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Explanatory Meeting on the Acquis

Food Safety, Veterinary & Phytosanitary Policy

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union

Health and Consumers

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Overview of the new Animal Health Law, current & future provisions for imports into the Union

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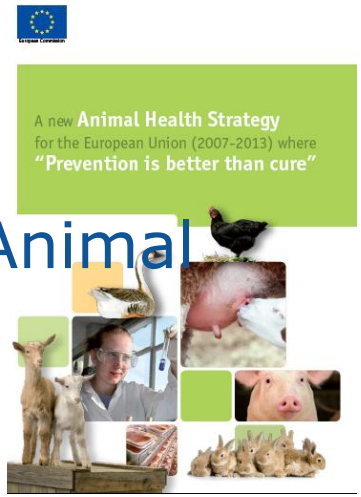
In this presentation:

- *Background information of the AHL (main Act)*
- *Supplementary legislation: DAs & IAs*
  - **What is the difference between a DA & an IA?**
  - **Description of the AHL DAs & IAs**
- *Overview of current import provisions*
- *Future import provisions: structure DA Entry into the Union*
- *Timings and consultation*

Animal Health Policy



- 2006: ***Evaluation of Community*** Animal Health Policy (CAHP)
  - **Need for a single strategy for animal health**
- Animal Health Strategy 2007-2013

  "Prevention is better than cure"
- Action Plan for the Animal Health Strategy
  - **EU Animal Health Law (AHL) is considered the most important tool for the implementation of that Strategy**

Animal Health Law (AHL)

- ✓ **Regulation (EU) 2016/429 on transmissible animal diseases ("Animal Health Law")***
  - ✓ Adopted : **9 March 2016**
  - ✓ OJ publication: **31 March 2016**
  - ✓ Regulation in force: **21 April 2016**
  - ✓ Apply as of: **21 April 2021** (within 5 years of entry into force)

*Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (Text with EEA relevance)

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Aims of the new Animal Health Law

- ***A single, robust legal framework*** *for animal health*
  - **Simplify existing rules:**
    - Numerically (from ca. 40 Directives and Regulations)*
    - In substance
- *More* ***risk based, proactive, preventive behaviour***
- ***Responsibilities*** *of keepers, operators, veterinarians, competent authorities, etc.*
- *Improved* ***response to emerging diseases***

*****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), ***Disease control*** (e.g. Dir 2003/85/EC, 2001/98/EC, 2005/94/EC, etc…)

Important new elements

1. ***Responsibilities*** *of keepers, operators, veterinarians, competent authorities, etc.*
2. *More* ***risk based approach*** *incl. prioritisation & categorisation of diseases for EU intervention*
3. *More* ***prevention*** *(biosecurity, surveillance, improved knowledge on animal health, use of vaccines, emerging diseases, AMR)*
4. ***Easy and safe*** *trade*

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1. Responsibilities for animal health

- *Operators:*
  - **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 animal health awareness, awareness on interaction between animal health, animal welfare and human health and on resistance to treatments ('One Health')**
- *Competent Authorities to ensure resources, personnel, laboratories, etc.*

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2. Risk based approach: scope of the Union intervention

- *EU limits its intervention and prioritise resources:*
  - **asses diseases as regards the added value for the intervention at EU level**
  - **prioritise diseases for the EU intervention**
- *Disease **listing and prioritisation/categorisation:***
  - **listing of diseases requiring EU intervention (AHL:** Article 5(1) and Annex II**)**
  - **which measures to be applied for which diseases**
- *Listed diseases for:*
  - **disease preparedness, awareness and disease control measures**
  - **disease eradication & disease freedom (compulsory/optional)**
  - **animal health requirements for intra-EU movements and entry**
  - **disease notification & reporting, surveillance**

3. Prevention

- *More prevention:*
  - **Biosecurity at farms, in transport, assembly, at borders**
  - **Surveillance, disease notification and reporting: enhanced and more structured**
  - **Improved knowledge, disease awareness & preparedness** (contingency plans)
  - **Use of vaccines (and other VMPs): clearer policy for their use** (in relation to disease prevention and control measures)
  - **AMR pathogens considered as "diseases"**
    - Different disease preventive and control measures may be applied
  - **Emerging diseases: more tools to control**

4. Easy and safe trade

- *Enhanced convergence with international standards on animal health (OIE)*
- *Requirements for export*
  - **similar to the "General Food Law"**
- *Added flexibility for animal (or product) movements*
  - **where involved health risks allow so**
  - **recognising and incentivise good practices (e.g. surveillance and biosecurity)**

Delegated Acts (DAs) and Implementing Acts (IAs) under AHL

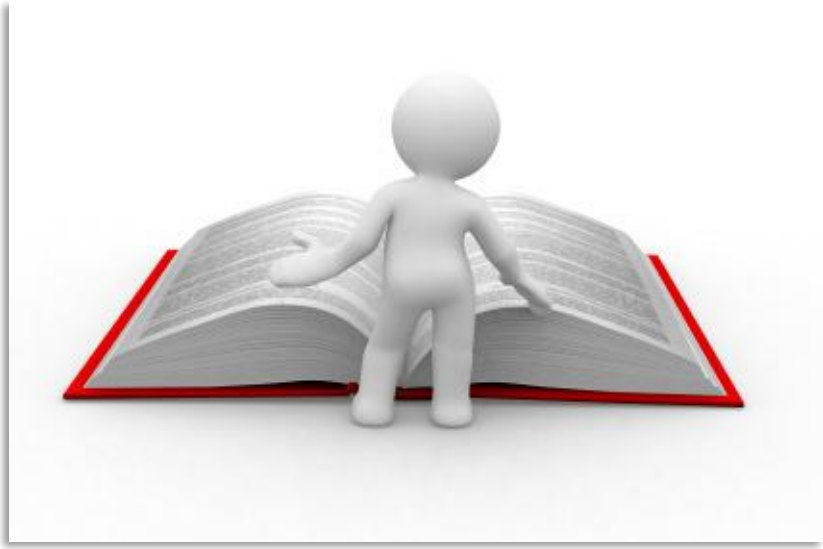
- ***DAs and IAs to complement the basic act:***
  - Commission to adopt "key"* DAs and IAs 24 months before the date of application of the Regulation
  - Other rules will be developed later (2019 onwards)

- ***Structure of DAs and IAs:***
  - Following different Parts, Titles or Chapters of the AHL

*"Key" acts determined by the EP and the Council (AHL, Article 274)

DAs & IAs – what's the difference?

Topic	DAs	IAs
Definitions	Acts that supplement or amend non-essential elements of the basic act (AHL)	Acts of administrative or technical nature
Role of EP & Council	EP & Cl delegate powers to the Commission to draft and adopt	• The EP & Cl give implementing powers to the Commission to adopt measures • EP & Cl have the right of information & scrutiny
How are they run?	Expert Groups: chaired by the Commission to get advise (national experts/ other interested parties)	• Comitology procedure (examination or advisory)* • Meetings of reps of MSs that provide an opinion *Choice depends on the nature & impact of the IA (the basic act specifies which procedures should be used)



AHL structure and secondary legislation: DAs & IAs

Part I – General rules

Part II – Disease notification, reporting, surveillance, eradication programmes, disease freedom

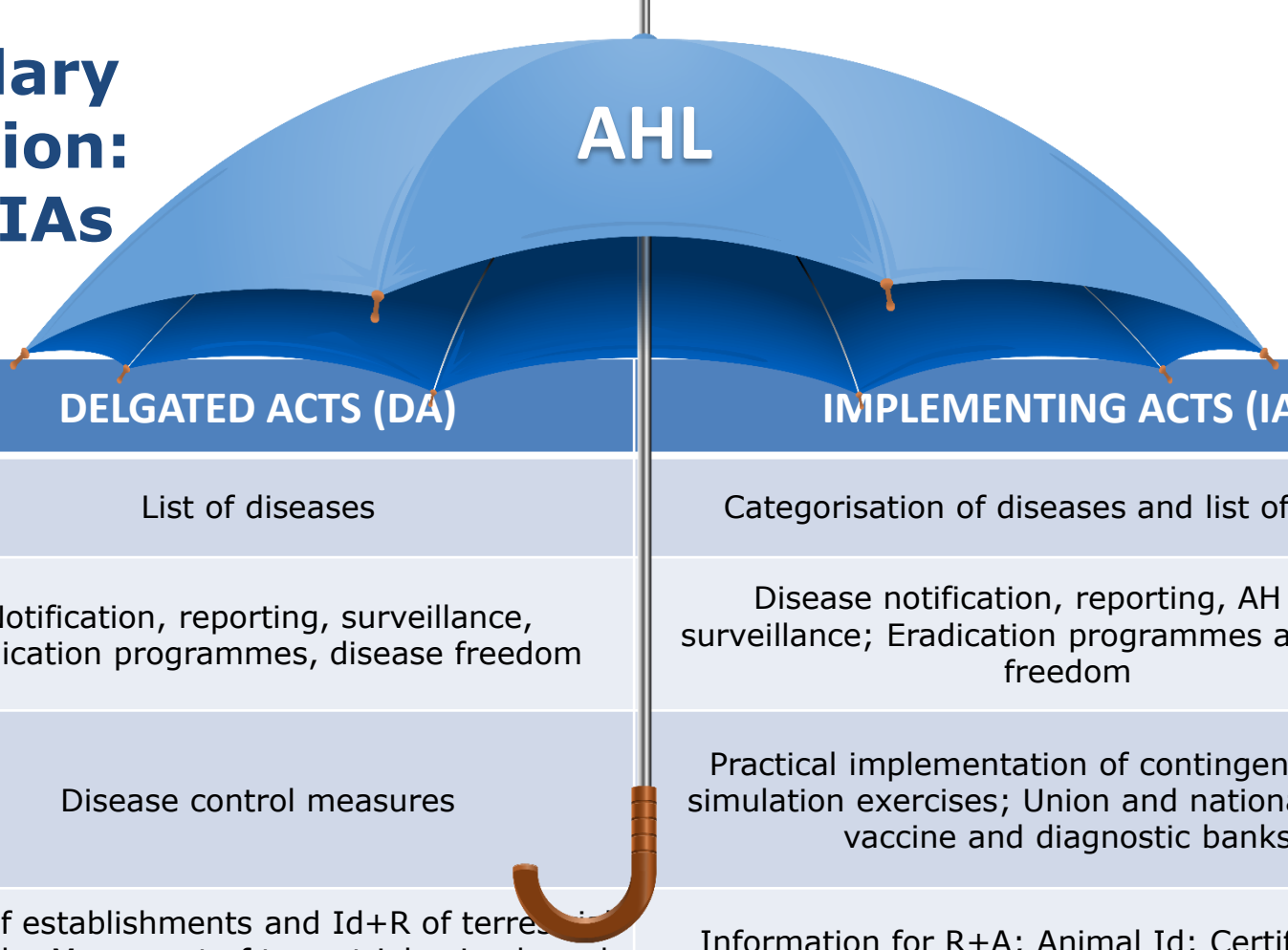
Part III – Disease awareness, preparedness, control

Part IV, Title 1 – Registration , approval, traceability and movements (terrestrial)
Part IV, Title 2 – Registration , approval, traceability and movements (aquatic)
Part IV, Title 3 – Other animals and their products

Part V – Entry into EU

Part VI – Non-commercial pets
Part VII – Emergency measures
Parts VIII-IX – Common and transitional provisions

Secondary legislation: DAs & IAs



PART	DELGATED ACTS (DA)	IMPLEMENTING ACTS (IA)
I	List of diseases	Categorisation of diseases and list of species
II	Notification, reporting, surveillance, eradication programmes, disease freedom	Disease notification, reporting, AH visits, surveillance; Eradication programmes and disease freedom
III	Disease control measures	Practical implementation of contingency plans, simulation exercises; Union and national antigen, vaccine and diagnostic banks
IV.1	R+A of establishments and Id+R of terrestrial animals; Movement of terrestrial animals and PAO; GP R+A of establishments and movements	Information for R+A; Animal Id; Certificates for movements of animals and PAO; GP information for R+A, certificates, etc.
IV.2	R+A of establishments & types of establishments (exemptions for certain types of transporters); Movement of aquatic animals and PAO from aquatic animals	Information for R+A; Certificates for movements of aquatic animals and PAO of aquatic animals, etc.
V	Entry into the EU of live animals, germinal products and PAO	List of third countries, territories Certificates

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Part I – General Rules

DA

List of diseases

(Art 5 AHL)

Published in the OJ
CDR 2018/1629

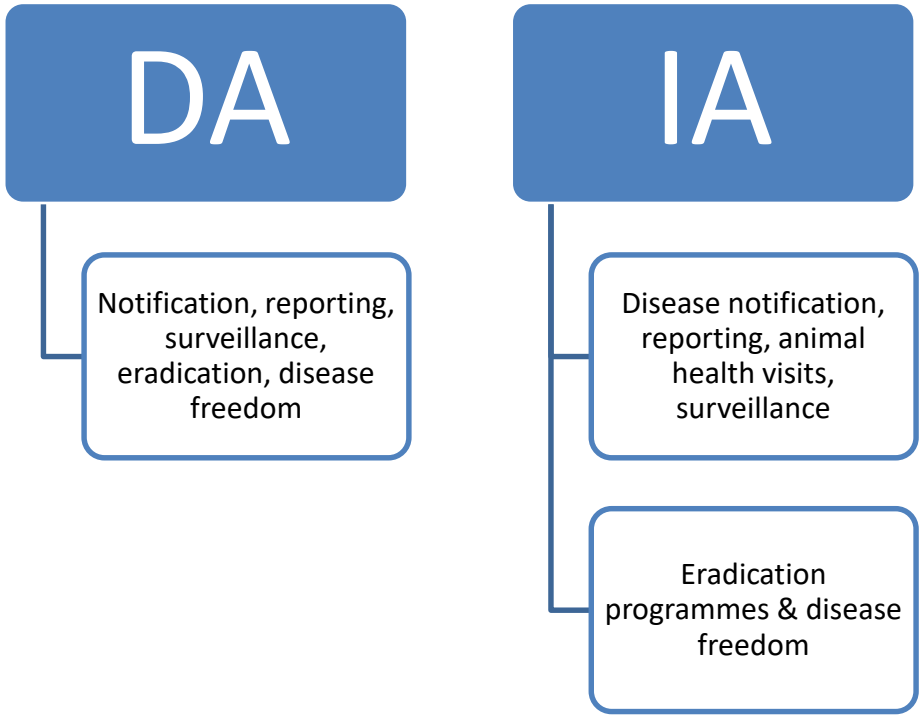
IA

Categorisation of diseases: A, B, C, D & E

(Art 8(2)&(3)/ Art 9 (1)&(2)

Published in the OJ
CIR 2018/1882

Part II – Notification, reporting, surveillance, eradication, disease freedom



Part III – Awareness, preparedness & control

DA

- Disease control measures – List A, B & C

IA

- Practical implementation of contingency plans, simulation exercises (Art 44 AHL)
- Union & national antigen, vaccine & diagnostic banks (Art 50 of AHL)

Part IV/1 – Terrestrial: registration, approval, I&R, movements

DA

- Terrestrial: registr. & approval of establishments + Id. & registr. animals
- Movement of animals & POAO
- Germinal: : registr. & approval of establishments + traceability & movements

IA

- Terrestrial: info for registr. & approval, exempted establishments, transporters, exemptions from record keeping
- Animal Id.
- Terrestrial & POAO: model AH certificates, self-declarations, notification & movements
- Germinal: info for registration & approval, exempted establishments, transporters, exemption from record keeping, traceability, model AH certificates, self-declarations, movement notification

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Part IV/2 – Aquatic: registration, approval, movements

DA

- Info for registr. & approval, types of establishments, transporters exempted, exemptions for record keeping
- Movement of animals & POAO

IA

- Aquatic animals & POAO: AH certificates, self-declaration, notification movements

Part V – Entry into the EU – animals, POAO & GP

DA

- Entry of live animals, POAO & GP

IA

- List of 3rd countries & territories
- AH certificates

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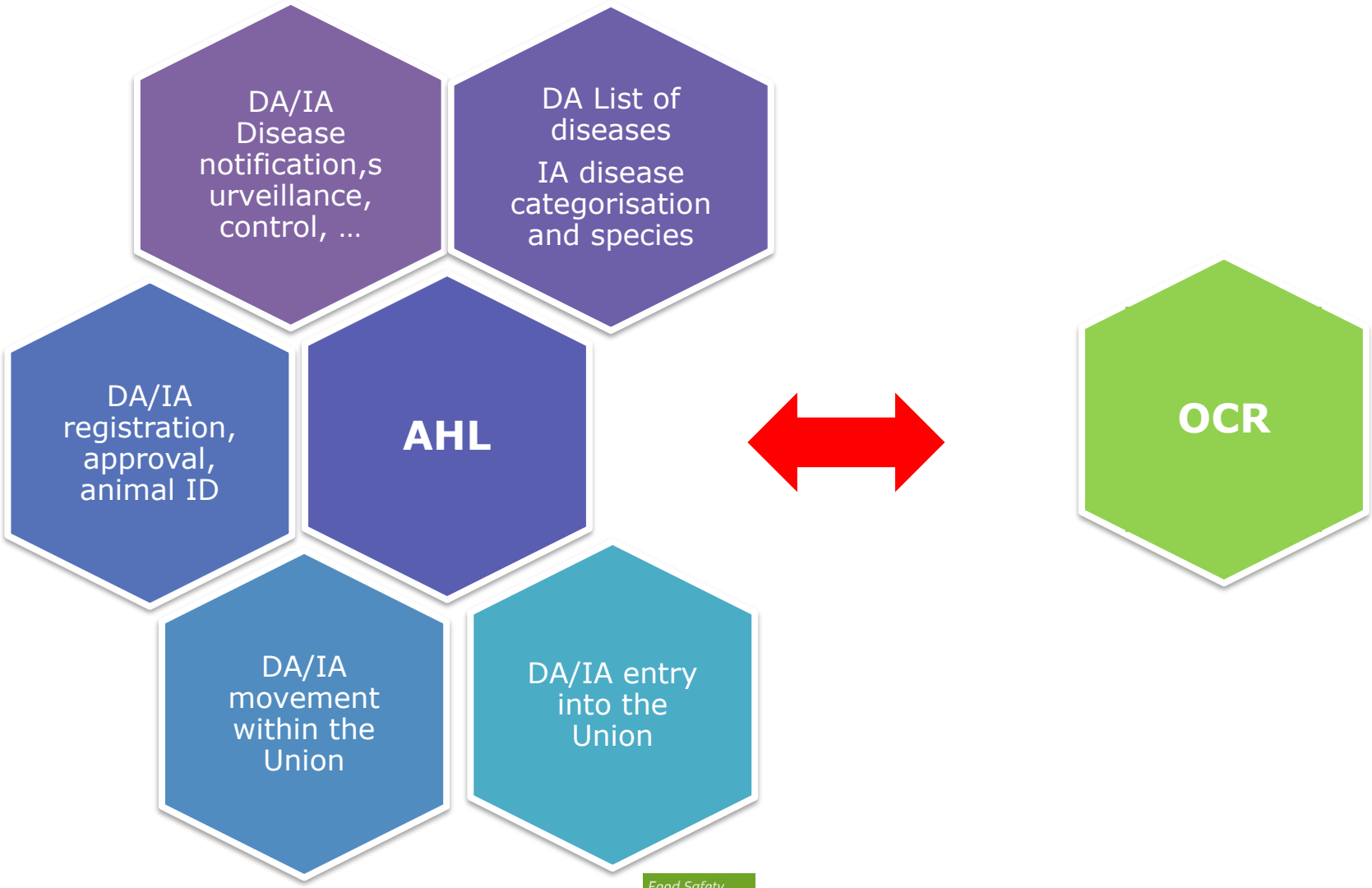
Summary DAs & IAs

AHL Part	DAs	IAs	Total (DAs+IAs)
Part I	1	1	2
Part II	1	2	3
Part III	1	2	3
Part IV/1	3	4	7
Part IV/2	2	1	3
Part V	1	2*	3
Total	9	12	21

***to be developed between 2019-2021**


DA/IA Disease notification,s urveillance, control, …
DA List of diseases
IA disease categorisation and species
DA/IA registration, approval, animal ID
AHL
DA/IA movement within the Union
DA/IA entry into the Union
OCR

Current legislation on imports

EU policy needs to:

- *Follow WTO rules and SPS which follows OIE & CODEX standards*
- *Be scientifically based: the European Food Safety Authority (in Parma, Italy) gives scientific advice to the Commission and to Member States*
- *Agreed by EU Member States (Standing Committee on the Food Chain and Animal Health)*

The EU legislative framework for imports

Dir. 72/462/EEC
Live animals(ungulates) + products
Animal Health & Public health

REPEALED

Products of animal origin

Animal Health
Dir.2002/99/EC

Public health
Hygiene package

Reg 852/2004/EC
Reg 853/2004/EC
Reg 854/2004/EC
Reg 882/2004/EC

Repealed by OCR

Repealed by AHL

Live animals

Animal health
Dir. 2004/68/EC

Repealed by AHL

EU Legislation: imports

Products of animal origin

Animal health
Dir. 2002/99/EC

Public health - Hygiene Package:
Reg. 852/2004/EC, 853/2004/EC
Residues Dec. 2004/432/EC
Reg 882/2004/EC (official controls)

legal base

Example:
Fresh meat Reg. 206/2010
Meat products Dec. 2007/777/EC
Poultry meat Regulation (EC) No 798/2008
Game meat Regulation (EC) No 119/2009

Implementation (PAFF)

Veterinary controls: 97/78/EC

Horizontal Legislation

Repealed by DA Part V of AHL

Repealed by OCR

EU Legislation: imports

Live animals

Animal health

Ungulates Dir. 2004/68EC
Horses 2009/156/EC
Aquaculture Dir 2006/88/EC
Balai Dir. 92/65/EEC

Public health

Reg. EC No.999/2001

Residues Dec. 2011/163/EC

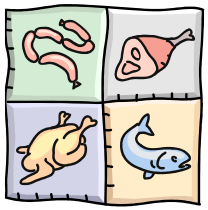
Example:
Ungulates (and meat from ungulates) Reg. 206/2010/EC

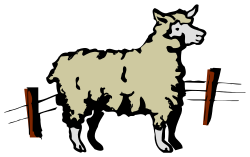
Repealed by DA Part V of AHL

Veterinary Controls: 91/496/EEC

Repealed by OCR

Implementing legislation - Import requirements





Product

- **Type: beef offal, sheep meat…**
- **Treatment: temperature, pH, deboned…**
- **Purpose: human consumption, feed…**

- Certificate
- Animal (transport, clinical exam, slaughter…)
- Treatment (temperature, deboned…)

Origin

- **Country**
- **Establishment**

- Animal health status
- Animal health legislation
- Structure and powers of veterinary services

Animal

- **Species**
- **Disease**

- Certificate
- Quarantine
- Testing

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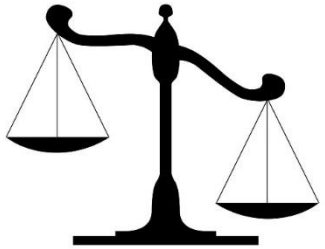
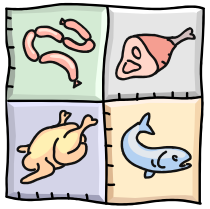
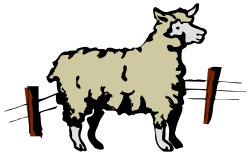
Enforcement legislation -animal products & live animals





Council Directive 97/78/EC

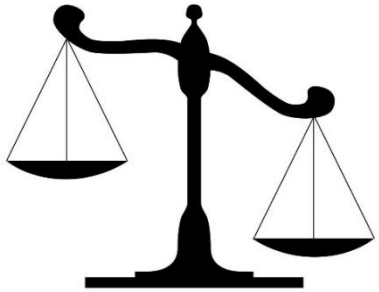
*laying down the principles governing the organisation of veterinary checks on **animal products** entering the Community from third countries*



Council Directive 91/496/EEC

*laying down the principles governing the organization of veterinary checks on **animals** entering the Community from third countries*

The control chain



Third country

Import legislation:
- Origin
- Product

BCP

Enforcement

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- Controls on intra-Union trade
- animal identification
- animal by-products and waste

Union-wide measures and controls

- disease prevention
- bio-security

On-farm measures and controls

Personal imports

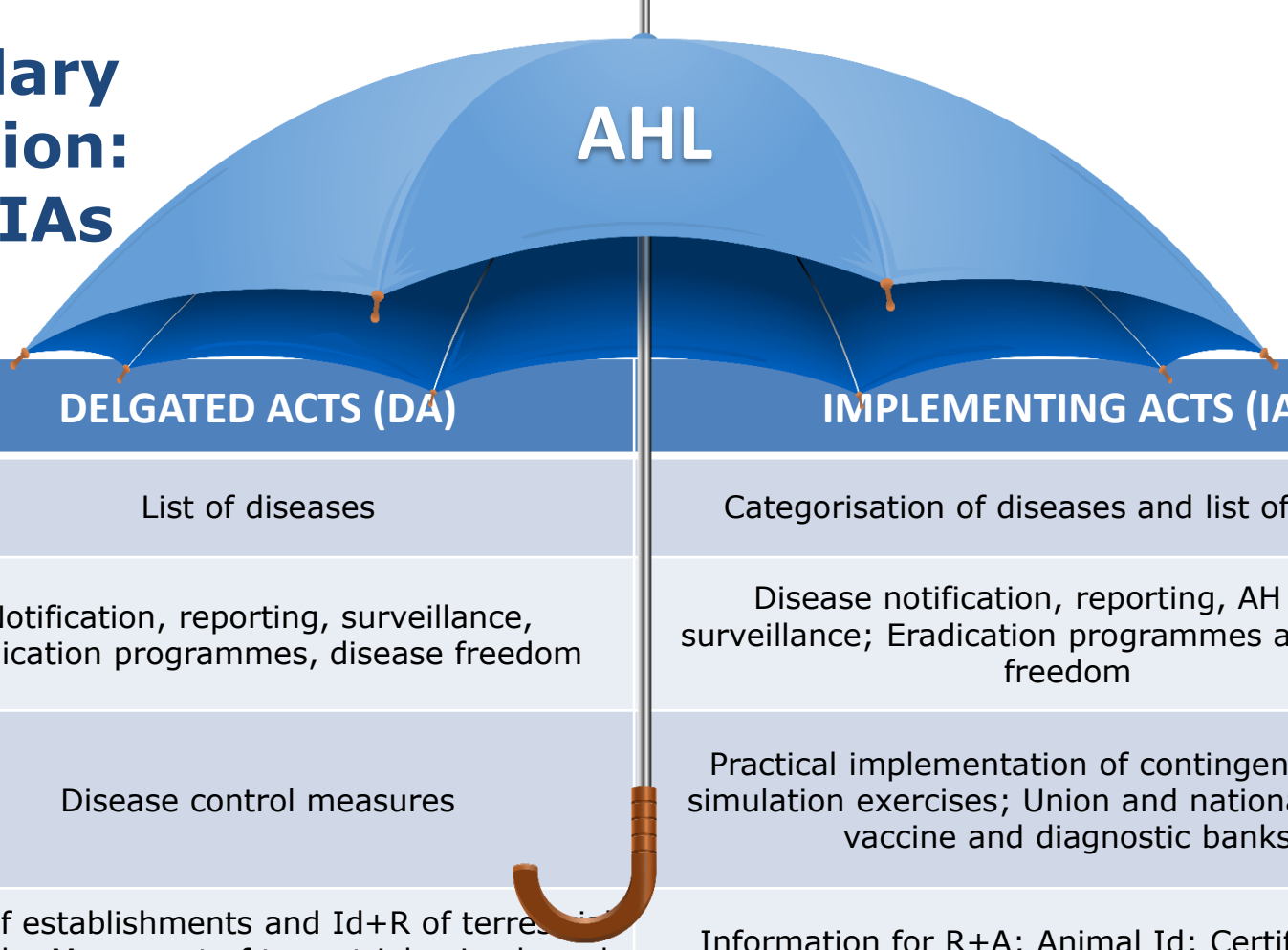
Council Regulation (EC) No 206/2009

Lays down permanent rules preventing personal consignments of meat and milk from entering the EU

Enforcement

Information on the results of the enforcement of this regulation must be sent by MSs to the Commission every year

Secondary legislation: DAs & IAs



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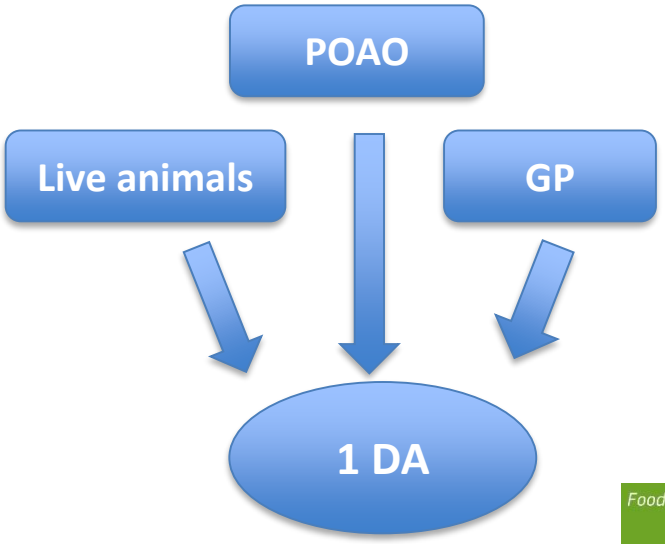
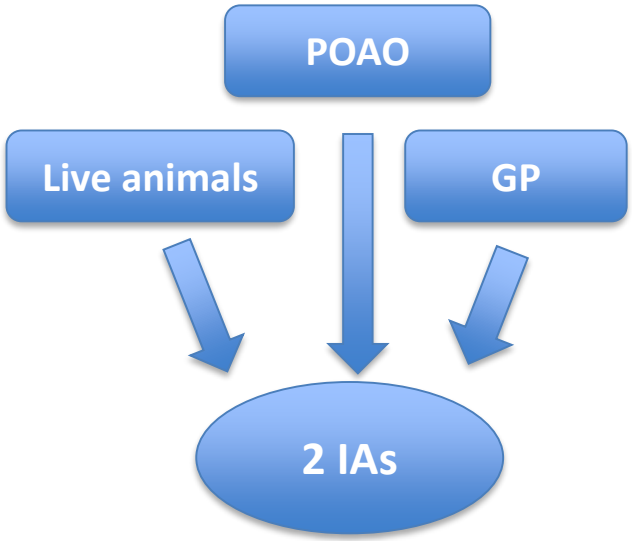
Entry into the Union

Part AHL	Delegated Acts (DA)	Implementing Acts (IA)
V	Requirement for entry into the Union of live animals, products of animal origin and germinal products	List of third countries/ territories Certificates





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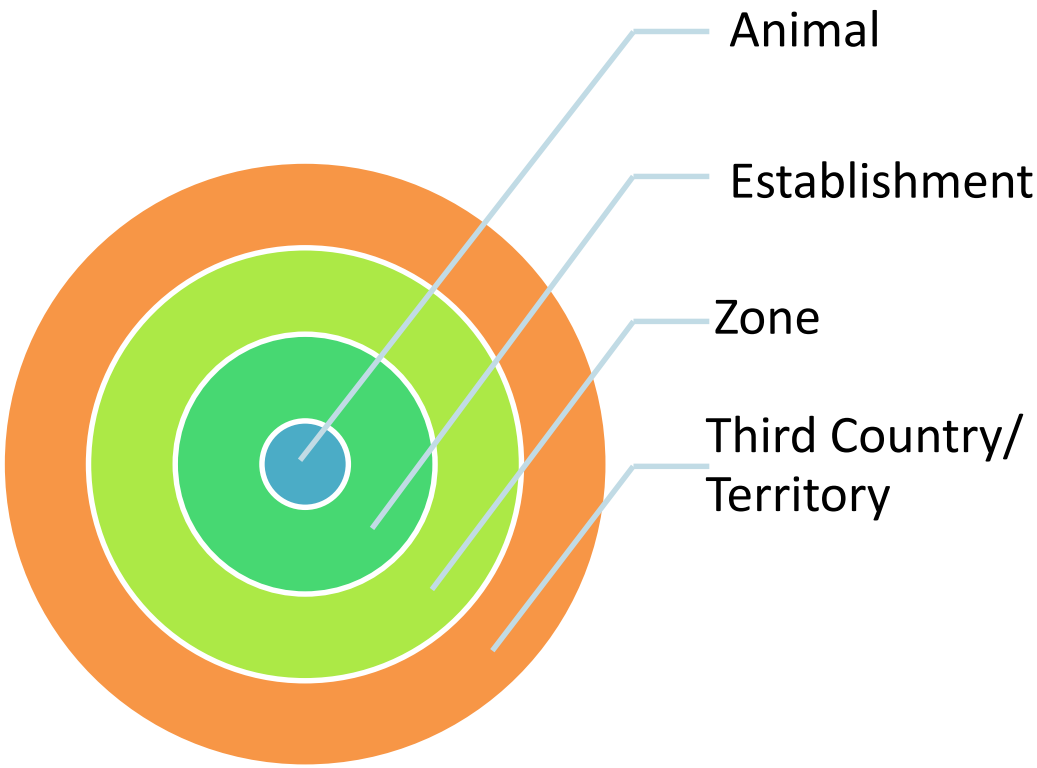
Structure new DA Entry into the Union

DA Part	Topic
I	General Rules – Subject matter, scope & definitions
II	AH requirements for the entry into the Union of Terrestrial Animals Title 1 – General AH requirements Title 2 – AH requirements for ungulates Title 3 – AH requirements for poultry & captive birds Title 4 - AH requirements for honey bees & bumble bees
III	AH requirements for the entry into the Union of Germinal Products
IV	AH requirements for the entry into the Union of Products of Animal Origin – Terrestrial only
V	AH requirements for the entry into the Union of Aquatic Animals & Products of animal origin of aquatic animals
VI	Transit through the Union

Approach – Part I General Rules

- Title 1 – Subject matter, scope & definitions
- Title 2- General AH requirements
  - Obligations for the CA at BCP of 1st arrival
  - Obligations for the importer
  - Requirements as regards animal diseases
  - National legislation of the country/ territory of origin
  - The establishment of origin

Approach – Parts II to V



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Timing and Consultation

- Deadline for adoption

Spring 2019

- Consultation with MSs + Iceland, Norway, Switzerland (expert groups)
- Consultation with stakeholders (AHAC)

Ongoing

- Feedback mechanism
- SPS notification

Beginning of 2019

Questions?

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