

# Study supporting the Evaluation of the EU Animal Health Law

AHAC Meeting | 5<sup>th</sup> September 2024

# Agenda

	topic	by
10.10 – 10.20	Presentation of the study team, objective and general approach	Bérénice Dupeux, Ecorys
10.20 – 11.20	Presentation of the activities	
	Consultation strategy	Bérénice Dupeux , Ecorys Ron Bergevoet, WUR
	Activities performed in the inception phase	Alexandre Mohamedaly, Ecorys Camilla Campana, Ecorys
	Intervention Logic	
	Evaluation Matrix	

## Objective of today's meeting

- Introduce the project and provide some background
- Get your support to participate in the different consultation activities
- Open your network for us to be able to collect the relevant information



# Presentation of the Team



Strong track record in projects for DG SANTE and EFSA.  
Experience in data collection, stakeholders' consultations, and the synthesis of findings



WAGENINGEN  
UNIVERSITY & RESEARCH

Extensive track record in academic research projects on animal health and welfare, including risk assessment, development of indicators, and involvement of sensor technology.



Very good understanding and knowledge of animal health policy in the EU, its implementation at the national level and its linkages with other relevant EU legislation.



Experience in animal health and welfare, including assessing the level of adoption and compliance with the Animal Health Law and the new Official Control Regulation

## External Review Board

Diverse background  
and extensive  
experience

**High Level Experts**  
Dirk Pfeiffer  
Nuno Vieira  
Alberto Laddomada

Contribute mostly to the inception phase and finalisation phase of the study:

1. Review the proposed methodologies and ensure the comprehensiveness of the study
2. Review the replies to the Study Questions
3. Go to in case of doubt or uncertainties from the Study Team



# Objectives and approach



## Objectives

Ex-post evaluation of the Animal Health Law, including its adopted delegated (and implementing acts).

- Collection of quantitative and qualitative evidence on the performance and implementation of the Law.
- Is it Fit for purpose? (performance assessment)
- What are possible improvements? (monitoring obligations and simplification)





## Part I

Subject matter, aim, scope and definitions; Listed diseases, emerging diseases and listed species; Responsibilities for animal health

- ★ **Reg. (EU) 2018/1629** (List of diseases)
- ★ **Reg. (EU) 2018/1882** (Categories of diseases)

## Part II

Disease notification, reporting, surveillance, eradication programmes, disease freedom

- ★ **Reg. (EU) 2020/689** (Surveillance, eradication & disease free status)
- ★ **Reg. (EU) 2020/202** (Disease notification/ reporting)
- ★ **Reg.(EU) 2020/690** (Listing Union Surveillance Programmes & Compartments)
- ★ **Regulation (EU) 2021/620** (Listing of existing disease free and eradication programmes)

## Part III

Disease awareness, preparedness, control

- ★ **Reg. 2020/687** (Prevention & control of Cat A, B & C diseases )
- ★ **Reg. (EU) 2022/139** (Management of vaccine banks)
- ★ **Reg. (EU) 2022/140** (Rules for vaccine banks)

## Part IV

Registration, approval, traceability and movements (terrestrial); Registration, approval, traceability and movements (aquatic); Other animals and their products

- ★ **Reg.(EU) 2019/2035** (Registration & approval establishments & traceability) (T)
- ★ **Reg. (EU) 2020/688** (Intra EU movements) (T)
- ★ **Reg. (EU) 2020/2154** (Intra EU movements) (TPAO)
- ★ **Reg. (EU) 2020/686** (Approval establishments & intra EU movements) (G)
- ★ **Reg. (EU) 2020/691** (Rules for aquaculture animal establishments & transporters of aquatic animals ) (A)
- ★ **Reg. (EU) 2020/990** (Movement of aquatic animal and their products (A) (APAO)
- ★ **Reg. (EU) 2021/963** (Registration & identification horses)
- ★ **Reg. (EU) 2021/520** (Registration & identification ( except horses)) (T)
- ★ **Reg. (EU) 2020/999** (Operators application for approval & Traceability) (G)
- ★ **Reg. (EU) 2021/2037** (Derogation from registration & for record keeping by certain transporters ) (A)

## Part V

Entry into EU

- ★ **Reg. (EU) 2020/692** (Entry into the EU) (T) (A) (G) (TPAO) (APAO)
- ★ **Reg. (EU) 2021/404** (List of Third Countries)
- ★ **Reg. (EU) 2020/2235; 2020/2236; 2021/403** (on animal health Certificates) (T) (A) (G) (TPAO) (APAO)

## Part VI; VII; VIII / X

Non-commercial pets; Emergency measures; Common and transitional provisions

### Legend:

★ Implementing act    ★ Delegated act    (T) Terrestrial animals & hatching eggs    (TPAO) Terrestrial products of animal origin    (A) Aquatic animals    (APAO) Aquatic products of animal origin    (G) Germinal products



# Approach

## Approach to an evaluation: Better Regulation guidelines and toolbox

Evaluation is an evidence-based judgement of the extent to which an existing intervention is:

- **effective** in fulfilling expectations and meeting its objectives;
- **efficient** in terms of cost-effectiveness and proportionality of actual costs to benefits;
- **relevant** to current and emerging needs;
- **coherent** both internally and externally (with other EU interventions or international agreements); and
- has **EU added value** i.e. produces results beyond what would have been achieved by Member States acting alone.

( source: tool 47 better regulation toolbox )

## Scope

### Description

#### Time and cut-off date

2016 – 2023, with a focus on the period since 21 April 2021 till December 2023

#### Material scope

All parts, including delegated acts (and implementing acts) were adopted.

All kept animals, both terrestrial as well as aquatic animals kept for commercial purposes in addition to pet animals, including animals kept in laboratories and zoos.

#### Geographical scope

EU27 Member States (MS), but also European Economic Area (EEA) and candidate countries.

#### Evaluation criteria

**Effectiveness** (9 questions): the extent to which the legislation fulfils its expectations and meets its objectives;

**Efficiency** (5 questions): 1) the proportionality of actual costs to benefits of the AHL , 2) the distribution and magnitude of the costs and benefits and differences between MS, 3) administrative burden, 4) possible inefficiencies and 5) reporting obligations and simplification.

**Coherence** (7 questions): internal and external coherence (national and international dimension)

**Relevance** (4 questions): in view of its objectives, needs and new emerging challenges or targets

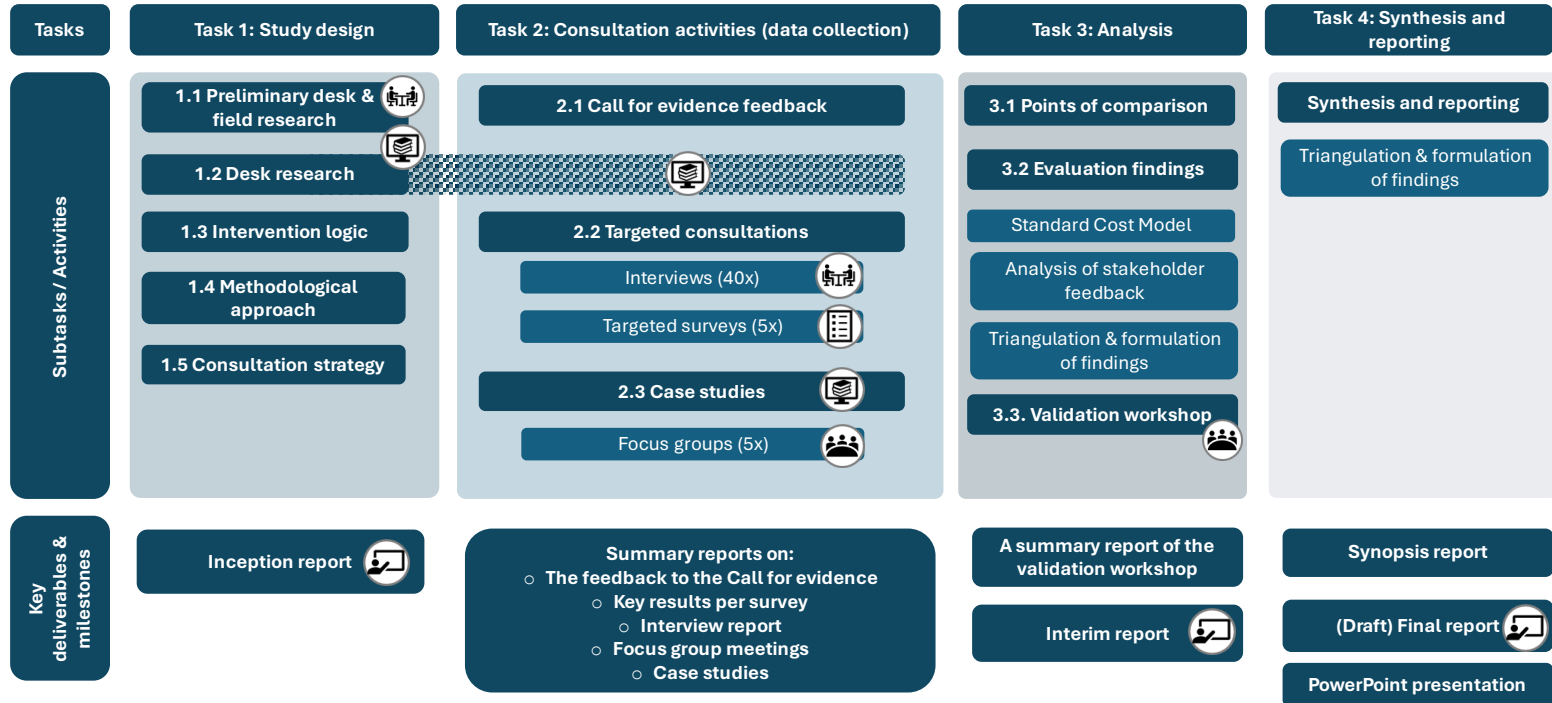
**EU added value** (3 questions): additionality of the EU legislation, potential improvements of the EU-level action

# Scope

Scope	Description
Target groups	<p>The scope of the assignment requires coverage of several types of stakeholders:</p> <ul style="list-style-type: none"> <li>▶ National competent authorities (of EU MSs and accessing countries) <ul style="list-style-type: none"> <li>▶ Different ministries might be involved depending on competencies</li> <li>▶ Difference services might be involved at different geographical levels</li> <li>▶ Subordinated agencies</li> </ul> </li>   <li>▶ International organisations, EU bodies , agencies and research organisation</li>   <li>▶ <b>EU CSOs and their National members</b> <ul style="list-style-type: none"> <li>▶ Farmers and Business Operators</li> <li>▶ Veterinarians</li> <li>▶ NGOs</li> <li>▶ Consumers</li> </ul> </li> </ul>

# Overall approach

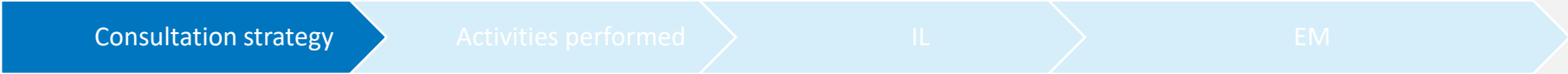
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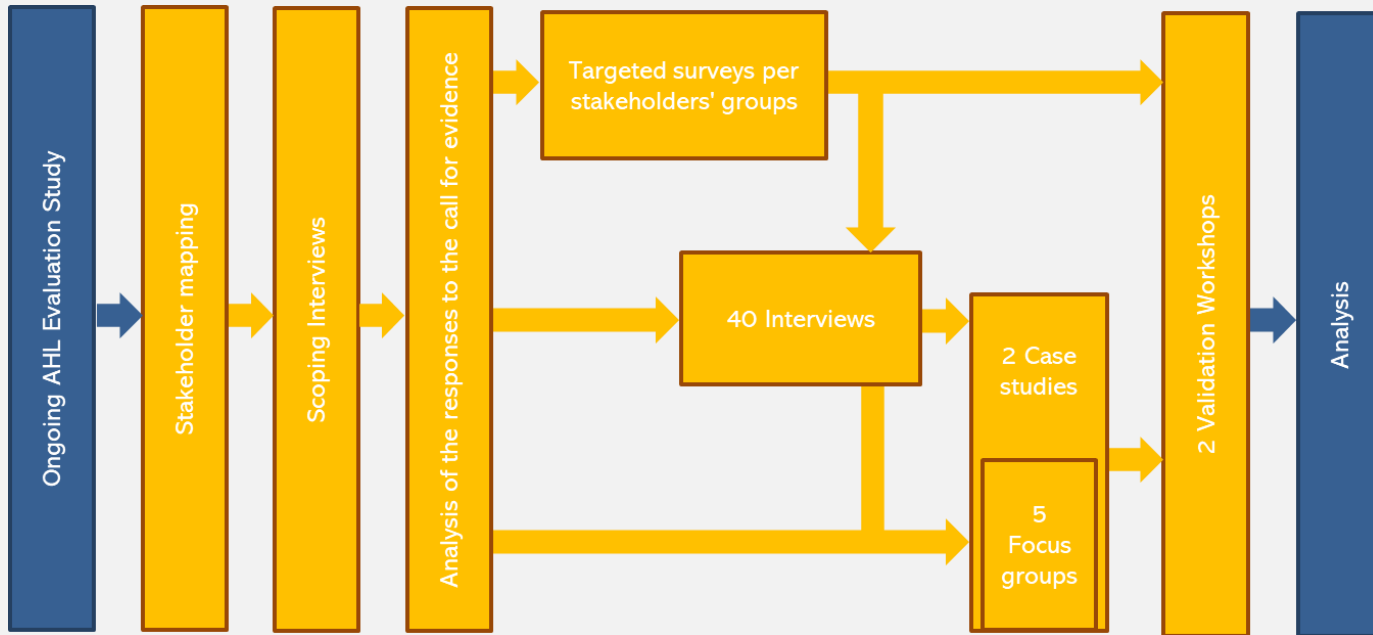
# Activities







# Overall consultation strategy



Consultation strategy		Activities performed	IL	EM		
		Sub-task:	Stakeholders consulted		Main outputs	
Task 1	Scoping Interviews	Sub-task 1.1: Preliminary desk and field research	DG SANTE COPA-COGECA FVE	Animal Health Europe	Inception report	
	Call for Evidence	Sub-task 2.1: Call for Evidence feedback	All stakeholders		Summary report	
Task 2	Targeted surveys	Sub-task 2.2: Targeted consultations	NCA's Livestock and aquaculture farmers	Animal farming and industry Veterinarians	Researchers International organisations	
	Interviews	Sub-task 2.2: Targeted consultations	NCA's NGOs	International organisations	Synopsis reports Interview reports	
	Focus groups	Sub-task 2.2: Targeted consultations	NCA's Livestock and aquaculture	farms Animal farming and	industry Veterinarians EU agencies	Synopsis report Summary report
Task 3	Validation workshops	Sub-task 3.3: Validation workshops	NCA's Livestock and aquaculture farmers	Animal farming and industry Researchers	Int.organisations EU agencies	Interim report Summary report

Consultation strategy

Activities performed

IL

EM

## Analysis of CFE responses

Dataset cleaning

- Preliminary screening
- Set aside campaign responses

Themes identification

- AI themes identification
- Preliminary coding system

Clustering of themes

- ~~Test and refine the coding system~~
- Roll out coding to the entire dataset

Analysis

- Assess responses by theme
- Breakdown by stakeholder group

Reporting

- Synthesis analysis into a factual summary report

## Targeted survey (4)

NCA

Members of PAFF

People responsible of technical implementation

Farmers

Different livestock sector  
Different operating scales

Animal farming & industry

Coverage of the supply chain

Veterinarian

EU umbrella representatives

Private and Public sector

NGOs, researchers, international organisations

Environmental food system dimensions

Consultation strategy

Activities performed

IL

EM

## Interviews (40)

Stakeholder categories (minimum number of interviews)	Selection criteria
<p>NCAs (20)</p>	<p>Departmental Diversity: :</p> <ul style="list-style-type: none"> <li>• Disease control (e.g. veterinary public health, epidemiology units)</li> <li>• Disease prevention (e.g. biosecurity, vaccination programs)</li> <li>• Policy development and regulatory affairs</li> <li>• Surveillance and monitoring</li> </ul> <p>Functional Roles: Select NCAs with varying functional roles, such as:</p> <ul style="list-style-type: none"> <li>• Field operations and inspections</li> <li>• Laboratory diagnostics and research</li> <li>• Data management and reporting</li> <li>• Training and capacity building</li> </ul> <p>Institutional Structure</p>
<p>Livestock &amp; aquaculture farmer representatives (2)</p>	<p>Stakeholders consulted are representative of the animal health value chain (from farmers to retailers and transport operators) and cover sufficiently different geographical areas of the EU, but also different animal sectors (pig sectors, cattle sector, poultry sector, etc.)</p>
<p>Animal farming &amp; industry representatives (2)</p>	
<p>Veterinarians (official, industry, private) (3)</p>	
<p>Others (NGOs, researchers, international organisations) (3)</p>	<p>At least one organisation for each type of stakeholder (e.g. NGO, researcher, and international organisation).</p>

## Thematic on which you will be consulted

**Targeted questionnaires** for each of the four stakeholder groups

- **Effectiveness**
  - Achievements of the objectives  
*e.g. To what extent has the AHL been successful in achieving its general and specific objectives?*
  - Opportunities for improvements  
*e.g. Do you see opportunities to improve and enhance stakeholder engagement under the AHL?*
- **Efficiency**
  - Additional costs and benefits incurred since the adoption of the AHL  
*e.g. In which of the following areas (clarity of rules and responsibilities, early detection and control, economic impacts of animal diseases outbreaks, etc.) did you observe (positive or negative) changes due to the adoption of the AHL?*  
*e.g. To what extent do you consider the overall costs of the AHL proportionate to the benefits?*
  - Opportunities for simplification  
*e.g. Are there opportunities to simplify the legislation or reduce unnecessary regulatory burdens without undermining the objectives of the AHL?*

## Thematic on which you will be consulted

- **Relevance**

- Whether the AHL is fit to address current and future challenges and needs

*e.g. To what extent do you find the provisions of the AHL fit and relevant to the current animal health challenges?*

*e.g. To what extent do you find the provisions of the AHL fit and relevant to address emerging needs and threats to animal health?*

*e.g. To what extent is the AHL fostering training for veterinarians, animal handlers and staff involved with animal health?*

- **Coherence**

- Potential inconsistencies within the AHL and with other EU legislation

*e.g. Have you identified any inconsistent or contradictory provisions within the AHL?*

*e.g. To what extent is the AHL coherent with the following sectorial legislation (on official controls, animal by-products, animal welfare, etc.)?*

- **EU added value**

- Whether the same results could have been achieved by national measures and systems alone

*e.g. Could the same results have been achieved by national animal health measures and system alone, without the need of EU intervention?*

## Case study 1 will focus on:

- Examining how each interviewed Member States has integrated AHL into the national framework
- The divisions of responsibilities for stakeholders, between/among stakeholders is since the AHL came into force
- Identify successful approaches and practices
- How suitable and fit for purpose is the AHL to respond to NCA needs.
- Regional differences in animal health control

Member States: NL, DE, ES, LI

## Case study 2 will focus on:

- Examining Member States' current arrangements for controlling animal health risks for intra-EU movements
- The proportionality and the flexibility of those arrangements in light of the animal health risk
- Animal health conditions for impots

Member States: DN, FR, IT, HU

Topic	Stakeholder group					
	Farmers	Veterinarians	Academics	CA	BO (industry)	BO (transporters)
Case Study 1: Implementation and enforcement		Focus group 2		Focus group 1		
Case Study 2: Cross-border Animal Movements	Focus group 4	Focus group 4	Focus group 5		Focus group 3	Focus group 3



## Validation workshop

### Objective:

1. Confirm the validity and completeness of the analysis, ensuring all relevant data sources and findings are correctly used and thoroughly tested.
2. Assess the reaction and potential uptake of conclusions and recommendations, ensuring no critical information is overlooked.

#### Workshop 1:

- In-person half-day WS in Brussels
- Maximum 40 persons from NCA
- Back-to-back to PAFF meetings on December 16-17
- Chatham House rule

#### Workshop 2:

- Virtually after Christmas break
- Between 50 and 70 participants from all stakeholder groups
- Chatham House rule

Consultation strategy

Activities performed

IL

EM

- Launch of the survey second half of September, for a minimum of four weeks.
- In parallel will be performing the interviews
- Subsequently, we will conduct the case studies and the focus groups
- Finally, you will be invited to the validation workshops in early 2025.

## Preliminary desk research

❑ 1<sup>st</sup> Identification, screening and analysis of relevant sources (see Annex 1: Preliminary list of data sources)

❖ Examples:

- World Organisation for Animal Health (OIE) documents
- EU Regulations
- EFSA publications
- SANTE Directorate for Health and Food Audits and Analysis reports, etc

❑ Regular checks to identify any new documents and studies that may be performed during the study

❑ All sources stored in a central database that serves as the central knowledge hub for our project team.

## Preliminary desk research

- ❑ Quantitative data from databases to be downloaded and centrally stored in Excel on our SharePoint.
  - ❖ Preliminary list of databases:
    - EUROSTAT: data on agricultural census, aquaculture, farm structure surveys, crop and animal statistics, etc.
    - FADN: farmers' income and business activities
    - ADIS: outbreaks of contagious livestock diseases
    - COMEXT: EU trade statistics
- ❑ [European Commission | Agri-food data portal \(europa.eu\)](https://ec.europa.eu/agri-food/) on livestock production & trade to be used as input.

## Scoping interviews

- ☐ Enabled us to assess if the proposed evaluation framework is appropriate and if specific stakeholders have information relevant for data collection

Table 1. Stakeholders for the scoping interviews

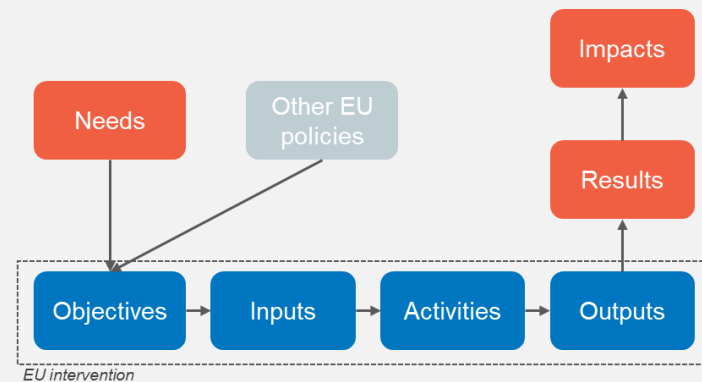
Category	Organisations
Commission	DG SANTE – Head of unit policy making Animal health Unit G.2
	DG SANTE Unit F.2 (Animals) Department for health and food audits and analysis (control on implementation)
Farmers Association	Committee of Professional Agricultural Organisations (COPA) – General Confederation of Agricultural Cooperatives (COGECA)
Veterinarians	Federation of Veterinarians of Europe (FVE)
International organisations and EU bodies and agencies	World Organisation for Animal Health (WOAH/OIE)
	Animal Health Europe
National Competent Authority	CVO from Hungarian
	CVO from Spain

## Intervention logic

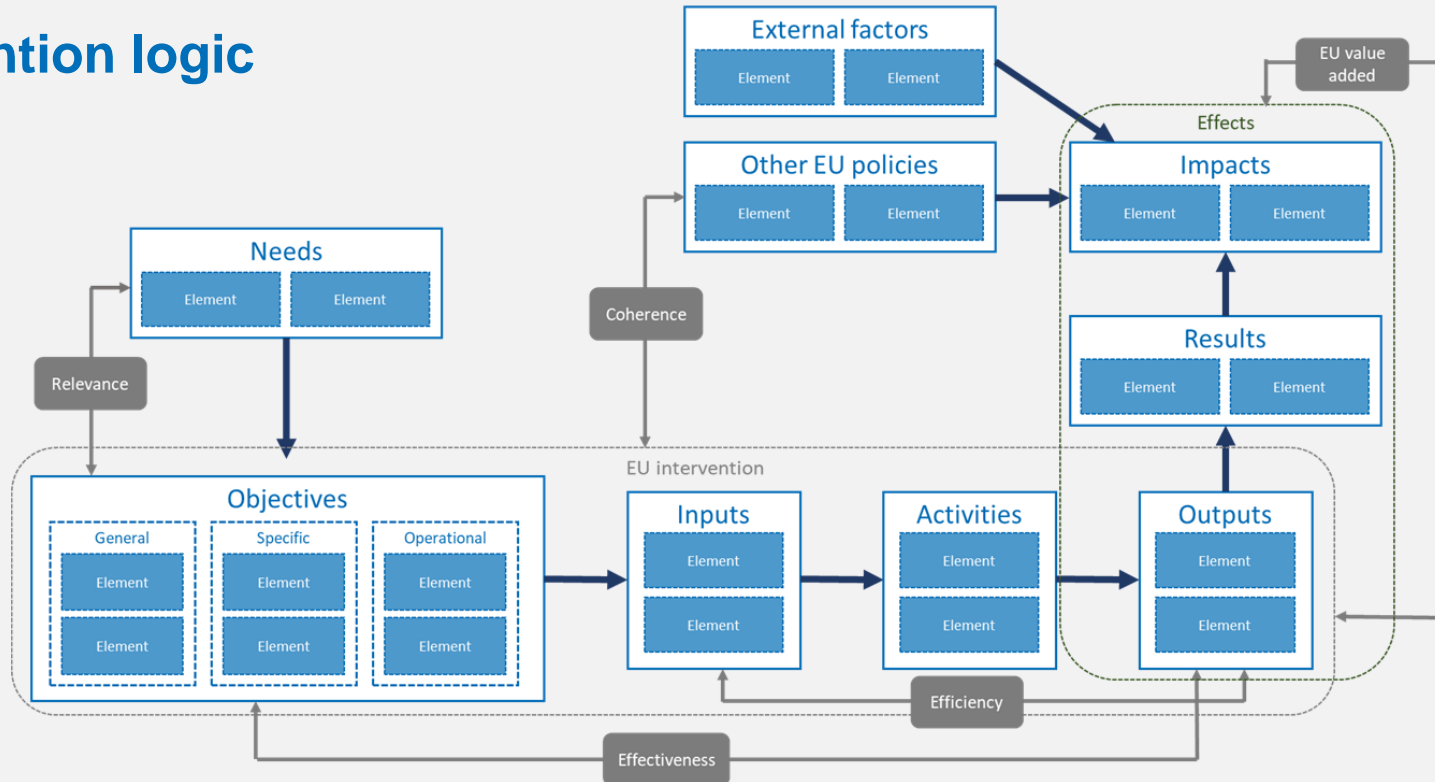
The intervention logic is the **starting point for any evaluation**:

- Provides a visual analytical framework to conduct the evaluation
- Summarises the expected logic of the intervention of the AHL
- Tool to identify the different steps and actors involved and their dependencies
  - Links the needs for the intervention to its objectives, the inputs with the activities
  - Defines outputs, results and impacts -> relevant for the identification of indicators for the evaluation

- Provides a (visual) narrative on the rationale of the intervention
- Closely linked with the evaluation matrix and analysis of the five evaluation criteria



# Intervention logic





## Relevance

The relevance analysis will cover to what extent the AHL continues to be relevant in view of its objectives, needs and emerging challenges. The analysis will explore whether the AHL:

- **is able to tackle current and emerging needs, such as the need to streamline and harmonise legislation across Member States** or the necessity to clarify the delineation of roles of relevant stakeholders involved in animal health.
- **is sufficiently flexible to adjust to changing circumstances**, such as new animal disease outbreaks, or whether the categorisation and prioritisation of diseases is still relevant.
- is relevant, adaptable, and necessary **in co-existence with national legislations** and technological development.
- **And if potential or foreseen issues arose after the introduction of the Regulation**, such as the threat of new pathogens from other countries.

## Efficiency

The efficiency analysis will focus on:

- **proportionality of actual costs to benefits** of the AHL
- **distribution and magnitude** of the costs and financial benefits
- differences in implementation of the costs between Member States
- **regulatory burdens** and possible inefficiencies
- reporting obligations and opportunities for **semplification**

**Cost-benefit analysis** will identify and quantify in monetary terms all costs and benefits associated with the AHL, such as

- compliance costs: e.g. costs of implementing biosecurity measures to prevent and control diseases for farmers or training costs for veterinarians
- enforcement costs for NCAs e.g. information and monitoring costs, costs for crisis management in case of outbreaks

## Effectiveness

The analysis of effectiveness aims to assess the extent to which the objectives of the AHL have been successfully achieved. It will focus on:

- **MSs challenges** encountered during the AHL implementation phase
- the extent to which the AHL legislation achieved its **general and specific objectives**
- level of clarity and **balance of roles and responsibilities** across stakeholders
- The socio-economic impact due to animal diseases reduction on **public health, animal welfare, economy and society**
- **strengths and weaknesses** of the AHL e.g. clearer responsibilities, prevention including biosecurity and surveillance
- main shortcomings in AHL both at the EU level and at the national level

## Coherence

The analysis of the coherence considers

- to what extent the AHL and delegated acts is coherent with itself i.e. **internal coherence**
- to what extent it is coherent with other relevant policy and legislative measures at EU, national and international levels i.e. **external coherence**.

The analysis will assess coherence with EU pieces of legislation related to **TSE, foodborne diseases, zoonoses**

But also with EU flagship policy initiatives, such as the **EU Green Deal, Farm-to-Fork Strategy** and **One Health Approach** and current and emerging policies for the long-term competitiveness of the EU agri-food sector.

## EU added value

The evaluation criterion of EU added value examines whether EU interventions yield results that go beyond ('over and above') what could be expected by individual measures of Member States.

The analysis will explore

- The **additionality of the AHL** and overall gains compared to national legislation only
- Potential room for improvements in the EU-level action



# Conclusion

- The success of the study is also dependent on the level of engagement of stakeholders. We aim to engage with you at all stages as well as with national organisations. Therefore, we encourage you to inform and forward your members about our consultation activities. Coming soon the survey !
- Apologies in advance for cross-posting!
- If you have questions, you can reach out to us at: [evaluationAHL@ecorys.com](mailto:evaluationAHL@ecorys.com)

Thank you, Questions?

