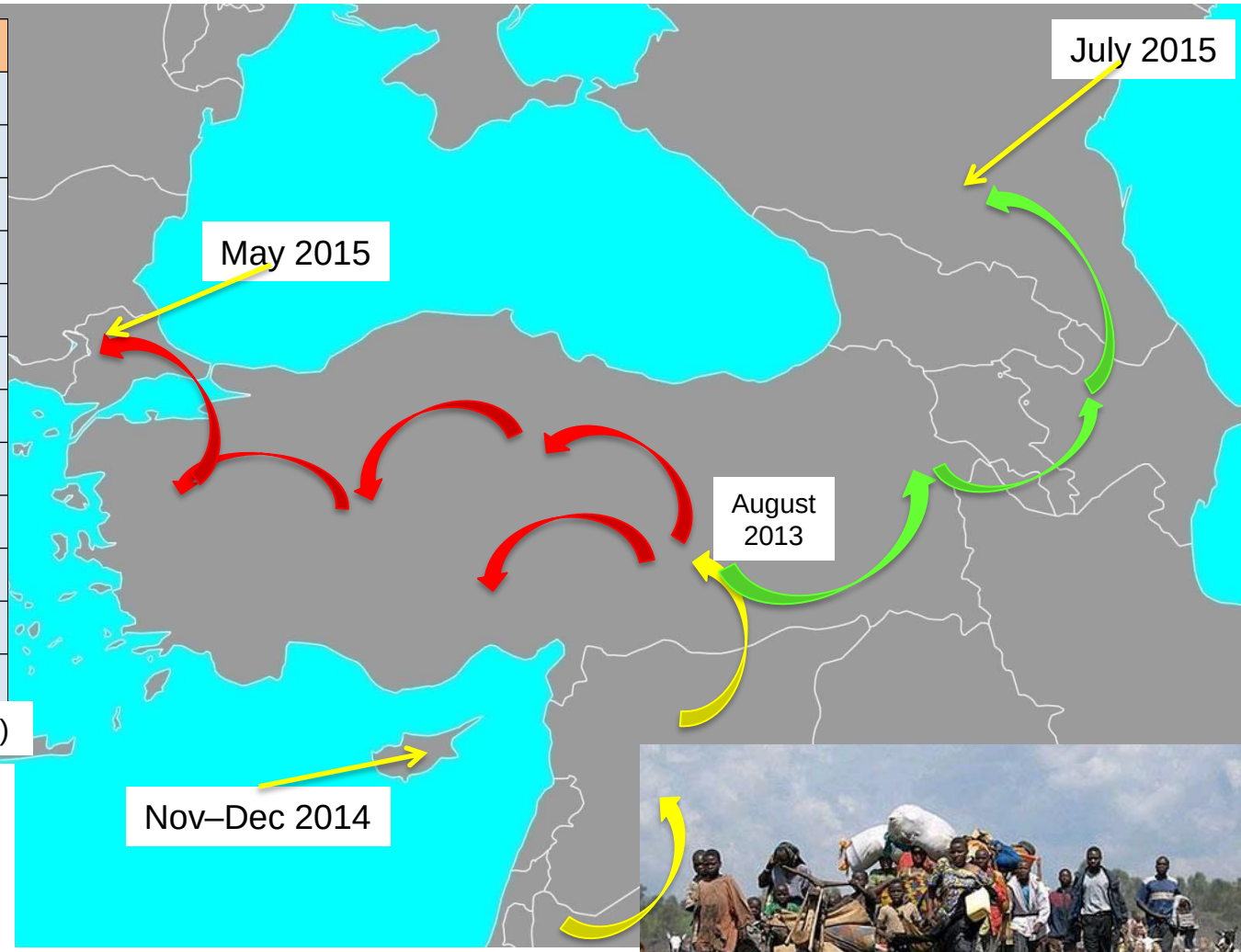
Spread of Lumpy skin disease



Spread of Lumpy skin diesease (LSD) 2013-2015 Middle-East, Turkey, Cyprus, Caucasus, Russia

Country	Period
Israel	2012 (July)
Lebanon	2012 (Nov)
Jordan	2013 (April)
Irak	2013 (August)
Turkey	2013 (August)
Egypt	2013 (Decem)
Iran	2014 (May)
AzerbaiJan	2014 (July)
Cyprus	2014 (Nov)
Kuwait	2014 (Nov)
Russia	2015 (July)
Greece	2015 (August)

Table from Dr Alessandro Rippani (OIE)



Lumpy Skin Disease epidemiological situation in recent years (Global)

Source : EFSA Journal 2015;13(1):3986, EFSA opinion on LSD , OIE 2015

Choosing a vaccine against LSDV

-Live attenuated LSDV vaccines provide good protection in cattle and is superior to sheeppox virus (SPPV) vaccines (Ben-Gera et al 2015)

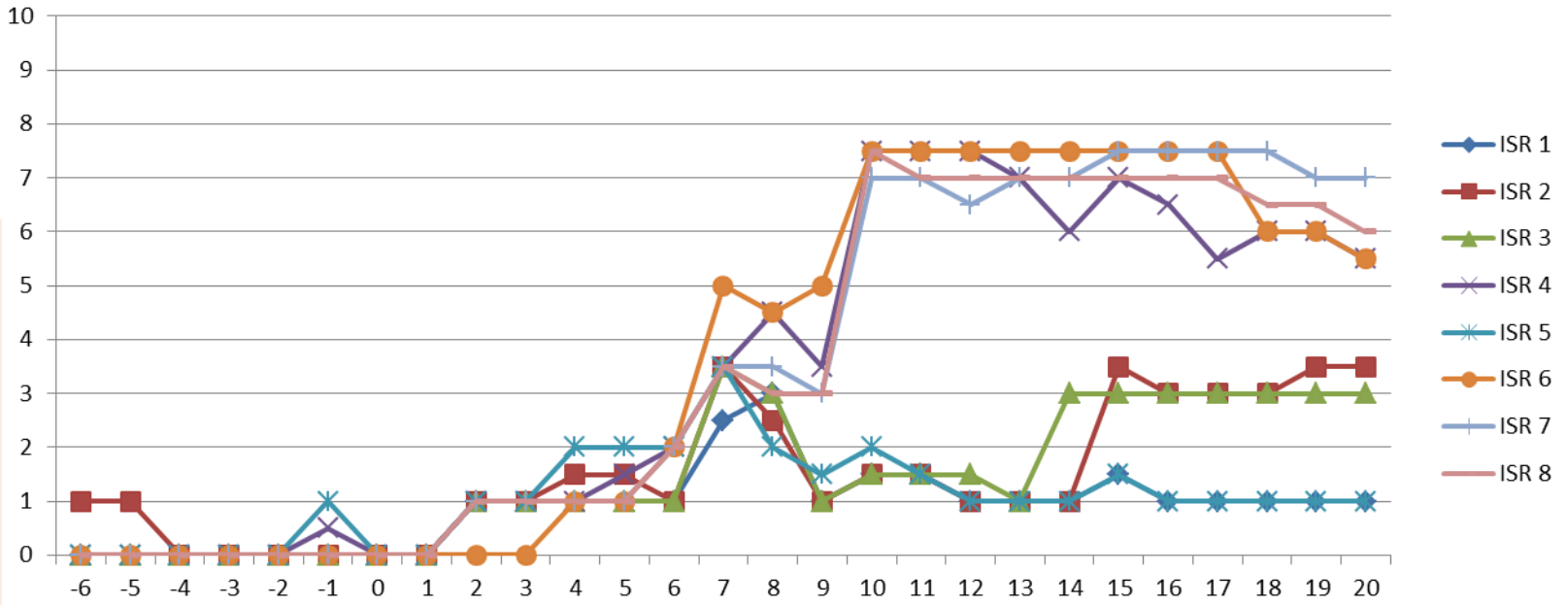
- Only vaccines with demonstrated efficacy and safety should be used
  - Independent vaccine challenge experiment
- - Vaccines should be produced according to Good Manufacturing Process (GMP), vaccine virus needs to be molecularly characterized, contain sufficient virus titre and be free of extraneous agents
- Where distribution of SPP and GTP overlaps with LSD

SPPV vaccines may be used for cattle against LSDV if sufficient vaccination coverage and other appropriate control measures in place

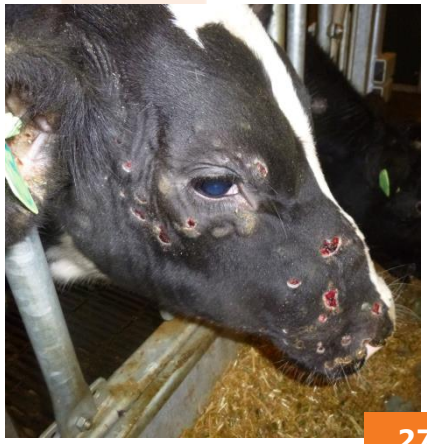
- GTPV containing vaccines are not yet used against LSD but has been demonstrated to provide good protection against LSDV

LSDV: Infection Model

- Infection route:
  - Intravenously
  - Intra-dermal: 4 sites, 2 on each side of the neck
- Infection dose: $10^{5.4\text{-}6}$ $TCID_{50}$/100 µl
- Number of animals per group: N = 8
- Clinical scoring (21 days) includes:
  - Body temperature, Lnn swelling, nodule development (number and size), feed uptake, conjunctivitis, general behaviour, local reaction (vaccination and challenge sites)
- Sampling
  - EDTA blood, buccal swabs: PCR, Virus isolation
  - Biopsies, tissues and organs: PCR , Virus isolation
  - Serum: IPMA and virusneutralisation test
  - Heparinized blood: IFN release



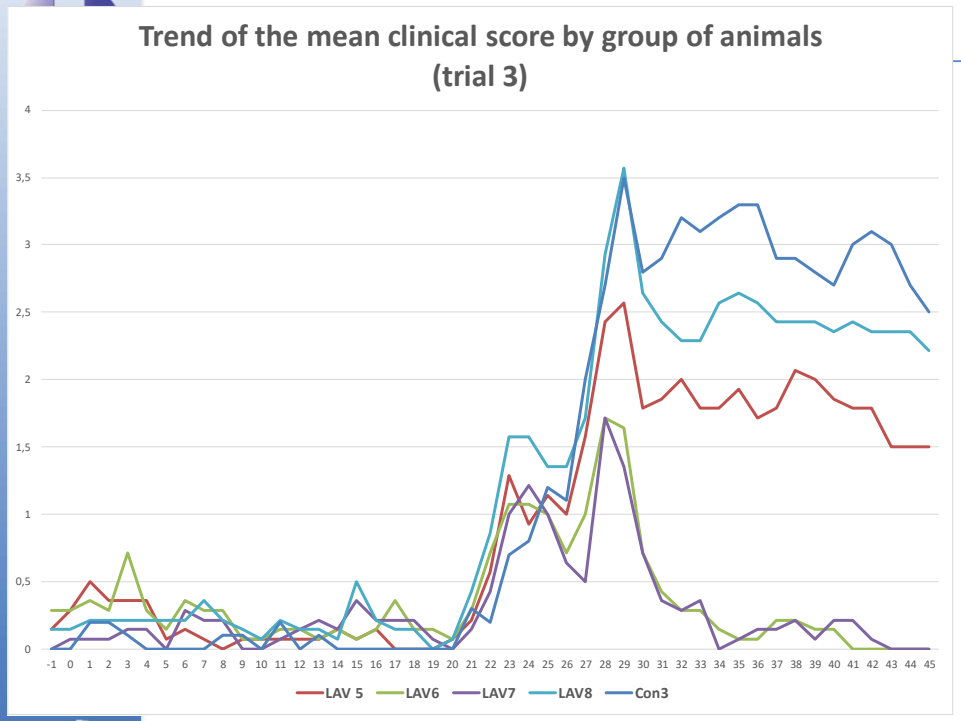
- Clinical signs after challenge Number of nodules / generalisation / clinical score
- Body temperatures: fever peak around 7/8 dpi
- Seroconversion: Onset : 4 to 13 dpi
- Virus detection in blood: detection as early as 2/3 dpi
- IFNg release upon stimulation *in vitro*

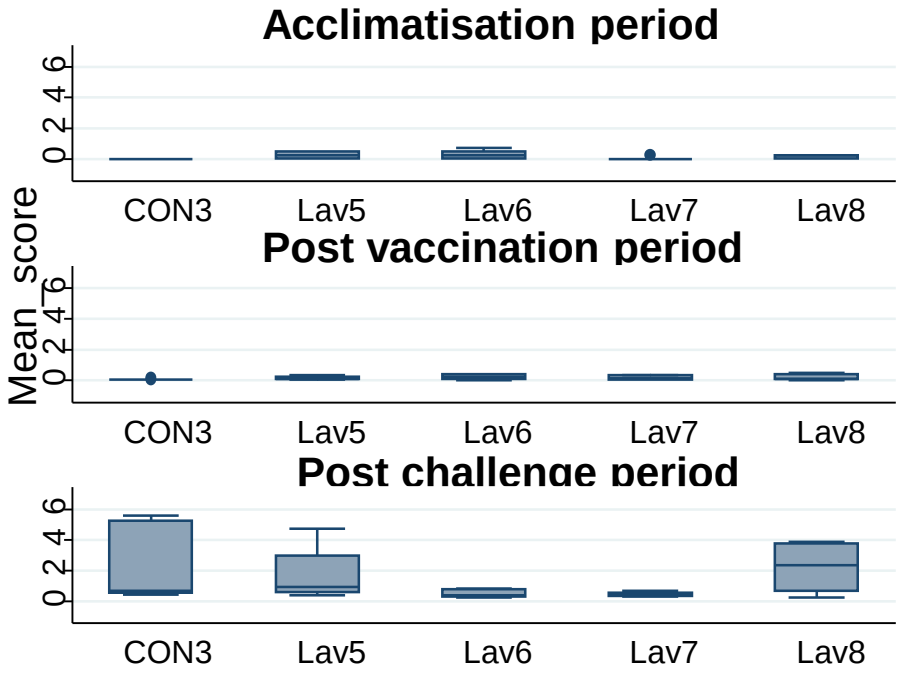


LSDV: Vaccine trials

- **Commercial available → Live attenuated vaccines (LAV)**
  - Sheeppox based (RM-65)
    - ✓ JoviVac (Jordan Bio-Industries Center (JOVAC); Jordan)
    - ✓ Abic (Abic Biological Laboratories Ltd (Phibro); Israel)
    - ✓ Penpox (Pendink Institute; Turkey)
  - LSDV-based
    - ✓ OBP (Onderste Poort; South-Africa)
    - ✓ LumpyVax (MSD; South-Africa)
    - ✓ HerbiVac (Deltamune, South-Africa)
  - Goatpox based
    - ✓ CapriVac (Jordan Bio-Industries Center (JOVAC);Jordan)
  - Sheep and goatpox based or LSDV? (Cfr Tuppurainen et al., 2014)
    - ✓ KSGP 0240/0180 (Jordan Bio-Industries Center (JOVAC)
- **New Inactivated Vaccine (MCI, Morocco)**
  - Sheeppox-based
  - LSDV-based

Results of Trial A





LAV6 & 7 = best efficacy

LSDV Vaccine trials: first conclusions

The LSD challenge model allows the identification of:

- Vaccines with very good potential
  - **No** viremia, elicits **high** Abs response and **good** IFNg release, **almost no** traces of viral DNA found in organs
  - Although very slight side effects after vaccination (fever)
- Vaccines with potential
  - **Almost no** viremia, elicts **good** Abs and IFNg response , **almost no** traces of viral DNA found in organs
- Vaccines (partially) failing to protect the animals
  - **Strong** viremia, **Low** Abs and IFNg response, virus **widely spread** in the organs. Animals in this groups also **secreted** the virus as detected by buccal swabs.
- None of the LAV vaccines protected against the initial fever spike !
- Inactivated vaccines: boost needed; promising results.

European Commission

An additional role for EURLs: Future Trends on EU vaccine banks

✓More sophisticated vaccine requirements.

✓Active involvement of the **EURLs** in quality / safety controls.

Tenders in the pipeline for vaccines' purchase (EU Vaccine banks)

➢Call for tender for up to 2 million doses of **Peste des Petits Ruminants vaccines**

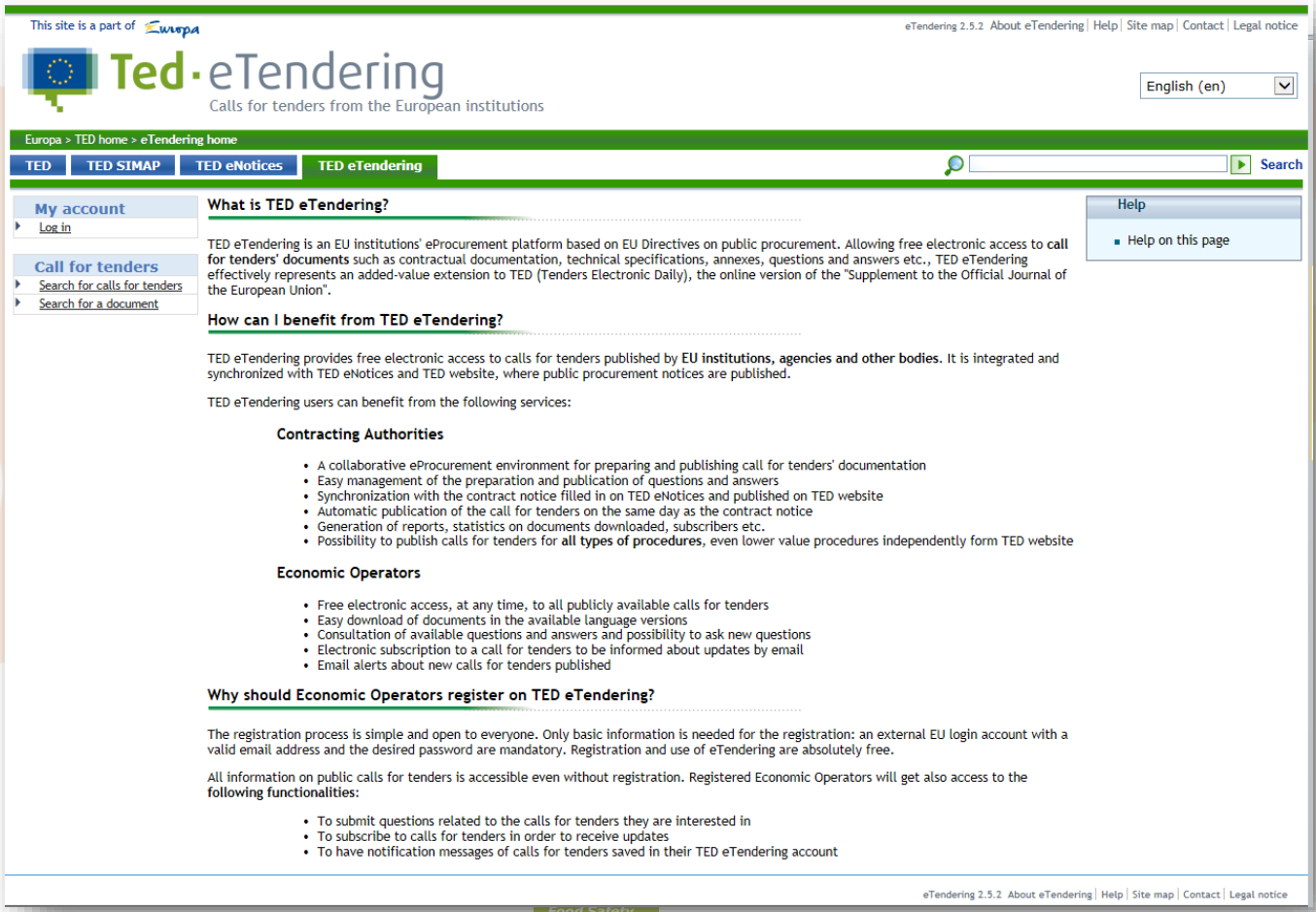
➢Call for tender for **Lumpy Skin Disease vaccines**

➢Call for tender for **Sheep & Goat Pox** vaccines

European Commission

EU vaccine banks tenders available on the TED eTendering website

https://etendering.ted.europa.eu/general/page.html?name=home



EURL website

All general information about EURLs in one tab in "Horizontal Topics":

List of all EURL with links to

- **the website of the EURL**
- **the connected NRL network**

Link to EURL work programmes of the last years

Completely updated

https://ec.europa.eu/food/ref-labs_en

European Commission

ANIMALS

European Commission > Food Safety > Animals

HEALTH | FOOD | ANIMALS | PLANTS | AMR

AMR Workshop – Antimicrobial consumption in animals: achievements and challenges in data collection (26/04/2017)

The main aim of the workshop is to explo how data on antimicrobial consumption animals can be improved. The discussion v also provide technical input for proposed leg provisions at EU level.

All highlights

FOOD SAFETY: OVERVIEW

- ANIMAL HEALTH POLICY DEVELOPMENT
- ANIMAL DISEASES
- TRACES
- ANIMAL WELFARE
- LIVE ANIMALS
- IDENTIFICATION
- ANIMALS PRODUCTS
- ZOOTECHNICS
- SEMEN, OVA & EMBRYOS
- VETERINARY BORDER CONTROL
- MOVEMENT OF PETS

HORIZONTAL TOPICS RELATED TO FOOD SAFETY

- GENERAL FOOD LAW
- BETTER TRAINING FOR SAFER FOOD
- FITNESS CHECK OF THE FOOD CHAIN
- FOOD CHAIN FUNDING
- FUTURE OF EU FOOD SAFETY
- EXPERT GROUPS
- OFFICIAL CONTROLS AND ENFORCEMENT
- COMMITTEES
- INTERNATIONAL AFFAIRS
- EU REFERENCE LABORATORIES
- HEALTH AND FOOD AUDITS AND ANALYSIS

Share

TWITTER FEEDS

EU Food Safety @Food_EU

#BioTechEU Conference on Modern #Biotechnologies in #Agriculture #innovation #foodsafety #EU - agenda & streaming europa.eu/!MF47rh pic.twitter.com/jZaaKd85Pj

45m

EU Food Safety @Food_EU

#fipronil #EU #foodsafety twitter.com/V_Andriukaitis...

30m

More tweets

QUICK LINKS

- European Food Safety Authority (EFSA)
- Health and food audits and analysis
- Trade Control & Expert System (TRACES)
- Travelling with pets
- Better Training for Safer Food (BTSF)
- E-News
- Press Releases
- Events
- Videos
- Infographics and factsheets

Conclusions

The EU [*and international*] reference activities system in outbreaks situations **brings**

☐ Confidence between actors

Linked with **research activities it adds**

☐ Reactivity and anticipation

Linked with **surveillance** involving **stakeholders and international partners, it should improve**

☐ Global understanding and prevention of outbreaks

The contents of this presentation are the views of the author and do not necessarily represent an official position of the European Commission.

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Better Training for Safer Food
BTSF

European Commission
Consumers, Health, Agriculture and Food Executive Agency
DRB A3/042
L-2920 Luxembourg

Food Safety

Regional Workshop on Animal Disease Preparedness

Tsviatko Alexandrov

Better Training For Safer Food

The EU import regime for live animals and food of animal origin. Conditions to meet to export to the EU market– Controls at import – Products of animal origin - TRACES

Tokyo, Japan
12-15 June 2018

Food Safety

Content

- EU Animal health policy
- The EU single market
- Import conditions and provisions
- EU official control. Legislation. Import controls
- Animal health control measures. Regionalization
- Import of animals and animal products.
- Export to EU from non-EU Countries. Mechanism
- TRACES

EU animal health policy

Reaching and maintaining a high status throughout the EU of:

- animal health
- animal welfare
- food safety
- establishment and functioning of the EU single market

The EU single market

Only if:

- Following risk analyses;
- Veterinary controls at place of origin and destination;
- Veterinary certification;
- Animal and animal product traceability: -animal identification -farm registration -TRACES (TRAde Control and Expert System);
- Animal Disease control, comprehensive control and eradication measures;
- Notifiability of diseases - Transparency / ADNS (Animal Disease Notification System).

Import Conditions

The EU works to ensure that:

Europe's food supply is the safest in the world; and

all imports, regardless of origin, **must fulfill the same high standards as products from the EU itself**.

Provisions for imports

- Harmonized legislation related to animal health/food safety
- Import requirements. Phytosanitary measures to be met prior to import and internal movement of commodities
- Regionalization reflects the EU internal rules and OIE standards
- Veterinary controls at EU external borders, Mandatory inspection at EU point of entry
- Overall control, FVO Inspections

EU Official controls

Aiming at:

- **prevent or eliminate risks** which may arise, either directly or via the environment, for human beings and animals, or reduce these risks to an acceptable level;
- guarantee **fair practices as regards trade** in food and feed;
- ensure **protection of consumers' interests**, including labelling of food and feed and any other form of information intended for consumers.

Import controls

According to **Regulation (EC) No 882/2004** on official controls – sets an integrated and uniform approach to official controls along the agri-food chain, the import controls:

- varies according to the sector;
- mandatory channeling and common framework for border controls on animals and goods entering the EU;
- uniform frequencies for checks for live animals, products of animal origin, plants and plant products, as those commodities might pose a risk in relation to animal or plant health respectively;
- list of animals and goods subject to systematic controls established by the Commission (voted within PAFF meetings).

Import control

- according to the new AHL- **Regulation (EU) 2017/625** (adopted 17/03/2018 and replacing Reg 882/2004/transition period), import control is:

  - risk-based and targeted (less burdensome and businesses alike);
  - documentary checks for all consignments; Identity and physical checks at a frequency depending on the risk (based on the criteria, established by the Commission);
  - Common Health Entry Document (CHED) for the prior notification of consignments;
  - a new integrated computerised system for official controls (Integrated Management System for Official Controls, IMSOC) (integrates TRACES, RASFF, Europhyt, AAC);
  - close cooperation among Competent Authorities, customs authorities and other involved to ensure timely exchange of relevant information.

Animal health control measures

The EU has a set of specific legislation for a number of animal diseases depending on their potential social and economic impact and it includes:

- notification obligations;
- diagnostic methods;
- measures to be applied in case of suspicion and confirmation of disease;
- **regionalization measures**, where applicable.

Regionalization (1)

- Main objective: Prevention of the introduction into or spread within the EU of risk organisms.
- Based on provisions laid down in WTO/SPS - IPPC (International Plant Protection Convention)
- Achieved by harmonised legislation on imports and Community movements and harmonised control measures for specific diseases

Regionalization (2)

- the best approach to maintain adequate disease control with minimum restrictions to trade (mitigate negative trade effects caused by sanitary or phytosanitary measures);
- export from a regionalized area, although the health status of country may not be favorable in most of their territory;
- export opportunities to countries with little chance to do so to countries with a higher sanitary or phytosanitary level;
- reaching and maintaining a high status of animal health throughout the EU

Import of animals and products of animal origin

- presents a high level of risk as they can transmit serious human and animal diseases;
- live animals or products of animal origin can only enter into the EU, if:

✓ they meet the specific import conditions laid down in the Union legislation;
✓ undergone satisfactorily specific checks by veterinary border control;
✓ a Common Veterinary Entry Document (CVED) is issued from TRACES.

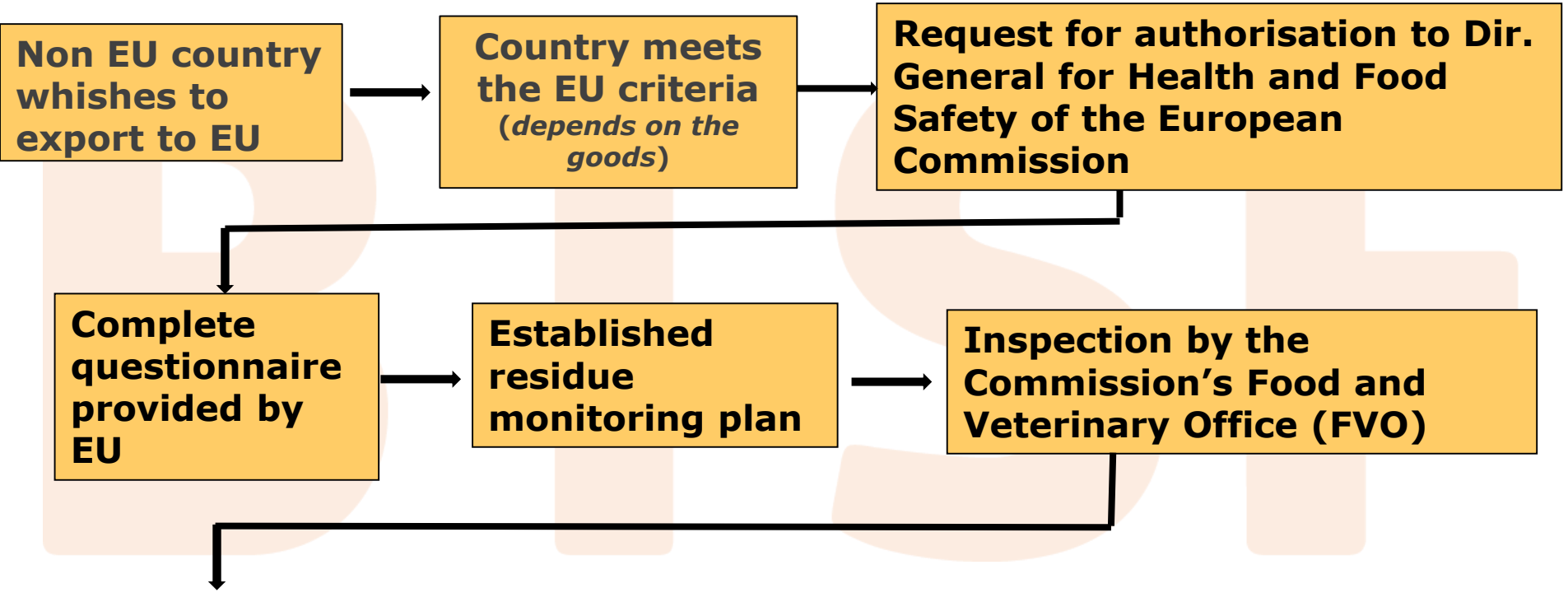
Export to EU from non-EU Countries (1)

- The third country **must be approved to export** a specific category of animal and food of animal origin and **must be in the list** of approved third countries for that specific category of food

- Listing of Third Country /or establishments (the countries must be on a positive list of eligible countries)

Export to EU from non-EU Countries (2)

Mechanism



Export to EU from non-EU Countries (3)

Countries whishing to export to EU should apply:

- Transparency and Quality of veterinary services. The authorities must be empowered, structured and resourced;
- Adapt sanitary or phytosanitary measures to EU conditions; hygiene and public health requirements are met.
- **Established residue monitoring** in place to verify compliance with EU requirements on residues of veterinary medicines, pesticides and contaminants.

Export to EU from non-EU Countries (4)

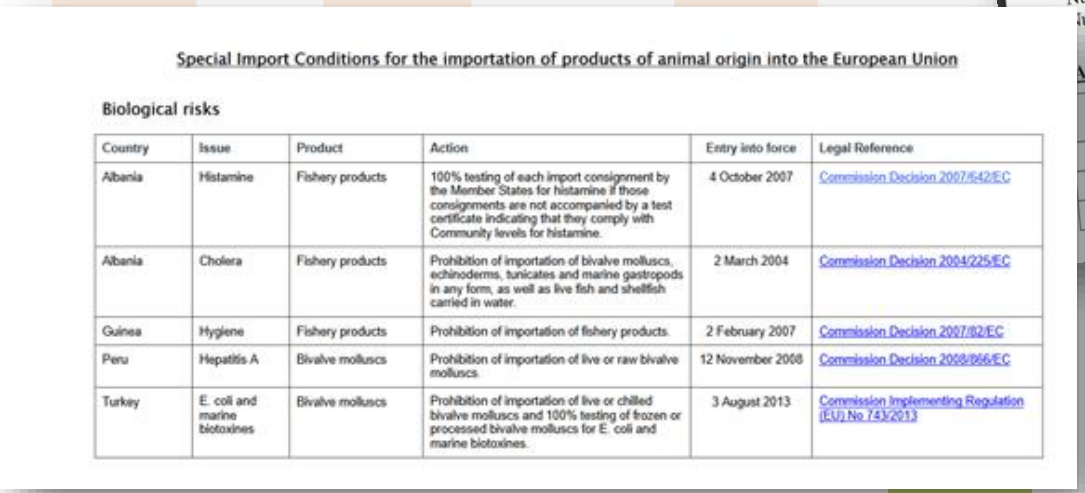
Countries whishing to export to EU should apply:

- Measures to maintain free-status of regions and provide evidence that areas on a country's territory are pest or disease-free or of low pest or disease prevalence;
- Surveillance within and outside the infected regions: early and rapid disease detection and meet and implement EU control measures;
- Have laboratories that comply with certain minimum requirements, ensuring sufficient capability for disease diagnosis.
- Audited by the Directorate General for Health and Food Safety
- Lists of third countries approved for import of live animal and animal products

Approved country/establishments for export to EU

Imports are only authorized from **approved establishments**

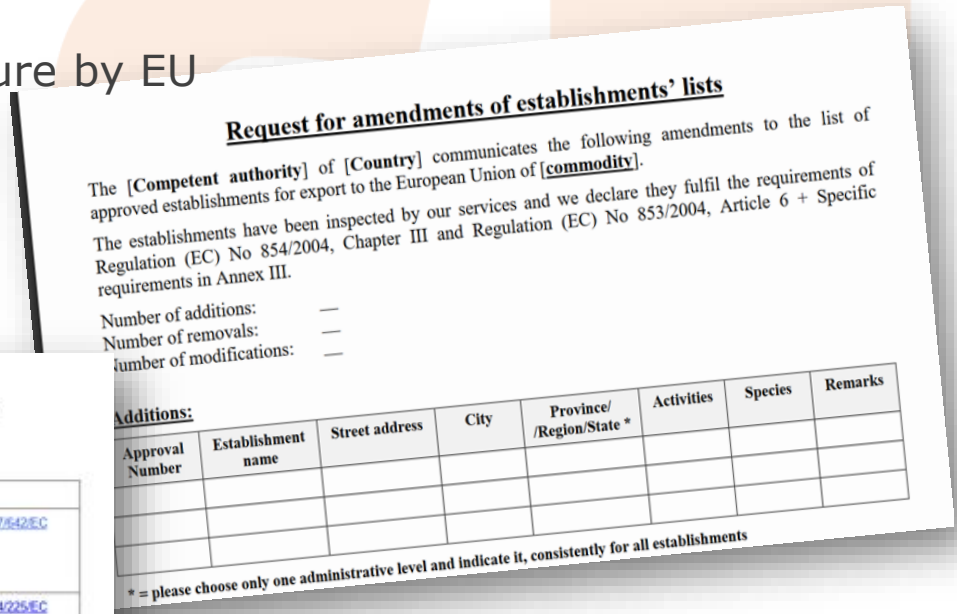
- Application and pre-approval procedure by EU



Special Import Conditions for the importation of products of animal origin into the European Union

Biological risks

Country	Issue	Product	Action	Entry into force	Legal Reference
Albania	Histamine	Fishery products	100% testing of each import consignment by the Member States for histamine if those consignments are not accompanied by a test certificate indicating that they comply with Community levels for histamine.	4 October 2007	Commission Decision 2007/642/EC
Albania	Cholera	Fishery products	Prohibition of importation of bivalve molluscs, echinoderms, tunicates and marine gastropods in any form, as well as live fish and shellfish carried in water.	2 March 2004	Commission Decision 2004/225/EC
Guinea	Hygiene	Fishery products	Prohibition of importation of fishery products.	2 February 2007	Commission Decision 2007/82/EC
Peru	Hepatitis A	Bivalve molluscs	Prohibition of importation of live or raw bivalve molluscs.	12 November 2008	Commission Decision 2008/866/EC
Turkey	E. coli and marine biotoxines	Bivalve molluscs	Prohibition of importation of live or chilled bivalve molluscs and 100% testing of frozen or processed bivalve molluscs for E. coli and marine biotoxines.	3 August 2013	Commission Implementing Regulation (EU) No 743/2013



Request for amendments of establishments' lists

The [**Competent authority**] of [**Country**] communicates the following amendments to the list of approved establishments for export to the European Union of [**commodity**].

The establishments have been inspected by our services and we declare they fulfil the requirements of Regulation (EC) No 854/2004, Chapter III and Regulation (EC) No 853/2004, Article 6 + Specific requirements in Annex III.

Number of additions: —
Number of removals: —
Number of modifications: —

Additions:

Approval Number	Establishment name	Street address	City	Province/ /Region/State *	Activities	Species	Remarks

* = please choose only one administrative level and indicate it, consistently for all establishments

European Commission

TRACES

You are a **non-EU** country, *dealing with...*

Import certificates

REFERENCES

Veterinary certificate to the EU (IMPORT)
Commission Decision 2007/240/EC laying down new veterinary certificates for importing live animals, semen, embryos, ova and products of animal origin into the Community.

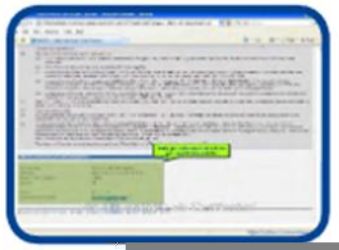
Non-EU country
origin

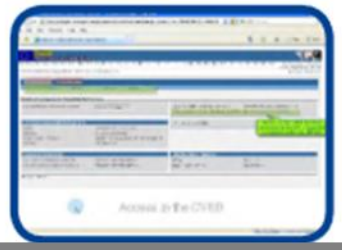
EU/EFTA Border
Entry Point

Import certificates (IMPORT)

PART I
Consignment
economic operator
or
competent authority

PART II
Certification
competent authority





You are a **non-EU** country, *dealing with...*

Official documents for non-EU countries

REFERENCES

Common Entry Document (CED)
Common Veterinary Entry Document: Animals (CVEDA)
Common Veterinary Entry Document: Products (CVEDP)
Common Health Entry Document for Plants and Plant products (CHED-PP)
Available to any non-EU country on a voluntary basis.

European Commission

Non-EU country
origin

Non-EU country
transit/destination

Official documents for non-EU countries

REQUIRED

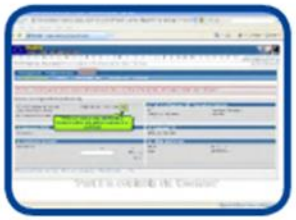
PART I
Consignment
economic operator or competent authority

PART II
Decision
competent authority

PART III
Control
competent authority

view video

Submission *- Part I*
The economic operator prepares Part I of the official document to be submitted to the competent authority of the origin country.



view video

Certification *- Part II*
The competent authority of the origin country processes Part II of the official document.

view video

Control *- Part III*
The competent authority of transit or destination country records the checks on the official document.

TRACES

TRAde Control and Expert System

- OBJECTIVES: vet single windows
- The Integrated Computerised Veterinary System - TRACES – provides assistance and certification for all veterinary authorities within an informatics network to improve the sanitary protection of EU.
- TRACES integrates EU and non EU competent veterinary authorities

TRACES: POLICY AREAS

- Animal Health
- Animal Welfare (EU exclusive)
- Veterinary Public Health

TRACES: Goals

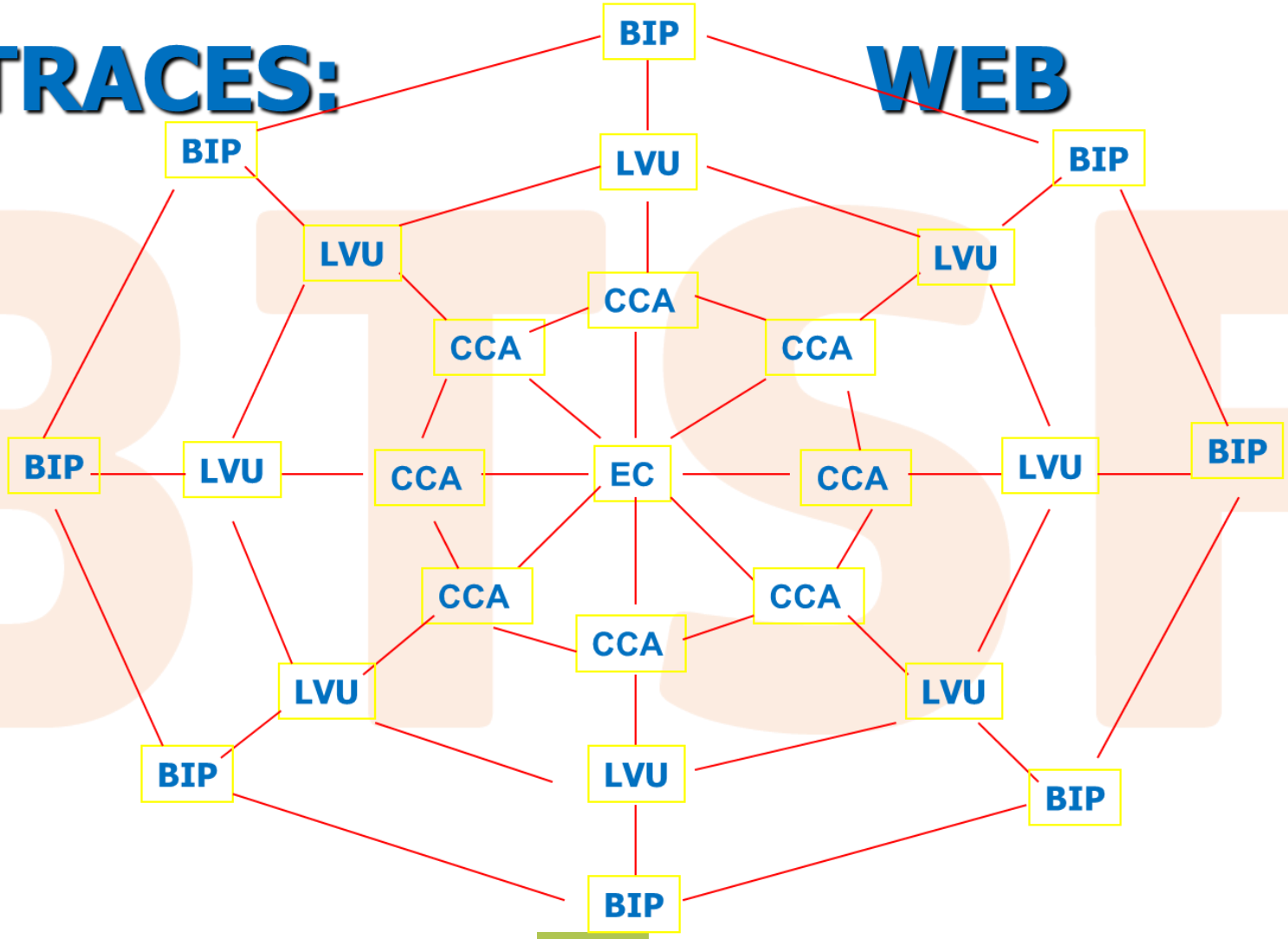
- Control of animals and animal products;
- Outbreaks: trace back and forth;
- Assistance in decision-making;
- Central risk assessment and warning;
- Reduction in administrative workload.

TRACES: Main characteristics

- Electronic workflow;
- Centralized updating of the information and alert awareness and risk assessment;
- Interoperability; (Custom Nomenclature)
- Multilinguism

European Commission

TRACES: WEB



Food Safety

Workflow of information

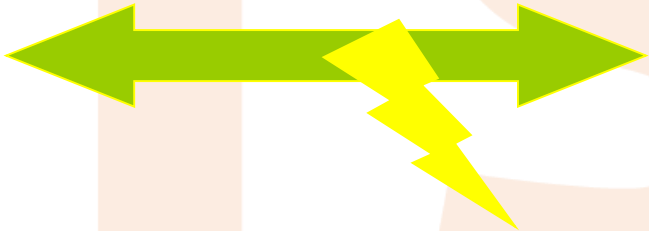
Creation (EO)

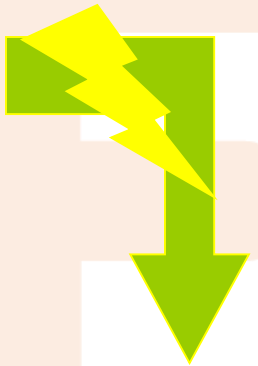
Certificate

Route Plans

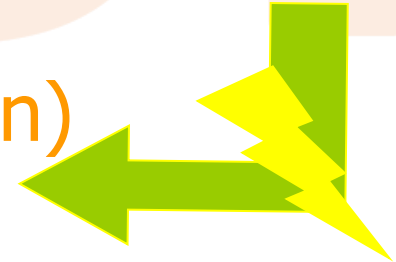
CVEDs

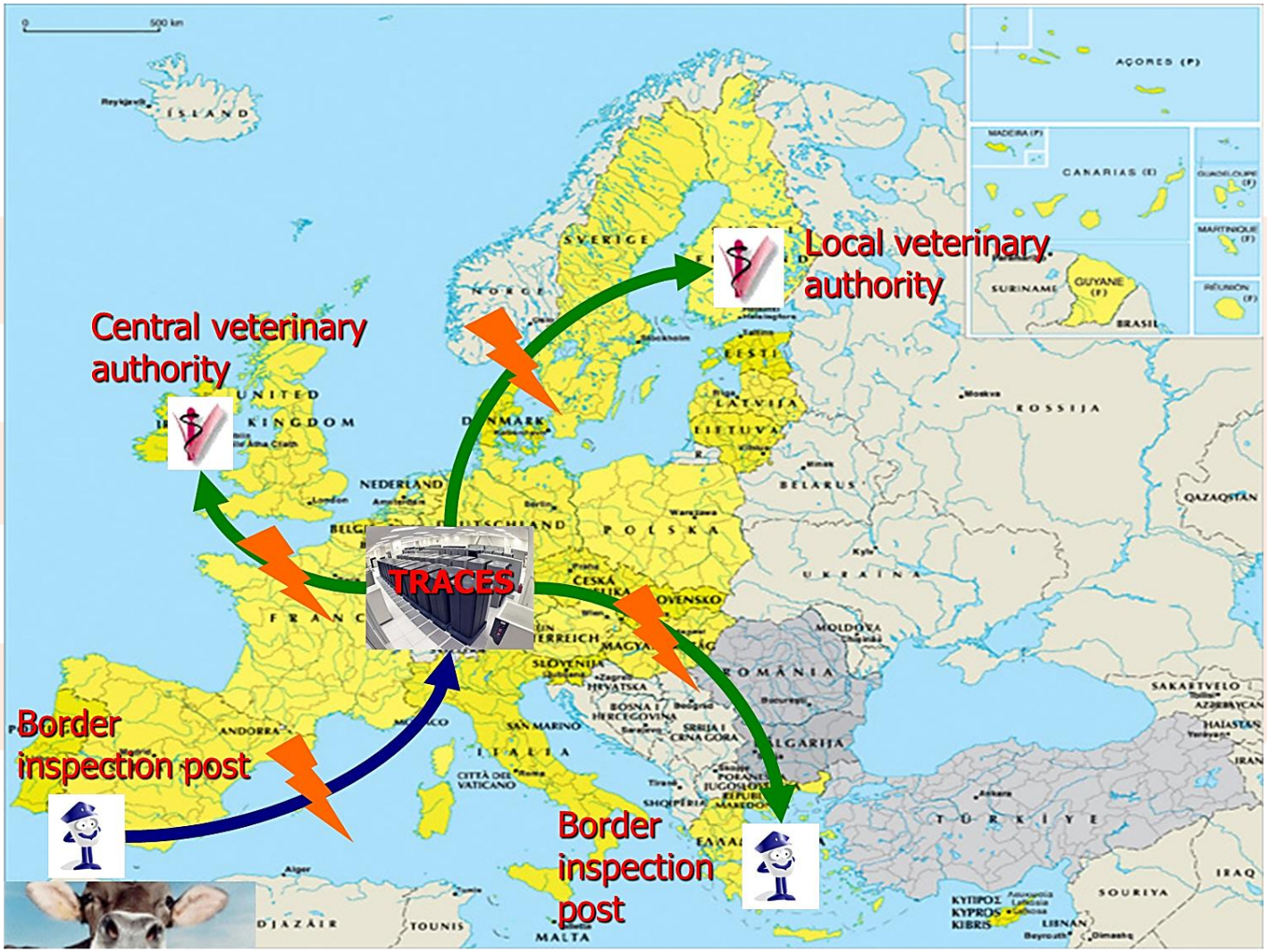
Validation (CA Origin)





- Control (CA En route, destination)




Local veterinary authority
Central veterinary authority
TRACES
Border inspection post
Border inspection post

TRACES - Trade Control | EU law - EUR-Lex

webgate.ec.europa.eu/sanco/traces/common/welcome.do

TRACES (classic)
TRAde Control and Expert System

bg bn bs cs da de el en es et fa fi fr hr hu il in it ko lt lv me mk mt nl nw pl pt ro ru sk sl sq sr sv tr uk vi zh

/TRACES/Welcome Page

- Welcome Page
- TRACES Data Warehouse
- QlikView
- Veterinary Documents
- Intra Trade Animal Health Certificates
- CVED for Animals
- CVED for Animal Products
- Veterinary certificate to EU
- Export Health Certificates
- Common Entry Document (CED)
- CHED-PP
- Commercial Document
- Declaration Document
- Empty Certificate
- Reporting
- Rejected Consignments - CVED for Animals
- Rejected Consignment - CVED for Animal Products
- Authorities and Users
- User and Organisation Management
- User Management
- Organisations
- Private Veterinarian
- Change Password

Welcome

19/05/2017 | TRACES Newsletter

If you wish to subscribe to the TRACES newsletter click here

17/05/2016 | TRACES FEEDBACK

Helpdesk: **sante-traces@ec.europa.eu**
Helpdesk tel.: **+ 32 2 297 63 50**
DG SANTE website : **LINK**
TRACES Toolkit *(URL for bookmarking)*: **https://circabc.europa.eu/w/browse/ac0bd3d2-66ae-4234-b09c-a3fa9854acfd**
TRACES presentations: **LINK**
TRACES leaflet: **LINK**
TRACES introduction video: **LINK**

Latest news

27/04/2018 | TRACES TRAINING and ACCEPTANCE

In order to address a severe security risk, TRACES Acceptance and Training environments will be unavailable for a short period of time around 20 minutes, on May 7, between 17h00 a

17/04/2018 | Installation of TRACES Version 6.40

A new version of TRACES (**6.40**) will be implemented on Monday 23 of April from 17:00 to 19:00 (GMT+1). TRACES will not be available during this period. This new version is alread
Acceptance environment: https://webgate.acceptance.ec.europa.eu/sanco/traces/ For more details, the Release Note can be downloaded at: https://circabc.europa.eu/w/browse/9ee1
The TRACES team stay at your disposal for any further information.

12/04/2018 | The Import and Intra certificates 2074/2005 (2018/320) Salamanders are now available in the Traces application

The Import and Intra certificates **2074/2005 (2018/320) Salamanders** are now available in the Traces application under CN-code 01069000.

26/03/2018 | QlikView report CED

The QlikView report on CEDs has been improved. There are new fields in the Quick Information Display and data are now covered back to year 2013.

06/03/2018 | TRACES EXPORT to Russia remains available

The pilot project with Russia is extended for the certificates and entry points mentioned in the **information of 03/10/2016, 25/11/2016, 24/04/2017 and 26/07/2017**
module will remain available under those modalities until further notice.

07/02/2018 | The amended Import certificate 2007/25 (2017/2410) Pet Birds is now available in the Traces application

The amended Import certificate **2007/25 (2017/2410) Pet Birds** is now available in the Traces application and amends the old version 2010/734 Pet Birds. There will be a transi
which the old version will be disabled.

User and Organisation Management
- User Management
- Organisations
- Private Veterinarian
- Change Password
- Modify User Profile

Establishment List Publications
- EU Establishments list per sector
- EU Establishments list per country
- Third Country Establishments list per sector
- Third Country Establishments list per country
- Third Country Bovine Holding Lists
- Establishments by Section
- Establishments by Country

Help To Decision Management
- Re-enforced Check

Legislation
- Legislation

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The amended Import certificate **2007/25 (2017/2410) Pet Birds** is now available in the Traces application and amends the old version 2010/734 Pet Birds. There will which the old version will be disabled.

31/01/2018 | TRACES and Namibia

We would like to inform you that Namibia (NSI Fishery Inspectorate) have started to use TRACES and the consignments directed to the BIPs of the EU (the first consignm IMPORT certificates issued in TRACES for consignments destined to EU/EFTA. We would like to invite the BIP's colleagues and TRANSITAIRS to use the functionality "Clonir to Namibian authorities to get a feedback on the decision taken by the inspectors of BIP.

19/12/2017 | New version for certificate INTRA EII Bees (Apis mellifera) and bumble bees (Bombus spp.) updated

The new version of intra-Union trade 92/65 (2017/2174) EII Bees (Apis mellifera) and bumble bees (Bombus spp.) has been updated in TRACES

12/12/2017 | Harmonised health certificate from the EU to Chile for export of Laboratory mice

The harmonised health certificate from the EU to Chile for export of **Laboratory mice** has been activated in TRACES.

19/10/2017 | Passage of CHED-PP to TNT

ATTENTION: From 7 November 2017 onwards, Common Health Entry Documents for plants (**CHED-PP**) will need to be done in Traces New Technology (TNT). From available in Production https://webgate.ec.europa.eu/tracesnt/login and in Acceptance https://webgate.acceptance.ec.europa.eu/tracesnt/login For more information pleas

16/10/2017 | Extension of Pilot project - TRACES EXPORT to Russia until 31/01/2018.

The pilot project with Russia is extended until 31/01/2018 for the certificates mentioned in the information of 03/10/2016, 25/11/2016, 24/04/2017 and 26/07/2017 on th

29/09/2017 | Export Certificate and Export Declaration from the EU to Hong Kong for export of Pork/Beef/Mutton (Meat/Offal)

A new **Export Certificate** (for animals that were slaughtered within the exporting EU member state) and **Export Declaration** (for animals that were slaughtered in an e EU member from which the consignment is exported) from the EU to Hong Kong for export of **Pork/Beef/Mutton (Meat/Offal)** will be available in the TRACES applica certificate will remain available for a transitional period until 1 December 2017.

26/07/2017 | Pilot project - TRACES EXPORT to Russia.

The pilot project with Russia is extended to the **veterinary certificate for the export of bovine semen from the EU to the Russian Federation (RU)** with code 0511 **export of boar semen From the EU to the Customs Union (EEU)** with code 0511 99 85.

24/04/2017 | Reminder: TRACES and certification toward Russia

The use of certificates in the TRACES format is only possible for certificates issued by TRACES, for the eligible products and for the designated entry points (see messag cases, only certificates in the format negotiated with the Russian authorities printed on security paper are authorized.

24/04/2017 | The pilot project for the use of the TRACES EXPORT module for certification to Russia launched on 25/10/2016 is extended until 01/09/20

As from 24/04/2017, in addition to the certificates listed under the information of 03/10/2016 and 25/11/2016 on the welcome page of TRACES, the certificate **(RU) Ve and other ready for consumption meat products, exported from the EU to the Russian Federation** may be used with the following codes: 1602 10 00, 1602 20, 39, 1602 41, 1602 49, 1602 50, 1602 90, 1603 00. Moreover, from 24/04/2017 entry points in Russia will no longer be limited to inspection posts in the Kaliningrad region regions of **Tver** (Tver (Migalovo)-Тверь (Мигалово)) , **Pskov** (Burachki-Бурачки, Ubylinka-Убылинка, Shumilkino-Шумилкино, Pytalovo-Пыталово, Pechora-Pskov- Печо

TRACES: Management module

- Certification: INTRA, CVEDA, CVEDP
- Notification
- Control
  - Documentary, Identity and Physical checks
  - Welfare check
  - Laboratory test (Animal health, Public health, Residues)

Common Veterinary Entry Document - CVED

EUROPEAN COMMUNITY

The Common Veterinary Entry Document, CVED

Part I : Details of consignment presented

1. Consignor / Exporter
Name: Saha Farms Co Ltd
Address: 44/4 Moo 11, Nawamin Road, Kannayaw, Kannayaw District, 10230 Thailand
Thailand (general) Bangkok
Country: Thailand (TH)

2. CVED reference number: CVEDP.GB.2009.0005125 - V1
Local reference number: HIN18694
Place of inspection: Felixstowe, P
TRACES Unit Number : GB13099
300351

3. Consignee
Name: Mostell Ltd
Address: Hanger 2, Locharbriggs Coldstore, Catherinefield Industrial Estate
DG1 Dumfries
Country: United Kingdom (GB)

4. Person responsible for load
Name: Hine Freight Services Ltd
Address: 8 Victoria Street, Felixstowe, Suffolk
IP11 Felixstowe
Country: United Kingdom (GB)

5. Importer
Name: Mostell Ltd
Address: Hanger 2, Locharbriggs Coldstore, Catherinefield Industrial Estate
Dumfries
Country: United Kingdom (GB)

6. Country of origin: Thailand + ISO code: TH
7. Country from where consigned: Thailand + ISO code: TH
Place of loading: UK1656EC, BROWNS COLDSTORE
CATHERINEFIELD INDUSTRIAL ESTATE, LOCHARBRIC
DG1 Dumfries
United Kingdom (GB)

9. Arrival at BIP (estimated date): 05.02.2009 00:00

10. Veterinary documents
Number(s): AC0615010920016
Date of issue: 06.01.2009
Establishment of origin(where relevant): Saha Farms Co. Ltd/TH
Veterinary approval number: 99

11. Vessel name / Flight No.
Aeroplane: ☐ Ship: ☒ Railway wagon: ☐ Road vehicle: ☐
Identification:: YM UPWARD
Documentary references: N480023879

12. Nature of goods, Number and type of packages
Other prepared or preserved meat, meat offal or blood meat products / Aves

13. Commodity Code (CN, minimum first 4 digits): 1602
14. Gross weight (kg): 21,000
15. Net weight (kg): 20,000

Number of packages: 2000
Type of packages: Carton
Temperature: Chilled: ☐ Frozen: ☒ Ambient: ☐

16. Seal number and Container number
YMLB809346/YMLU5332260

NEW

17. Transhipment to ☐
EU BIP
TRACES unit no.
3rd country
3rd Country ISO code:

18. For transit to 3rd Country ☐
To 3rd Country
+ ISO code
Exit BIP:
TRACES unit no.

19. Conform to EU requirements
Conforms ☒
Does NOT conform ☐

20. For re-import ☐

21. For internal market
Human consumption: ☒
Animal feedingstuff: ☐
Pharmaceutical use: ☐
Technical use: ☐
Other: ☐

22. For NON- Conforming consignments
Customs warehouse ☐ Registered No.
Free zone or Free warehouse ☐ Registered No.
Ship supplier ☐ Registered No.
Direct to a ship ☐ Name
Port

23. Declaration
I, the undersigned person responsible for the load detailed above, certify that to the best of my knowledge and belief the statements made in section I of this document are true and complete and I agree to comply with the legal requirements of directive 97/78/EC, including payment for veterinary checks, for repossession of any consignment rejected after transit across the EU to a third country (Article 11.1.c), or costs of destruction if necessary.

Place and date of declaration: 29.01.2009 / Hine Freight Services Ltd, 8 Victoria Street, Felixstowe, Suffolk, IP11,
Name of signatory: Adrian Hine
Signature

en

1/ 1

TRACES: Rejected consignments

- CVEDP 97/78 art 17 CVEDA 91/496 art 12
- Automatic display of all rejected consignments
  - within a time frame
  - in relation with country and CN Code

TRACES: Benefits

- Avoidance of resources redundancy
- Standard application of laws and procedures
- Work simplification for official services
- Increase in security and speed of data transmission
- Cooperation between services
- Fight against fraud
- Speed up of BIP administrative procedures
- Provision to trade partners updated and translated certificates
- Direct access to the EU decisions

The contents of this presentation are the views of the author and do not necessarily represent an official position of the European Commission.

Questions?

AETS - Application Européenne de Technologies et Services

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Better Training for Safer Food
BTSF

European Commission
Consumers, Health, Agriculture and Food Executive Agency
DRB A3/042
L-2920 Luxembourg

Food Safety

Official controls in EU

Novelties introduced by Regulation 2017/625

Tokyo 12-15 June 2018

Andrea DIONISI
European Commission
DG Health & Food Safety
Bilateral International Relations

Health and Food Safety

European Commission

Health and Food Safety

European Commission

Key principles

Simplification

Harmonisation

Efficiency

Transparency

The risk based approach is maintained

European Commission

Inter-institutional steps of the Official Controls Regulation (EU) 2017/625

COM proposal: 2013

Political agreement: 15 June 2016

Parliament vote in plenary

Adoption
15 March 2017

Published 7 April

Official Journal of the European Union

Entry into force
28 April 2017

Application date:
14.12.2019

Health and Food Safety

European Commission

Defining specific rules over the next 2 years before the application dates of OCR, Animal Health and Plant Health Laws

Animal Health Law 2016/ 429

Official Controls Reg. 2017/ 625

Plant health Law 2016/ 2031

drafting **tertiary legislation (delegated & implementing acts) to implement the 3 legislations**

21.04. 2021

14.12.2019 for most of the provisions

14.12.2019


General rules

European Commission

Extended scope

- Food and food safety
- Feed and feed safety
- GMOs
- Animal health
- Animal welfare
- Animal by-products
- Plant health
- Plant protection products
- Organic production

European Commission

The risk based approach

Controls to be performed "regularly, on a risk basis and with appropriate frequency"

Own controls, including private quality schemes

Risks associated with animals and goods, activities, location…and the likelihood that consumers might be misled

Operator's past record

European Commission

Obligations of the operators

Provide information on their name, legal form and specific activities

Give access to computers and premises, to the extent necessary

Assist and cooperate with the staff of the competent authorities

European Commission

Minimum disruption of business

Official controls shall be carried out in a manner that the administrative burden and operational disruption for operators are kept to the minimum necessary

European Commission

Official controls and export

Reg. 882/2004: *"Official controls shall be applied, with the same care, to exports outside the Community…"*

Reg. 625/2017 (14/12/2019-): *"…apply to official controls performed for (…) animals and goods (…) to be exported from the Union"*

Official controls carried out regularly, on a risk basis and with appropriate frequency

In case of non-compliance:
Restrict or prohibit the export of animals and food/goods

European Commission

Control framework

"Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country."
(Article 12 of "General **F**ood **L**aw Reg. 178/2002")

Risk based, **including fraud**

Multi-annual control plans

Health and Food Safety

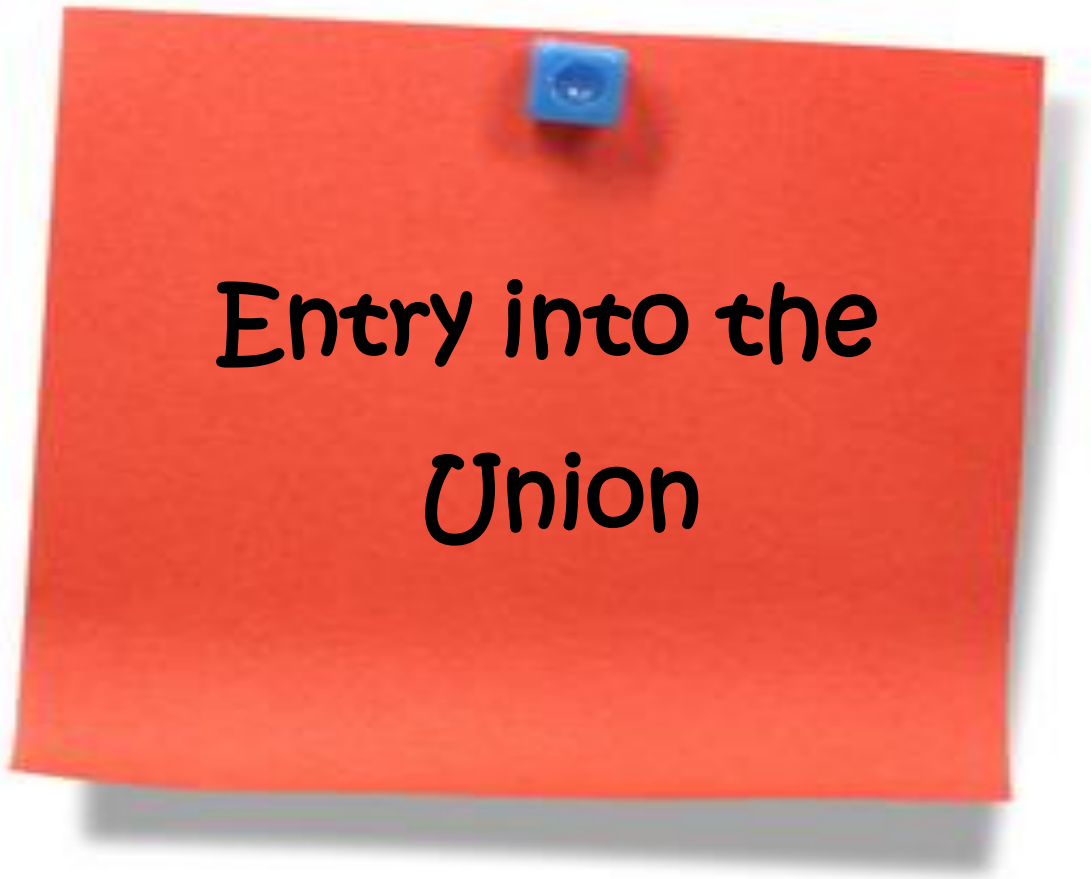
European Commission

Additional features in Reg. 2017/625

"In the case of exports outside the Union, competent authorities may also be required, in accordance with Union legislation, to verify the conformity of animals and goods with requirements established by the third country of destination of such animals or goods."

"In the case of exported animals and goods for which Union rules apply in relation to the issuance of the export certificate, the IMSOC shall enable the competent authorities (…) to exchange, in real time, data, information and documents concerning such animals and goods and the outcome of controls performed…"*

*information management system for official controls


Entry into the Union

European Commission

Import controls

Main message:

- **The OCR will not change the sanitary conditions established for non EU Countries**
- **The new OCR will not have major impact on imports into EU**
- **Rules and procedures for imports into the EU will be fine-tuned**

European Commission

Import controls in Reg. 2017/625

A common, risk based framework for border controls on all animals and goods entering the EU

Border Control Posts (BCPs) will replace the different Border Inspection Posts (BIPs) and Designated Points of Entry (DPEs)

Minimum requirements for facilities, equipment and staff will apply throughout all BCPs

A single standard document (CHED*) for the prior notification of consignments

*common entry health document

Transmitted to the BCP through IMSOC (including Europhyt)

European Commission

Entry into the Union – main rules

Animals, products of animal origin, germinal products, animal by-products, plant, plant products and certain feed and food of non-animal origin* =

Designated **BCP** of first arrival

Animals and goods whose inherent risks do not require systematic border controls =

An **appropriate place** within the customs territory of the Union

Always documentary checks; risk based identity and physical checks

Regular, risk based controls with appropriate frequency (established by MS)

New IT system. Same set of measures in cases of non-compliance, including enforcement measures

* A **list with CN codes** to be established

European Commission

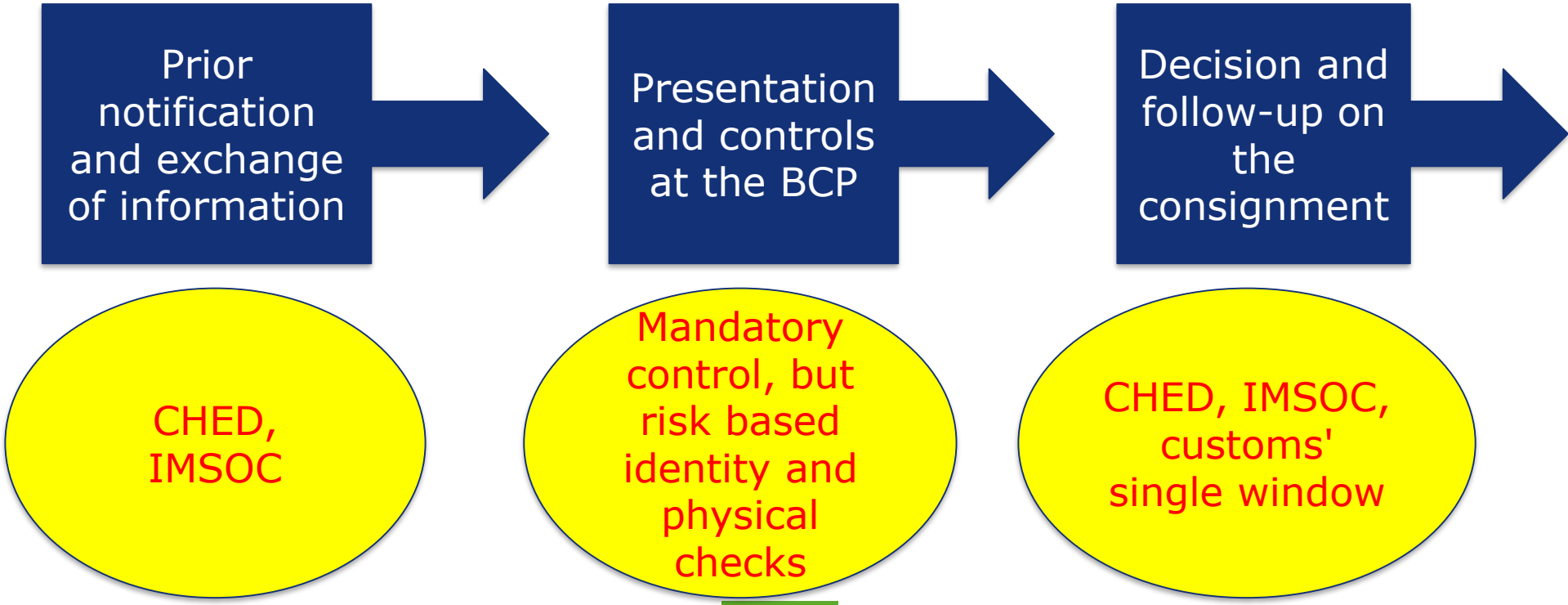
Same slide as before: in addition, over the last months, the term "Channelling" is being defined in different ways , so we suggest not to mention it for the moment"

High risk	Low risk
Animals, products of animal origin, germinal products, animal by-products, plant, plant products and certain feed and food of non-animal origin = Designated **BCP** of first arrival	Animals and goods whose inherent risks do not require systematic border controls = An **appropriate place** within the customs territory of the Union
Always documentary checks; risk based identity and physical checks	**Regular, risk based controls with appropriate frequency (established by MS)**

New IT system. Same set of measures in cases of non-compliance, including enforcement measures

European Commission

Border control process



Official certification rules

When **EU agri-food chain legislation requires an official certificate, or when** official certificates are necessary for the purposes of
exporting consignments of animals and goods:

Certifying officers shall be impartial and free from any conflict of interest and have received appropriate training

Signed by the certifying officer and issued on grounds of direct knowledge and facts and data relevant for the certification

Commission is empowered to establish e.g. technical arrangements to ensure the issuance of accurate and reliable official certificates, and prevent risk of fraud

The competent authorities shall take all appropriate measures to prevent the issuance of false or misleading official certificates or the abuse of official certificates

Appropriate measures to be taken in the case of false or misleading official certificates or in the case of abuse of official certificates, e.g. the temporary suspension of the certifying officer from its duties

European Commission

Entry into the Union I

CN code list of animals and goods to be checked at BCPs (IA)

Categories to be added to the list (DA)

Non-compliance action (IA)

Border control procedures (DAs)

Border control procedures (IAs)

Border Control Posts (DA)

Training (DA)

Health and Food Safety

European Commission

Entry into the Union II (DA, art 126)

List of third countries

List of establishments

Official certificates, attestations or other evidence

Any other necessary requirement (e.g residue monitoring plan)

European Commission

Entry into the Union

- **The official control rules actually into force will be changed;**
- **Some procedures, as pre-listing, are not anymore included in the basic rules;**
- **The enforcement acts will redefine such aspects on the basis of the experience matured;**

European Commission

CDR 126 (1) – proposal for certification at entry

Certification required for:

- *All products of animal origin*
- *Composite products*
- *Sprouts and seeds for sprouting*

=> *Maintenance of all current certificates + additional certificate for import of rendered fats, reptile meat, insects.*

European Commission

CDR 126 (1) – additional specific conditions for imports

- *Fishery products*
- *Live bivalve molluscs etc.*
- *Raw materials for fresh meat meat preparations, meat products, …*

=> *STATUS QUO*

- *Composite products*

=> *NEW*

Health and Food Safety


Next steps

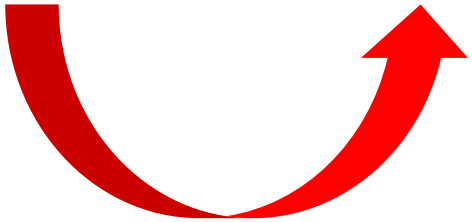
European Commission

Entry into force and application

Entry into force:
28 April 2017

Main date of application:

14 December 2019



Health and Food Safety

European Commission

Implementation of Reg. 2017/625

EMPOWERMENTS are given to the Commission to ensure the implementation of the Regulation through…

Implemented Acts (IA): HOW?

(Uniform conditions for implementation)

Delegated Acts (DA): WHAT?

(Supplement or amend non-essential elements)

European Commission

What must be done

- Repeal of Regulation (EC) No 854/2004 on official control of food of animal origin by Regulation (EU) 2017/625 (OCR) from December 2019.

- Delegated and Implementing Regulations needed to replace the provisions of that Regulation, so to fix:

  1) Controls of products of animal origin intended for human consumption (essentially on meat inspection)
  2) Import conditions for food

Empowerments

European Commission

Example I: Specific control rules

- Fresh fishery products, directly landed
- Unskinned, furred wild game
- Vessels leaving the EU (ship supply)
- Wood packaging material
- Feed accompa-nying animals
- Distance sales
- Plant products, on account of subsequent destination
- Refusal of entry by 3rd country (re-import)
- Goods entering in bulk (plants)
- "Neum Corridor" (HR-B&H-HR)
- Animals and goods exempted in accordance with Art 48

Empowerments

European Commission

Example II: Animals and goods exempted from controls at BCPs

- Trade samples and display items
- Scientific purposes
- Consumed by crew and passagers
- Personal luggage and for personal use
- Small consignments sent to natural persons
- Pet animals (non-commercial movement)
- Specific treatment, not exceed quantities
- Low risk or no specific risk (e.g. remote Greek islands)

European Commission

Other examples

Proposal for criteria and conditions for ante-mortem (AMI) by the official auxiliary (OA) in the slaughterhouse under the supervision of the OV

- *Checks of food chain information and animal identity*
- *Preselection of animals*
- *OV immediately informed in case of abnormalities and carrying out AMI him/her self*
- *OV regularly verifies work of OA*

Health and Food Safety

=> *STATUS-QUO*

European Commission

Proposal for criteria and conditions for AMI by the official auxiliary (OA) in the slaughterhouse under the responsibility of the OV

- *Only when an OV carried out a full AMI at the holding of provenance*
- *OV immediately informed in case of abnormalities and carrying out AMI him/her self*
- *OV regularly verifies work of the OA*
- *Never in case of officially controlled animal diseases*

=> ***STATUS-QUO but clearer separation of what is allowed under the supervision from under the responsibility***

European Commission

Proposal for criteria and conditions for AMI and post-mortem inspection (PMI) in case of emergency slaughter outside the slaughterhouse

- *Always the OV*

=> ***Stricter than current rules which foresee today AMI by any veterinarian***

European Commission

Proposal for criteria and conditions for AMI at the holding of provenance

- *Allowed in all species, individual examination of animals must be possible*
- *Always by the OV, whose certification on the findings must accompany the animals*
- *Limited checks at arrival in slaughterhouse (e.g. on animal welfare rules during transport)*
- *Maximum 3 days before slaughter except in small farms of farmed game (28 days)*

=> ***Status-quo on conditions but extension to all species and some more flexibility for farmed game***

European Commission

Official Control Regulation

Main message:

- **OCR it is not a revolution;**
- **It could be considered as an adaptation/alignment to the best practices that EU has in the veterinary field;**
- **It establishes a better coordination of activities risk based for all.**

European Commission

Planning

- *Four expert group meetings were already organised between June 2017 and April 2018*
- *One more expected to follow*
- *Public consultation from July 2018 onwards*
- *SPS notification in September-October 2018*
- *Submission to EP before end of 2018*

European Commission

Conclusions

- **The sanitary conditions established for non EU Countries will not change and we do not expect impact on imports into EU;**
- **Rules and procedures for imports into the EU will be fine tuned;**

European Commission

Further information

Official Controls webpage on DG Health and Food Safety website:

http://ec.europa.eu/food/safety/official_controls/legislation_en

Questions & answers:
http://ec.europa.eu/food/sites/food/files/safety/docs/oc_qa_ocregulation_20170407_en.pdf

Health and Food Safety

European Commission

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Directorate General Health and Food Safety
Bilateral International Relations

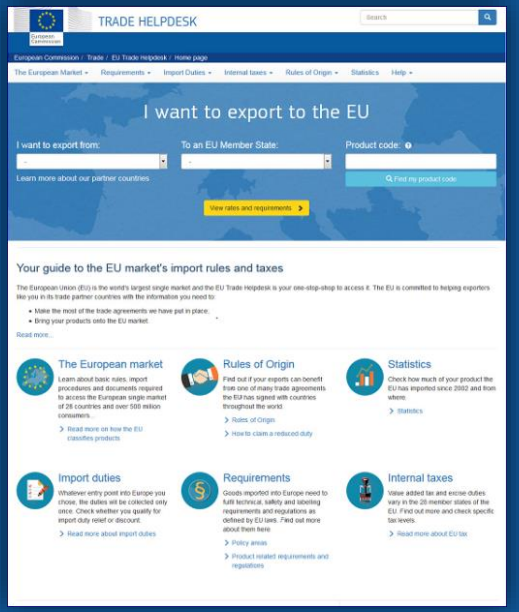
E-mail: Andrea.dionisi@ec.europa.eu

Health and Food Safety

How to export to the European Union

EU Trade Helpdesk

Your online guide to access the EU market



tradehelpdesk.europa.eu

European Commission, Directorate-General for Trade

What is the EU Trade Helpdesk?

- A website on how to export to the EU
- A source of information on EU import duties, product requirements, rules of origin, internal taxes and trade statistics
- A database on trade in goods
- Usable free of charge, without registration formalities
- Available in English, French, Spanish and Portuguese

Types of data

What can you find on the Trade Helpdesk website?

EU product requirements for goods imported to or circulating on the EU single market (health, safety, technical standards, marketing standards)

EU custom duties, duty discounts, quota database

How to benefit from reduced duties – the rules and proofs of origin according to trade agreements or preferential schemes

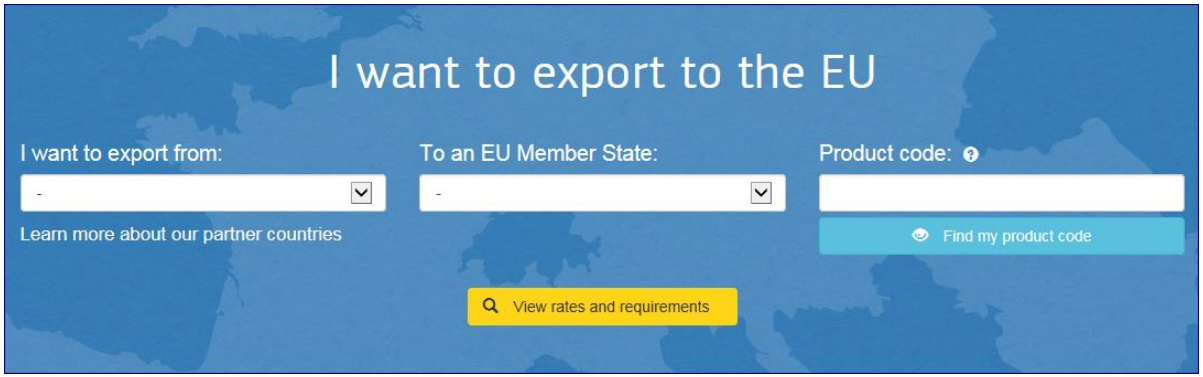
Who to contact for advice

Competent authorities, customs offices, chambers of commerce in EU countries

Trade statistics

All recent trade flows – product by product, country by country

How to access EU data for your product?



1. Go to tradehelpdesk.europa.eu
2. Fill in the exporting and importing country and the product you intend to export to the EU; if needed, click on "find your product code" and browse the "tree" of classification codes to find the correct code for your product
3. Click on "view rates and requirements"

EU data for your product

1st tab: import procedures

Three types of information:

1. Information on the EU's import procedures
2. The main documents you need for customs clearance
3. Import formalities and competent authorities for the EU country you have defined as importing country

EU data for your product

2nd tab: product requirements

The list of EU requirements applying to your product.

These documents explain each requirement and link to the **EU law** it is based on.

They also include

- specific **certificates** you may need,
- the **competent authorities** in the importing country,
- More information relating to the importing country, e.g. specific labelling or packaging provisions.

EU data for your product

3rd tab: import duties

- The first row shows the import duty exporters from non-EU countries should generally pay

- The following rows show which **duty discount** you can claim for your product according to either
  - the Generalized System of Preferences the EU grants to lower-middle income countries, or
  - a trade agreement signed between the country you are exporting from and the European Union

- This tab will also show you any **quota** or **antidumping duties**

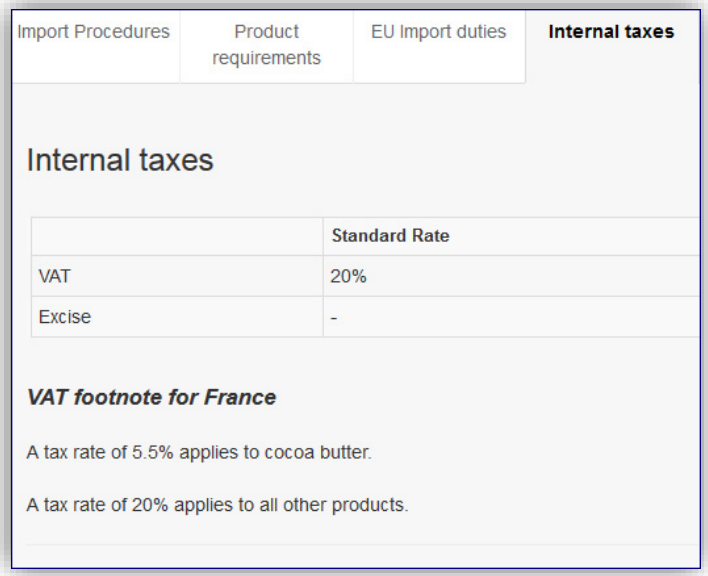
EU data for your product

4th tab: internal taxes

The internal taxes for your product in the EU importing country you selected.

This information includes:

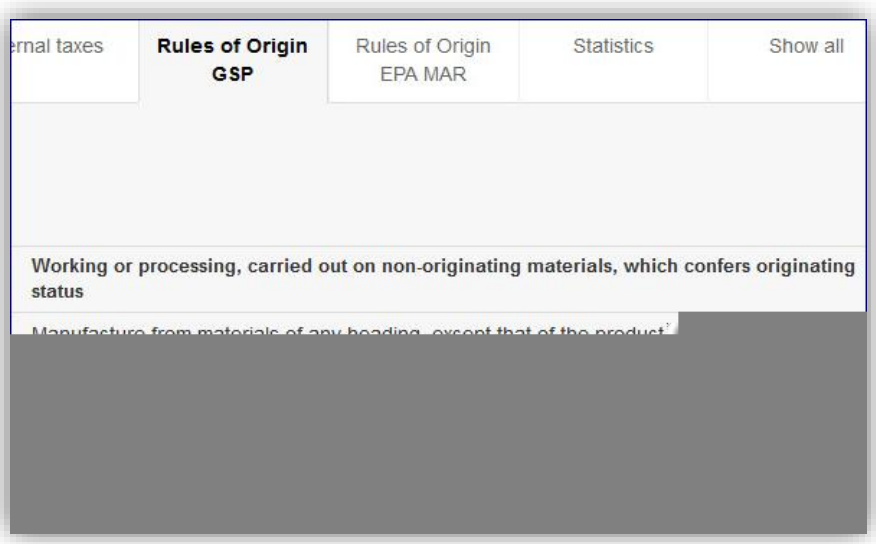
- Value-Added-Tax (VAT)
- Excise duty applying to alcoholic beverages, manufactured tobacco products and energy products, e.g. motor and heating fuels



Note that internal taxes are not harmonised in the EU and hence they vary from one country to another.

EU data for your product

5th tab: rules of origin



If your product can benefit from a duty discount this tab will show you the conditions, i.e. the rules of origin for your product.

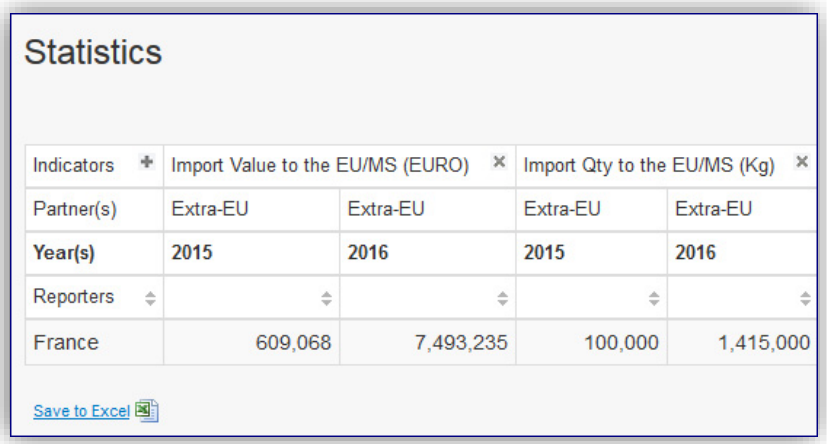
These rules describe how "originating status" is determined in the agreement or preferential scheme in place.

You will find more information relating to the rules of origin of a specific agreement, e.g. the "cumulation" provisions and the "proofs of origin" in the Trade Helpdesk Website section "Rules of Origin".

EU data for your product

6th tab: trade statistics

- If your product is already imported into the European Union you may check the trade flows between the exporting and importing country.
- To find all trade flows between non-EU countries and the European Union please go to section "Statistics" on the Trade Helpdesk Website.


Statistics

Indicators	Import Value to the EU/MS (EURO)		Import Qty to the EU/MS (Kg)	
Partner(s)	Extra-EU	Extra-EU	Extra-EU	Extra-EU
Year(s)	**2015**	**2016**	**2015**	**2016**
Reporters				
France	609,068	7,493,235	100,000	1,415,000

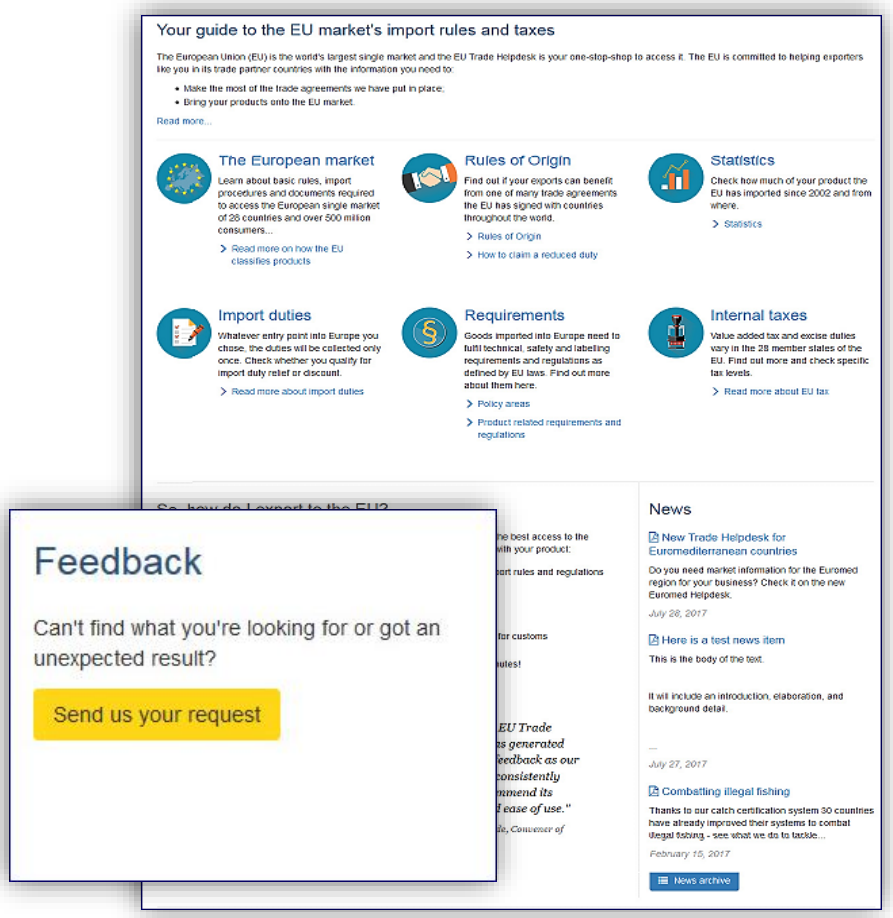
Save to Excel

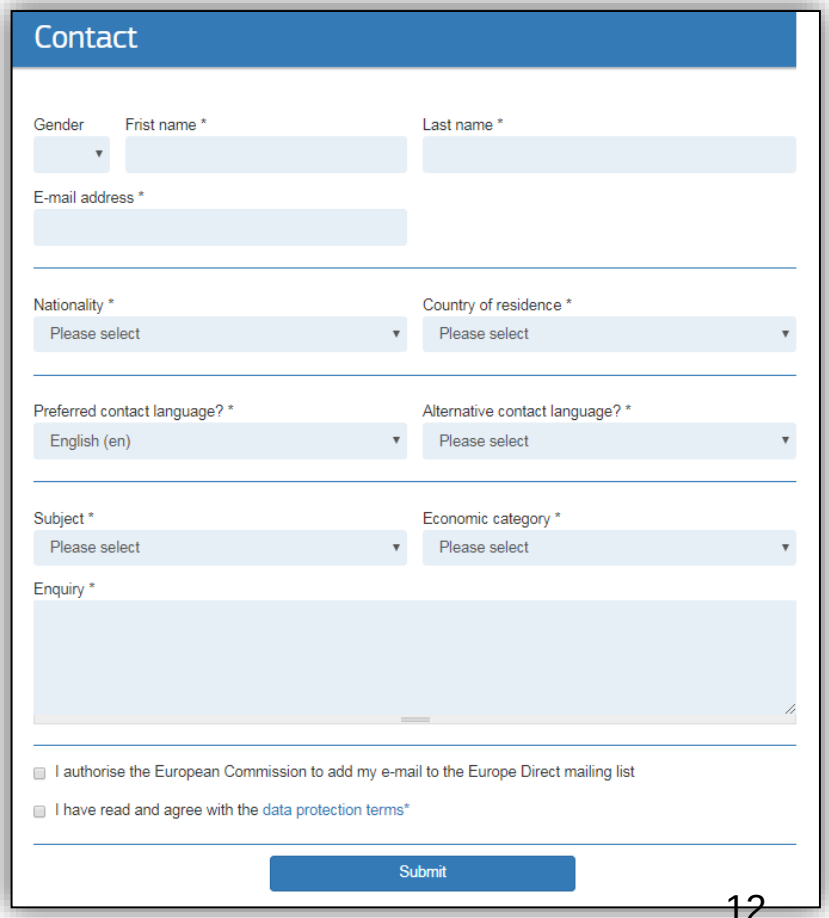
Need more information?

- Browse the Trade Helpdesk Website

More information

- Contact us!

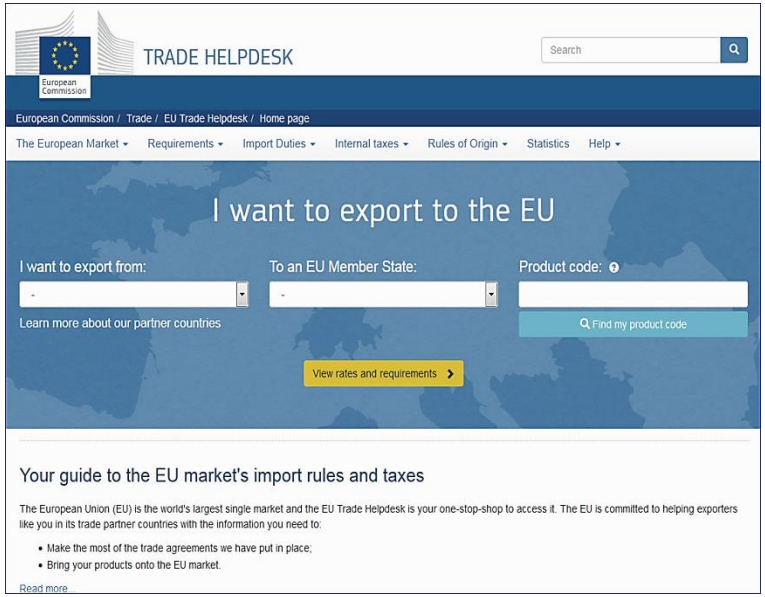




European Commission

EU Trade Helpdesk

Your online database for the EU market



Watch our video tutorial on Youtube.com

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