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EVALUATION

of 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)

Accompanying the document

REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

on the evaluation of Regulation (EU) 2016/429 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')

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Glossary

Term or acronym	Meaning or definition
ADIS	Animal Disease Information System
AHL	Animal Health Law
AMR	Antimicrobial Resistance
ASF	African Swine Fever
BSE	Bovine spongiform encephalopathy
BRG	Better Regulation Guidelines
BT/BTV	Bluetongue (Bluetongue virus)
BTSF	Better Training for Safer Food
BVD	Bovine Viral Diarrhoea
CBA	Cost-Benefit Analysis
CfE	Call for Evidence
CPs	Control Programmes
CSF	Classical swine fever
COMEXT	External Trade Database
CVO	Chief Veterinary Officer
DG SANTE	Directorate General for Health and Food Safety

EBL	Enzootic Bovine Leukosis
EC	European Commission
EEA	European Economic Area
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EHD	Epizootic Haemorrhagic Disease
EMA	European Medicines Agency
EU	European Union
EUROSTAT	Statistical Office of the European Communities
EUVET	EU Veterinary Emergency Team
FMD	Foot-and-mouth disease
FVE	Federation of Veterinarians of Europe
HPAI	Highly Pathogenic Avian Influenza
IA and DA	Implementing and Delegated Act
IBR	Infectious Bovine Rhinotracheitis
IHN	Infectious Haematopoietic Necrosis
IT	Information Technology

MS	Member State
NCA	National Competent Authority
NGO	Non-Governmental Organisation
OCR	Official Control Regulation
PPR	Peste des Petits Ruminants
SPGP	Sheep Pox and Goat Pox
SME	Small and Medium-sized Enterprise
SPS	Sanitary and Phytosanitary Measures
TRACES	Trade Control and Expert System
TSE	Transmissible Spongiform Encephalopathies
WAHIS	World Animal Health Information System
WOAH	World Organisation for Animal Health
WTO	World Trade Organisation

1. Introduction

Transmissible animal diseases do not respect national borders. While they primarily affect animal health, agricultural and aquaculture production, some also pose risks to human health and can generate significant economic and societal costs. For decades, the European Union has established harmonised rules to prevent and control such diseases. The first EU acts in the field date back to 1964, and the development of the Single Market in the 1990s further expanded and reinforced this regulatory framework.

Regulation (EU) 2016/429[1] on transmissible animal diseases, the *'Animal Health Law'* or *AHL*, adopted in 2016, fundamentally modernised this framework. It replaced 39 Directives and Regulations and established a single, coherent legal basis for EU animal health policy. Building on the EU Animal Health Strategy 2007–2013, *"Prevention is better than cure"*, the AHL preserves the EU internal market by ensuring high animal health status and safe movements of animals and their products across the EU. It protects human health by providing measures to prevent and control zoonotic diseases such as tuberculosis, brucellosis, rabies or avian influenza. The AHL introduced a more risk-based and preventive approach, strengthened disease preparedness and surveillance, clarified responsibilities of operators and authorities, while integrating the One Health perspective. It also sought to simplify legislative structure and enhance flexibility to respond to emerging and evolving threats.

The AHL lays down rules for the prevention and control of listed transmissible animal diseases, for the traceability and registration of animals and establishments, and for animal health requirements governing movements within the Union and entry into the Union of animals and their products. It is complemented by a comprehensive set of delegated and implementing acts that operationalise its core provisions. In accordance with Article 282 of the AHL, the Commission is required to evaluate the Regulation. This evaluation fulfils that legal obligation by assessing the extent to which the AHL has achieved its objectives since entering into force on 21 April 2016, with a particular focus on the application since 21 April 2021 until the completion of the evaluation report.

The evaluation assesses the five compulsory Better Regulation criteria: effectiveness, efficiency, relevance, coherence, and EU added value (see Annex III for the evaluation matrix). It assesses whether the Regulation has delivered a single EU animal health policy based on prevention and risk prioritisation, clarified roles and responsibilities, improved preparedness and response, facilitated safe trade, and contributed to simplification and proportionality. The findings of this evaluation are intended to inform future Commission action, including potential review, targeted adjustment or simplification of the AHL and its delegated acts.

1.1 Scope

The evaluation covers the interventions established by Regulation (EU) 2016/429 and together with the delegated acts referred to in Article 264. Between 2020 and 2024, 13 delegated acts were adopted to operationalise the Regulation, several of which were

[1] 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), http://data.europa.eu/eli/reg/2016/429/2016-03-31.

already amended during this period. Where certain implementing acts are essential for the functioning of the AHL framework, they are also considered, insofar as necessary, to ensure a comprehensive assessment of the overall legal architecture.

The evaluation examines how the AHL framework operates in practice regarding terrestrial and aquatic animals, across the following core areas:

- prioritisation and categorisation of animal diseases of Union concern;
- early detection, notification and reporting of diseases, surveillance, eradication programmes and disease–free status;
- disease awareness, preparedness and control;
- registration and approval of establishments and transporters, identification and registration of animals, and traceability of products thereof;
- movements of terrestrial and aquatic animals, germinal products and in certain cases of products of animal origin within the Union;
- entry into the Union of animals, germinal products, and products of animal origin and the export of such consignments from the Union;
- non–commercial movements of pet animals into a Member State from another Member State or from a third country or territory; and
- emergency measures to be taken in the event of a disease emergency situation.

The timeframe covered extends from the adoption of the AHL in 2016 to 2024, with particular focus on the period since its application on 21 April 2021. The geographical scope encompasses all EU Member States. Where relevant, reference is also made to European Economic Area (EEA) countries and EU candidate countries.

The evaluation was supported by an external study contracted by the European Commission (DG SANTE) and supervised by an Inter-Service Coordination Group (ISCG) chaired by DG SANTE, with participation from other relevant services. The ISCG ensured methodological robustness, coordination across services and consistency with Better Regulation standards.

The evaluation excludes matters governed by separate legal frameworks and therefore falling outside the scope of the AHL. These include, in particular, transmissible spongiform encephalopathies (TSE), zoonoses monitoring, zootechnics, animal welfare, veterinary medicinal products and residues, and feed and food safety in general. While these EU policy areas naturally shape the broader regulatory environment in which the AHL operates, these are not assessed in their own right. They are considered solely for the purpose of assessing coherence, and only insofar as their provisions interact directly with the implementation of animal health rules.

Further procedural details, including the composition of the ISCG, the evaluation timeline, and details regarding the external contract are presented in Annex I.

1.2 Methodology

The evaluation was conducted using a mixed-methods approach, combining qualitative and quantitative analysis. Given the complexity and breadth of the AHL framework, the

methodology was designed to assess both the legal architecture and its practical implementation across Member States[2]. The main analytical components included:

- desk research, including systematic review of the AHL and its delegated and relevant implementing acts, as well as analysis of the evolution of the legal framework since 2016;
- quantitative analysis of disease, surveillance and trade data, drawing on key EU information systems, in particular IMSOC including ADIS and TRACES NT, as well as scientific data from EFSA, COMEXT and Eurostat. This included trend analysis and cross-country comparisons where appropriate;
- targeted stakeholder consultations, including surveys, interviews and case studies, covering competent authorities, business operators, veterinarians, laboratories, professional associations, NGOs and academic experts across Member States;
- comparative analysis of national implementation, including control systems, enforcement practices, biosecurity requirements, preparedness, taking into account differences in epidemiological contexts across Member States and non-EU countries; and
- triangulation of findings, combining legal analysis, stakeholder evidence, scientific opinions, e.g. from EFSA, outbreak reports, audit findings, and relevant economic literature.

In addition, the evaluation considered lessons learned from recent disease events, which provided real-world tests of the functioning of surveillance systems, biosecurity obligations, emergency preparedness mechanisms, and operator responsibilities.

The evidence sources included EU databases and reports, surveillance and outbreak data, EFSA opinions, Commission audits, stakeholder input, and detailed external study .

Where data gaps existed, the evaluation relied on plausible stakeholder indications and assumptions, which were validated through the consultation processes wherever possible.

1.3 Limitations

The evaluation was conducted at a relatively early stage of the AHL's application. Although the Regulation entered into force in 2016, it has applied only since 21 April 2021. As a result, full alignment of national legislation and administrative systems remains ongoing in several Member States. The assessment therefore reflects an implementation phase that is still evolving.

Timing and data constraints: the limited duration of application restricts the observation of longer-term effects, particularly those related to structural prevention, behavioural change and resilience. The completeness and comparability of data across Member States vary and were in some cases affected by delays in the adoption or implementation of delegated and implementing acts. During the reference period, pre-existing national provisions often continued to operate alongside AHL requirements. This overlap makes it difficult to isolate impacts that can be attributed exclusively to the AHL.

Analytical constraints: the consolidation of the legal framework and the introduction of new governance and risk-based mechanisms required adaptation of national systems. As legacy national approaches remained in place during this transition, this limits the assessment of the full operational effects of the AHL in a stable regulatory environment.

[2] The key assumptions and methodological considerations are detailed in Annex II.

Scientific and analytical factors: the AHL's preventive and risk-based design is intended to generate effects that materialise over time, including improved preparedness, earlier detection and strengthened biosecurity practices. Such outcomes depend on complex epidemiological, behavioural and institutional dynamics. Several indicators are influenced by external drivers, including evolving disease patterns, global trade developments and geopolitical events. Quantitative data on administrative costs and benefits, particularly in relation to prevention and biosecurity, remain incomplete and in some cases rely on qualitative evidence.

Operational pressures: implementation during the reference period coincided with significant animal health events, including unprecedented outbreaks of highly pathogenic avian influenza (HPAI), African swine fever (ASF) and the expansion of bluetongue virus (BTV), as well as the COVID-19 pandemic. These events placed sustained pressure on national authorities and may have affected both implementation timelines and the availability of evidence. Stakeholders also highlighted the difficulty of distinguishing effects attributable to the AHL from broader transitional dynamics or independently evolving national legislation.

To mitigate these limitations, the evaluation triangulated evidence across multiple data sources and stakeholder groups, complemented gaps with case studies and validation workshops. Taken together, these limitations mean that the evaluation should be interpreted as an early-stage assessment of implementation progress and emerging trends, rather than as a definitive appraisal of long-term impacts. A more comprehensive assessment of structural effects, including cost-efficiency and resilience outcomes, will require additional time and more mature data following full stabilisation of implementation across Member States.

2. What was the expected outcome of the intervention?

2.1 Problem definition

Before the adoption of the AHL, the Union's animal health framework consisted of a large number of Directives, Decisions and, to a more limited extent, Regulations addressing specific diseases or thematic areas. These instruments had developed incrementally over several decades and differed in structure, terminology and level of detail. As a result, implementation across Member States was fragmented and uneven, leading to variations in preventive practices, surveillance systems and reporting arrangements.

The pre-existing framework was predominantly reactive, with a strong focus on post-outbreak response. Provisions on prevention, preparedness and biosecurity were limited or inconsistently harmonised. Contingency planning and early detection mechanisms varied between Member States, and there was no structured system for disease prioritisation, listing or categorisation at Union level.

Differences also existed in national responses to disease suspicion or confirmation, as well as in certain areas of animal identification, movement controls, registration of establishments and traceability. Surveillance methodologies were not always comparable, and administrative procedures could be duplicative or burdensome.

At the same time, increasing pressure from transboundary animal diseases, including ASF and HPAI, highlighted the substantial animal health, public health and economic impacts of large-scale outbreaks. Disease events demonstrated the need for more coherent preparedness, rapid response mechanisms and coordinated action across the Union.

From a trade perspective, rules governing intra-Union movements were dispersed across multiple legal acts and were often rigid and difficult to update. As many provisions were embedded in Directives adopted by the Council or co-legislated with the European Parliament, adapting them to evolving epidemiological realities or international standards was complex and time-consuming. Import requirements were likewise scattered and not always transparent, in some cases being specified primarily through certification statements rather than consolidated legal provisions describing health requirements.

Taken together, the multiplicity of disease-specific instruments and the absence of a consolidated legal framework resulted in a lack of a clearly defined, single EU animal health policy based on common principles and prioritisation.

2.2 Objectives

Against this background, Regulation (EU) 2016/429 established a single, risk-based regulatory framework governing the prevention and control of animal diseases transmissible to animals and, where relevant, to humans. It constitutes the core legislative instrument implementing the EU Animal Health Strategy 2007–2013 ("Prevention is better than cure"), reflecting a policy shift towards a more preventive, science-based and coherent Union framework. Its general intervention logic is illustrated in Figure 1 below.

The general objective of the AHL is to ensure a high level of animal health within the Union, thereby supporting sustainable agricultural and aquaculture production, contributing to public health protection and food security, and safeguarding the proper functioning of the internal market.

To achieve this general objective, the AHL pursues the following specific objectives:

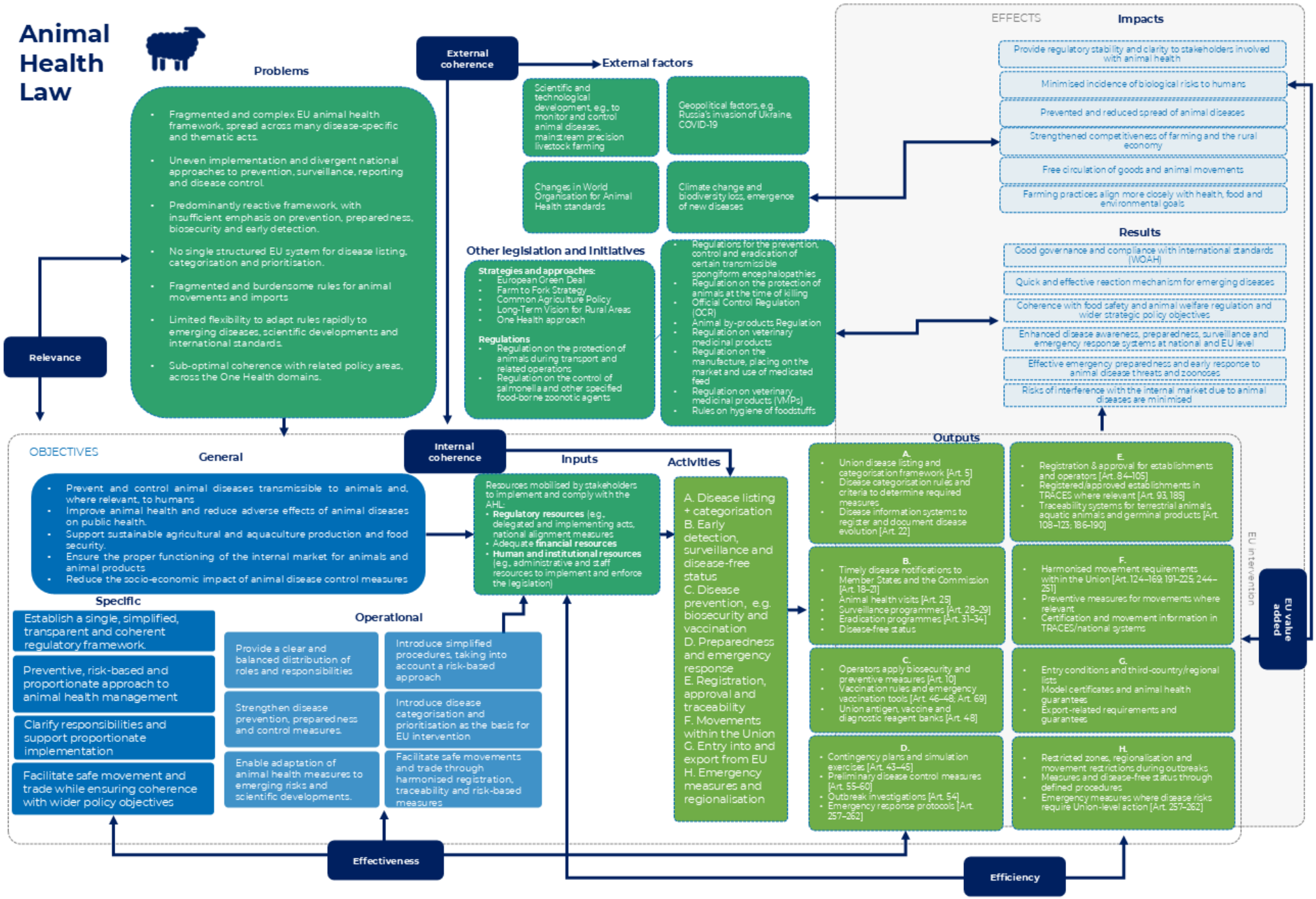
- establish a single, simplified, transparent and coherent regulatory framework, replacing the previously fragmented disease-specific legislation;
- introduce a structured system for disease listing, prioritisation and categorisation to enable proportionate, risk-based measures;
- strengthen prevention and preparedness through reinforced biosecurity obligations,
- surveillance systems and vaccination frameworks;
- clarify and rebalance the roles and responsibilities of operators, veterinarians and competent authorities;
- ensure that disease-control measures are proportionate, science-based and aligned with relevant international standards;
- improve flexibility and adaptability of the framework to emerging risks and evolving epidemiological situations;
- enhance coherence with related Union policies, including animal welfare, food safety and public health; and
- reduce the socio-economic impact of animal diseases and minimise unjustified or disproportionate disruptions to intra-Union and international trade.

The Regulation lays down harmonised rules covering

- prevention, early detection, notification, surveillance, control and eradication of listed diseases;
- registration and approval of establishments and transporters;
- identification and traceability of animals and germinal products;
- movement requirements within the Union;
- entry into and export from the Union;
- non-commercial movements of pet animals; and
- emergency measures in case of serious disease situations.

In pursuing these objectives, the AHL adopts an integrated approach consistent with the One Health perspective, recognising the interlinkages between animal health, public health, food and feed safety, antimicrobial resistance, animal welfare, biodiversity and climate-related risks.

Figure 1: AHL General intervention logic


Animal Health Law
Problems
Fragmented and complex EU animal health framework, spread across many disease-specific and thematic acts.
Uneven implementation and divergent national approaches to prevention, surveillance, reporting and disease control.
Predominantly reactive framework, with insufficient emphasis on prevention, preparedness, biosecurity and early detection.
No single structured EU system for disease listing, categorization and prioritisation.
Fragmented and burdensome rules for animal movements and imports
Limited flexibility to adapt rules rapidly to emerging diseases, scientific developments and international standards.
Sub-optimal coherence with related policy areas, across the One Health domains.
Relevance
External coherence
External factors
Scientific and technological development, e.g., to monitor and control animal diseases, mainstream precision livestock farming
Geopolitical factors, e.g. Russia's invasion of Ukraine, COVID-19
Changes in World Organisation for Animal Health standards
Climate change and biodiversity loss, emergence of new diseases
Other legislation and initiatives
Strategies and approaches:
European Green Deal
Farm to Fork Strategy
Common Agriculture Policy
Long-Term Vision for Rural Areas
One Health approach
Regulations
Regulation on the protection of animals during transport and related operations
Regulation on the control of salmonella and other specified food-borne zoonotic agents
Regulations for the prevention, control and eradication of certain transmissible spongiform encephalopathies
Regulation on the protection of animals at the time of killing
Official Control Regulation (OCR)
Animal by-products Regulation
Regulation on veterinary medicinal products
Regulation on the manufacture, placing on the market and use of medicated feed
Regulation on veterinary medicinal products (VMPs)
Rules on hygiene of foodstuffs
EFFECTS
Impacts
Provide regulatory stability and clarity to stakeholders involved with animal health
Minimised incidence of biological risks to humans
Prevented and reduced spread of animal diseases
Strengthened competitiveness of farming and the rural economy
Free circulation of goods and animal movements
Farming practices align more closely with health, food and environmental goals
Results
Good governance and compliance with international standards (WOAH)
Quick and effective reaction mechanism for emerging diseases
Coherence with food safety and animal welfare regulation and wider strategic policy objectives
Enhanced disease awareness, preparedness, surveillance and emergency response systems at national and EU level
Effective emergency preparedness and early response to animal disease threats and zoonoses
Risks of interference with the internal market due to animal diseases are minimised
OBJECTIVES
General
Prevent and control animal diseases transmissible to animals and, where relevant, to humans
Improve animal health and reduce adverse effects of animal diseases on public health.
Support sustainable agricultural and aquaculture production and food security.
Ensure the proper functioning of the internal market for animals and animal products
Reduce the socio-economic impact of animal disease control measures
Specific
Establish a single, simplified, transparent and coherent regulatory framework.
Preventive, risk-based and proportionate approach to animal health management
Clarify responsibilities and support proportionate implementation
Facilitate safe movement and trade while ensuring coherence with wider policy objectives
Operational
Provide a clear and balanced distribution of roles and responsibilities
Introduce simplified procedures, taking into account a risk-based approach
Strengthen disease prevention, preparedness and control measures.
Introduce disease categorisation and prioritisation as the basis for EU intervention
Enable adaptation of animal health measures to emerging risks and scientific developments.
Facilitate safe movements and trade through harmonised registration, traceability and risk-based measures
Internal coherence
Inputs
Resources mobilised by stakeholders to implement and comply with the AHL:
Regulatory resources (e.g., delegated and implementing acts, national alignment measures
Adequate financial resources
Human and institutional resources (e.g., administrative and staff resources to implement and enforce the legislation)
Activities
A. Disease listing + categorisation
B. Early detection, surveillance and disease-free status
C. Disease prevention, e.g. biosecurity and vaccination
D. Preparedness and emergency response
E. Registration, approval and traceability
F. Movements within the Union
G. Entry into and export from EU
H. Emergency measures and regionalisation
Outputs
A.
Union disease listing and categorisation framework [Art. 5]
Disease categorisation rules and criteria to determine required measures
Disease information systems to register and document disease evolution [Art. 22]
B.
Timely disease notifications to Member States and the Commission [Art. 18–21]
Animal health visits [Art. 25]
Surveillance programmes [Art. 28–29]
Eradication programmes [Art. 31–34]
Disease-free status
C.
Operators apply biosecurity and preventive measures [Art. 10]
Vaccination rules and emergency vaccination tools [Art. 46–48; Art. 69]
Union antigen, vaccine and diagnostic reagent banks [Art. 48]
D.
Contingency plans and simulation exercises [Art. 43–45]
Preliminary disease control measures [Art. 55–60]
Outbreak investigations [Art. 54]
Emergency response protocols [Art. 257–262]
E.
Registration & approval for establishments and operators [Art. 84–105]
Registered/approved establishments in TRACES where relevant [Art. 93, 185]
Traceability systems for terrestrial animals, aquatic animals and germinal products [Art. 108–123; 186–190]
F.
Harmonised movement requirements within the Union [Art. 124–169; 191–225; 244–251]
Preventive measures for movements where relevant
Certification and movement information in TRACES/national systems
G.
Entry conditions and third-country/regional lists
Model certificates and animal health guarantees
Export-related requirements and guarantees
H.
Restricted zones, regionalisation and movement restrictions during outbreaks
Measures and disease-free status through defined procedures
Emergency measures where disease risks require Union-level action [Art. 257–262]
EU intervention
EU value added
Effectiveness
Efficiency

2.3 AHL in practice

Scope and overall architecture

The AHL establishes a comprehensive and harmonised legal framework for the prevention and control of animal diseases transmissible to animals and, where relevant, to humans. Its scope covers terrestrial and aquatic animals, wildlife where epidemiologically relevant, germinal products and other products of animal origin, as well as operators, establishments, and movements within the Union and entry from third countries.

The Regulation applies across all Member States and, where relevant, EEA countries. It integrates prevention, preparedness, surveillance, control, trade and traceability requirements within a single regulatory structure, replacing a fragmented body of disease-specific legislation that had developed incrementally over several decades. The intervention logic of the AHL is structured around a dual-layer architecture:

The first layer consists of horizontal, general animal health rules that apply irrespective of the disease situation. These include clearly defined responsibilities for operators and competent authorities, biosecurity obligations, requirements for registration and approval of establishments, and systems for identification and traceability. This baseline layer is designed to ensure continuous prevention and a minimum level of preparedness across the Union.

The second layer consists of disease prevention and control measures triggered through a structured system of listing and categorisation of animal diseases. Diseases of Union concern are assessed according to harmonised criteria and assigned to categories reflecting the level of intervention required. This enables proportionate, risk-based application of surveillance, eradication and control measures.

Together, these two layers create a framework in which general prevention applies at all times, while additional measures are activated according to epidemiological risk. The architecture is intended to ensure coherence, proportionality and predictability in the Union's approach to preventing, detecting and controlling transmissible animal diseases.

2.3.1 Structured disease listing and categorisation

A central innovation of the AHL is the establishment of a harmonised system for listing and categorising animal diseases of Union concern. Under the previous legislative framework, triggers for Union intervention were dispersed across multiple instruments and lacked a unified structure, which limited transparency and consistency.

The AHL introduces a single framework for identifying diseases requiring Union action and assigning them to categories reflecting the level of intervention considered necessary. Categorisation is determined by the nature and intensity of measures to be applied, including surveillance obligations, disease control measures, eradication programmes and disease-free status requirements. The listing and categorisation process is based on harmonised risk criteria and informed by scientific assessment, with periodic review to ensure alignment with evolving epidemiological and scientific developments.

Within this system, the Commission adopts and updates the lists and the associated rules, while primary Member States implement the measures corresponding to each disease category and report their disease status. By linking intervention levels directly to risk assessment and predefined criteria, the framework is intended to ensure robustness, proportionality, adaptability, improve prioritisation of resources and enhance predictability in Union action.

The expected outcomes of this pillar are clearer prioritisation of diseases requiring Union intervention, more targeted and risk-based prevention and control measures and increased legal certainty for competent authorities and operators regarding the obligations triggered by each disease category.

2.3.2 Early detection, surveillance and disease-free status

The AHL establishes a harmonised framework for early detection, notification and reporting of listed diseases, supported by structured surveillance systems, eradication programmes and rules governing the granting and maintenance of disease-free status.

Member States are responsible for designing and implementing surveillance systems in accordance with harmonised requirements, while operators are subject to defined obligations to notify suspected cases without undue delay and ensure own surveillance in their establishments. The framework clarifies the respective roles of operators, official veterinarians and competent authorities in sampling, diagnosis and reporting. National and Union reference laboratories contribute to methodological consistency and quality assurance, while the Commission supports coordination and comparability at Union level.

Surveillance requirements include case definitions, minimum sampling standards, notification deadlines and information-sharing obligations. Where epidemiologically relevant, surveillance may extend to wildlife. This architecture is intended to improve comparability of surveillance outputs across Member States and strengthen the reliability of disease reporting.

The expected outcomes of this pillar are earlier detection and confirmation of suspect cases, more timely and consistent notifications, enhanced transparency of disease status and more robust foundations for eradication programmes and the recognition or recovery of disease-free status.

2.3.3 Strengthening prevention through biosecurity and vaccination

A core objective of the AHL is to shift the Union's animal health framework towards a stronger preventive orientation. Prevention is supported through reinforced biosecurity obligations, structured surveillance, mandatory animal health visits and a revised approach for vaccination.

Operators are required to apply general and activity-specific biosecurity measures appropriate to the risks associated with their activities. Mandatory animal health visits are intended to support early detection and promote continuous improvement of biosecurity practices at establishment level. Competent authorities are responsible for oversight and enforcement, ensuring that preventive obligations are applied consistently across the

Union. This clearer allocation of responsibilities is designed to embed prevention as a shared and continuous obligation rather than a reactive response to outbreaks.

The AHL also introduces a revised approach to vaccination. It provides a broader and more flexible legal framework allowing vaccination to be used not only as an emergency control tool but also, where appropriate, as a preventive measure. The framework sets conditions for vaccination strategies and enables the establishment of Union antigen and vaccine banks to support coordinated responses where necessary.

The expected outcomes of this pillar are strengthened biosecurity practices at establishment level, enhanced preparedness through systematic preventive measures, and greater flexibility for Member States to deploy vaccination strategies in a risk-based and proportionate manner.

2.3.4 Disease preparedness and emergency response

The AHL reinforces the Union's framework for disease awareness, preparedness and outbreak response by establishing common principles and minimum requirements applicable across Member States. It emphasises preparedness as a continuous obligation, requiring systems and procedures to be in place before the occurrence of disease events.

Member States are required to take disease control measures in accordance with the harmonised rules setting out how outbreaks are to be managed, while disease categorisation determines the applicable level of intervention. Control measures, such as stamping-out, cleaning and disinfection, and, where appropriate, vaccination, are applied in accordance with predefined conditions. These are accompanied by post-outbreak surveillance and structured procedures for lifting restrictions and recovering disease-free status. The framework enables competent authorities to delineate restricted and infected zones on the basis of harmonised principles and epidemiological assessment.

To that end Member States are also required to establish, maintain and periodically test contingency plans for certain listed diseases, including through simulation exercises. Operators and veterinarians have defined roles in disease awareness, early detection and initial response. The Commission supports coordination at Union level, drawing on scientific advice to ensure that control measures are risk-based and proportionate.

By linking categorisation to predefined disease control measures and response tools including establishing clear conditions for setting up and lifting restrictions and recovering disease-free status, the framework is designed to enhance legal clarity and predictability during crisis situations.

The expected outcomes of this pillar are better overall preparedness of Member States, more predictable disease control rules with enhanced capacity to contain disease spread during outbreaks, enabling faster and more coordinated responses to disease events, more consistent application of control measures across Member States, and mitigation of adverse impacts on animal health, public health and trade, while avoiding disproportionate disruption.

2.3.5 Registration, approval and traceability

The AHL establishes a structured framework for the registration and approval of operators and establishments, as well as for the identification and traceability of animals, germinal products and products of animal origin. These elements form a foundational component of disease prevention and control by enabling competent authorities to trace movements and apply measures effectively.

Activities falling within the scope of the Regulation are subject to registration or approval, accompanied by defined record-keeping obligations. Competent authorities are responsible for maintaining registers, taking decisions on approval, and, where necessary, suspending or withdrawing authorisations in accordance with criteria laid down in delegated and implementing acts. The framework applies to establishments and operators whose activities present epidemiological relevance.

Identification systems and movement documentation requirements are aligned with risk-based official controls, ensuring that traceability obligations correspond to the level of risk associated with different activities. The framework also provides for proportionate arrangements and defined derogations in low-risk situations.

The expected outcomes of this pillar are improved transparency regarding operators and establishments, strengthened traceability across the supply chain, enhanced capacity to manage disease risks linked to movements, and increased mutual confidence between Member States in the consistent application of animal health requirements within the internal market.

2.3.6 Movements within the Union

The AHL establishes harmonised animal health requirements for movements of animals, germinal products and products of animal origin within the Union. These requirements are based on identification and record-keeping rules, defined movement conditions for listed disease and specific animal species and categories as well as proportionate arrangements for low-risk situations. These movement requirements are aligned with the relevant international standards of the World Organisation for Animal Health (WOAH).

Transport operators are subject to defined cleaning and disinfection obligations to reduce the risk of disease spread during movement. In the event of outbreaks, the framework provides for temporary restrictions, zoning and channelling measures designed to manage movements in accordance with the epidemiological situation.

Harmonised attestations and certification requirements support traceability and enable competent authorities to verify compliance. The expected outcomes of this pillar are safe, predictable and proportionate movement rules across the Union, safeguarding animal health across in the Union and ensuring smooth operation of the internal market through the consistent application of animal health requirements.

2.3.7 Entry into and export from the Union

The AHL establishes a harmonised framework governing the entry into the Union of animals, germinal products and products of animal origin, as well as the export of such consignments. The objective is to ensure that imported consignments meet animal health requirements equivalent to those applicable to movements within the Union, thereby maintaining a consistent level of protection.

Under this framework, the Commission defines entry conditions, establishes and updates lists of authorised third countries or regions, recognises regionalisation where appropriate, and adopts model health certificates. The system provides structured and transparent requirements across different commodities, reflecting harmonised animal health guarantees.

The framework operates in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and is aligned with relevant international standards, including those of the WOAH. It allows, where appropriate, for the recognition of equivalence and regionalisation, supporting risk-based trade management.

The expected outcomes of this pillar are credible and transparent management of external disease risks, strengthened confidence in the Union's animal health guarantees, and stable and predictable trade conditions based on clear and consistent requirements.

2.3.8 Non-commercial movements of pet animals

The AHL establishes a harmonised framework governing the non-commercial movements of pet animals between Member States and from third countries or territories. These provisions complement the general movement rules applicable to animals, while addressing the specific context of animals accompanying their owners.

The framework sets conditions relating to identification, health requirements and accompanying documentation, with the objective of ensuring a high level of protection for animal and public health while facilitating legitimate movements. Competent authorities are responsible for verifying compliance with these requirements, and the Commission adopts implementing measures to support uniform application across Member States.

The provisions governing non-commercial movements of pet animals apply from April 2026. As these rules were not yet applicable within the evaluation period, their implementation and effects cannot be assessed at this stage and are outside the scope of this evaluation.

2.3.9 Emergency measures and regionalisation

Emergency measures applicable for certain diseases, including the structured use of regionalisation in the event of a disease outbreak are amongst crucial elements of the AHL. Regionalisation allows control measures to be geographically targeted, focusing

restrictions on affected areas while permitting movements from unaffected zones subject to defined conditions. This risk-based differentiation is designed to support effective disease containment while maintaining continuity of trade within the Union and with third countries.

Emergency response under the AHL is based on harmonised Union rules complemented by Member States' contingency plans, which define command structures, resources and communication arrangements.

The expected outcomes of this pillar are coherent and coordinated outbreak management across Member States, limitation of disease spread through geographically targeted measures, and a transparent and predictable pathway for restoring regular movement and trade conditions.

2.4 Interfaces with overlapping policy domains

Before the adoption of the AHL, animal health rules were dispersed across multiple disease- and sector-specific instruments, with varying degrees of interaction with food safety, zoonoses, official controls and other SPS legislation. These links existed but were not embedded in a unified risk-based structure.

The AHL establishes a single framework for animal disease prevention and control while operating alongside specialised Union legislation addressing specific sectors or risks. It does not replace these instruments but is designed to function in coordination with them, ensuring consistency while respecting distinct legal mandates.

Interaction within the food chain framework

The AHL is closely linked to the Official Controls Regulation (OCR, Regulation (EU) 2017/625[3]) which provides the horizontal framework for verification and enforcement across the food chain. While the AHL sets animal health obligations and control measures, the OCR governs how compliance is verified, including laboratory systems, delegation of tasks and cooperation between competent authorities. This institutional alignment is intended to support uniform implementation across Member States.

The AHL also operates alongside the General Food Law[4] and related food safety legislation. By addressing disease risks at animal and farm level, the AHL functions upstream of food safety law, reducing risks before they enter the food chain. Food and feed hygiene legislation establishes baseline hygiene obligations for primary production. The AHL complements these provisions by addressing biosecurity specifically from an animal health perspective, linking preventive measures directly to disease control objectives.

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3 Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, http://data.europa.eu/eli/reg/2017/625/oj.

4 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, http://data.europa.eu/eli/reg/2002/178/2026-01-01.

Veterinary medicinal products and residues

The AHL interacts with legislation governing veterinary medicinal products and residues where vaccines or treatments form part of disease prevention and control strategies. The authorisation, use and monitoring of veterinary medicines remain governed by dedicated legislation, while the AHL defines the disease control context in which such tools, particularly vaccination, may be deployed.

Environmental and wildlife legislation

The AHL applies to wildlife only where epidemiologically relevant for the prevention and control of listed diseases. Measures may include surveillance, notification and targeted control actions where necessary to protect animal or public health. Broader issues relating to wildlife conservation, habitat protection or population management remain governed by environmental legislation. The interaction is therefore operational rather than regulatory in scope.

Public health

The AHL interacts with Union public health legislation within a One Health approach. This includes links with Regulation (EU) 2022/2371[5] on serious cross-border threats to health, supporting coordinated risk assessment, information exchange and response, while respecting the different roles of each legal framework.

Surveillance and data exchange mechanisms are designed to facilitate coordination between animal health and public health authorities. This also includes surveillance in animals designed in a manner that it can inform public health authorities to take actions on the human health side, where necessary. This role supports coordinated risk assessment, information exchange and response between animal health and public health authorities, strengthening overall preparedness and crisis management while respecting the different roles of each legal framework.

Financial and crisis instruments

The AHL establishes obligations relating to surveillance, control and emergency measures but does not itself regulate Union financial instruments. Implementation of disease prevention and control measures may be supported through Union co-financing mechanisms and crisis instruments, which operate under separate legal bases.

Animal breeding rules

Animal breeding legislation governs breeding standards and trade in breeding animals, while operating in parallel with animal health requirements under the AHL.

Disease areas regulated outside the AHL

Certain disease areas remain governed by specific legislation due to their distinct risk profiles. Rules on transmissible spongiform encephalopathies (TSEs) and animal by-products (ABPs) are laid down in dedicated instruments, with the AHL applying only where disease-control measures generate operational links, e.g. culling, disposal or

5 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2371.

movement restrictions. Similarly, zoonoses legislation governs rules, operating in parallel with animal health requirements under the AHL.

Overall, the AHL is designed to integrate animal health policy within the broader Union regulatory framework, ensuring coordination with related domains while maintaining clear legal boundaries and avoiding duplication of regulatory objectives.

Animal welfare rules

The AHL does not contain provisions which regulate animal welfare. Animal welfare is regulated in a separate set of legislation. That legislation operates alongside and independently of the animal health rules.

However, the AHL recognises that animal health and welfare are linked: better animal health promotes better animal welfare, and vice versa. When disease prevention and control measures are carried out in accordance with the AHL their effect on animal welfare should be considered in order to spare the animals concerned any avoidable pain, distress or suffering. But the rules laid down in the AHL should not duplicate, or overlap with, the rules laid down in that animal welfare legislation[6].

2.5 Point(s) of comparison

Legal framework before 2016

Prior to the adoption of the AHL, the Union's animal health framework consisted of a large number of disease-specific or species-specific directives, decisions and a limited number of regulations adopted incrementally over several decades. These instruments varied in structure, terminology and level of detail. Their transposition into national law led to differences in implementation and interpretation across Member States, resulting in a fragmented regulatory landscape.

Surveillance and notification practices were not governed by a unified framework. Case definitions, sampling strategies and reporting requirements were in some instances absent from Union legislation or applied differently at national level. Notification timelines and laboratory quality standards were not fully harmonised, limiting comparability of surveillance outputs.

Rules concerning identification, traceability and movements were partially harmonised but differed across species and sectors. Documentation requirements varied, and movement conditions were often embedded in rigid legislative provisions. Registration and approval procedures for operators and establishments were governed by differing national approaches, including variations in thresholds for registration, approval criteria and publication of registers.

Preparedness and response arrangements also displayed heterogeneity. Contingency planning, simulation exercises, zoning and regionalisation practices were not embedded within a single structured framework. Preventive tools such as biosecurity and vaccination were addressed in a more limited or fragmented manner. The need for a more

6 EU animal welfare legislation - Food Safety - European Commission.

integrated and preventive approach had been identified in earlier policy reflections, including the Animal Health Strategy 2007–2013.

Overall, the pre-2016 framework provided substantive disease control tools but lacked a unified architecture linking prevention, surveillance, preparedness, trade and governance mechanisms within a coherent, risk-based system.

Epidemiological situation prior to 2016

Prior to the adoption of the AHL in 2016, the epidemiological situation in the Union was characterised by the continued management of long-standing transboundary diseases alongside the emergence and geographical expansion of new threats. The period reflected both the legacy of earlier major crises and evolving epidemiological dynamics influenced by wildlife reservoirs, vector distribution and cross-border transmission.

Earlier large-scale crises had largely been stabilised. Bovine spongiform encephalopathy (BSE), which peaked in the United Kingdom in 1996–1997, had been progressively brought under control through stringent Union measures adopted from 2001 onwards, resulting in a substantial decline in cases and the achievement of negligible risk status in most Member States. The foot and mouth disease (FMD) epidemic in the United Kingdom in 2001 was subsequently eradicated, demonstrating the importance of strict surveillance and rapid containment. Meanwhile, Classical swine fever (CSF) had also disappeared from domestic pig populations, following coordinated eradication efforts in many EU Member States.

From the mid-2000s onwards, new epidemiological patterns emerged. Vector-borne diseases also expanded geographically during this period. Bluetongue virus (BTV) - BTV 8 was first detected in the Netherlands during the 2006–2008 epidemic and spread rapidly across Europe. Rabies in parallel significantly pushed out of the EU mainly by intense oral vaccination campaigns of wildlife.

More recently, new incursions and spread of transboundary diseases occurred. ASF entered the Union in 2014, with confirmed cases in wild boar and domestic pigs in Lithuania, Latvia, Estonia and Poland. In subsequent years, the disease extended to additional Member States, including the Czech Republic and Romania in 2017, Hungary, Belgium and Bulgaria in 2018, and Slovakia in 2019. The epidemiology of ASF during this period was characterised by significant involvement of wild boar populations and repeated risk of re-introduction from neighbouring third countries. LSD emerged in south-eastern Europe in 2015–2016, marking its introduction into the Union and highlighting the role of vector transmission and cross-border spread.

HPAI occurred in recurrent epidemic waves, typically associated with migratory wild birds and seasonal patterns. While outbreaks required substantial control efforts, circulation patterns were largely linked to seasonal dynamics and wildlife interfaces.

These developments illustrated the increasing relevance of wildlife reservoirs, vector ecology and cross-border epidemiological drivers. Overall, the epidemiological context prior to 2016 combined successful containment of certain historic crises with the re-emergence and geographical expansion of other transboundary and vector-borne diseases, forming part of the policy environment in which the AHL was adopted.

3.How has the situation evolved?

The AHL establishes the Union's framework for the prevention and control of transmissible animal diseases. It applies across the food chain and governs how animal health risks are prevented, detected and managed within the Union.

By setting common rules and responsibilities, the AHL supports the functioning of the internal market for live animals and germinal products and provides a basis for coordinated action in both routine and crisis situations.

Between the adoption of the AHL in 2016, its entry into force, and its application from 21 April 2021, the Commission developed the secondary legislative framework necessary to operationalise the Regulation.

Prior to the date of application, the Commission adopted 11 delegated acts supplementing non-essential elements of the AHL and 17 implementing acts laying down technical and procedural rules required for its uniform application. In 2023 and 2024, two additional delegated acts were adopted concerning vaccination frameworks and poultry compartments. Taken together, these acts establish detailed provisions on disease listing and categorisation, notification and reporting obligations, surveillance requirements, movement conditions, registration and approval procedures, and the use of disease preventive and control tools.

Minimum and time-bound notification and disease reporting obligations were defined, together with harmonised surveillance requirements. The framework specifies preventive tools, including biosecurity obligations applicable to operators and competent authorities, and sets out the legal conditions under which vaccination may be used for prevention and control purposes. It also provides for Union antigen and vaccine banks for certain category A diseases such as FMD, CSF, LSD, SPGP, PPR.

In the area of movements, identification and traceability, species-specific registration, identification and record-keeping requirements were laid down in delegated acts. Harmonised movement conditions were established, including calibrated derogations and channelling arrangements linked to disease categories, zoning decisions and defined low-risk situations.

Operators and establishments are required to register or obtain approval in accordance with common criteria and procedures, including rules governing suspension and withdrawal. Member States are obliged to maintain and make available transparent registers.

Preparedness and response mechanisms were defined through harmonised principles of disease control including stamping-out and other control measures, vaccination strategies, post-outbreak surveillance and contingency planning. Compared to the previous framework, the requirement for prior Commission approval of each national contingency plan was removed.

The AHL framework also establishes structured rules for regionalisation during outbreaks. For entry into the Union from third countries, harmonised requirements were laid down in substantive legislation, including third-country listing, defined animal health

guarantees and model certificates, operating within the framework of the WTO SPS Agreement and aligned with relevant international standards.

This legislative and implementing framework constitutes the operational baseline against which the effectiveness, efficiency and coherence of the AHL are assessed in the subsequent chapter.

3.1 Sectoral background

The AHL operates within a sector of considerable economic scale. In 2025, the European Union had a significant livestock population: 132 million pigs, 72 million bovine animals, 54 million sheep and 10 million goats, and around 1.7 billion poultry birds ([7]).

There are approximately 4.1. million farms with livestock in the EU, representing 41% of all EU farms (2020 data) ([8]). In details, 21.6% of farms with livestock are classified as livestock specialists while 19.3% as mixed farming thus combining crops and livestock activity.

The majority of farms are small, with 41% having less than 2 hectares and around 60% having fewer than 5 livestock units (LSU). It must be noted that a majority of the farms below 5 LSU are in mixed farming systems and notably in two Member States: Romania and Poland ([9]).

EU aquaculture production amounted to approximately 1.1 million tonnes (live weight) in 2023, including finfish, molluscs and crustaceans, with a production value of around €4.8 billion.

In addition, other animal populations, such as horses, farmed deer, rabbits and bees, also contribute to the agricultural economy and these sectors should be considered to provide a more complete picture of animal production. Out of 2 020 breeders surveyed11 in 2015 from 12 Member States representing around 85% of the EU population of dogs and cats, 87% self-reported they were hobby breeders, and only 13% self-reported they were professional breeders. However, categories, definitions and thresholds of breeders differ depending on national legislation

The pet sector represents a further area of economic activity and social relevance, although harmonised EU-level statistics remain limited. The EU pet market for dogs and cats is supplied by a large but fragmented breeder population. In 2015, a survey of 2,020 breeders across Member States covering around 85% of the EU pet population found that 87% (≈1,750) were hobby breeders and 13% (≈260) professionals. One estimate suggests around 32,000 professional breeders in the EU[10].

Animals used for scientific purposes account for comparatively smaller numbers. Fur farming persists in a limited number of Member States and has declined over time, while

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7 Eurostat: Livestock populations (apro_mt_lscatl, apro_mt_lsgoat, apro_mt_lssheep, apro_mt_lspig, agr_r_animal). Farm structure (ef_lsk_poultry).

8 Eurostat: Farm structure (ef_m_farmleg).

9 Farm Sustainability Data Network (FSDN).

10 COMMISSION STAFF WORKING DOCUMENT Summarising evidence supporting the legislative proposal on the welfare of dogs and cats and their traceability https://food.ec.europa.eu/document/download/caf8cd1d-967a-4e60-a0e5-19401be1c6b3_en.

remaining of economic relevance in certain regions. Comprehensive Union-wide data are not available for animals kept in sports, entertainment or non-commercial contexts.

Taken together, these figures illustrate the scale, diversity and economic relevance of sectors covered by the AHL. They also demonstrate the potential exposure of significant production systems, trade flows and rural livelihoods to animal disease risks.

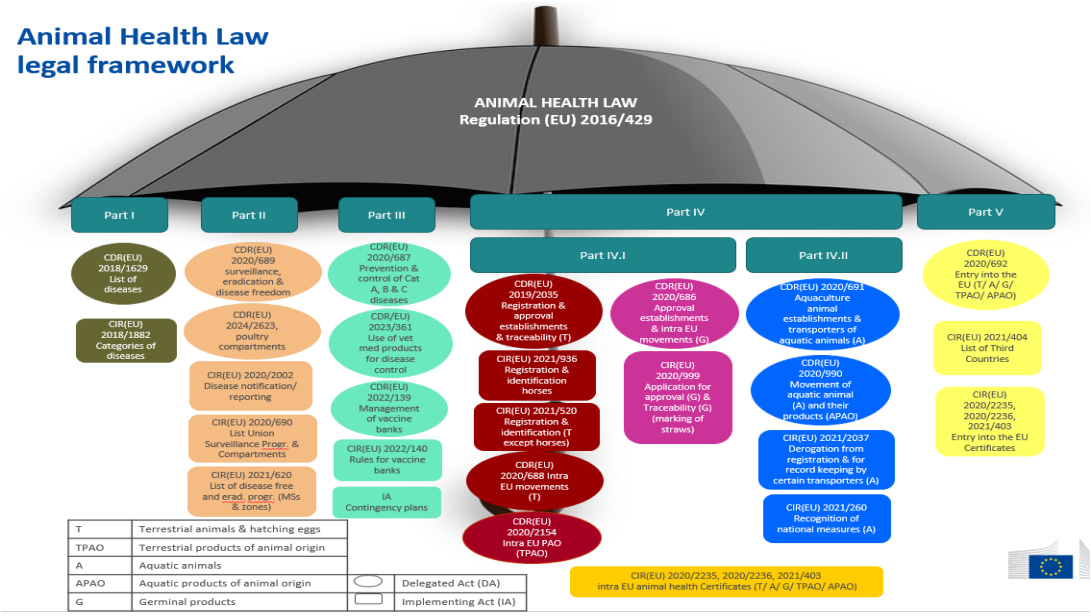
3.2 Legal evolution and transitional phase (2016–2021)

Between the adoption of the AHL in 2016 and its application from 21 April 2021, the Commission undertook the legislative work necessary to render the Regulation fully operational. This process involved repealing and replacing 39 separate legal and consolidating previously fragmented provisions into a single coherent legal framework supported by supported by delegated and implementing legislation.

To operationalise the AHL, the Commission prepared and adopted a series of delegated and implementing acts establishing directly applicable rules on all key elements and parts covered by the scope of the AHL.

In 2020 the Commission's reported on the exercise of its delegated powers[11] confirmed that substantial legislative development took place between 2018 and 2020, culminating in the adoption of delegated regulations forming the core of the secondary legal framework (see for more details in Annex VI). By the date of application, the Commission had adopted 10 delegated acts supplementing non-essential elements of the AHL and 13 implementing acts laying down detailed technical provisions (see Figure 2). These acts established the operational framework required for uniform application across Member States. A complete update list of all delegated and implementing acts is available at the Commission's animal Health Law website[12]

Figure 2: Key delegated and implementing acts accompanying the Animal Health Law



11 EUR-Lex - 52021DC0057 - EN - EUR-Lex.

12 Delegated and implementing acts - Food Safety - European Commission.

The tertiary legislation gave effect to the structured disease listing and categorisation system (categories A–E), establishing a single Union list of diseases subject to Union action and specifying the associated surveillance and control measures. It further specified preventive obligations, including biosecurity requirements, surveillance responsibilities, animal health visits and conditions for the use of vaccination. Union antigen and vaccine banks were established under the legal framework to support emergency preparedness.

The AHL and its implementing acts established reinforced notification and reporting obligations and provided the legal basis for the ADIS, the Union's computerised system for disease notification and reporting. Surveillance requirements, including Union surveillance programmes where relevant, were defined in secondary legislation.

Common principles for disease control measures, vaccination strategies and post-outbreak surveillance were laid down. Derogations for defined low-risk movements and provisions for zoning and channelling during outbreaks were specified in secondary legislation. Additional requirements were laid down for specific establishments and for transport operators.

Animal health requirements for entry into the Union were consolidated and harmonised in delegated and implementing acts, including third-country listing, model certification requirements and procedures for managing non-compliance. These rules replaced previously dispersed provisions laid down in multiple legal acts and certificates.

These legislative and supporting measures constitute the implementation framework against which the effectiveness, efficiency, coherence and EU added value of the AHL are assessed in the subsequent sections.

3.3 Implementation by the European Commission (2021 - 2024)

Between 2021 and 2024, the Commission operationalised the AHL through continued regulatory updates, coordination of outbreak response, technical support to Member States and the further development of information systems.

During this period, the Commission adopted additional delegated and implementing acts where necessary to clarify provisions, address practical implementation issues identified by Member States or stakeholders, and respond to evolving epidemiological developments. In particular, many amendments to implementing acts were triggered by outbreaks of HPAI (113 amendments), ASF (88), SPGP (63), PPR (35), l LSD (25) and Newcastle disease (ND) (11). These amendments primarily established emergency measures, particularly regionalisation, which allows disease control measures to be limited to affected areas while permitting certain activities and movements to continue in affected zones under defined conditions. The Commission also regularly updated import requirements and disease-related restrictions, in particular through amendments to Commission Implementing Regulation (EU) 2021/404, which lays down the lists of third countries or zones authorised for entry into the Union of animals and certain products of animal origin. Between 2021 and 2024, 139 implementing regulations amending Regulation (EU) 2021/404 were adopted, reflecting changes in the global animal health situation and the application of regionalisation principles.

In parallel, guidance documents, explanatory material and sector-specific communication tools were issued to support uniform understanding and application of the framework. Clarifications on surveillance obligations, movement rules, vaccination conditions and preparedness requirements were discussed in expert meetings, bilateral exchanges and in the PAFF Committee (Animal Health and Welfare and Controls and Import Conditions sections), particularly during the first years of application.

Capacity-building measures were implemented through the Better Training for Safer Food (BTSF) programme. Training activities covered surveillance, contingency planning, disease control measures, movements and emergency preparedness, contributing to a common understanding of the new framework among competent authorities. In 2021, the Commission also conducted a communication campaign and made information material available in all official Union languages, including factsheets, posters and explanatory videos. These materials were distributed to Member States and made publicly available.

The Commission further developed the ADIS as the central EU IT platform for notification and reporting of animal diseases. This IT system supports real-time information exchange between Member States and the Commission and has been progressively aligned with international reporting obligations, including links to the World Animal Health Information System (WAHIS) of WOAH.

In outbreak situations, coordination at Union level frequently began at an early stage, including preparatory exchanges prior to formal confirmation where appropriate. Rapid information exchange and alignment of measures took place through:

- meetings of the PAFF Committee (Animal Health and Welfare section);
- meetings of the EU Chief Veterinary Officers Working Party; and
- ad hoc expert-level technical discussions.

These mechanisms facilitated the adoption and updating of implementing acts establishing protective measures, regionalisation arrangements in affected areas. To support situational awareness and coordinated communication, the Commission facilitated regular information exchange by circulating information notes to Member States and, where relevant, to third countries, publishing outbreak data through ADIS, and ensuring coherence between EU notifications and international reporting obligations.

The Commission provided technical and expert support to Member States through several mechanisms, including:

- deployment of the EU Veterinary Emergency Team (EUVET) for on-the-ground technical assistance;
- activation of Union antigen and vaccine banks where vaccination was part of disease-control strategies;
- requests for scientific advice from EFSA to inform control measures; and
- support from EU Reference Laboratories (EURLs), including validated diagnostic methods, technical guidance and proficiency testing.

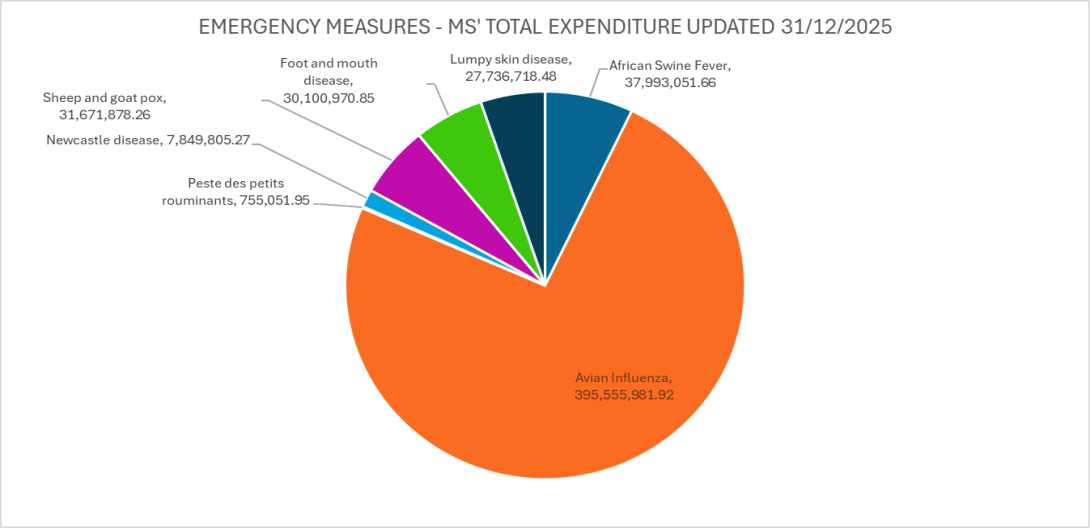
Additional surveillance and veterinary programmes in high-risk areas were supported through Union co-financing under the Single Market Programme. For example, in 2023 Member States submitted 126 programmes covering 11 diseases, while 10 additional programmes targeting ASF, l LSD and rabies were implemented in five neighbouring

third countries, with a total budget of around € 40.7 million. Funding focused in particular on ASF, HPAI, Salmonella, rabies, and TSE surveillance, supporting targeted surveillance, vaccination campaigns and control measures in areas at higher epidemiological risk. A comparable level of support was maintained in subsequent years. For example, in 2024, 111 programmes were submitted by Member States and nine by third countries, corresponding to an eligible budget of around € 40 million.

The EU provides also financial support to Member States during animal disease outbreaks through the veterinary emergency funding mechanism under the Single Market Programme (SMP). Since 2023, the Union co-finances up to 30% of eligible direct costs, including compensation to animal keepers and certain eradication and control measures, with the remaining share borne by the Member State. EU financial contributions for animal disease eradication and emergency measures remained significant during the evaluation period, amounting to €148.3 million in 2025, reflecting expenditure linked primarily to ASF and HPAI outbreaks.

Figure 3 below illustrates Member States' total emergency expenditure by disease (updated to 31/12/2025), showing a clear concentration of the eligible for EU cofinancing costs in a number of outbreaks. Avian influenza accounts for by far the largest share of expenditure (approximately €396 million), significantly exceeding all other diseases. Expenditure related to ASF, SPGP and other listed diseases represents comparatively smaller proportions of the total.

Figure 3: total expenditure of Member States updated as of 31/12/2025.



3.4 Implementation by Member States (2021–2024)

Following the date of application of the AHL in April 2021, all Member States initiated processes to align national legislation, administrative arrangements and veterinary systems with the new framework. However, the pace and extent of alignment differed.

Differences in administrative capacity, organisational structures and available resources influenced implementation trajectories. In Member States with federal or decentralised governance structures, alignment required coordination across multiple regional or institutional levels, which in some cases lengthened the adaptation process.

Legislative and administrative adjustments

In several Member States, implementation required the adoption or amendment of national legal acts in order to complement directly applicable Union rules, establish competent authorities' powers, and adapt sanction systems. These processes often involved parliamentary procedures and inter-ministerial coordination, contributing to variations in timing across Member States.

Budgetary constraints were reported in some cases, limiting the ability to recruit additional veterinary, legal or administrative staff specifically dedicated to AHL-related adjustments.

Official controls and enforcement

The Commission's 2022 report on official controls[13][14] confirms that all Member States carried out official controls covering animal health obligations, including surveillance, movement controls, biosecurity and outbreak response. However, the depth, frequency and maturity of these controls varied between Member States, reflecting differences in resources, organisational models and stage of adaptation.

While most Member States integrated AHL obligations and developed risk-based official control systems under the Official Controls Regulation (OCR), some continued to rely partly on control approaches developed under the pre-AHL framework. Commission audits on animal health topics verify Member State compliance with relevant EU legal requirements. They therefore provide substantial evidence on how the requirements of the AHL are being implemented in practice across Member States**.** Recurring findings from 2022-20224 include:

- incomplete or inconsistent application of biosecurity controls;
- partial non-compliance with surveillance or testing obligations in certain sectors;
- delays in updating contingency plans and inspection procedures;
- uneven application of risk-based controls across regions within the same Member State;
- sanction regimes not yet fully aligned with Article 268 AHL; and
- operational capacity limitations, including staffing constraints in veterinary services.

Sanctions and national flexibility

Article 268 of the AHL requires Member States to establish effective, proportionate and dissuasive sanctions. All Member States reviewed their national penalty systems following entry into application. However, progress in formally notifying national penalty provisions varied. According to the Commission's 2022 state-of-play update presented to

[13] Report from the Commission on the overall operation of official controls carried out in Member States (2022) to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.{SWD(2024) 208 final} 1_EN_ACT_part1_v3.docx.

the PAFF Committee in October 2023, only ten Member States had formally notified their national provisions by then.

The AHL also provides flexibility for national adaptation. Article 269 allows Member States to maintain or adopt more specific or stricter national measures in certain areas. Similar flexibility is provided under Articles 170, 171 and 226 for disease-control measures concerning terrestrial and aquatic animals. Several Member States made use of this possibility, particularly in areas such as identification and registration, traceability, establishment approval and biosecurity requirements. While this flexibility allows adaptation to national circumstances, it has contributed to variation in the detailed implementation of certain provisions.

Court cases

Regarding case law, there has been no ruling from the Court of Justice of the EU (CJEU) concerning the interpretation of the AHL. However, the EFTA Case E-8/24 Nordsjø Fjordbruk addresses the interpretation of Articles 10 and 269 of the AHL. The ruling on the case E-8/24 Nordsjø Fjordbruk, which was issued on 12 December 2024 by the Court of Justice of the European Free Trade Association (EFTA) (hereinafter, the 'EFTA Court'), represents the first decision of an international court on the AHL. While there is no doubt that this case bears relevance for the interpretation of the AHL, as transposed by Norway, it should nevertheless be noted that the rulings of the EFTA Court are directly binding only on the EFTA countries that are members of the European Economic Agreement (EEA Agreement), i.e. Iceland, Liechtenstein and Norway.

External constraints and concurrent pressures

Implementation coincided with the COVID-19 pandemic, particularly during the first year of application of the AHL Veterinary services and competent authorities were required to prioritise crisis management and essential controls, which in some cases delayed training activities and structural adjustments linked to the AHL.

At the same time, major animal disease events during the evaluation period required substantial administrative and operational resources (see Section 3.4), further influencing the speed of implementation in certain Member States.

Structural and cross-sectoral aspects

Audits and follow-up actions carried out under the Official control framework also highlighted structural issues affecting implementation in some Member States. In particular, audits on control measures for *Infection with Mycobacterium tuberculosis* complex and avian influenza highlighted situation where effective cross-sectoral collaboration was essential but not always sufficiently developed. These included coordination between animal health, wildlife and environmental authorities, in surveillance and response activities.

Key issues identified include:

- compensation and cost sharing schemes that may influence incentives for preventive measures;

- challenges in wildlife health management where coordination between animal health and environmental authorities was limited (e.g. tuberculosis in wildlife reservoirs) required; and
- the need for effective inter-sectoral coordination in areas linked to the One Health approach to support the surveillance and response.

Digital tools and system integration

Implementation of the AHL was supported by EU-level digital systems. ADIS became the central IT platform for harmonised disease notification and reporting, and its progressive alignment with WOAH's WAHIS system reduced duplication in international reporting.

The Integrated Management System for Official Controls (IMSOC), including TRACES, was used for movement notification and certification. During 2021–2022, the transition from TRACES Classic to TRACES NT overlapped with the early years of AHL application, creating additional operational adjustments for competent authorities.

Over the evaluation period, Member States progressively integrated AHL requirements into their national system and developed their official controls under the OCR. The AHL defines the substantive animal health obligations, while the OCR provides the verification and enforcement framework.

3.5 Adaptation by operators

Operators across the animal health chain, including farmers, veterinarians, animal keepers, transporters and other businesses, were required to adjust their practices following the application of the AHL.

Initial adjustments were particularly relevant where long-standing national practices differed from the new harmonised requirements, for example in relation to the registration of certain establishments (including smaller establishments) and the introduction of risk-based animal health visits. In several sectors, the shift towards more structured preventive obligations required changes in internal procedures, documentation and interaction with competent authorities.

The AHL clarified and harmonised responsibilities at Union level, including obligations relating to disease prevention, biosecurity, surveillance participation and notification of suspicions of disease outbreaks. Disease reporting became governed by directly applicable Union rules rather than predominantly national provisions, providing common criteria for when and how suspicions must be notified.

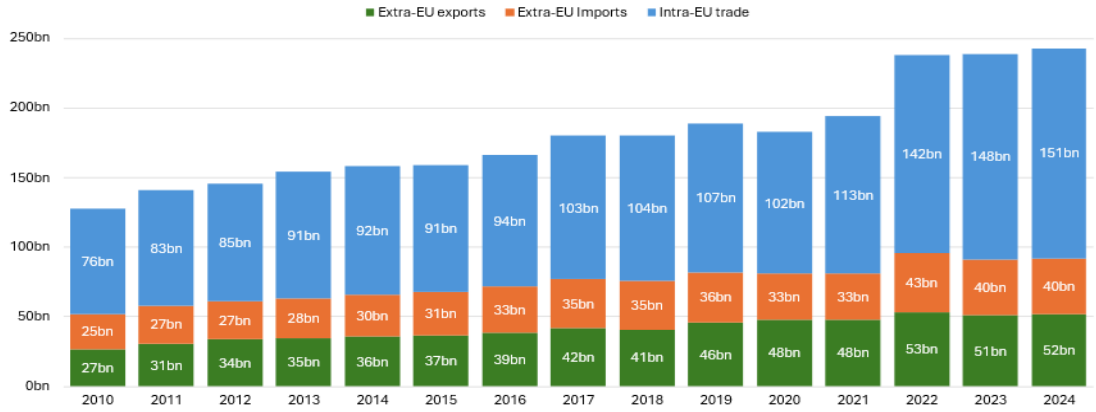
Operators were also required to interact more systematically with veterinarians in the context of preventive activities, animal health visits and awareness measures. The introduction of animal health visits represented a significant operational adjustment, particularly in the absence of detailed prescriptive implementing rules at Union level, leaving room for national approaches to organisation and delivery.

Movement rules and certification procedures were harmonised through directly applicable Union acts. Operators adapted to the use of EU digital systems, especially TRACES under the IMSOC framework, for the notification and certification of certain movements within the Union and for entry into the Union. The transition from TRACES

Classic to TRACES NT during the early years of application required additional adjustments. In some cases, digital systems progressively replaced paper-based procedures.

During the evaluation period, operators adapted their practices in a context marked by significant epidemiological challenges. At the same time, trade flows in live animals and animal products continued to evolve. Available COMEXT data indicate that intra-EU trade volumes recovered following the disruptions observed during the COVID-19 period, despite the occurrence of major animal disease outbreaks such as African swine fever, highly pathogenic avian influenza and bluetongue.

Figure 4 – EU Trade of live animals and animal products (EUR)



Source: External study

3.6 Epidemiological context

The evaluation period coincided with an unusually intense and complex epidemiological situation. Between 2016 and 2023, the animal health situation in the Union was characterised by a high and sustained burden of major transmissible animal diseases (TADs), placing continued pressure on animal health systems during the period in which the AHL was introduced and applied.

Figure 5– Overview of total animal disease outbreaks per year and per country from 2000 to 2024

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Austria	-	2	1	2	1	2	48	1	11	11	2	-	10	11	12	14	34	62	10	21	6	49	30	158	539
Belgium	8	41	39	23	11	2	706	-	56	19	13	1	8	10	2	7	5	26	200	501	29	49	199	214	28
Bulgaria	-	-	3	-	1	1	29	6881	6	12	3	18	-	6	2323	10	236	91	43	237	581	452	331	676	755
Croatia	-	-	-	-	-	-	-	-	1	10	17	8	15	29	74	24	63	30	7	1	50	11	41	1146	88
Cyprus	-	-	-	-	1	1	1	4	-	-	6	-	-	-	1	-	171	1	-	-	-	-	6	-	-
Czechia	-	-	2	4	8	9	18	11	12	11	4	2	2	6	17	1	5	282	31	15	7	90	22	107	155
Denmark	1	6	138	2	1	2	30	1	17	2	4	1	-	2	4	2	39	18	38	11	85	302	159	131	892
Estonia	-	-	-	-	-	-	-	2	-	-	-	2	-	-	41	741	1058	640	233	80	68	123	55	67	36
Finland		1	-	-	1	-	-	-	7	6	1	3	1	-	-	-	9	12	5	-	-	72	26	34	6
France	212	607	2397	163	127	45	43	15640	38035	103	16	8	5	131	111	366	1788	2990	867	371	257	633	409	967	488
Germany	15	139	127	56	69	77	1189	20929	3269	333	142	109	92	112	82	119	302	826	131	206	1037	4133	3082	2136	1848
Greece	15	173	-	-	-	5	30	2	78	192	69	29	105	115	3336	123	111	64	43	54	380	20	25	16	637
Hungary	-	-	-	-	-	-	41	46	164	32	24	22	10	36	125	58	283	97	244	1086	4337	2667	887	689	827
Ireland	-	234	325	183	126	69	69	25	23	9	2	3	4	1	-	1	1	10	3	1	18	48	64	26	5
Italy	7489	6437	657	2143	528	237	347	526	688	396	284	275	516	6379	1749	541	1357	2942	403	171	229	478	672	1586	2029
Latvia	-	-	-	-	-	-	-	-	-	-	-	-	20	46	219	769	870	961	699	372	323	307	922	806	974
Lithuania	-	-	-	-	-	-	-	-	-	1	-	5	-	1	76	136	332	1384	1526	504	260	325	342	503	574
Luxembourg	-	-	12	1		1	5	1315	19	2	-	-	-	-	-	-	1	4	1	-	31	4	3	5	2
Netherlands	2	44	24	260	6	3	459	5800	69	22	4	9	2	10	7	3	51	26	11	-	69	206	805	446	146
Poland	-	-	4	5	17	27	40	40	17	60	18	22	28	266	195	212	211	965	2574	2561	4343	3968	2293	2960	2584
Portugal	124	110	86	133	104	52	34	174	100	137	14	6	5	10	2	48	44	8	8	3	7	29	41	107	141
Romania	-	-	1	-	-	40	418	995	134	138	7	422	1552	1289	2669	418	350	360	1467	2517	2042	2806	866	1130	571
Slovakia	-	-	8	9	15	4	10	11	10	8	4	-	-	7	1	5	4	69	4	39	412	1684	574	559	225
Slovenia	-	-	1	1	1	1	28	2	-	6	6	3	2	4	1	5	30	48	4	1	6	10	36	30	128
Spain	286	114	143	181	450	186	68	7955	3062	452	138	17	19	110	438	37	96	67	24	9	174	71	244	423	541
Sweden	-	1	-	1	-	1	16	1	29	4	1	5	1	2	3	6	22	31	13	-	9	144	74	168	59
Total	8.152	7.909	3.968	3.167	1.467	765	3.629	60.361	45.807	1.966	779	970	2.397	8.583	11.488	3.646	7.473	12.014	8.589	8.761	14.760	18.681	12.208	15.090	14.278

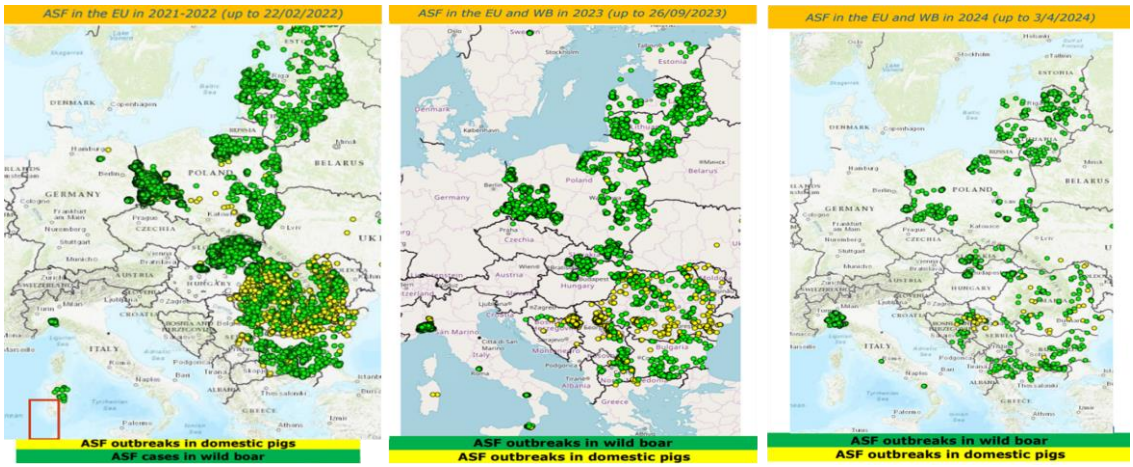
Source: External study.

African swine fever

ASF continued to spread across several regions of the Union, affecting both domestic pigs and wild boar populations. The number of affected Member States increased from 10 in 2019 to 14 by 2023, with first detections in Germany, Italy, Croatia and Sweden, and re-emergence in the Czech Republic and Greece.

ASF remained predominantly a disease of wild boar populations, with occasional spill-over into the kept pig sector. Control was complicated by wildlife reservoirs and environmental persistence. During the period, several Member States regained disease-free status in certain areas (e.g. Belgium in 2020 and Sweden in 2024), and in other affected Member States restrictions were progressively lifted in defined zones following improvements in the epidemiological situation. Since 2023, no additional Member States have reported new ASF incursions.

Figure 6 – Evolution African swine fever outbreaks in the EU, 2021 – April 2024



Sheep pox and goat pox

After decades of absence in parts of western Europe, SPGP re-emerged. Spain reported separate outbreaks in 2022–2023 in the regions of Andalusia and Castilla-La Mancha, which had been disease free since 1968. The authorities confirmed, 30 outbreaks, leading to the culling of over 52,000 small ruminants. The last outbreak was reported in May 2023, and Spain self-declared disease-free status to WOAH in November 2023.

In 2023, Greece reported sporadic outbreaks affecting approximately 2,000 animals in Central Greece and the island of Lesvos, and Bulgaria reported a single incursion in a border region after ten years of absence. These events required application of emergency measures and significant field operations.

Bluetongue

BT continued to pose challenges due to its vector-borne nature and circulation of multiple serotypes. Between 2021 and 2023, serotypes 1, 3, 4, 8 and 16 were reported across several Member States. BTV-4 was the most widespread, with 146 outbreaks across eight countries affecting approximately 25,000 susceptible animals. BTV-8 affected France, Spain and Belgium, while more limited outbreaks of BTV-1 and BTV-16 occurred in southern Member States. Vaccination strategies differed between Member States, ranging

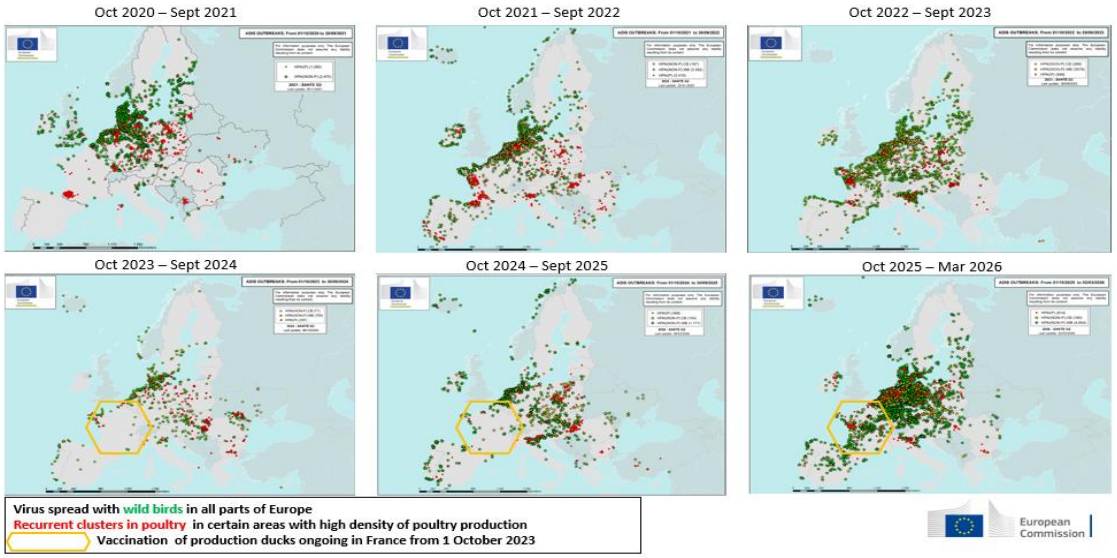
from compulsory vaccination to voluntary schemes or no vaccination, reflecting epidemiological conditions and national policy choices.

Highly pathogenic avian influenza

The most significant epidemiological pressure during the evaluation period came from HPAI. A major epidemic began in October 2021, driven mainly by H5N1. Between 2021 and 2023, HPAI affected wild birds, poultry and captive birds in up to 26 Member States.

The 2021–2022 season was the largest recorded HPAI epidemic in EU poultry, with approximately 2,400 outbreaks and nearly 50 million poultry affected. France was particularly impacted, with around 1,400 affected establishments, in particular in the duck and goose fattening sector. Recurrence of outbreaks in this sector led to the introduction of preventive vaccination in 2023. From late 2022 onwards, H5N1 was increasingly detected in mammals, including wild carnivores and fur-farmed species, although such cases remained limited. Outbreaks in wild birds continued into 2023, with a new epidemic season beginning in autumn 2023 linked to migratory bird movements.

Figure 7 – Evolution of Highly pathogenic avian influenza outbreaks in the EU, October 2020 – March 2026



Foot-and-mouth disease

Beyond the targeted scope of this evaluation, in early 2025, FMD re-emerged in the Union for the first time in decades, placing significant pressure on animal health systems. Germany was the first Member State affected, reporting a confirmed case in cattle after more than 35 years without occurrence. Subsequent detections were reported in neighbouring Hungary and Slovakia, requiring close regional coordination with successful eradication of the diseases and regaining of disease-free status under WOAH of both countries in the same year

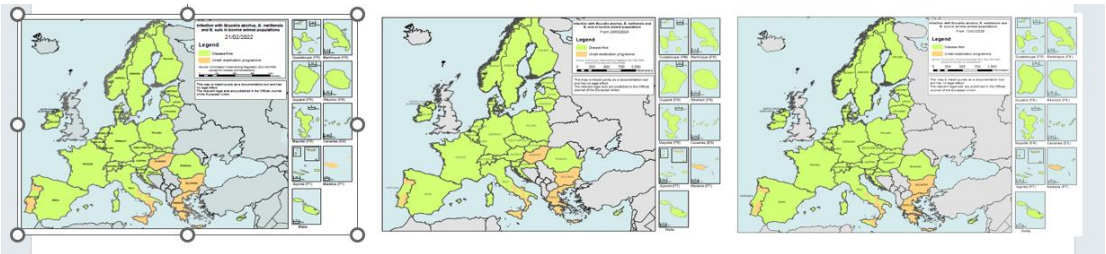
The outbreaks led to the application of harmonised emergency measures under the AHL, including stamping-out, movement restrictions and the establishment of protection and surveillance zones. Management of the situation required large-scale mobilisation of veterinary services and activation of contingency plans, with repeated adjustments of restricted areas as the epidemiological situation evolved. The economic impact was

substantial, reflecting direct and indirect costs related to disease-control measures, including culling, compensation, eradication activities, surveillance and movement restrictions, as well as trade-related consequences. For example, due to FMD Slovakia and Hungary reported high direct losses in 2025, e.g. over €10 million in Slovakia and more than €4 million in Hungary.

Infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*

The epidemiological situation for brucellosis remained heterogeneous across the Union. Most Member States, particularly in northern and central Europe, have achieved officially brucellosis-free status, reflecting gradual progress in eradication. However, eradication programmes continue in several southern and south-eastern regions. In particular, parts of southern Italy, Greece and certain Balkan regions continue to implement control programmes targeting infections in cattle, sheep and goats, with the aim of progressively expanding disease-free areas.

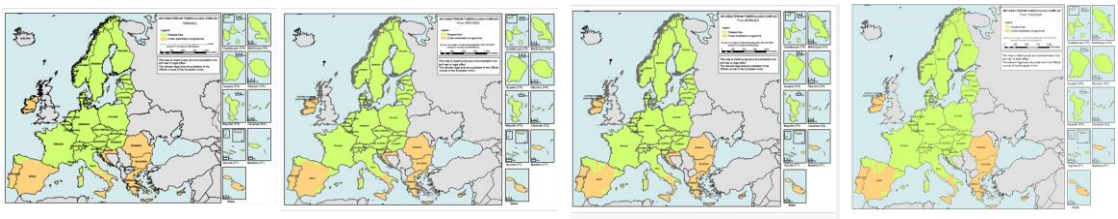
Figure 8 – Infection with Brucella abortus, Brucella melitensis and Brucella suis in bovine animal population, in the EU, 2022 – 2026



Infection with *Mycobacterium tuberculosis* complex

Bovine tuberculosis caused by the *Mycobacterium tuberculosis* complex continues to persist in certain parts of the Union. Most Member States have achieved officially tuberculosis-free status, particularly across northern, central and eastern Europe. However, eradication programmes remain necessary in several regions, including Ireland, Spain, Portugal and parts of southern and south-eastern Europe, where the disease continues in cattle populations.

Figure 9 – Evolution of *Mycobacterium tuberculosis* complex status in the EU, 2022 - 2026

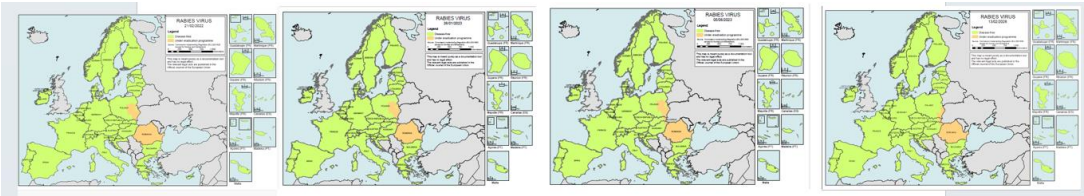


Rabies

Rabies remained largely under control within the Union during the evaluation period, with only sporadic detections and continued progress in maintaining disease-free status

across most Member States. Most Member States maintained rabies-free status, reflecting the long-term success of oral vaccination programmes in wildlife, combined with surveillance and monitoring activities. However, a limited number of Member States in Eastern Europe continued to implement eradication programmes, particularly in border regions with neighbouring endemic areas in third countries.

Figure 10 – Evolution of rabies status in the EU, 2022–February 2026



Taken together, these developments illustrate the dynamic and heterogeneous epidemiological environment in which the AHL began to be implemented. During this period, Member States were required to manage simultaneous outbreaks of emerging and re-emerging diseases, maintain long-term eradication programmes, and adapt surveillance and control strategies to evolving epidemiological risks. At the same time, both the Commission and Member States were still adapting to the AHL and its supplementary legislation. Implementation also coincided with other structural pressures, including the migration from TRACES Classic to TRACES NT, the operational effects of the COVID-19 pandemic and evolving climatic conditions influencing vector-borne disease dynamics. These contextual factors formed part of the operational environment in which the AHL was applied during its initial years.

4. Evaluation findings

The evaluation questions covering all evaluation criteria are presented in Annex III.

4.1 To what extent was the intervention successful and why?

4.1.1. Effectiveness

The evaluation finds that the AHL has been largely effective in establishing a more harmonised, risk-based and preventive Union framework for animal health. It replaced a fragmented legal landscape with a single framework covering prevention, surveillance, preparedness, disease control, traceability, movements and coordinated response.

The AHL has particularly strengthened legislative coherence, clarified responsibilities for competent authorities, veterinarians and operators, and introduced a more structured system for disease listing, categorisation and proportionate measures. It has also reinforced the legal basis for surveillance, early notification, traceability, regionalisation and the use of vaccination.

Evidence from consultations, surveys, interviews and case studies indicates that these changes have improved preparedness, coordination and the capacity for earlier detection and more targeted responses. EU IT tools such as ADIS and

TRACES, together with regionalisation, have supported disease management and helped maintain intra-Union trade during outbreaks.

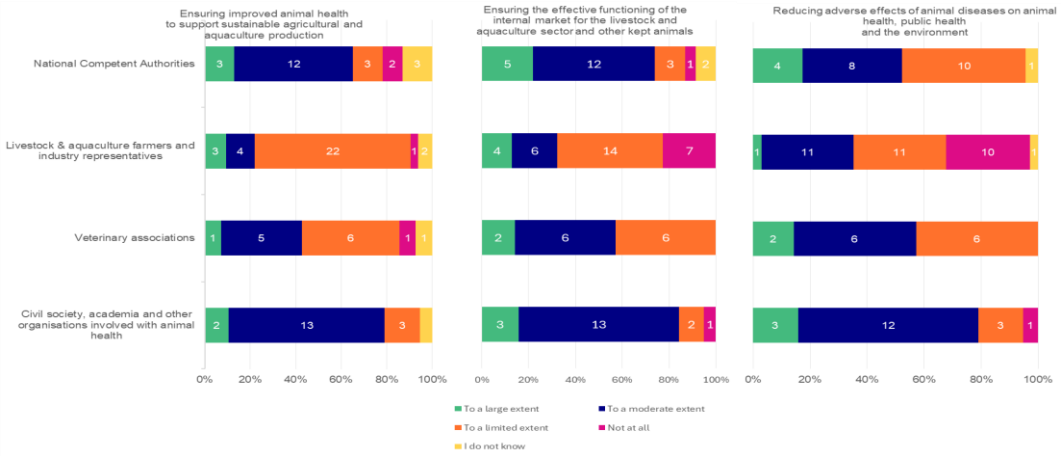
At the same time, effectiveness in practice remains uneven across Member States and sectors. Differences in legislative alignment, administrative capacity, veterinary workforce availability, digital systems and enforcement affect consistent application, while some provisions, notably animal health visits, contingency planning and certain biosecurity obligations, are not yet fully implemented.

Overall, the AHL has achieved its core objective of modernising the EU animal health framework and strengthening the conditions for prevention and coordinated disease control. Its full effectiveness will depend on continued implementation, practical simplification and support for consistent application across Member States.

The general objective of the AHL is to ensure a high level of animal health within the Union, supporting sustainable agricultural and aquaculture production, contributing to public health protection and food security, and safeguarding the proper functioning of the internal market. The evidence indicates that this objective has been achieved to a large extent. The AHL has established a common legal architecture for prevention, surveillance, preparedness, disease control, traceability and animal movements, replacing a fragmented set of disease- and sector-specific instruments with a single framework. Stakeholders widely recognise that this has shifted Union animal health policy towards a more preventive, risk-based and coordinated system.

Survey results show generally positive, though mixed, perceptions of the achievement of the general objectives (see Figure 11). More than half of respondents consider that the AHL has contributed positively to disease prevention and control and to the functioning of the internal market, while slightly fewer report improvements in animal health supporting sustainable production. National competent authorities, civil society and academia tend to express more positive views, while farmers and industry representatives are more cautious, often pointing to compliance costs and practical implementation challenges.

Figure 11 –To what extent has the AHL been successful in achieving its general objectives?



N = respectively 90, 88 and 87
Source: external study

At the same time, the full achievement of the general objective in practice is constrained by uneven national implementation, differences in administrative capacity, veterinary workforce shortages, variable digital readiness and the fact that many expected benefits are preventive and therefore not directly observable.

Evidence from stakeholder consultations[15], feedback from the CfE, and country case studies, including Austria, Italy and Spain, confirms that the intervention logic of the AHL is broadly coherent, relevant and aligned with stakeholder needs.[16]

However, effectiveness in practice has been affected by the pace and unevenness of implementation across Member States. Although the AHL provided for a five-year transition period between its adoption in 2016 and its application in 2021, implementation was affected by delays in certain delegated acts and by constraints linked to the COVID-19 crisis.

The Commission supported the transition through temporary and practical measures, including continued use of certain animal health certificates for entry into the Union until October 2021, derogations for intra-Union certificates, flexible compliance and enforcement approaches, discussions in the PAFF committee, communication activities and capacity-building under the BTSF programme.[17] These measures helped Member States during the adjustment phase, but also show that achievement of the AHL's objectives depends not only on legislative design but also on implementation capacity.

Survey evidence from national competent authorities, although limited in coverage, supports this conclusion: six out of nine respondents[18] reported that significant adaptation was still ongoing, while only one reported full completion and one reported that only minimal adaptation was needed. Interviews and validation workshop discussions further indicate that several Member States remain in the process of consolidating national

15 External study, Annex V, p XCVI.
16 External study p 56 , Annex V p XCVI.
17 European Parliament (2020) Parliamentary question - E-004906/2020(ASW). Available here.
18 External study, p 57.

legislation, with two reporting remaining legal gaps and six reporting ongoing legislative consolidation.

Country examples illustrate both progress and remaining gaps. Austria has progressively repealed legacy legislation, culminating in the adoption of a new Animal Health Act in 2024. Italy adopted a comprehensive package of legislative decrees in 2022, followed by corrective measures in 2024, although implementation of certain provisions, including Article 25 on animal health visits, remains incomplete. Spain updated its identification and traceability system through Royal Decree 787/2023, as amended in 2024, while maintaining flexibility for regional authorities. In Germany, progress has been slower, partly due to the federal legislative structure requiring coordination across Länder.[19] Taken together, this indicates that uniform implementation of the AHL has not yet been fully achieved, limiting the extent to which the broader objectives can already be considered fully realised in practice.

Achievement of the specific objectives:

The first specific objective is to **establish a single, simplified, transparent and coherent regulatory framework** replacing the previously fragmented legislation. The evidence indicates that this objective has been largely achieved in terms of legal coherence, transparency and consolidation, but only partially in terms of simplification in practice.

From a legislative perspective, the AHL has created a single Union framework by consolidating numerous legal acts into one Regulation, clarifying the overall structure of the regime and improving the allocation of responsibilities across the animal health chain. Survey evidence supports this conclusion: 13 out of 17 national competent authorities considered that the AHL had improved the delineation of responsibilities between competent authorities, veterinarians and operators, while 11 out of 17 reported a clearer allocation of roles.

However, simplification has not yet been fully realised operationally. Eight out of 17 national competent authorities reported that the framework remains complex due to the coexistence of the AHL with legacy national legislation, the large number of delegated and implementing acts, and the need to cross-reference with other Union instruments, notably Regulation (EU) 2017/625 on official controls. Stakeholders, including competent authorities, veterinarians and operators, also reported difficulties in identifying the applicable rules and called for clearer, more practical guidance.

Implementation has also required significant administrative, financial and IT resources. Some Member States, such as Austria, Italy and Spain, have largely modernised their legal frameworks and updated key systems, as described above[20]. Others introduced targeted support measures to facilitate implementation. For example, Bulgaria established a dedicated working group involving policymakers, veterinary authorities and stakeholders to support integration, while Hungary launched a broad communication campaign to promote understanding and compliance. Still, many MSs remain engaged in more fundamental restructuring of national rules and administrative practices.

19 External study, p 52.
20 External study, p 55.

Common challenges nevertheless persist across Member States, including the complexity of the multi-layered legal framework, adaptation of IT systems, shortages in the veterinary workforce, and the need for more consistent enforcement. These differences affect the uniform application of key provisions and, consequently, the overall effectiveness of the AHL. Continued guidance, training and practical support at Union level therefore remain important to support more consistent implementation. Overall, the objective of establishing a single and coherent Union framework has been largely achieved, while simplification and ease of application have so far been achieved only partially.

Disease listing, prioritisation and categorisation

A large majority of national competent authorities (13 out of 17) considered that the categorisation system has improved prioritisation and supported more proportionate and risk-based measures, particularly for transboundary animal diseases. Stakeholders also indicated that the system has increased transparency, supported more harmonised decision-making and facilitated resource allocation according to risk. Scientific assessments by EFSA[21] provide the basis for disease categorisation. Consultation evidence further indicates that competent authorities generally consider the system to have improved disease management and early detection through more targeted surveillance and control[22].

However, challenges remain in practical application. Six out of 17 NCAs reported difficulties in applying categories in complex or rapidly evolving epidemiological situations, while some stakeholders highlighted uncertainties in interpreting certain categories, particularly in borderline cases. Frequent updates through delegated and implementing acts, while necessary to reflect changing risks, have also been identified as a source of uncertainty and uneven implementation.

Some stakeholders noted that these updates can be difficult to follow in practice, and that clearer, more structured guidance would improve predictability and more consistent application of risk-based measures. Overall, the categorisation system provides a strong basis for proportionate, science-based intervention, although evolving epidemiological developments and climate-related pressures continue to test its operational adaptability.

In practice, beyond the categorisation system itself, authorities also apply additional risk-based prioritisation criteria. Audit evidence from Member States such as Denmark and Hungary shows that some authorities use risk factors such as establishment size, compliance history and outbreak records to prioritise inspections and surveillance activities.

Strengthening prevention and preparedness

Consultation evidence indicates that the AHL has strengthened the preventive dimension of the Union framework through clearer obligations on surveillance, early detection, notification, reporting, biosecurity and contingency planning**.** A majority of NCAs (12 out of 17) reported improvements in surveillance systems and early detection capacity.

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21 EFSA AHAW Panel 2017. Scientific opinion on an ad hoc method for the assessment on listing and categorisation of animal diseases within the framework of the Animal Health Law. *EFSA Journal* 2017; 15(7):4783, 42 pp. https://doi.org/10.2903/j.efsa.2017.4783.

22 See Annex V - Synopsis report.

Veterinarians also indicated greater awareness and earlier notification of suspected cases. Preparedness has improved through more systematic use of contingency plans and simulation exercises, including in response to recent outbreaks of HPAI and ASF. Mandatory notification deadlines and clearer reporting obligations have supported faster information exchange and more timely application of control measures.

At the same time, implementation of these tools remains uneven. Mandatory animal health visits under Article 25 are not consistently applied across Member States. Stakeholders reported that veterinary workforce shortages, cost considerations and the structural characteristics of extensive farming systems limit implementation, particularly in smaller or remote establishments. This is especially relevant for sectors such as small ruminants and backyard farming, where limited veterinary coverage may weaken early detection.

Country evidence illustrates these differences, including more systematic monitoring in intensive sectors and less consistent coverage in extensive systems. In Ireland, cattle farms benefit from regular tuberculosis testing, while many smaller and remote sheep farms do not receive routine visits; a voluntary biosecurity scheme exists but is not mandatory. In Romania, commercial pig farms are regularly monitored, whereas the large number of backyard farms makes consistent oversight more difficult. In the Netherlands, structured veterinary engagement remains stronger in intensive sectors, with less consistent coverage in more extensive sectors such as sheep and hobby farming. Stakeholders also pointed to the financial burden for small-scale farmers and limited veterinary availability in rural areas.

Preparedness tools also vary in quality and frequency. Audit findings and case studies, including Denmark, Sweden and Hungary[23] show that regularly updated contingency plans and simulation exercises improve chains of command, communication flows and operational readiness. Conversely, outdated or incomplete plans reduce response efficiency. Stakeholders also pointed to uneven coordination regarding wildlife surveillance and interfaces with environmental authorities.

The AHL has also strengthened prevention by reinforcing biosecurity obligations, surveillance and movement controls, thereby contributing to a more structured and preventive animal health regime. While these measures can generate financial and administrative costs in some settings, particularly for farmers required to invest in fencing, controlled access points or hygiene infrastructure, these costs are linked to stronger preventive capacity and improved preparedness.

Biosecurity implementation differs significantly across sectors. Evidence, including findings from an FVE study,[24] indicates higher levels of compliance in the pig and poultry sectors, where biosecurity requirements are longer established and enforcement more systematic. By contrast, dairy, beef, sheep and goat sectors show lower and more uneven implementation, often linked to extensive production systems, lower margins and more limited enforcement capacity. Aquaculture stakeholders also reported unclear guidance, inconsistent inspection practices and called for more species-specific requirements to

23 External study, p 67.
24 External study, p 82.

avoid uneven application across regions. In peripheral or mountainous areas, limited veterinary availability further constrains implementation.

Traceability systems are widely regarded as a key strength, enabling effective monitoring of animal movements and supporting disease control. However, veterinarians and operators reported additional administrative workload linked to documentation and reporting obligations, particularly for smaller establishments and sectors with limited administrative capacity. The scale of benefits also varies across Member States. In countries with well-developed systems, the AHL has mainly consolidated existing practices, whereas Member States with less developed systems reported more substantial gains in surveillance and preparedness, albeit with higher adaptation costs.

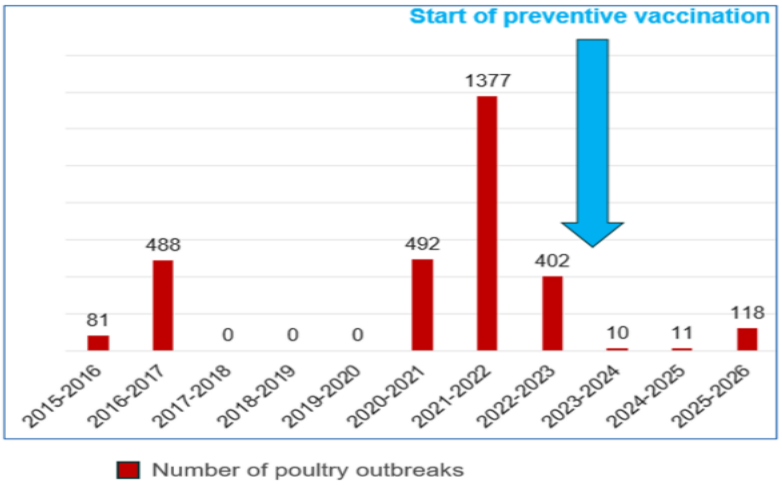
The AHL has also enabled more flexible use of vaccination, where justified by the epidemiological situation. Several Member States have implemented vaccination strategies against listed diseases, including preventive vaccination against HPAI in France and bluetongue vaccination in Spain, France, the Netherlands and Bulgaria. Stakeholders noted that the AHL has provided a clearer EU legal basis for such measures.

The experience with preventive vaccination against HPAI in France is particularly illustrative, as shown in Figure 12. Following the introduction of preventive vaccination in the poultry sector, the number of outbreaks declined markedly. Available data indicate an approximately 99% reduction between 2021–2022 (1,377 outbreaks) and 2023–2024 (10 outbreaks) after vaccination was introduced. The subsequent increase in 2025–2026 (118 outbreaks) nevertheless shows that vaccination can substantially reduce, but not eliminate, outbreak risk and must be combined with other measures such as biosecurity and movement controls.

Beyond the direct reduction in outbreaks, preventive vaccination also generated wider economic and sectoral benefits. Previous HPAI crises had significantly affected the French poultry sector, including the foie gras industry, with impacts on production and sales. Outbreaks also triggered trade restrictions from key partners such as China, Japan and the United States, affecting the wider poultry value chain from hatcheries to processors, including smaller producers. Repeated culling and prolonged crisis management also placed sustained pressure on farmers and veterinary services. By reducing the frequency and scale of outbreaks, vaccination helped limit these broader economic and operational disruptions.

Stakeholders acknowledged that the AHL has provided a clearer EU legal basis for emergency vaccination and has supported the implementation of vaccination strategies in response to evolving disease risks. At the same time, some stakeholders noted that further adaptation may be needed in specific situations, for example where restrictions on vaccination in disease-free areas do not fully reflect local epidemiological realities or changing climate-related conditions. These observations point less to shortcomings in the framework itself than to the need for refinement as implementation experience grows.

Figure 12 – Results of poultry vaccination against HPAI in France



Source: DG SANTE

Taken together, these elements show that the objective of strengthening prevention and preparedness has been achieved in terms of framework design and direction, but only partially and unevenly in practice across sectors and territories.

Clarify and rebalance the roles and responsibilities

By replacing previously fragmented legislation with a single harmonised framework, the AHL has provided a clearer allocation of obligations and reduced uncertainty regarding responsibilities for prevention, notification, surveillance, control and recovery measures. The principle of shared responsibility is explicitly embedded in the framework: operators are responsible for biosecurity, early detection, notification and own surveillance under Articles 24 and 25; veterinarians play a role in surveillance and animal health under Article 25; and competent authorities are responsible for surveillance enforcement under Article 26.

Interviewed NCAs reported that this clearer distribution of tasks has facilitated more structured coordination during outbreaks, reduced overlaps in control activities and improved compliance awareness, particularly among veterinarians and larger commercial operators. Survey evidence also supports this conclusion: 81% of respondents (N=69) considered that the AHL has improved the delineation of responsibilities between competent authorities, veterinarians and operators, while 11 out of 17 NCAs reported a clearer allocation of roles.

Several NCAs noted during the validation workshop that greater transparency in rules and procedures has supported more open decision-making and helped build trust among stakeholders. By clarifying responsibilities and introducing more structured governance arrangements, the AHL has also strengthened channels for information exchange and engagement, including with farmers and other operators. NCAs are generally well engaged at Union level through regular exchanges, including meetings of the PAFF committee.

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While the practical translation of legal provisions into guidance and day-to-day implementation still varies across Member States, the overall direction of change is positive. The evidence therefore indicates that the AHL has largely achieved the objective of clarifying and rebalancing responsibilities across the animal health chain.

Proportionate and science-based disease control measures

The AHL has strengthened the Union's capacity to apply targeted disease-control measures while limiting unnecessary disruption to movements and trade. Strengthened traceability rules, regionalisation, restricted zones and proportionate movement controls enable disease containment without resorting systematically to blanket national bans. Evidence from interviews and case studies confirms the practical value of these tools, including during SPGP outbreaks in Spain (Box 1) and in the continued management of ASF (Box 2). Although implementation may require case-specific flexibility, these mechanisms are operational and broadly effective.

Box 1 – Sheep Pox and Goat Pox in Spain in 2022

Following outbreaks of Sheep Pox and Goat Pox (SGP) in Spain in 2022, progressively stricter measures were introduced after restricted zones were established. From February 2023, movement restrictions applied. In Castilla-La Mancha, all movements were banned except for immediate slaughter, while movements from fattening establishments were allowed only to slaughterhouses following prior clinical inspection. From April 2023, movements from restricted zones to free areas required clinical inspection at least 24 hours before departure, with transport in sealed and disinfected vehicles. In June 2023, Spain notified the Commission that certain flocks previously moved for transhumance were now located in newly designated restricted zones and needed to return to their place of origin. The Commission therefore authorised a one-off derogation under a specific sanitary protocol, limited to the flocks concerned and without changing existing EU zoning or control measures.[25]

Box 2 – ASF and regionalisation

The EU approach to managing ASF has been progressively developed through Commission Implementing Regulation (EU) 2021/605 and its successor, Implementing Regulation (EU) 2023/594. These acts establish a structured regionalisation framework based on Restricted Zones I, II and III, reflecting the presence and spread of ASF and allowing measures to be calibrated according to risk. The framework is updated regularly to reflect the evolving epidemiological situation, including the continued persistence of ASF in wild boar populations. In 2024, several Member States, including Italy, Greece and Poland, saw adjustments to restricted zones. Some regions achieved reductions in restrictions following effective control measures, while certain areas in Czechia and Germany were delisted or downgraded after prolonged periods without new cases. This dynamic adjustment of restricted zones helps ensure proportionate and

[25] External study, p.70.

risk-based containment measures while avoiding unnecessary disruption beyond affected areas.[26]

As shown in these examples, the framework is operational and effective, although it may require case-specific flexibility, and well aligned with relevant international standards, including those of WOAH. It supports science-based intervention through structured procedures for listing diseases, surveillance and recognition of disease-free status.

Measurable progress in disease control can be observed through control-related outputs, although these indicators should be interpreted with caution. Since the AHL became applicable in 2021, successive updates to Implementing Regulation (EU) 2021/620 show an expansion of recognised disease-free status for several animal diseases across the Union.[27]

Several Member States have achieved or expanded disease-free status for bovine viral diarrhoea, with Austria, Denmark, Finland and Sweden recognised as disease-free for their whole territory, together with several German Länder. Progress has also been recorded for viral haemorrhagic septicaemia, with six Member States currently listed as disease-free compared with five at the time of the initial adoption of the Regulation, and for infectious haematopoietic necrosis, for which five Member States are currently listed as disease-free[28]. Disease-free recognition has also expanded for certain other diseases, including brucellosis and rabies. Member States have also continued to implement eradication programmes under the AHL framework, including programmes targeting enzootic bovine leukosis in Croatia and bovine viral diarrhoea in Ireland.

At the same time, the broader epidemiological context must be considered. Since 2021, the Union has experienced significant outbreaks of ASF, HPAI and BTV. Disease dynamics are strongly influenced by external factors such as climate change, wildlife reservoirs and trade patterns, making direct attribution to the AHL difficult. Within this context, the AHL contributes by providing a harmonised legal framework and common procedures that support more coordinated prevention and control efforts across Member States. Many of its benefits are also preventive in nature, including outbreaks avoided or mitigated, and are therefore not directly observable without counterfactual modelling.

Overall, the evidence indicates that the AHL has materially strengthened the basis for proportionate and science-based disease control across the Union, while measurable outcomes remain influenced by wider epidemiological developments.

Improve flexibility and adaptability to emerging risks

Compared with the pre-AHL framework, the AHL enables technical measures to be updated more readily through delegated and implementing acts. This has strengthened the Union's ability to respond to new scientific evidence and changing disease situations.

26 External study, p.71.

27 Commission Implementing Regulation (EU) 2021/620 of 15 April 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of the disease-free and non-vaccination status of certain Member States or zones or compartments thereof as regards certain listed diseases and the approval of eradication programmes for those listed diseases, http://data.europa.eu/eli/reg_impl/2021/620/oj.

28 External study,p.68.

Frequent amendments, targeted derogations and emergency measures indicate that the framework can adapt when circumstances require it, although some stakeholders noted that updates can be difficult to track in practice.

Recent developments illustrate this need. Persistent challenges linked to HPAI and ASF have required both immediate containment measures and longer-term management responses. Vector-borne diseases such as BTV have also highlighted the need to adjust categorisation, vaccination approaches and movement conditions as risks evolve. Stakeholders further pointed to the importance of timely coordination on vaccination, including regulatory pathways, procurement and stockpiling.

The evaluation also identified positive examples of vaccination under the AHL, showing that the framework supports a more flexible and preventive approach where justified. Some stakeholders nevertheless considered that further adaptation may be needed in specific situations, particularly where existing restrictions do not fully reflect local epidemiological realities or climate-related developments.

Digital tools also contribute to adaptability by supporting coordination, traceability and disease management. However, performance remains uneven across Member States, and further progress in interoperability, practical guidance and predictability of system updates would strengthen their contribution.

Overall, the evidence indicates that the AHL has broadly delivered on its flexibility and adaptability objectives, while continued refinement would further strengthen responsiveness to future risks.

Enhance coherence with related Union policies, including animal welfare, food safety and public health.

The AHL operates alongside the Official Controls Regulation, food safety legislation, public health legislation and animal welfare rules. Its provisions on surveillance, disease notification, traceability and movement controls contribute to a more integrated approach to risk management across the animal health chain. These mechanisms facilitate information exchange and support more coordinated responses, particularly in relation to zoonotic diseases and cross-border health threats.

Stakeholder feedback and consultation evidence indicate that this has strengthened links between animal health and public health systems, notably through improved data sharing and earlier detection of risks. Union IT systems such as ADIS, in combination with other EU tools, have supported more structured communication, transparency and timely decision-making, contributing to earlier detection of risk.

At the same time, achievement of this objective remains uneven in practice. Coordination across policy areas depends not only on the AHL itself, but also on national implementation and interaction with other legislative frameworks. Stakeholders, particularly from the public health and research sectors, noted that while the AHL provides a solid basis for cooperation, its practical contribution to a broader One Health approach remains partial.

Links with certain policy areas, notably animal welfare and environmental policy, also remain less developed operationally. Stakeholders reported that coordination may be

limited in specific situations, for example during outbreaks requiring restrictive measures or in areas involving wildlife and environmental domain.

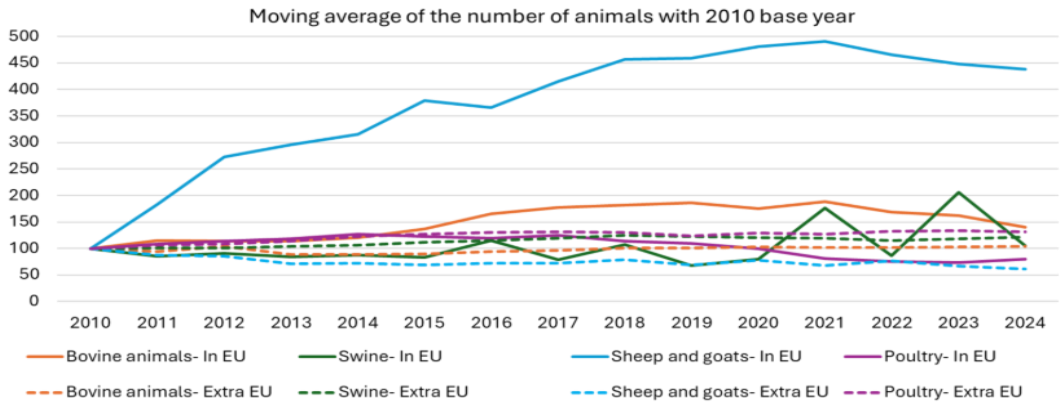
Overall, the AHL has provided a strong legal and structural basis for greater coherence with related Union policies, particularly in relation to public health as regards surveillance, data exchange and coordinated response. Full realisation of this objective will depend on continued efforts to strengthen practical coordination across animal, human and environmental health systems in line with the One Health approach.

Reduce the socio-economic impact of animal diseases and minimise trade disruptions

Harmonised rules on animal movements have contributed to greater safety, predictability and transparency in intra-Union exchanges. A majority of NCAs (10 out of 17), together with industry stakeholders, reported that common requirements and certification procedures have strengthened trust between Member States. Instruments such as regionalisation have also enabled targeted restrictions during outbreaks while helping maintain trade flows.

Trade data and stakeholder feedback indicate that the internal market has remained resilient. Intra-Union trade recovered strongly after 2021 despite outbreaks of ASF, HPAI and BTV, suggesting that the AHL framework has supported continuity of trade. Survey results (N=87) show an overall positive, though not unanimous, assessment: 51 respondents considered that the AHL had largely or moderately improved the functioning of the internal market, while 25 considered that improvements were limited and 9 that no improvement had been achieved. Interview evidence from 13 Member States similarly indicates that NCAs generally view the harmonised framework and clearer governance tools as having improved consistency of application. Supporting evidence also includes implementing acts establishing restricted zones, case studies such as Spain and Denmark, and COMEXT trade data showing strong recovery of intra-EU trade after 2021 despite outbreaks of African swine fever, highly pathogenic avian influenza and bluetongue. Please see Figures 4 and 13

Figure 13 – Volume Index of EU movements and exports of live animals



Source: External study

While TRACES is generally recognised as a useful tool for managing cross-border animal movements, some users reported operational limitations, including unannounced system

updates affecting accessibility and delays in issuing certificates. These difficulties have at times increased administrative complexity and disrupted planned movements, particularly during the initial implementation phase. Stakeholders also called for further digitalisation and better integration of identification, health and certification data. However, the efficiency of certification systems depends largely on national digital infrastructure and implementation choices, which go beyond the scope of the AHL itself.

At the same time, meat and livestock stakeholders reported market disturbances during ASF outbreaks, particularly in Germany, where buyers or trading partners refused products from restricted regions despite EU regionalisation rules allowing trade from unaffected zones. This suggests that the functioning of the internal market has been supported to a moderate to large extent, although not uniformly across sectors or epidemiological situations. More broadly, the objective of reducing the socio-economic impact of animal diseases has been achieved only to a moderate extent, as substantial costs and burdens remain, particularly for smaller operators and during outbreaks.

Limitations

The findings on the achievement of the general and specific objectives of the AHL should be interpreted in light of three structural constraints. These do not reflect shortcomings of the AHL framework itself but rather affect the extent to which its impacts can be measured and compared across the Union.

First, implementation remains uneven across the Union. Legislative alignment is still ongoing in several Member States, while provisions such as animal health visits, contingency planning and simulation exercises are not yet applied consistently. As the AHL is implemented through national administrative, veterinary and IT systems, differences in capacity and enforcement affect outcomes and limit comparability.

Second, many benefits of the AHL are preventive and therefore not directly observable. The framework is designed to reduce the likelihood and scale of outbreaks, but avoided events cannot be measured directly. Disease trends and disease-free status reflect a combination of AHL measures, pre-existing national programmes and wider epidemiological developments. Robust attribution would require dedicated counterfactual modelling beyond the scope of this evaluation.

Third, animal disease dynamics are strongly influenced by external factors beyond the legislation itself, including climate change, wildlife reservoirs, vector spread, production structures and trade flows. Recent outbreaks of ASF, HPAI and BTV, but not exclusively, illustrate that deteriorating epidemiological trends cannot automatically be interpreted as regulatory failure.

These constraints do not call into question the value of the AHL itself but do indicate that structural improvements and implementation progress can be assessed more robustly than direct impacts on disease incidence overall.

Overall assessment of achievements

Overall, the impact of the AHL on Member States is clearly positive, although the scale of visible change varies by starting conditions. In Member States with mature systems, the AHL has mainly consolidated and standardised existing practices. In others, it has

driven more substantial legislative modernisation, clearer governance and stronger alignment with science-based standards. Across the Union, it has strengthened harmonisation, legal coherence and the common operational basis for coordinated disease management. Continued intra-EU trade during repeated outbreaks also indicates greater systemic resilience.

Unexpected effects identified during implementation appear mainly linked to timing, uneven national alignment and resource constraints rather than weaknesses in the framework itself. Stakeholders nevertheless highlighted the need for clearer guidance, more consistent application and fairer cost-sharing arrangements.

This evaluation hence concludes that the AHL has largely achieved its core objective of establishing a coherent, modernised and risk-based EU animal health framework. Objectives relating to legislative coherence, clearer responsibilities and disease categorisation have largely been achieved. Objectives relating to surveillance, preparedness, traceability and internal market functioning have been achieved to a moderate to large extent. Objectives relating to simplification, uniform implementation and measurable animal health outcomes have so far been achieved only partially or to a moderate extent. Further progress now depends primarily on continued implementation, practical refinement and more consistent application across Member States.

4.1.2. Efficiency

The AHL has generated uneven and partly quantifiable costs and benefits for operators, veterinarians, and NCAs. While short-term compliance costs, such as legal adaptation, administrative restructuring, training, surveillance expansion, and biosecurity investments, are immediate and visible, long-term benefits like improved disease prioritisation, clearer responsibilities, stronger coordination, and better crisis preparedness remain difficult to quantify comparably across the EU.

A key limitation of the assessment is the AHL's recent implementation (since 2021), with incomplete national alignment and underused flexibility in some Member States. As a result, robust cost-benefit quantification is not yet possible, and findings rely on stakeholder perceptions, case studies, and national examples.

The short-term efficiency impact is mixed, with high administrative burdens, particularly where national systems were unprepared. However, the medium-to-long-term outlook is broadly positive, with potential for greater efficiency through targeted surveillance, optimised resource allocation, and stronger prevention provided implementation becomes more uniform, administrative fragmentation reduces, and digital/regulatory tools are better utilised.

The evaluation of the AHL's efficiency considers whether the costs incurred by Member States, stakeholders, and the European Commission, since 2021 have been proportionate to the benefits achieved.

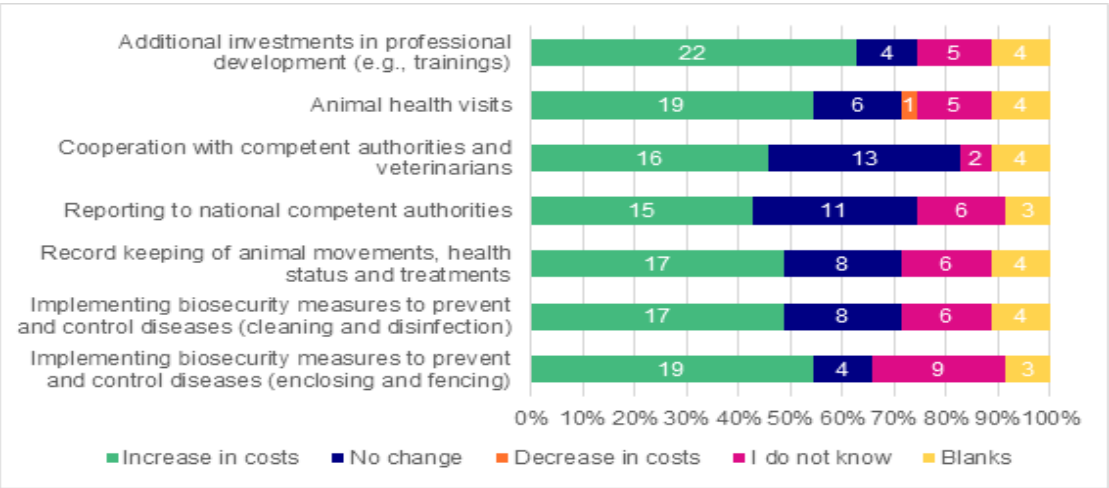
Current evidence indicates that the AHL has generated both additional costs and benefits for businesses, veterinarians and NCAs, though these remain unevenly distributed and

only partially quantifiable. The available data is largely perception-based, as the AHL has only been in force since 2021 and harmonised quantitative metrics are still limited. Costs, such as those related to legal adaptation, administrative reorganisation, training, reporting, surveillance expansion, and biosecurity compliance, are immediate and highly visible, particularly for farmers and NCAs. In contrast, benefits like improved disease prioritisation, clearer allocation of responsibilities, stronger coordination, better traceability, and potentially fewer or less severe outbreaks are preventive and structural in nature, making them harder to quantify in a robust and comparable manner across the EU. While stakeholders already recognise these benefits, their long-term and preventive nature complicates efforts to measure them effectively.

Consultation evidence from the CfE (2024, 215 respondents) shows that stakeholders perceive animal movement (86/215) and general implementation costs (69/215) as the most significant cost drivers, while traceability (4/215), disease control (4/215), and enforcement (5/215) are less frequently cited. Hobbyists (167/215) report the highest cost burdens, whereas farmers (6/215), NCAs (2/215), other operators (3/215), and veterinarians (1/215) are less affected, indicating that cost pressures are concentrated in specific stakeholder groups. However, these results should be interpreted with caution due to overrepresentation of certain stakeholders (notably hobbyist) and the absence of bias correction[29].

Survey data (Figure 14) further reveals that farmers face increased costs under the AHL, particularly in training (22/35 respondents), veterinary visits (19/35), biosecurity (17/35), and record-keeping (17/35). These costs vary by farm size, animal type, and national implementation, with smaller farms and aquaculture operators bearing a disproportionately higher burden. However, these findings reflect perceptions from a limited sample and should be interpreted with caution. They do not allow firm conclusions on the magnitude or distribution of the cost across the stakeholder group.

Figure 14: Survey replies to the question 'In which of the following area(s) did you see a change in costs since the adoption of the AHL?', by livestock and aquaculture farmers and industry representatives.



Source: External study.

29 External study, p 99.

The stakeholder group most frequently reports increased costs for professional development, particularly training (22/35 respondents). A notable example is Italy's mandatory training programme, established under the Ministry of Health Decree of 6 September 2023[30] ,which requires livestock and aquaculture farmers, as well as transporters, to complete 18 hours of training every three years on legal requirements, major diseases, biosecurity, and related topics. The decree permits a 30% reduction in training duration based on the number of animals per establishment.

Cost estimates (Table 1, 2020 data) indicate that training fees range from €140 to €200 per farmer, varying by provider and livestock species[31]. Bovine farmers bear the highest total costs, given their larger representation among Italian livestock farmers, while apiculture and swine sectors face the lowest estimated costs. The total annual cost for training across all livestock species in Italy is approximately €47 million. Costs in other Member States may vary due to differences in training content, delivery methods, and duration.

Table 1 – Cost estimation for mandatory training for livestock farmers in Italy

Species	Average training fee (EUR)([47])	Periodicity	Duration	Hourly earnings of Italian farmers (EUR)([48])	N. of farmers affected in Italy *(100% modality)*([49])	N. of farmers affected in Italy *(30% reduction)*	Total cost (EUR)	Total cost (EUR)/ year
Apiculture	180	Once every 3 years	18 hours *(100% modality)* 12,6 hours *(30% reduction)*	20.4	22610	-	7610526	2536842
Bovines	173.3				22810	73370	43906057	14635352
Ovine and caprine	140				50010	37170	40123049	13374350
Poultry	180				13980	43110	26490650	8830217
Swine	180				15760	22390	18409198	6136399
							Total	**47100382**

Source: External study

Respondents report increased costs in several key areas under the AHL:

Biosecurity measures (e.g., fencing, disinfection, equipment) require additional investment or staff, with costs varying by national legislation and sector. For poultry and pig farmers previously lacking biosecurity measures beyond standard practices, compliance costs average €10,000 per farm for items like protective clothing, cleaning

30 External study, p.100.
31 External study, Annex 3, p70.

equipment, and infrastructure (fences, window coverings)[32]. Cost variations reflect differing national and sectoral requirements.

Veterinary health visits (Article 25) have increased costs for 19/35 respondents, particularly in dairy, beef, and sheep sectors. Small-scale farmers and those without private quality assurance (QA) systems face greater burdens. Where QA schemes already mandate regular visits (e.g., Italian/Dutch poultry and pig sectors), no additional costs arise. Average annual costs range from €150–350 per farm, influenced by visit frequency, combined purposes, and farm remoteness.

Outbreak-related restrictions (e.g., for ASF, HPAI) incur compliance costs as part of disease-control measures. While these costs are inherent to effective prevention frameworks, small-scale operators struggle with absorption, particularly where compensation is perceived as insufficient or delayed. This highlights implementation challenges rather than flaws in the AHL's logic.

Record-keeping costs have risen for over 50% of respondents (17/35), especially for newly covered operators (e.g., hobby poultry farms) where exemptions are not applied by the national authorities. In Italy, costs stem from stricter interpretations of AHL Article 4(27) (establishment definitions) and TracesNT improvements[33]. In the Netherlands, initial registration and health plan development require 1.5 hours (€36.3 per farmer), with annual record-keeping demanding 8–12 hours (10 hours for average-sized farms, 198 LSU/holding)[34]. Total annual record-keeping costs for Dutch farmers are estimated at €7 million, representing 0.06% of the Dutch livestock industry production value (around EUR 11 billion) (Table 2).

Table 2 – Cost estimation for record keeping for farmers in the Netherlands

Type of activity	Time spent (hours)	Hourly earnings of Dutch farmers (EUR)54	Farmers affected in the Netherlands	Total cost (EUR)
Application for registration and development of animal health and treatment plans (one-off)	1.5	24.2	-	36.3
Record keeping (yearly) for the average farm size	10	24.2	10760	2603920
Record keeping (yearly) for below-average farm size	8		16310	3157616
Record keeping (yearly) for above-average farm size	12		4540	1318416
			Total	**7079952**

Source: External study

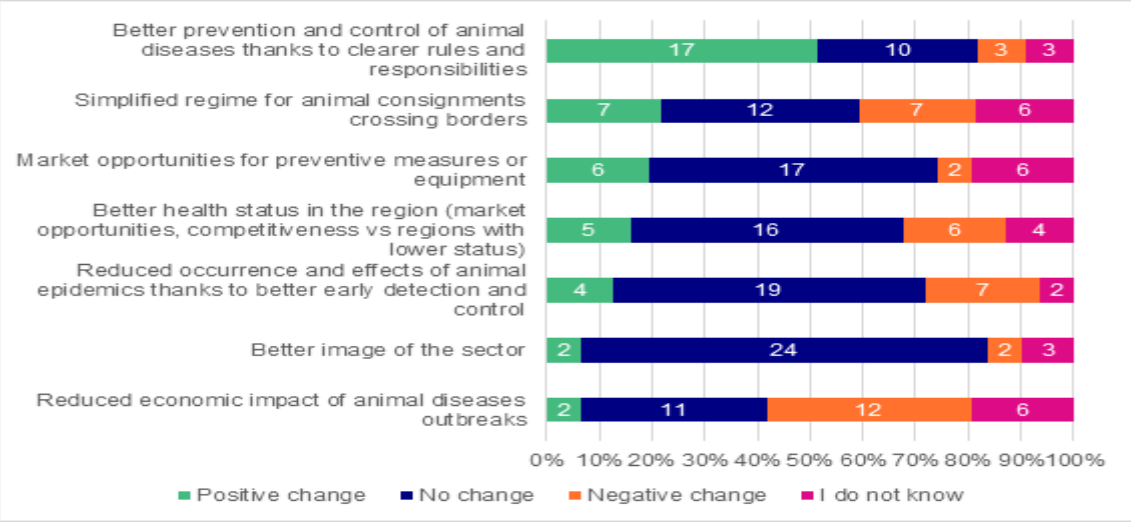
[32] External study, Annex 3, p LVI.
[33] External study,p.102.
[34] External study,p.102.

In parallel to the consultation findings, available EU-27 data on agricultural production cost structures (based on Eurostat EAA) show that veterinary expenditure has remained broadly stable (around 1–2% of total farming costs). This indicates no significant change at aggregate level. Reported increases are therefore more likely linked to factors such as higher disease pressure and related surveillance needs, including the registration of previously unregistered establishments, rather than to the AHL itself[35]

Current survey evidence (Figure 15) shows that farmers perceive the AHL's benefits as limited or still emerging, reflecting its early implementation stage and preventive focus. Most respondents report no significant changes in market opportunities, cross-border trade, regional health status, or disease occurrence/impact.

However, 17/35 respondents note positive effects in disease prevention and control, attributing improvements to clearer rules, responsibilities, and structured approaches. Sector-specific benefits include aquaculture cost savings (~25%) and reduced antibiotic use/fewer endemic diseases linked to Article 25 (animal health visits)[36].

Figure 15 – Survey replies to the question 'In which of the following area(s) did you observe (positive or negative) changes due to the adoption of the AHL?', by livestock and aquaculture farmers and industry representatives.



Source: External study.

Additional qualitative evidence indicates improvements in early disease detection and overall animal health status, particularly through enhanced surveillance. For example, better early detection of avian influenza has helped reduce outbreak impacts in certain regions

Some stakeholders estimate potential cost savings of 10–15%, with some suggesting up to 25% due to improved regional health status, though these figures remain difficult to verify and compare. Reputational benefits have also been noted, with one transport association reporting a 15–20% increase in perceived sector value, attributed to stronger prevention, biosecurity, and surveillance measures. However, public perception remains

35 Eurostat, Economic Accounts for Agriculture (EAA), EU-27 agricultural production cost structure, showing veterinary expenditure consistently at around 1–2% of total costs over 2005–2025.

36 External study, Annex 3, p. LIX.

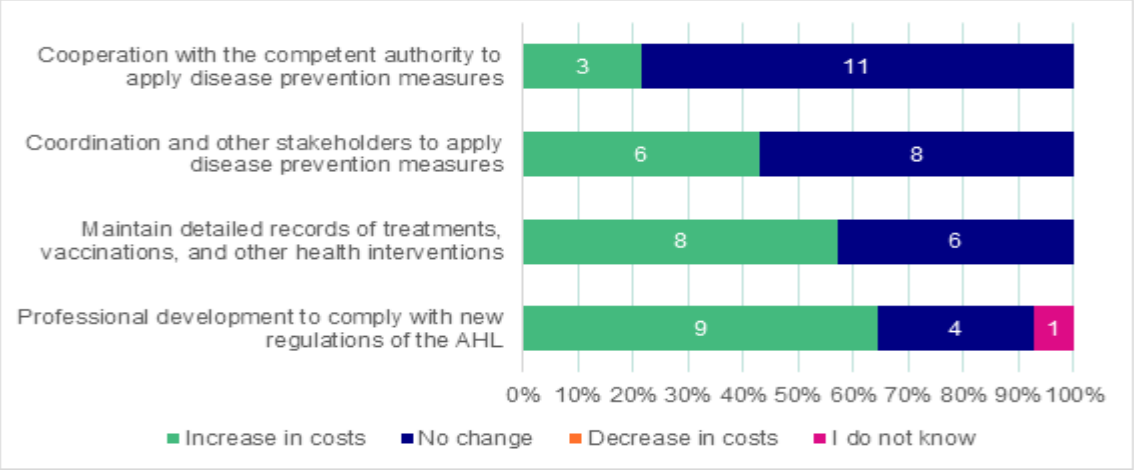
sceptical, influenced by recurring outbreaks and vaccination concerns, which limits the visibility of these benefits.

Despite progress, 12 out of 35 respondents still report a negative economic impact from disease outbreaks, highlighting the ongoing financial burden at the farm level, which can outweigh short-term preventive benefits. More broadly, stakeholders acknowledge that disease control programmes contribute to improved animal health, welfare, and food safety, as well as reduced antibiotic use and disease-related losses. However, these benefits remain difficult to quantify and are not yet fully reflected in stakeholders' overall efficiency perceptions.

For veterinarians, the primary efficiency challenge is increased indirect compliance costs and administrative workload, rather than changes in core clinical tasks. Survey data (Figure 16) from veterinary associations shows that 9 out of 14 respondents report higher costs, particularly due to additional training and professional development, reporting requirements and adaptation to digital tools (e.g., checklists, databases, on-site systems). In several Member States, veterinarians highlight the lack of harmonised training, particularly on biosecurity and implementation, forcing them to seek independent training and increasing time and financial costs. Staff shortages further exacerbate these pressures, especially in remote areas, where limited veterinary availability raises per-visit costs and threatens the economic viability of mandatory animal health visits. This can either increase costs for farmers or reduce the sustainability of veterinary practices. However, these reflect broader structural and organisational challenges in the veterinary sector and cannot be directly attributed to the AHL.

Figure 16 – Survey replies to the question 'In which of the following area(s) did you see a change in costs since the adoption of the AHL?', by veterinary associations.

The figure includes only adjustment and administrative cost categories.



Source: External study.

The AHL has delivered mainly structural and operational benefits for veterinarians. Surveys, interviews, and workshops indicate clearer responsibilities, more standardised disease control, and, in some cases, defined eradication criteria (e.g. bovine viral diarrhoea). Some veterinarians report improved information exchange (3/14) and earlier

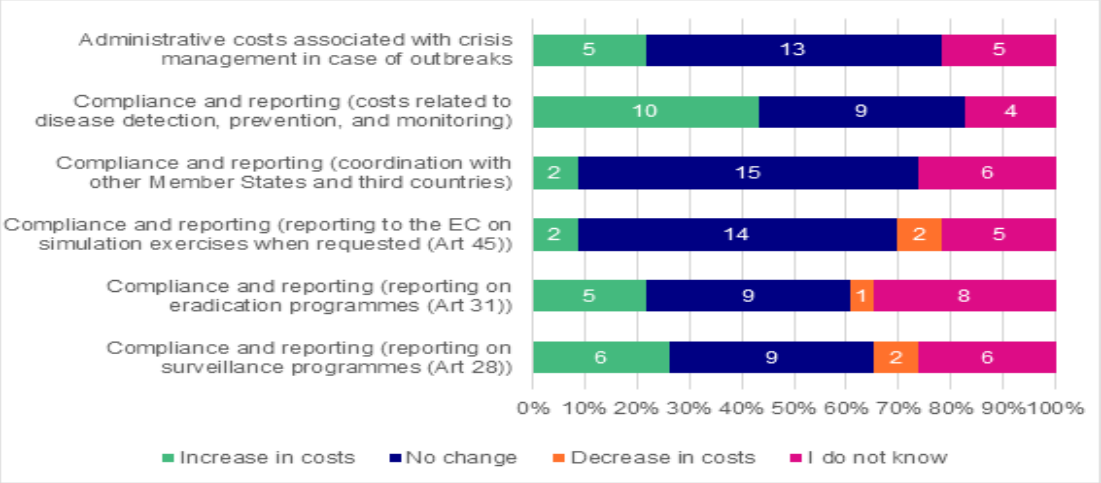
alignment on detection and control (6/14)[37],enabling timelier interventions and reducing outbreak impacts (3/14)[38].

However, 64% (9/14) observed no measurable reduction in outbreaks or economic impact, reflecting early implementation, indirect benefits, which are less immediately visible or quantifiable and variability across Member States.

For NCAs, results are mixed (Figure 17), with most reporting no cost changes in crisis management (13/23), coordination (15/23), and simulation reporting (14/23)[39].

Figure 17 – Survey replies to the question 'In which of the following area(s) did you see a change in costs since the adoption of the AHL?', by NCAs.

The figure includes only administrative and adjustment cost categories.



Source: External study.

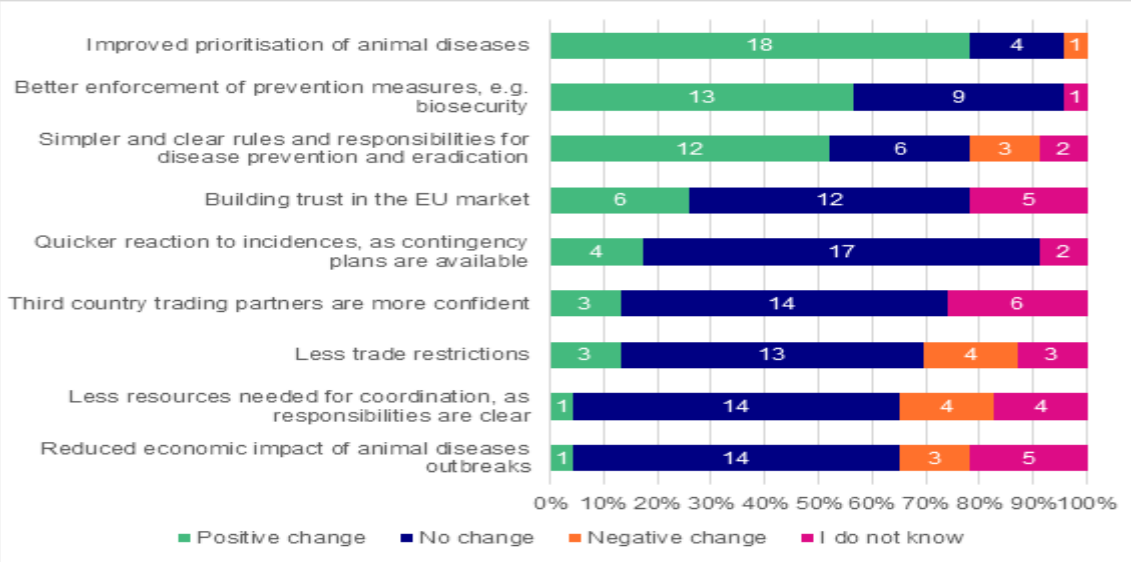
Cost increases were reported in key operational areas, such as disease detection, prevention, and monitoring, with 10/23 respondents indicating higher costs. These reflect the AHL's preventive, risk-based approach and the broader epidemiological context. Expanded surveillance, inclusion of wildlife and pets, and registration of previously unregistered establishments have increased staffing, data management, and laboratory needs. Concrete examples from consultations show ~15% cost increases in Poland and Austrialinked to wildlife surveillance for African swine fever. The HPAI situation has required reinforced early detection (testing, reporting, data management), while in the Netherlands, extended registration obligations increased administrative workload [40].

Evidence from specific MSs highlights significant implementation efforts. Denmark required 8–10 man-years plus additional staff (8 FTEs in 2022, 6 in 2023, 3 in 2024)[41]. In Germany, one NCA recruited an extra FTE for surveillance, while in Italy, administrative burden increased due to fragmented data systems and complex EU reporting and co-financing procedures.

37 External study, p. 102.
38 External study, p. 104.
39 External study, Annex 3, p. CV.
40 External study, Annex 3, p. LI.
41 External study, Annex 3, p. LXIV.

Despite these costs, NCAs report clear structural benefits. Most observed positive effects in disease prioritisation (18/23) and from the harmonised EU framework (19/23) as the survey indicates (Figure 18). Around half noted improved clarity of rules (12/23[42]), and 13/23 reported better biosecurity awareness[43], though implementation remains uneven.

Figure 18 – Survey replies to the question 'In which of the following area(s) did you observe (positive or negative) changes due to the adoption of the AHL?', by NCAs.



Source: External study.

Interview and validation workshop evidence shows the AHL has improved targeted surveillance, resource allocation, transparency, and coordination between Member States, supporting consistent disease control and market trust.

For specific diseases, the AHL has delivered notable benefits. For diseases like IBR and BVD, EU disease-free status supports trade and reduces disease related losses. For ASF and HPAI, benefits are systemic: coordinated surveillance, harmonised rules, and regionalisation enabling targeted control while maintaining trade.

However, many NCAs report no observable change: no reduction in outbreak impact (14/23), no faster reaction times (17/23), and no lower coordination costs (14/23), reflecting early implementation and wider epidemiological factors[44]..

Overall assessment of proportionality

The overall assessment of the AHL's proportionality reveals significant variations in perception across stakeholder groups. Survey results 77 respondents; Figure 20) show mixed perceptions: 19 consider benefits outweigh costs, 18 see costs as proportionate, 28 believe costs outweigh benefits, and 12 are uncertain.

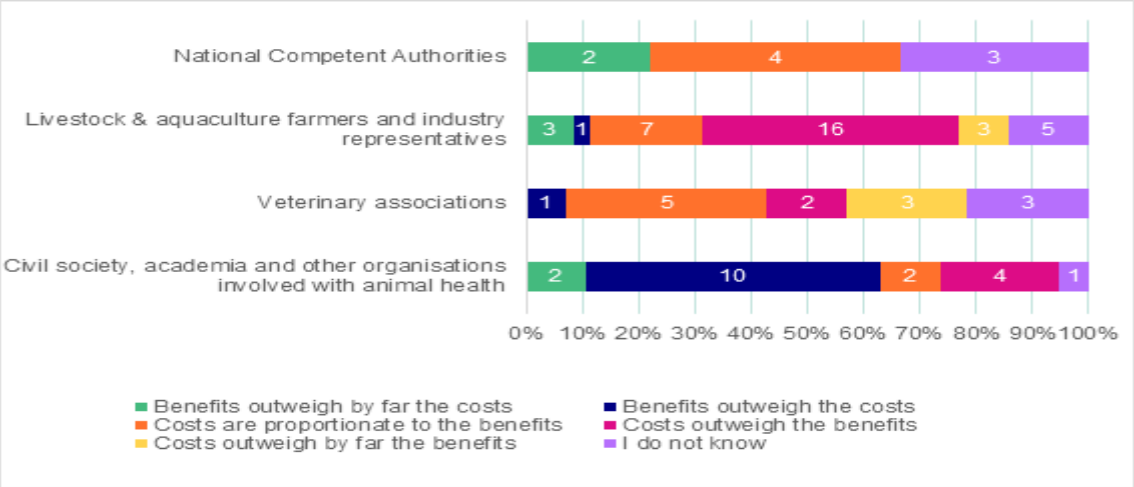
42 External study, Annex 3, p. 107.
43 External study, p. 107.
44 External study, p. 107.

Farmers and industry representatives tended to view view costs as outweighing benefits (16/35), given the immediate and tangible compliance burdens at the farm level, with only 4/35 reporting that benefits exceed costs. In contrast, national competent authorities (NCAs) offer a more balanced perspective, with 6/9 considering costs either proportionate or outweighed by benefits, while 3/9 believe costs exceed benefits. Veterinary associations present mixed views: 5/14 see costs as proportionate, 5/14 believe costs outweigh benefits, and 4/14 feel benefits surpass costs. Civil society, academia, and other organizations express the most positive assessment, with 12/19 stating that benefits outweigh costs, compared to 6/19 who see costs as predominant.

These differences reflect the timing and nature of impacts. Costs are front-loaded, visible and directly borne by operators and authorities, while benefits are longer-term, structural, and preventive, often linked to avoided losses and improved preparedness, making them difficult to quantify. Variations across MSs are further influenced by diverse starting conditions, administrative capacities, epidemiological pressures (e.g., outbreaks of ASF, HPAI, BTV), and varying stages of implementation.

Overall, the AHL shows potential for proportionate or net positive outcomes in the medium to long term, contingent on continued implementation, reduced administrative burden, and stronger evidence of long-term benefits.

Figure 19 – Survey responses to the question "To what extent do you consider the overall costs of the AHL proportionate to the benefits?", per stakeholder group.



Source: External study.

Administrative burden and complexity remain key concerns under the AHL. Stakeholders consulted under the CfE, including farmers and veterinarians highlight its multi-layered structure (basic Regulation, delegated/implementing acts, national rules), leading to interpretation challenges, duplicated reporting (e.g. TRACES, ADIS), and continued paper-based processes.

Burden increased with expanded obligations: registration of new operators (e.g. Netherlands[45]), detailed record-keeping (8–12 hours/farmer; ~EUR 7 million/year),

45 External study, Annex 3 p. LXV.

training (~EUR 47 million/year[46]), and animal health visits (~EUR 400/farm[47]). Inefficiencies in certification and TRACES (duplication, instability, delays) affect trade. Proportionality issues persist (e.g. identical requirements for small/large establishments, inconsistent thresholds, sampling delays up to 72h).

Fragmented systems and divergent interpretations (e.g. "commercial transport") create legal uncertainty and duplication across identification and traceability tools (passports, vaccination records, certificates). Stakeholders call for better digital integration (e.g. TRACES). Sector-specific issues persist, notably in aquaculture, where inconsistent categorisation restricts movements and creates trade barriers, with disproportionate requirements for smaller operators.

Additional challenges include duplicative reporting, inconsistent certification, delays (e.g. breeding), non-risk-based biosecurity measures (e.g. prolonged restriction zones), and limited veterinary capacity. NCAs also highlight added complexity from overlap with disease-specific rules (e.g. ASF). NCAs confirm increased costs, mainly outbreak-driven (~15% Austria; up to 50% Poland), alongside high implementation costs (8/23 NCAs; Denmark 8–10 man-years[48]).

Overall, these factors have led to short-term inefficiencies - duplication, delays, higher workload, limited interoperability, reduced trade, and less time for clinical work. These are largely transitional, linked to regulatory layering, system fragmentation and proportionality issues, and are expected to decrease with further streamlining, improved digital integration, and more proportionate application.

Reporting obligations and potential for simplification

The AHL establishes comprehensive reporting obligations (registration, record-keeping, notification, TRACES movements, surveillance, disease-free status), widely seen as necessary for its preventive approach. Most NCAs report no or moderate cost increases (e.g. 9/17 no change; 6 increases[49]), indicating reliance on existing systems.

Challenges stem mainly from implementation: misaligned national systems, duplication, divergent definitions (e.g. "case", "commercial transport"), fragmented data, and delays affecting sectors like aquaculture, transport, and breeding.

Some stakeholders also highlight opportunities for simplification and cost reduction. They emphasise that preventive measures, such as coordinated vaccination, are more cost-effective than reactive outbreak responses (e.g. France HPAI vaccination (Table 3), €93.6 million in 2020-2021[50] vs €1.1 billion outbreak costs).

Table 3 – Cost distribution for the HPAI vaccination campaign in France

Activity	Budget Share (%) of the vaccination campaign	Paid by	Amount EUR mln	State EUR mln	Farmers EUR mln

46 External study, Annex 3 p. LVIII.
47 External study, Annex 3 p. LXXXV.
48 External study, Annex 3, p. LI.
49 External study, Annex 3, p. LXIV.
50 External study, Annex 3, p. LXXXVII.

Buying the vaccine	24	State	22464	22464	0
Vaccine storage and transport	4	State	3744	3744	0
Supervision of vaccination (official vets)	18	State	16848	16848	0
Vaccination operations	27	State/Farmers	25272	13204	12068
Monthly visits for active surveillance	8	State	7488	7488	0
Active surveillance analyses	17	State	15912	15912	0
Passive surveillance analyses	2	Farmers	1872	0	1872
TOTAL	**100%**		**93600**	**79660**	**13940**

Source: External study.

At the same time, some simplifications are already in place (e.g. AHL Article 139 derogations). For example, "Alpenweideviehverkehr" seasonal cross-border grazing arrangements between Austria, Germany, Switzerland, Liechtenstein, and Italy allowing local livestock movements without full certification under specific risk-mitigation conditions), showing how the AHL can support pragmatic, risk-based solutions while maintaining health safeguards.

Overall, simplification lies in better implementation, including digitalisation, interoperability, and EU-national alignment, rather than revising core obligations.

Limitations

Assessment is constrained by incomplete national alignment and early implementation stage, making impacts hard to isolate and long-term benefits not yet fully visible.

4.1.3 Coherence

The evaluation concludes that the AHL is overall coherent, establishing a consistent, structured, and risk-based legal framework for animal health at the EU level. Its design based on disease categorisation, clearly defined responsibilities, and integrated measures ensures strong alignment between its objectives, instruments, and expected outcomes.

No significant internal contradictions or overlaps have been identified within the AHL itself. The few reported issues relate primarily to technical elements, interpretation, or practical application rather than flaws in the legislative design.

External coherence is generally strong, particularly with EU food safety, public health, and internal market frameworks, as well as international standards. However, partial misalignments persist in specific areas, including animal welfare, environmental policy, financing instruments, and disease-specific regimes such as transmissible spongiform encephalopathies (TSE).

While the AHL demonstrates high legislative coherence, the practical benefits of such coherence is not yet fully achieved due to differences in national implementation, interpretation, and administrative capacity. These divergences affect consistency and predictability across Member States.

Overall, the AHL provides a solid legislative foundation, with remaining challenges primarily linked to implementation, policy interactions, and the need for further alignment over time.

This evaluation assessed clarity and consistency both within the AHL (internal coherence) and in relation to broader EU legislation and external policy (external coherence).

Internal coherence

The AHL demonstrates a satisfactory level of internal coherence, with its core components (disease listing, surveillance, prevention, movement rules, emergency measures) forming an integrated system for disease control and trade. Most NCAs, veterinarians, and operators report no fundamental contradictions or major overlaps within the surveys and interviews.

Identified issues are limited and technical: e.g. exclusion of hatching eggs from traceability, ambiguity on "other veterinarians" (Article 14(c)(i)), and complexity in disease control and disease-free status (notably IBR). Some inconsistencies stem from divergent interpretations ((e.g. "disease prevention", "terrestrial animals"), delays in implementing provisions (e.g. Article 37)[51] *and i*nteraction with disease-specific measures (Commission Implementing Regulation (EU) 2023/594[52] on ASF). Overall,

[51] External study, p.131.

[52] Commission Implementing Regulation (EU) 2023/594 of 16 March 2023 laying down special disease control measures for African swine fever and repealing Implementing Regulation (EU) 2021/605 http://data.europa.eu/eli/reg_impl/2023/594/oj.

identified issues are primarily implementation-related or reflects evolving epidemiological needs rather than stemming from deficiencies in the design of the framework.

External coherence with EU legislation and policies

The AHL is overall coherent with relevant EU legislation and policies, though coherence varies across areas. It provides a structured basis for coordination with food safety, public health, and official controls, linking surveillance, notification, traceability, and movement rules to support integrated risk management and a One Health approach.

The AHL is supported by a set of Union-level digital systems, in particular the ADIS and TRACES, which operate within the broader framework of IMSOC established under Regulation (EU) 2017/625. These systems link animal health rules with official controls, certification, and information exchange, though interoperability gaps between EU and national databases create practical coherence challenges, such as data structure differences and process duplication.

The strongest coherence is with the EU food safety and official controls framework, where the AHL's prevention, surveillance, and biosecurity measures support food safety objectives and align with Regulation (EU) 2019/6[53] on veterinary medicinal products, helping reduce antimicrobial use and combat antimicrobial resistance.

The AHL also contributes the EU public health policies, particularly Regulation (EU) 2022/2371[54] on cross-border health threats, by strengthening animal disease surveillance and notification, facilitating early detection and coordinated responses between public health and veterinary authorities. While the AHL and public health frameworks have distinct objectives, they are mutually reinforcing and support a One Health approach.

Coherence with animal welfare legislation is more partial. While no direct legal contradictions were identified, several stakeholders, including NCAs and civil society organisations, highlighted operational tensions between disease control measures (e.g., culling, movement restrictions) and animal welfare requirements. Around one-third of farmers and industry operators report difficulties in balancing animal health and welfare compliance, especially in emergencies, pointing to a need for better coordination of IT instruments like TRACES NT with Regulation (EC) No 1/2005[55] on animal transport protection.

Coherence with EU financing instruments, including Regulation (EU) 2021/690[56], is also limited**.** While the AHL promotes a preventive and risk-based approach, funding

53 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, http://data.europa.eu/eli/reg/2019/6/oj.

54 Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU, http://data.europa.eu/eli/reg/2022/2371/oj.

55 Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97, http://data.europa.eu/eli/reg/2005/1/2019-12-14.

56 Regulation (EU) 2021/690 of the European Parliament and of the Council of 28 April 2021 establishing a programme for the internal market, competitiveness of enterprises, including small

mechanisms are largely oriented towards emergency response and compensation. Stakeholders, including NCAs and civil society, noted that this creates a misalignment between policy objectives and financial incentives and called for clearer links between prevention measures and funding eligibility.

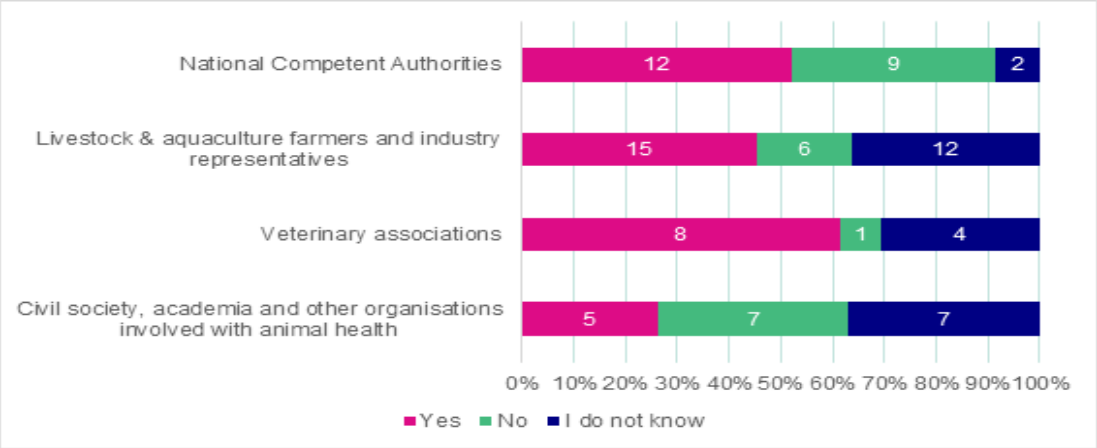
Additional coherence challenges arise from the AHL's coexistence with pre-existing disease-specific frameworks, in particular Regulation (EC) No 999/2001[57] on transmissible spongiform encephalopathies. Stakeholders note that maintaining a separate TSE regime outside the AHL's disease categorisation system leads to fragmentation, complicates prioritisation, and poses practical implementation and funding challenges.

Coherence of implementation across Member States

The structural consolidation under Effectiveness supports the AHL's internal coherence, with its risk-based design aligned to prevention and control objectives. However, full coherence across Member States is not yet achieved due to differences in national systems[58], administrative capacity, and prior alignment.

Implementation varies: some Member States (e.g. Spain, Italy, Latvia) required limited adjustments, while others (e.g. Bulgaria, Austria, Hungary, Denmark) needed more substantial reforms. Survey results show 40/91 respondents identified divergences in interpretation and application, affecting consistency and predictability of cross-border movements (Figure 20).

Figure 20 – Survey replies to the question 'Have you identified any diverging provisions, interpretations and /or application issues between AHL and the animal health measures and systems in your country?'



Source: External study.

Despite these challenges, the AHL provides a common legal framework that facilitates coordination and gradual convergence. Remaining issues relate to differences in

and medium-sized enterprises, the area of plants, animals, food and feed, and European statistics (Single Market Programme) http://data.europa.eu/eli/reg/2021/690/oj.

57 Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, http://data.europa.eu/eli/reg/2001/999/oj.

58 External study, Annex 3, p. CXXXVIII.

administrative capacity, legal traditions, and coexistence with legacy frameworks (e.g. TSE, zoonoses).

Overall, the AHL has improved coherence at EU level, while practical integration at national level remains ongoing.

International coherence and harmonisation

The AHL aligns with WOAH standards, serving as a science-based reference for disease prevention, control, and trade. It supports harmonisation of sanitary requirements, particularly for imports into the EU, with third countries often adapting their systems to meet EU standards (e.g. Switzerland).

The AHL is also coherent with the EU's obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), as its risk-based approach, including regionalisation, reflects internationally recognised standards and contributes to predictable trade conditions. It also contributes to WTO SPS discussions (ASF, HPAI).

However, global impact remains moderate: alignment by third countries is voluntary and market-driven. Many prioritise bilateral arrangements over EU rules, limiting AHL influence on exports, while its role remains stronger for import standards.

Cooperation, information exchange and joint response

The AHL has strengthened international cooperation, particularly with WOAH, improving information exchange on animal diseases. The integration of ADIS with WOAH WAHIS enhances data exchange timeliness and completeness, supporting transparency and coordinated responses to transboundary diseases. Stakeholders also highlight the AHL's role in sharing scientific information through EFSA, which plays a key role in risk assessment and communication. However, further improvements could be achieved by proactively promoting the AHL internationally.

Regarding the "Do No Significant Harm" principle, the AHL has largely neutral environmental effects, with some benefits for wildlife surveillance and early detection. However, control measures for major diseases (e.g. ASF, avian influenza) may conflict with biodiversity objectives (e.g. culling, restrictions). Stakeholders also note challenges in wildlife surveillance, due to ecological complexity and resource constraints, as well as limited links with broader EU environmental policies, such as the Circular Economy Action Plan. While one national competent authority suggested potential circularity opportunities through disease monitoring, civil society and academic stakeholders emphasised the need for stronger coordination between animal health and biodiversity policies.

Coherence with EU strategic objectives and One Health

The AHL is conceptually aligned with key EU strategic frameworks, including the One Health approach and the Long-Term Vision for Rural Areas. It contributes primarily through strengthened disease prevention, harmonised rules, and support for the internal market. However, stakeholder perceptions vary: civil society and academia view the AHL as making a significant contribution to sustainability, particularly through improved biosecurity and resilience, while NCAs, farmers, and industry representatives see its impact as moderate, citing uneven implementation and limited integration with

environmental and rural development policies. Around half of farmers and industry stakeholders perceive a clear contribution to the Long-Term Vision for Rural Areas.

The AHL supports the internal market by harmonising animal health requirements and enabling safe intra-EU movements, thereby underpinning the competitiveness of the food sector. However, differences in national implementation and enforcement create challenges for maintaining a level playing field and can undermine confidence in cross-border equivalence.

The AHL reflects the One Health approach by recognising the interconnection between animal and human health, strengthening surveillance, prevention, and early detection of pathogens. Through harmonised disease notification requirements and the ADIS system, including its interoperability with WAHIS, the AHL enhances data sharing, transparency, and early warning, facilitating risk assessment and coordinated responses, particularly for zoonotic diseases. However, implementation remains partial, with limited environmental integration and structured cross-sectoral cooperation between animal health, human health and environment sectors. Public health officials note that the AHL's disease categorisation, while useful for animal health management, is insufficient to fully operationalise a comprehensive One Health approach. Emerging zoonotic diseases requiring transnational and interdisciplinary responses are not always adequately addressed within national intervention priorities.

Additionally, wildlife surveillance under the AHL remains largely focused on listed diseases (e.g., ASF, rabies, avian influenza), with complementary initiatives like ENETWILD[59] aiming to improve harmonised surveillance of zoonotic diseases in wildlife. Stakeholders emphasise the need for stronger cross-sectoral integration to fully realise the One Health approach in practice.

Overall, the AHL is coherent with EU strategic objectives and supports the One Health approach, though further efforts are needed to strengthen practical integration across policy areas and ensure more consistent implementation. The AHL provides a robust legislative framework, with remaining challenges primarily operational, relating to national implementation differences, partial policy alignment, and the need for stronger cross-sectoral coordination. These challenges do not undermine the overall coherence of the framework but highlight areas for further alignment, guidance, and coordination across the EU.

4.2 How did the EU intervention make a difference and to whom?

The evaluation finds that the AHL delivers clear EU added value by providing a common animal health framework that Member States could not have achieved as effectively through separate national action. This is particularly evident in the

[59] ENETWILD is an initiative coordinated by the European Food Safety Authority that supports the harmonised collection, analysis and sharing of data on wildlife populations and wildlife diseases across the EU. It develops methodologies and provides data to improve risk assessment and surveillance of zoonotic and emerging diseases at the wildlife–livestock–human interface, thereby contributing to the implementation of the One Health approach; Home - Enetwild.

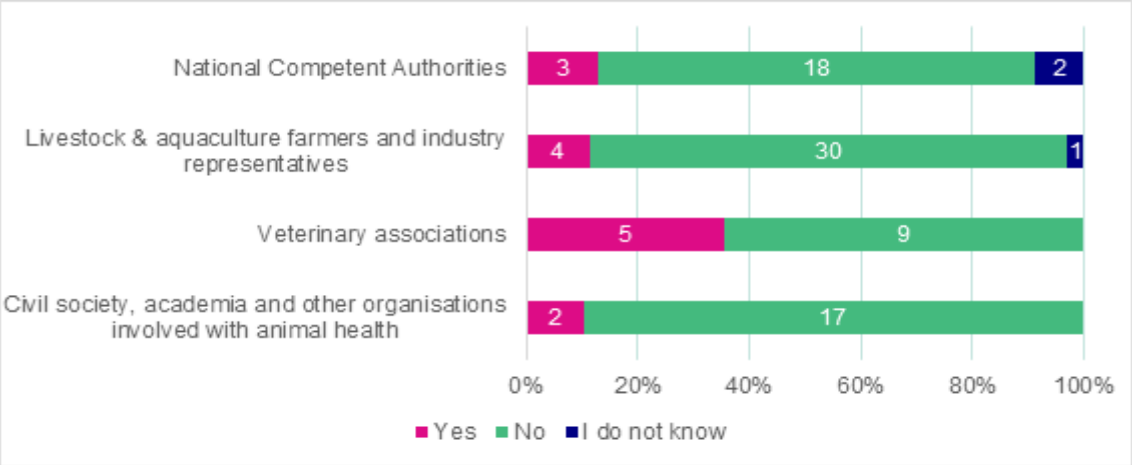
management of transboundary animal diseases and in safeguarding the smooth functioning of the internal market for animals and animal products.

Common EU rules on surveillance, traceability, animal movements and disease control enable coordinated action, faster responses to outbreaks and greater mutual trust between Member States. Tools such as regionalisation further help contain disease risks while preserving trade continuity where justified.

While differences in national implementation can affect the consistency of outcomes, they do not undermine the overall added value of EU action. Overall, the AHL provides substantial benefits in terms of effectiveness, legal certainty and market confidence that go beyond what national measures alone could reasonably deliver.

The evidence indicates that the AHL has achieved the objective of ensuring coordinated and effective animal health management across Member States to a large extent**.** Its core contribution lies in establishing a single, harmonised framework for disease prevention, surveillance, control, animal movements and certification across the Union. In the targeted survey, a large majority of respondents (see Figure 21) confirmed that all key stakeholder groups consider that comparable results could not have been achieved through national action alone (81% overall), including 18 out of 23 national competent authorities (NCAs), 30 out of 35 farmers and industry representatives, 9 out of 14 veterinary associations and 17 out of 19 civil society and research organisations. In addition, 30 out of 35 industry respondents indicated that maintaining current levels of intra-EU movements without increasing disease risks would not be feasible without a harmonised EU framework.

Figure 21 – Survey replies to the question 'Could the same results have been achieved by national animal health measures and systems alone, without the EU AHL?'



Source: External study (N= 91)

The added value of EU action is particularly evident in areas requiring cross-border coordination. National competent authorities and industry stakeholders highlighted the importance of regionalisation and compartmentalisation, which allow the safe continuation of trade from unaffected areas during outbreaks. Stakeholders referred in

particular to France's experience[60] during highly pathogenic avian influenza outbreaks, where these tools helped preserve trade continuity while containing disease risks.

National authorities and veterinary stakeholders also emphasised the role of common traceability and notification systems, notably ADIS, in enabling timely information exchange and coordinated responses between Member States. Industry representatives and competent authorities further pointed to harmonised EU rules and model certificates as important factors supporting transparency, credibility and recognition in trade with third countries. Practitioners also underlined wider system benefits, including clearer allocation of responsibilities for operators and a common legal basis facilitating the integration of wildlife surveillance into preparedness and contingency planning.

These mechanisms generate benefits across stakeholder groups. Competent authorities benefit from predictable coordination tools and common rules; operators and farmers from greater market stability and fairer competitive conditions; veterinarians from more harmonised practices across Member States; and civil society and research organisations from stronger confidence in animal and public health protection.

Some limitations nevertheless affect the extent to which EU added value is fully realised in practice. Differences in national implementation and the use of flexibility provisions can affect the predictability of animal movements and create uneven conditions for operators. In addition, given that the AHL has applied fully only since 2021, further time and evidence will be needed to assess its full impact on longer-term animal health outcomes and trade flows.

Proportionality and balance between EU and national action

The evaluation finds that the balance between EU action and national flexibility is broadly appropriate and proportionate. The AHL establishes common Union rules while allowing Member States to adapt measures to national epidemiological conditions through risk-based approaches, regionalisation and targeted derogations. Consultation evidence shows broad agreement across stakeholder groups that such a harmonised framework is necessary, given the cross-border nature of animal diseases and the need to safeguard the internal market.

Overall, the framework is considered justified at EU level, with challenges arising mainly from implementation rather than from the design of the framework itself. The main issue identified is the need to ensure that national implementation remains sufficiently aligned to preserve coherence, predictability and mutual trust across the Union.

Areas for further strengthening

While the AHL delivers clear EU added value, stakeholders identified targeted opportunities to further strengthen EU-level action. Farmers and industry representatives emphasised the value of concise, sector-specific guidance adapted to different production systems.[61] National authorities and veterinarians also called for greater consistency across Member States, while preserving necessary flexibility, including stronger minimum biosecurity baselines and better exchange of good practices through practical guidance,

60 External study, Annex 3, p. CCLIV.
61 External study, Annex 3, p VIII.

case libraries and peer learning.[62] Strengthening implementation capacity, in particular through more effective use of the veterinary workforce and improved access to consolidated EU guidance, was also identified as a priority. These improvements would enhance the effectiveness of the framework without calling into question its overall design or added value.[63]

4.3 Is the intervention still relevant?

The evaluation finds that the AHL remains relevant to current and emerging animal health challenges. Its risk-based and flexible design enables it to respond to changing epidemiological conditions, including pressures linked to climate change, wildlife reservoirs and global trade.

Stakeholders broadly confirm its relevance, though more mixed views from farmers, industry and veterinarians reflect practical implementation challenges.

The framework provides a coherent, integrated approach and has demonstrated adaptability in recent outbreaks.

Remaining challenges relate mainly to implementation. Differences in national systems, capacity and digitalisation create fragmentation, duplication and administrative burden. These issues stem primarily from implementation rather than the AHL's legal design. Overall, the AHL remains fit for purpose, while requiring targeted adjustments and effective implementation in a changing risk environment.

Relevance and fitness for purpose

The objective of the AHL is to provide a comprehensive, risk-based framework capable of addressing current and emerging animal health challenges. The available evidence indicates that this objective remains broadly valid and that the framework continues to be relevant and fit for purpose.

Consultation results (see Figure 22) show that 53 out of 91 respondents (58%) considered the AHL's provisions fit for purpose, including 14 respondents to a large extent and 39 to a moderate extent. Support nevertheless varies across stakeholder groups. The most positive assessments were recorded among national competent authorities, where 21 out of 23 respondents expressed a positive view, including a relatively high share to a large extent (8 respondents). Civil society, academia and other organisations active in animal health also reported strong support, with 15 out of 19 respondents (79%) considering the AHL fit for purpose.

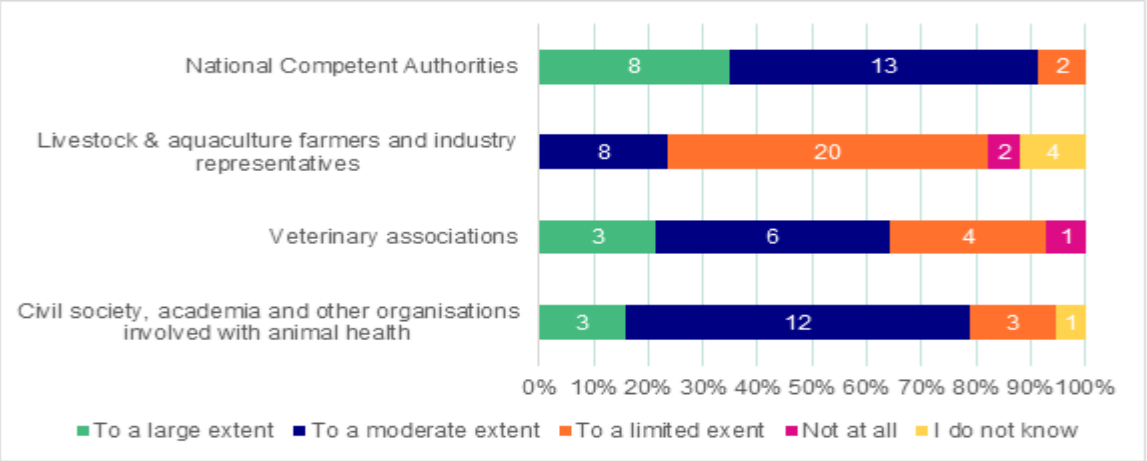
Views among farmers, industry representatives and veterinary associations were more mixed, with a greater share indicating that the framework is fit for purpose only to a limited extent. This suggests broad recognition of the continued relevance of the AHL,

[62] External study, Annex 3, p V.

[63] Foundational work for this has been provided by Duarte et al. (2025, Methods to assess on-farm biosecurity in Europe and beyond. Preventive Veterinary Medicine 239: 106486), offering a comprehensive overview of biosecurity assessment methods in Europe.

while highlighting differing perceptions linked to practical implementation experience and regulatory burden.

Figure 22 – Survey replies to the question 'To what extent do you find the provisions of the AHL fit and relevant to the current animal health challenges?'



Source: external study (N= 91).

The AHL's continued relevance stems from its comprehensive and forward-looking design. By integrating prevention, preparedness, surveillance, movement controls and disease management within a single framework, it replaced fragmented disease-specific legislation with a more coherent and risk-based approach. Stakeholders widely consider this better suited to addressing increasingly complex risks, including emerging and vector-borne diseases. The framework also supports safe intra-EU movements by reducing the risk of divergent national measures disrupting trade and the internal market. Stakeholders nevertheless emphasised that sufficient flexibility remains necessary to respond to evolving epidemiological conditions.

The framework appears broadly adaptable across Member States, although differences in administrative capacity and existing systems affect the speed with which some key risk-based elements are operationalised. While some countries, e.g. Ireland, Germany, France, Italy and the Netherlands, have already operationalised key elements such as animal health visits and biosecurity, others are still adapting their frameworks.

Disease categorisation is also widely regarded as a key lever for supporting harmonised and proportionate action. However, for certain diseases, divergent national approaches to vaccination and control continue to create challenges for intra-EU movements, indicating scope for further alignment potentially to the detriment of the flexibility.

Training and knowledge dissemination also contribute to continued relevance. The BTSF programme is widely valued by competent authorities, while stakeholders emphasise the need for continued practical guidance and training, particularly for operators facing evolving risks.

Capacity to adapt to evolving threats

A key objective of the AHL is to provide a flexible framework capable of responding to evolving animal health threats. The available evidence indicates that this objective has been largely achieved. By combining a basic regulation with delegated and implementing

acts, the AHL allows rules to be updated in light of scientific evidence and operational experience. Stakeholder consultations and case studies indicate that this design has enabled adjustments to surveillance, prevention and control measures during outbreaks while maintaining alignment with epidemiological risks.

For example, Delegated Regulation (EU) 2020/687[64] was amended to improve the proportionality and coherence of disease control measures and to reflect new scientific evidence and outbreak experience, illustrating the framework's capacity to adapt over time. The disease listing and categorisation system further strengthens adaptability by linking measures to risk. Diseases requiring harmonized Union intervention (Categories A and B), such as ASF, FMD and HPAI, trigger rapid and coordinated responses across Member States. For other diseases (Categories C, D and E), the framework allows greater flexibility, enabling Member States to tailor measures to national epidemiological conditions and available resources.

Recent outbreaks demonstrate the practical value of this approach. Large-scale HPAI outbreaks, including in France and the Netherlands, led to additional control and vaccination strategies, while the emergence of new bluetongue virus (BTV-3) strains required adjustments to surveillance and movement rules. Compared with the previous disease-specific directives, the AHL provides a more coherent and risk-based system for adapting measures to changing epidemiological developments.

At the same time, flexibility for certain Category C, D and E diseases has resulted in varying national approaches (see Box 3), particularly for diseases involving vectors or wildlife reservoirs. Differences in vaccination strategies, surveillance systems and movement requirements have created inconsistencies across Member States. For intra-EU movements, this has generated practical challenges, including divergent health conditions between origin and destination countries, additional administrative requirements and, in some cases, trade disruptions.

Box 3 – Bluetongue virus[65]

Bluetongue virus is present in several Member States and illustrates both the adaptability of the AHL framework and the challenges created by divergent national implementation. In 2023, BTV-3 emerged in the Netherlands, severely affecting sheep populations and causing morbidity and mortality in cattle. BTV-3 outbreaks in Belgium and Germany also led to the loss of disease-free status, while Spain continued to report BTV-1 and BTV-4.

As a Category C disease, bluetongue allows Member States to apply measures aimed at preventing spread to disease-free areas or those operating eradication programmes. This flexibility has enabled national responses tailored to local epidemiological conditions, including different vaccination and control strategies.

64 Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases, http://data.europa.eu/eli/reg_del/2020/687/oj.

65 External study, p. 145.

However, these differing approaches have also created challenges for intra-EU animal movements. Under Delegated Regulation (EU) 2020/688[66], movements may take place under agreed health conditions, but these conditions can vary between origin, destination and transit Member States. Stakeholders reported that this has created complexity, legal uncertainty and, in some cases, trade disruption.

During consultations, certain stakeholders called for a more harmonised EU approach to bluetongue management. Views differed on whether this should involve reclassification of BTV-3, broader changes covering multiple serotypes, or more uniform pre-movement health requirements.

In addition, the coexistence of the AHL with certain disease-specific frameworks, notably TSEs and Salmonella, has in some cases created overlaps that are not fully aligned with the AHL's risk-based approach, resulting in additional burden and reduced coherence. For example, the Netherlands reported around EUR 4.2 million in extra BSE/TSE monitoring costs in 2024, partly linked to BTV-3 outbreaks that increased the number of animals subject to routine testing and raised expenditure by around 20%[67]. These issues appear to stem mainly from interactions between policy frameworks and implementation arrangements rather than from shortcomings in the design of the AHL itself.

Issues requiring further attention

Only a limited number of issues requiring further attention were identified, i.e. vector-borne diseases such as BTV that illustrate clearly the need for continued coordination, as divergent national approaches to surveillance, vaccination and movement restrictions can create frictions for intra-EU movements. Stakeholders also identified practical improvements to ADIS, noting that simplified pre-notification followed by updates could improve timeliness during urgent situations.

The interaction between the AHL and wider EU policies, particularly on antimicrobial use, was also raised. Some veterinarians and livestock representatives expressed concerns that rigid implementation of reduction measures may in specific cases constrain professional judgement. These concerns relate primarily to policy interaction rather than the design of the AHL itself.

Overall, the AHL remains relevant and fit for purpose. The remaining issues identified are targeted and operational in nature, pointing mainly to the need for continued coordination, practical simplification and effective implementation support across the Union.

What are the conclusions and lessons learned?

5.1 Conclusions

66 Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs, http://data.europa.eu/eli/reg_del/2020/688/oj.

67 External study, Annex 3, p. 146.

This evaluation finds that the AHL has been effective in establishing a modern, coherent and risk-based framework for animal health in the Union, replacing a fragmented set of disease-specific rules with a more integrated legislative architecture. Its core mechanisms, linking disease listing and categorisation to proportionate surveillance, movement conditions and control measures, provide a structured basis for coordinated action and contribute to improved predictability in disease management across Member States. Regardless, these conclusions should be read considering the methodological limitations of the evaluation and the relatively short period since the AHL became applicable in 2021. Some effects, especially those linked to structural improvements in prevention and preparedness, are likely to become more visible as implementation continues.

The AHL has strengthened disease prevention and control through enhanced surveillance, clearer notification obligations, EU-wide tools such as ADIS, reinforced biosecurity and clearer responsibilities for authorities, operators and veterinarians. It also provides a solid framework for vaccine banks, vaccination, regionalisation and compartmentalisation, supporting more targeted outbreak responses. However, effectiveness is constrained by uneven implementation across Member States. Differences remain in surveillance, timeliness of notification, preventive measures and use of flexibility tools. The wider legal framework and uneven dissemination of guidance have also affected understanding and consistent application in some cases. Overall, while the AHL has significantly improved EU prevention, preparedness and coordinated disease control, its full effectiveness depends on more consistent implementation and sufficient national capacity.

Regarding efficiency, the AHL has simplified and harmonised important administrative procedures, notably through clearer rules for establishment registration and approval, harmonised health documentation, and EU-level IT systems that support coordination and reporting. Efficiency gains remain uneven, however, due to differing administrative practices, legacy systems and varying veterinary and laboratory capacity. Certain preventive obligations, such as animal health visits and additional registration requirements, created additional costs, especially where such measures were previously absent. These costs appear broadly proportionate to the benefits, though quantitative evidence remains limited.

The AHL remains highly relevant in the current epidemiological and policy context. It addresses increasing disease pressures, evolving risks and growing trade complexity through a preventive and risk-based approach. Recent outbreaks of ASF, HPAI, FMD and LSD confirm the continued need for a coordinated EU framework. The AHL is also well aligned with broader EU objectives, notably the One Health approach.

The evaluation finds a high degree of internal coherence, with disease categorisation creating a structured link between surveillance, movement conditions and control measures. External coherence with the Official Controls Regulation, food safety and zoonoses legislation, veterinary medicinal products and feed legislation is overall strong. Some operational interfaces, particularly with animal welfare rules, e.g. when implementing disease control measures such as movement restrictions and culling during outbreaks, can nevertheless create practical challenges.

The evaluation confirms the clear EU added value of the AHL. Harmonised rules on surveillance, prevention, control, movements and entry into the Union support coordinated action, a level playing field and safe trade. Union-level tools such as disease

categorisation, vaccine banks, ADIS, EU laboratory networks and regionalisation underpin effective cross-border coordination. Requirements for entry into the Union broadly mirror EU standards and are consistent with WOAH standards and WTO/SPS principles. These results could not have been achieved to the same extent by Member States acting alone.

Taken together, the AHL has significantly strengthened the EU animal health framework by shifting the focus towards prevention, improving preparedness and creating a more coherent legislative structure. Its full benefits, however, depend on consistent implementation and sufficient administrative and operational capacity across Member States. Given the recent application of the framework and phased adoption of implementing measures, not all intended effects can yet be fully observed. Continued monitoring therefore remains important.

5.2 Lessons learned

Implementation to date has shown in this evaluation that the AHL provides a strong and modern framework for EU animal health policy. At the same time, several lessons emerge for the continued functioning of the complex, risk-based EU regulatory system:

Strengthening the single policy and legal framework: the AHL has established a clearer and more coherent legal structure. However, the number and complexity of delegated and implementing acts, combined with uneven national alignment, can affect accessibility, legal clarity and consistent application. Continued efforts to improve guidance, explain links between legal acts and raise stakeholder awareness remain important.

Clarifying responsibilities of different actors and strengthening compliance: the AHL has strengthened the allocation of responsibilities. However, outbreak situations show that effective implementation also depends on clear coordination arrangements, operational planning and a common understanding of roles. Differences in enforcement and sanctioning approaches can also affect consistency.

Disease categorisation needs to stay responsive to changing risks: the disease listing and categorisation system provides a strong basis for proportionate and science-based measures. Its continued effectiveness depends on remaining responsive to epidemiological risks, including emerging, vector-borne and wildlife-related diseases, and to different regional contexts.

Preparedness requires regular updating and testing: the AHL has strengthened contingency planning and crisis-management tools. Their effectiveness depends on plans being regularly updated, practically tested and supported by sufficient veterinary and administrative capacity across Member States.

Regionalisation and compartmentalisation require consistent use: these tools can support more targeted disease control while helping maintain movements and trade. Their benefits depend on a common understanding and consistent application by authorities and operators, including recognition by trading partners where relevant.

Ensuring consistent and proportionate implementation while reducing complexity: the AHL's risk-based approach and flexibility are key strengths, allowing measures to be tailored to different epidemiological situations. At the same time, differences in the use of derogations, national measures and interpretation have contributed to uneven implementation, which may affect consistency and the level playing field within the internal market. While the AHL has simplified and modernised the previous framework, administrative burden and complexity may persist where national rules diverge or additional requirements are introduced. This underlines the importance of consistent implementation, clear understanding of available flexibilities and continued simplification in practice.

Prevention depends on implementation capacity: the stronger focus on prevention is a central feature of the AHL. However, implementation of preventive measures, including biosecurity, vaccination, surveillance and animal health visits, remains uneven and is closely linked to resources, in particular national veterinary and administrative capacity. Experience to date suggests that the benefit of the preventive approach depends on consistency across MS.

Effective vaccination requires practical readiness: the AHL enables a broader and more flexible use of vaccination, which has already contributed to mitigating the impact of certain diseases as well as establishment of the vaccine banks against several diseases. At the same time, practical challenges remain, including availability of vaccines, logistical constraints and broader conditions affecting uptake and deployment, such as wider acceptance of commodities from a vaccinated animal population by certain trading partners.

Funding directly influences implementation: experience with the AHL indicates that the distribution of costs between operators, national authorities, Member States and the Union have a direct impact on incentives, acceptance and the practical implementation of preventive and outbreak-related measures. This is particularly relevant for farmers and other operators affected by movement restrictions, culling, mandatory biosecurity upgrades, additional registration requirements or animal health visits. Where costs linked to prevention or disease control are perceived as disproportionate, or where compensation and support arrangements lack predictability, this may affect willingness to invest early in preventive measures, timely reporting of suspicions or broader acceptance of control actions. Differences in national financing and compensation systems may also create uneven implementation conditions across Member States. Experience to date suggests that stable, predictable and sufficiently targeted financial support can play an important role in supporting compliance, preparedness and the effective functioning of the framework across the Union.

Coherence benefits from continued cross-sector cooperation: the AHL is broadly coherent with related EU frameworks and provides a strong basis for applying the One Health approach through animal disease surveillance, prevention and control. At the same time, fully operationalising One Health in practice depends on effective cooperation across animal, human and environmental health systems, particularly for zoonotic and wildlife-related risks, where cross-sectoral coordination remains uneven. While overall alignment is strong, certain interfaces with pre-existing rules, notably on animal welfare, TSEs and zoonoses, may still affect the clarity and efficiency of the wider framework.

Annex I. Procedural Information

1. Lead DG, Decide Planning / CWP references

The evaluation was led by DG SANTE and overseen by an Inter-Service Steering Group (ISSG), co-chaired by DG SANTE. It was registered in the DECIDE/Agenda Planning database under reference PLAN/2023/2653 and is listed in the 2026 Commission Work Programme as the "Report from the Commission to the European Parliament and to the Council on the evaluation of Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law')".

2. Exceptions to the Better Regulation Guidelines

No exceptions were made to Better Regulation Guidelines during this Evaluation.

3. Organisation and timing

An Inter-Service Coordination Group (ISCG) assisted DG Health and Food Safety in the evaluation process. The ISSG included Commission services from the Secretariat-General, the Legal Service, DG TRADE, DG ENV, DG AGRI, DG MARE and DG GROW. In total, six meetings were held in relation to the evaluation of the Animal Health Law, with the final meeting taking place on 13 April 2026. During this meeting, the ISSG discussed the draft Staff Working Document ('SWD') and the draft final report. Several Commission services provided written comments on the evaluation documents. These comments were taken into account in the revised version of the SWD and its annexes.

4. Evidence and sources

The evidence underpinning this Staff Working Document (SWD) is drawn from an external evaluation study, a call for evidence, and targeted consultation activities. The evidence base consists of two main components: analysis of available documentation and stakeholder consultation.

The SWD is primarily informed by an evaluation study carried out by an independent contractor under framework contract No SANTE/2024/G2/007 - SI2.919570 ("Study supporting the Evaluation of the EU Animal Health Law"). The study was conducted between September 2024 and October 2025 under the guidance of the Inter-Service Coordination Group (ISSG).

Its objective was to collect and analyse data to support the European Commission's evaluation of the Animal Health Law (AHL), with a particular focus on the five Better Regulation criteria: effectiveness, efficiency, relevance, coherence and EU added value. This assessment examines the extent to which the legislation functions in practice across Member States and for relevant stakeholders, identifying both strengths and areas for improvement, in line with Article 282.

The study covers the implementation of Regulation (EU) 2016/429 over the period 2016–2024, with a primary focus on its application since 21 April 2021. The geographical scope includes all 27 EU Member States, with more limited consideration of European Economic Area (EEA) countries and candidate countries.

Additional evidence is drawn from a call for evidence launched in March 2024, which gathered input from 942 stakeholders. This input supports the identification of key issues and informs ongoing reflections on potential improvements to the AHL framework.

Several policy areas interact with the AHL and influence its practical implementation. The Official Controls Regulation establishes the framework for enforcement of animal health measures, while IT systems within IMSOC, including TRACES and ADIS, create operational interdependencies in both routine activities and disease outbreaks, significantly contributing to procedural simplification. Although governed partly by separate legal frameworks, these systems are integral to disease notification, traceability and enforcement, and therefore directly affect the functioning of the AHL.

The AHL also contributes to the EU's One Health approach, notably through coordinated surveillance, data sharing and risk assessment for zoonotic diseases, requiring interaction with public health authorities and laboratory networks.

Interfaces with sanitary and phytosanitary (SPS) rules are relevant for import conditions, listing of third countries and establishments, and intra-EU movements of animals and animal products.

Environmental legislation is considered only where it directly affects operational aspects of disease control, such as wildlife disease management or the disposal of animal by-products during outbreak response.

Other areas, such as animal welfare, veterinary medicinal products, residue monitoring, food safety and plant health, interact with specific aspects of disease management but do not materially alter the core obligations of the AHL. EU financial support under the Single Market Programme (SMP) is considered where it directly supports implementation, for example through co-financing of eradication programmes or emergency measures.

This delineation ensures that the evaluation remains focused on the performance of the AHL itself, in line with Better Regulation principles. Only interactions that have a substantive impact on effectiveness, efficiency, relevance, coherence or EU added value are assessed.

Annex II. Methodology and Analytical models used

The methodology of the SWD evaluation is mixed methods. This is an approach that uses both quantitative and qualitative data sources in harmony to answer and affect the outcome of the evaluation. The chosen approach has certain strengths and disadvantages, that this annex will cover.

The strengths are better and more comprehensive insights to the evaluation. This heightened insight is key to understand the extend of the performance and the depth of how it functions, which is not possible under just quantitative or qualitative methods. This also allows for flexible by being less strict on the methods and higher validity and reliability through triangulation. As the requirements of the evaluation is to produce sound knowledge in depth

The disadvantage to the approach lies in the higher complexity, resources and troubles with the analytical framework. Integrating both qualitative and quantitative approaches requires a data integration, which is both complex and resource demanding. If the data integration is not done properly through triangulation both validity and reliability will be low. Additionally, there is a risk of potential bias due to nature of interpretation of both quantitative and qualitative results. To reduce the disadvantages, multiple sources and a synthesis of both methods.

The work group picked the mixed method approach, because other methodological approaches are insufficient in obtaining both in depth knowledge and numerical data to truly capture how the SWD performs. The specific methods used are interviews, survey, desk research and case studies. The quality of the analysis is high due to a combination of triangulation, inclusion of supporting studies and other sources.

The evaluation does contain limitations, that must be addressed.

1. Limited data, which is mitigated by triangulation and reinforcement of additional sources.
2. Implementation time of legislation reduces the full measurable effect.

Stakeholder consultation strategies. The consultation strategies used primarily “call for evidence” and other tools. These tools are interviews (40+), targeted survey (3 to 5), focus groups and workshops. The timeline ranges from Q1 2024 to Q1 2025. The strategy has successfully managed to capture the feedback and opinions of various relevant stakeholders in a good balance. This means the evaluation is representative of how national authorities, industry and other civilian actors are affected by the legislation.

The evaluation is good on validity and okey on reliability. In terms of reliability, the evaluation does contain some problems due to limited data. This has the consequence, that the evaluation cannot guarantee a reproduction of the same results over multiple tests. To mitigate this, additional studies and desk research has been used to support the data we have. In terms of validity, the evaluation uses multiple indicators to truly capture the effects of the legislation (see annex 3). Thus, Validity is good, where mitigation measures are indirectly built into the evaluation due to multiple indicators meaning, if some indicators fail others will detect it.

Annex III. Evaluation matrix and, where relevant, Details on answers to the evaluation questions (by criterion)

Effectiveness

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
Effectiveness					
Effi 1.1 What were the main challenges in the implementing phase after April 2021? To what extent have these been addressed?	1.1.1 To which extent were MS able to align their national legislation with the new EU legislative framework in due time? To which extent did MS opt for an alignment of national law with AHL by consolidating existing text versus repealing existing text? 1.1.2 Which were the challenges faced by MS in implementing the AHL after its	1.1.1 Level of alignment of national legislation to AHL across MS 1.1.2 Identification of challenges in the implementation of AHL in Member States 1.1.3-4 Measures taken at EU level	1.1.1 Number of Member States that have fully aligned their national legislation	- MSs reports	Member States were largely able to align their national legislation with the AHL within the required timeframe, contributing to a more harmonised framework. However, the extent and approach varied: some consolidated existing legislation into the new framework, while others repealed and replaced national rules. Differences in alignment reflect varying administrative capacity and legal traditions. Key challenges included the complexity of the framework, uneven clarity of certain provisions, limited administrative and veterinary resources, and differences in national interpretation. Practical issues also arose from gaps in digital systems, workforce constraints, and partial implementation of obligations such
			1.1.1 Number of Member States that have partially aligned their national legislation	- MSs reports	
			1.1.1 Number of Member States that have not aligned their national legislation	- MSs reports	
			1.1.1 Degree of significance of the lack of adaptation	- Audit reports	
			1.1.1 Type of alignment carried out by MS	- MSs reports	
			1.1.1 Timing of legislative adaptation	- Annual reports	
			1.1.2 Challenges identified by stakeholders that affect the implementation of the AHL at national level	- Audit reports	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	entry into force? (e.g. complexity of the regulations; lack of clarity ; insufficient resources, resistance from stakeholders, lack of coordination) 1.1.3 How and to which extent were challenges addressed at the EU level? 1.1.4 How and to which extent were those challenges addressed at national level?		1.1.2 Types of challenges identified by stakeholders (uneven starting point, regulatory, administrative, financial, technical, cultural, etc.)	- MSs reports - Audit reports	as biosecurity, animal health visits, and contingency planning. At EU level, challenges were addressed through guidance, coordination mechanisms, and digital tools such as ADIS and TRACES, which improved surveillance, notification, and data exchange. The AHL itself strengthened legal clarity, defined responsibilities, and introduced structured approaches to disease management, supporting more coordinated implementation. At national level, Member States addressed challenges through legislative adjustments, administrative measures, and gradual strengthening of implementation systems. However, progress remains uneven, with continued differences in enforcement, resource allocation, and system capacity affecting the full and consistent application of the AHL External study, p. 52
			1.1.2 The size and structure of MS affect the implementation of AHL	- Audit reports	
			1.1.3 Measures taken at the EU level to address identified challenges (Number of Implementing Acts/Delegated Acts)/and the amendments to these Acts	- Eu legislation changes EU website	
			1.1.3 Timing of Adoption of tertiary legislations	- Audit reports	
			1.1.3 Evidence of adequate and regular training sessions organised	- Annual reports - Audit reports	
			1.1.3 Best practices shared		
			1.1.4 Measures taken at national level to address identified challenges (e.g. establishment of Task force, Committee, training session)	- Ms reports - Audit reports	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
Effe 1.2 To what extent has the AHL legislation achieved its general and specific objectives?	1.2.1 What progress has been made towards the achievement of the general objective of preventing and controlling animal diseases transmissible to animals or humans by: - ensuring improved animal health to support sustainable agricultural and aquaculture production [Art.1(2.a.i)] - ensuring the effective functioning of the internal market for the livestock and aquaculture sector and other	1.2.1.1 Evidence of progress towards the general objectives 1.2.1.2 The AHL is effective in preventing and controlling animal diseases 1.2.1.3 Stakeholder perception on the AHL contribution to the achievement of expected results 1.2.1.4 Measurable improvements in the health status of animals since the implementation of AHL 1.2.1.5 Availability and effectiveness of training programmes focused on animal health and sustainable practices 1.2.1.6 Stability, competitiveness, growth of livestock and aquaculture market 1.2.1.7 Evidence of no significant disruptions in the Internal market	1.2.1.1 Stakeholder views on the reasons for (un)success in achieving the general objective	- Input during PAFF and other meetings by stakeholders	The AHL has made clear progress towards achieving its general and specific objectives by establishing a harmonised and prevention-oriented framework, improving disease control, and supporting trade through tools such as regionalisation and traceability. It has also simplified the legal framework and introduced a flexible, risk-based approach to emerging diseases. However, its full effectiveness is not yet realised due to uneven implementation, complexity in practice, and the early stage of application, which limits a complete assessment of outcomes. External study p 60
			1.2.1.1 Number of areas declared disease-free following to the implementation of eradication programmes	- https://food.ec.europa.eu/animals/animal-diseases/surveillance-eradication-programmes-and-disease-free-status_en#disease-free-areas	
			1.2.1.1 Change in the number and quality of animal health visits from veterinarians [Art.25] since the introduction of AHL	- Audit reports	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	kept animals [Art.1(2.a.ii)] - reducing adverse effects of animal diseases on animal health, public health and the environment [Art.1(2.a.iii)]?		1.2.1.2 Appropriate systems are in place to ensure the traceability of kept terrestrial animals, aquatic animals and germinal products [Art. 108-123; 186-190]	- Audit reports	
			1.2.1.2 Appropriate (preventive) measures are undertaken for movements of kept animals [Art124-169; 191-225; 244-251]	- Audit reports	
			1.2.1.2.2-3 The availability/number of veterinarians carrying out regular visits is deemed suitable by stakeholders	- Audit reports	
			1.2.1.2 The frequency of health visits is deemed suitable by stakeholders	- Audit reports - FVE report on art. 25	
			1.2.1.1 Number and quality of contingency plans and simulation exercises conducted [Art.43;45]	- MS reports - Audit reports	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
			1.2.1.1 Union antigen, vaccine and diagnostic reagent banks are established and provide sufficient stocks and supplies [Art.48]		
			1.2.1.4 Uptake (and number) of training among staff and veterinarians [Art.13]	- MS reports - Audit reports	
			1.2.1.5 Strengthened competitiveness of farming and the rural economy (I)	- Interviews	
			1.2.1.6 Market data (volumes, prices, trade flows) are maintained or increased	- Desk research: Comext database and Eurostat - Focus groups (Questions on potential benefits for trade due to AHL introduction)	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
			1.2.1.6 Trade flows are maintained and undisrupted	- Desk research: Comext database and Eurostat - Focus groups (Questions on potential benefits for trade due to AHL introduction)	
	1.2.2 To which extent did the AHL achieve its specific objective of establishing a single, simplified, transparent and clear regulatory framework by providing a clear and balanced distribution of	1.2.2.1 There is adequate clarity across actors regarding their roles and responsibilities 1.2.2.2 There is adequate balanced distribution of roles and responsibilities 1.2.2.3 The AHL has introduced simplified procedures 1.2.2.4 The regulatory framework reduces complexity and	1.2.2.2.1-2 Stakeholders' views regarding clarity and benefit of the role and responsibilities outlined by the AHL	- Survey	
			1.2.2.3 Stakeholder views on the new rules and procedures introduced by the AHL	- Survey	
			1.2.2.4 Stakeholder views on the rules and procedures that were already covered by the AHL and that have been updated and simplified	- Survey	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	roles and responsibilities and introducing simplified procedures?	administrative burden for stakeholders 1.2.2.5 There is evidence of effective responses due to simplified procedures	1.2.2.4 Good governance and compliance with international standards (WOAH) (R)	- Interviews with international organisations	
			1.2.2.5 Existing and well-functioning online information system to register and document the evolution of diseases [Art.22] (O)	- Desk research: disease notification systems and audit reports	
			1.2.2.5 and 1.2.1 Number and of disease notification within MS, to other MS and to the EC [Art 18-21] (O)	- Disease notification systems and audit reports	
			1.2.2.5 Protocols have been developed to ensure effective and rapid emergency measures in cases of outbreak or hazard [Art. 257-262] (O)	- Disease notification systems and audit reports	
			1.2.2.5 Existing and well-functioning online information system to track animal movements	- Traces valuation	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
			1.2.3.6 Degree of coordination between veterinary and human health authorities		
	1.2.4 To which extent did the AHL achieve its specific objective of ensuring consistency among principles of animal health, animal welfare and food safety legislation?	1.2.4.1 The AHL ensures, through its principles, consistency with the principle of animal welfare 1.2.4.2 The AHL ensures, through its principles, consistency with the principle of food safety 1.2.4.3 The AHL ensures, through its principles, consistency with the principle of One Health	1.2.4.1-3 Coherence with food safety, animal welfare, One Health regulation and wider strategic policy objectives	- Surveys - Findings from EQ coherence - Interviews - Case studies	
	1.2.5 To which extent did the AHL achieve its specific objective of reducing the socio-economic impact of animal diseases on public health, animal welfare, economy and	1.2.5.1 The social impact of animal diseases in terms of public health is reduced thanks to the AHL 1.2.5.2. The social impact of animal disease in terms of (reduced) animal welfare is reduced	1.2.5.1.1 Reduction in disease incidents of more dangerous, rapidly spreading both animal and zoonotic)disease (with a focus on Cat A diseases)	- ADIS	
			1.2.5.1.4 Stakeholders' views on the social impact of AHL	- Surveys	
			1.2.5.2.1 Improved public perception of animal health	- Call for Evidence - Interviews	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	society while reducing the risks of trade disruption?	1.2.5.3 The economic impact of animal diseases is reduced 1.2.5.4 Trade flows are improved by the implementation of the AHL	1.2.5.2.2 Reduction of animal health disparities across socio-economic groups (MS eastern versus western/ Farmers small versus bigger)	- Interviews - Focus groups	
			1.2.5.2.3 Reduction of animal health disparities across socio-economic groups (MS eastern versus western/ Farmers small versus bigger)	- Case studies	
			1..2.5.2.4 Risks of interference with the internal market due to animal disease are minimised (R)	- Surveys	
			1.2.5.2.5 Trade flows are maintained without significant disruptions.	- Desk research: Comext database	
Effe 1.3 How do these results compare with the initial expectations?	1.3.1 Has the AHL led to an improvement in terms of disease control and prevention? 1.3.2 How do the results compare	1.3.1 The implementation of AHL meets the initial expectations as outlined in the Impact Assessment, Strategy and Legislation 1.3.2 Stakeholders' view on the implementation of AHL and the initial expectations	1.3.1 Number of outbreaks of listed disease	- : Adis	The results of the AHL broadly align with initial expectations. It has delivered a flexible, coherent, and risk-based framework, supporting prevention, improved coordination, and internal market stability. The shift towards a proactive approach has
			1.3.1 Trade of live animals and animal products to 3rd countries	- Desk research: Comext database	
			1.3.2. Stakeholders' view on results alignment with initial expectations	- Call for Evidence	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	to the expectations set forth in the Impact Assessment and the Animal Health Strategy 2007-2012, as well as in the legislation? 1.3.3 Is the One Health principle reflected in the national legislation related to animal health?	1.3.3 National legislation reflects the One Health approach in their legislation related to animal health	1.3.3 Stakeholders' view regarding AHL contribution to the one health approach	- Surveys (Q33 on coherence)	strengthened preparedness and response capacities. However, implementation has been more complex than anticipated, with delays and inconsistencies in aligning national legislation across Member States. External study , p 82
Effe 1.4 What are the strengths and weaknesses of the AHL, in particular in relation to specific provisions, regarding:	1.4.1 Does the AHL clearly outline the roles and responsibilities across different actors involved in animal health?	1.4.1 Roles and responsibilities for actors, e.g. competent authorities and stakeholders, are clearer and are defined in the AHL 1.4.2 EU priorities and their articulation with the AHL	1.4.1 Stakeholders' views on the clarity of roles and responsibilities defined by the AHL	- Interviews	The AHL's key strengths include clearer roles and responsibilities across stakeholders, improved coordination, and a strong risk-based approach enabling targeted EU intervention through tools such as disease categorisation and
			1.4.2 Stakeholders' views on the priorities for the EU intervention and limiting factors are clearly outlined in the AHL	- Surveys (linked to external coherence)	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
- clearer responsibilities - Priorities for EU intervention - prevention, including biosecurity and surveillance?	1.4.2 Is the link with EU priorities clearly set in the AHL? 1.4.3 Are there any limiting factors in linking the AHL to the wider EU priorities? 1.4.4 Has prevention, including biosecurity and surveillance, improved in the EU since the adoption of the AHL?	intervention logic are clearly set in the AHL text 1.4.3 Limiting factors that could hamper the consistency of the AHL with wider EU priorities are mentioned in the AHL text 1.4.4 Level of improvement of prevention, biosecurity and surveillance	1.4.3 Stakeholders' views on the priorities for the EU intervention and limiting factors are clearly outlined in the AHL	- Surveys (linked to external coherence)	regionalisation. It has strengthened prevention, particularly through biosecurity and surveillance, and modernised the legal framework, supporting measures like vaccination and maintaining trade during outbreaks. However, weaknesses remain in uneven implementation, limited stakeholder engagement, and gaps in communication. Biosecurity and prevention measures are not consistently applied across sectors and Member States, with particular challenges for small-scale operators. In addition, capacity constraints and limited expertise in applying risk-based approaches reduce overall effectiveness. External study, p.83
			1.4.4 Qualitative description of the action MS take to increase biosecurity, including enforcement measures	- Annual reports - Audit reports	
			1.4.4 Qualitative description of the action MS take to increase surveillance incl. enforcement measures	- Annual reports - Audit reports	
			1.4.4 Stakeholder views on the overall improvement in terms of biosecurity and prevention in the EU that can be attributed to the AHL	- Interviews	
			1.4.4 Number of outbreaks of contagious livestock disease	- ADIS	
			1.4.4 Number of training sessions taken up by animal keepers, especially farmers	- Annual reports	
			1.4.4 (Stakeholders views on) the reaction time	- Interviews	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
Effe 1.5 What are the main shortcomings that need to be addressed?	1.5.1 Are there any shortcomings that can arise from the overall functioning of the AHL at EU level?	1.5.1 Any shortcomings at EU level that may stem from the functioning of the AHL at EU level can be easily identified and tackled	1.5.1 Examples of shortcomings identifiable that can be linked to the functioning of the AHL at EU level	- Case studies	The main shortcomings relate to insufficient support and guidance for farmers in applying biosecurity and disease detection measures, as well as uneven implementation of training and awareness programmes across Member States. Stakeholders also highlight the lack of adequate funding mechanisms and balanced cost-sharing across the value chain as key barriers to effective prevention and response. However, given the partial and ongoing implementation of the AHL, it remains difficult to fully distinguish structural shortcomings from transitional implementation challenges. External study , p 89
			1.5.1 Stakeholder views on possible shortcomings linked to the implementation of the AHL at EU level	- Case studies	
	1.5.2 Are there shortcomings in the implementation at national level?	1.5.2 Any shortcomings that may stem from the implementation of the AHL at national level can be easily identified and tackled	1.5.1 Example of shortcomings identified by MS at national level during outbreaks of contagious livestock diseases	- Case studies	
			1.5.1 Stakeholder views on possible shortcomings linked to the implementation of the AHL at national level	- Case studies	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
Effe 1.6 To what extent do the AHL's risk-based approaches effectively prioritise resources and actions based on the severity and likelihood of different threats?	Idem to EQ	1.6.1 The AHL's risk-based approaches effectively prioritise resources and actions based on the severity and likelihood of different threats	1.6.1 Stakeholders' views on the AHL's risk-based approaches effectively prioritise resources and actions based on the severity and likelihood of different threats	- Case studies	The AHL's risk-based approach is generally effective in prioritising resources and actions, allowing tailored and proportionate responses based on disease risk, and is widely supported for its scientific basis and flexibility. It supports more efficient use of resources by focusing on high-risk situations. However, stakeholders highlight the need for more flexibility and more frequent updates to disease categorisation, particularly for persistent and emerging diseases. Overall effectiveness remains difficult to fully assess due to ongoing and uneven implementation across Member States. External study p 92
Effe 1.7 Does the AHL enhance transparency in decision-making processes related to animal health?	Idem to EQ	1.7 The AHL enhances the transparency in decision-making processes	1.7.1 Stakeholders views on the transparency in decision-making processes is enhanced	- Case studies - Call for Evidence - Interviews	The AHL has fostered greater transparency and openness in decision-making; however, some limitations were shared in terms of more deeper involvement of stakeholders . Extrenal study p 94

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
Effe 1.8 Does the AHL enhance the resilience of animal health systems?	Idem to EQ	1.8.1 The AHL has an overall positive effect on the resilience of animal health systems is enhanced	1.8.1. Stakeholders views on the impact of the AHL on the resilience of animal health systems	- Interviews	The AHL has enhanced the EU's capacity to detect, contain, and respond to outbreaks through structured mechanisms like zoning, regionalisation, and traceability. These tools allow for targeted restrictions rather than blanket bans, helping maintain internal market stability even during disease events. Stakeholders acknowledged the AHL's contributions to resilience but also highlighted its limitations in swiftly addressing emerging diseases, especially under changing climate and ecological conditions. External study p.96
		1.8.2 The AHL has a positive effect on the competitiveness of the EU agri-food sector in the face of changing environmental, social and economic conditions	1.8.2 Stakeholder views on the impact of the AHL on the competitiveness of the EU agri-food sector	- Interviews	
			1.8.2 Data and statistics linked to the competitiveness of the EU agri-food sector	- Desk research: Comext database - Inputs from other EQs	
			1.8.2 Intra-EU trade and trade with 3rd countries	- Desk research: Comext database - Inputs from other EQs	
Effe 1.9 What were the unexpected or unintended effects	Idem to EQ	1.9 Stakeholders examples of unexpected or unintended effects that stem	1.9 Stakeholders examples of unexpected or unintended effects that stem from the implementation of the AHL		The unintended effects refer mainly to higher-than-expected administrative effort and slower alignment of national legislation. In

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
which have occurred during implementation?		from the implementation of the AHL	1.9 Stakeholders examples of the impacts of such occurrences		addition, tools such as regionalisation are not always applied or recognised consistently between Member States, reducing their effectiveness and affecting confidence in intra-EU disease management. However, these effects are largely linked to the ongoing and partial implementation of the AHL, which limits a full assessment at this stage. External study p.96

Efficiency

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
Efficiency					
Effi 2.1 Has the implementation of the AHL generated incremental costs and benefits for different stakeholders? Are the costs proportionate to the benefits of the AHL?	2.1.1 What are the incremental costs and benefits for stakeholders impacted by the AHL (i.e., Cas of MS and accessing countries, livestock and aquaculture farmers, animal farming and industry operators, veterinarians, and competent authorities of major trading partners) versus baseline scenario (pre-AHL) for all key activities? 2.1.2 Are incremental	2.1.1. Assessment of incremental costs and benefits per each stakeholder group	2.1.1 (direct and indirect) incremental Costs for operators (livestock and aquaculture farmers, animal farming and industry representatives): • cost of implementing biosecurity measures to prevent and control disease • costs of traceability systems for animal and animal products and for complying with animal movements • costs of implementing emergency measures in case of outbreaks • costs for training and education	- Surveys - Interviews - Desk research	The AHL has increased short-term costs (e.g. administration, training, biosecurity, reporting), while benefits are mainly structural and preventive—improved coordination, clearer responsibilities, and better preparedness—and remain difficult to quantify. It is not yet clear that benefits outweigh costs. Perceptions are mixed: farmers and industry often see higher costs, while NCAs and veterinarians report a more balanced view, and academia is more positive. Overall, the AHL shows potential for benefits to outweigh costs in the medium to long term, although this is not yet clearly substantiated. Costs are unevenly distributed, with farmers (especially small-scale), NCAs, and veterinarians bearing the main burden, while benefits are broader, long-term, and less tangible.

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	benefits larger than the incremental costs?		2.1.1 (Direct and indirect) Costs for veterinarians: • costs of training and education • cost of implementing new technologies for health surveillance • costs and admin burdens for cooperation and communication activities	- Surveys - Interviews	External study p. 98
			2.1.1 Costs for NCAs: • costs for compliance and reporting • costs of harmonization and coordination • cost for crisis management in case of outbreaks	- Surveys - Interviews	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
			2.1.1 Costs for EU officials: • costs and resources for data maintenance • regulatory and oversight costs • Cost for training • Developing and amending delegated acts	- Surveys - Interviews	
			2.1.1 (Indirect) Cost for the public: • consumer and production costs	- Surveys - Interviews	

		2.1.2 The benefits outweigh the costs/stakeholders consider the benefits to outweigh the costs	2.1.2 Benefits for operators (livestock and aquaculture farmers representatives and animal farming & industry representatives (SMEs) • benefits from clearer rules and responsibilities • benefits from market opportunities for preventive measures or equipment • benefits from a better image of the sector financial benefits of reduced disease instance • financial benefits of better health status in the region (market opportunities, competitiveness vs regions with lower status) • benefits associated with the circulation of animals and trade	- Surveys - Interviews	
			2.1.2 Benefits for NCAs:	- Surveys	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
			• benefits from harmonisation and coordination • benefits from clearer roles and responsibilities	- Interviews	
			2.1.2 Benefits for the public: • benefits from improved human and animal health	- Surveys - Interviews	
			2.1.2 Cost-benefit ratio	- Surveys - Interviews	
Effi 2.2 Were the costs and benefits distributed as expected and of the magnitude expected? Are there significant differences between Member States?	2.2.1 Are the costs distributed among stakeholders as expected?	2.2.1 Comparative analysis of list of costs and benefits as identified in 2.1.1 (EQ #2.1) versus the baseline scenario	2.2.1 List of direct and indirect costs borne by stakeholders (total and distribution between stakeholders) - see 2.1.1.1-5	- Interviews	Costs are not yet distributed as initially expected, though this is largely perception-based and reflects early AHL implementation. They are somewhat uneven, with higher short-term burdens on some farmers (especially small-scale), NCAs, and veterinarians. Benefits are more diffuse and long-term, with clearer gains for authorities, while farmers report limited immediate benefits. Costs are immediate and measurable, whereas benefits are emerging and harder to quantify.
	2.2.2 Were the benefits distributed among stakeholders as expected?	2.2.2-3 Stakeholders' perception on distribution and magnitude of costs and benefits as expected	2.2.2 Qualitative description of stakeholders' perception of distribution	- Case studies	
	2.2.3 What is the magnitude of incurred costs and benefits for stakeholders?				

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	2.2.4 Are there significant differences in terms of costs and benefits between MS?	2.2.4 Differences between MS identified	2.2.4 List of significant differences between MS in terms of incurred costs and benefits	- Case studies	Differences between Member States are significant: those with stronger systems realise benefits faster, while others face greater challenges and delayed gains. External study p.115
Effi 2.3 Are there additional regulatory burdens and/or savings stemming from the implementation of the AHL? What elements of the legislation generate administrative burden and/or are overly complex?	2.3.1 Are there additional regulatory burdens and/or savings stemming from the implementation of the AHL?	2.3.1 Excessive procedures / timelines 2.3.1 Procedural savings due to better distribution of tasks 2.3.2 Excessive reporting requirements 2.3.2 Savings in resources dedicated to communication due to enhanced transparency	2.3.1 List of additional regulatory burdens and/or savings identified at MS level	- Case studies	The AHL has generated additional regulatory burdens, particularly in the short term, as stakeholders must navigate multiple new EU rules and their links with national legislation, creating complexity and administrative work. While the AHL provides flexibility and potential for simplification and cost savings through risk-based approaches, these opportunities remain underused. The constrain in the assessment by uneven implementation and ongoing alignment across Member States should be taken into account. External study ,p.119
	2.3.2 What elements of the legislation generate administrative burden and/or are overly complex?		2.3.2 Stakeholders' perception of admin burden and/or savings	- Case studies	
Effi 2.4 Have any inefficiencies been identified? How do these	Idem EQ	2.4.1 Inefficiencies identified in relation to challenges identified as per EQ #1.2	2.4.1 Stakeholder opinions, or policy research notes on major inefficiencies (administrative, operational, etc.)	- Interviews	Some inefficiencies have been identified, mainly in the early implementation phase. NCAs faced challenges registering new operators, farmers report added

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
impact different stakeholders?		2.4.2 Stakeholders identify inefficiencies and their impact	2.4.2 Stakeholder perception of inefficiencies	- Interviews	costs with unclear short-term benefits, delays occur in certification processes, and veterinarians face increased administrative workload. These issues are largely transitional and linked to uneven implementation, overlapping rules, and differing starting points across Member States. External study ,p.124
Effi 2.5 What reporting obligations stem from the regulation? Is there potential for simplification and cost reduction, for example through rationalisation, benefiting businesses and competent authorities?	Idem EQ	2.5.1 Available opportunities for simplification and cost/burden without hampering effectiveness	2.2.1 See inputs from 2.1.1	- Inputs from other EQs	The AHL introduces extensive reporting obligations within a harmonised EU framework. Challenges stem mainly from implementation, as overlaps with national rules create complexity and administrative burden. There is potential for simplification through better alignment, greater use of flexibility, and improved digitalisation (e.g. TRACES, interoperability). Preventive measures are considered cost-effective. External study, p.127
			2.5.1 Stakeholder opinion on the opportunities for simplification and cost/burden reduction	- Interviews	

Coherence

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
Coherence					
C 3.1 To what extent is the legislation coherent within itself? Have the different elements of the legislation operated together to achieve all the objectives of the legislation in a coherent way?	3.1.1 To what extent the different provisions of the AHL have been interpreted and/or applied in a way that guarantees its key objectives are fully met? 3.1.2 To what extent the AHL is coherent with the delegated and implementing acts adopted so far?	3.1.1 Existence of diverging interpretations and/or application issues regarding AHL provisions 3.1.2 Existence of inconsistent or contradictory provisions between the AHL and its delegated and implementing acts	3.1.1 Number of diverging provisions, interpretations and/or application issues regarding AHL provisions	- Surveys - Interviews - Desk research: legislative texts and case-law	The AHL demonstrates a high level of structural and conceptual coherence, with its components generally functioning together in a consistent manner to support its objectives. Most issues identified stem from differences in interpretation and implementation across Member States rather than from shortcomings in the legislation itself. Overall, the provisions have been applied in a way that supports the AHL's objectives, although such differences affect the extent to which these objectives are fully achieved in practice. The AHL is broadly coherent with its Delegated and Implementing Acts, forming a consistent and integrated legal framework, while some targeted technical clarifications could further enhance legal clarity and operational effectiveness. External study, p.131
			3.1.2 Number of inconsistent or contradictory provisions between the AHL and its delegated and implementing acts	- Interviews - Desk research: legislative texts and case-law - Call for Evidence	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	

C 3.2 Is this legislation coherent with other related EU pieces of legislation and policies?	3.2.1 To what extent is the AHL coherent with OCR?
	3.2.2 To what extent is the AHL coherent with ABP legislation?
	3.2.3 To what extent is the AHL coherent with animal welfare legislation?
	3.2.4. To what extent is the AHL coherent with EU legislation regulating veterinary
		3.2.1-3.2.8 Existence of diverging provisions, interpretations and/or application issues between the legislations considered
		
		3.2.8 Degree to which the AHL allowed making proper use of EU financing
			3.2.1-3.2.7 Number of diverging provisions, interpretations and/or application issues	- Surveys
				- Desk research:
				  - Literature
				  - EC legislative documents
				  - General Food Law
				  - Case-law
				- Call for Evidence
				- Case Studies
					The AHL is overall coherent with other relevant EU legislation, providing a consistent and risk-based framework aligned with food safety, public health, and internal market objectives. It shows strong coherence with the Official Controls Regulation, food hygiene, zoonoses, and veterinary legislation, while alignment with TSE and disease-specific rules is generally satisfactory.
					Coherence is moderate with animal welfare legislation and EU financing instruments, where further alignment is needed. No major contradictions are identified; remaining issues are mainly operational, linked to

	medicinal products and medicated feed? 3.2.5 To what extent is the AHL and its principles (risk-based, new scientific knowledge) coherent with the legislation regulating TSE's (Regulation (EC)nº999/2001) 3.2.6 To what extent is the AHL and its principles (risk based, new scientific knowledge) coherent with the legislation regulating foodborne diseases (Regulation (EC) nº2160/2003) and Regulation (EC) No. 853/2004 on the hygiene of food of animal origin		3.2.8 Number of cases in which the AHL prevented or hindered the proper and timely earmarking of EU financing	- Interviews	implementation differences across Member States. Overall, the AHL offers a solid and largely coherent framework, with some scope for improved alignment in specific areas. External study, p.133

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	3.2.7 To what extent is the AHL and its principles (risk based and new scientific Knowledge) coherent with other legislation regulating specific zoonoses (Directive nº2003/99/EC) 3.2.8 To what extent is the AHL coherent with the EU financing measures for the prevention and control measures of animal diseases?				
C 3.3 To what extent has the implementation of the AHL put in place a coherent animal health	3.3.1 To what extent have the provisions of the AHL been interpreted and/or applied in a way	3.3.1 Existence of diverging provisions, interpretations and/or application issues between AHL and MS animal health measures	3.3.2 Number of diverging provisions, interpretations and/or application issues	- Surveys - Interviews - Desk research	The AHL has established a coherent EU-level framework, but its implementation remains uneven across Member States due to different legal systems, capacities, and starting points. While some countries adapted

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
policy within the EU and in the territory of the Member States? Did the implementation of the AHL reveal any incoherent elements internally or externally, in particular with national animal health measures and systems?	that usefully complements animal health policy and legislation developed by MS? 3.3.2 To what extent the provisions of the AHL and other relevant EU legislation have been interpreted and/or applied in a way that usefully complements animal health policy and legislation developed by MS?	3.3.2. Existence of diverging provisions, interpretations and/or application issues between AHL, other relevant EU legislation and MS animal health measures			easily, others required significant changes, and full coherence with national frameworks is not yet achieved. The AHL generally complements national animal health policies and other EU legislation, but coherence is mixed in practice, with some gaps in alignment (e.g. TSE, zoonoses). Differences in interpretation and ongoing national adaptation affect consistency. Overall, coherence is progressing but not yet fully realised, as implementation is still ongoing across Member States. External study, p.135.
C 3.4 To what extent does the AHL facilitate	3.4.1 To what extent has the AHL been	3.4.1 Degree to which the AHL is perceived as an effective instrument to	3.4.1 Stakeholders opinion	- Interviews	The AHL is generally recognised as a strong framework for addressing global animal health

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
international collaboration on animal health to address global challenges and promote harmonisation of standards?	recognised as an effective model of regional governance in the animal health area? 3.4.2 To what extent has the AHL inspired the legislators of other jurisdictions outside the EU? 3.4.3 To what extent has the AHL raised concerns from the EU's trading partners?	tackle animal health and related challenges beyond national borders 3.4.2 Degree to which the AHL has promoted harmonisation of animal health standards outside the EU 3.4.3 Existence of SPS concerns about the AHL at the WTO level	3.4.2 Number of non-EU countries whose legislation has been/is being inspired by AHL	- Interviews	challenges and aligning with international standards, and is viewed by many stakeholders as a credible model of regional governance. It has supported legislative alignment in neighbouring countries and in export-oriented sectors seeking access to the EU market. However, its influence beyond the EU remains moderate, as uptake by third countries is uneven and broader harmonisation of standards is limited. While no major concerns from trading partners are consistently reported, the AHL's complexity and specific requirements can pose challenges for external alignment. External study, p.137
			3.4.3 Number of SPS concerns about the AHL still open at the WTO level	- Desk research - Interviews	
C 3.5 To what extent does the AHL promote cooperation with relevant international organisations, the exchange of	3.5.1 To what extent has the implementation of the AHL fostered cooperation in relevant international	3.5.1 Degree to which the AHL effectively promotes cooperation in international fora 3.5.2 Degree to which up to date the AHL has allowed exchange of information	3.5.1 Stakeholder perception on the degree to which AHL promotes cooperation	- Interviews	The AHL has strengthened the EU's role in international cooperation, particularly within organisations such as World Organisation for Animal Health, and has supported improved information exchange on transboundary animal diseases,
			3.5.1. Examples of cooperation in the context of AHL implementation	- Interviews	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
information and joint response measures?	organisations (e.g., WOAH/OIE)? 3.5.2 To what extent has the implementation of the AHL catered for the exchange of information and joint response measures in the context of relevant international organisations (e.g. through WAHIS)?	and joint response measures at the international level	3.5.2 Number of cases where exchange of information and joint response measures in relation to cross-border threats to animal health took place under the AHL framework	- Interviews	including through systems like World Animal Health Information System. Its contribution is mainly indirect, driven by EU engagement in international fora and trade-related objectives. While it facilitates cooperation and information sharing, further efforts in awareness-raising and technical support could enhance its visibility and uptake among international partners. External study, p.140
C 3.6 To what extent does the intervention comply with the 'do no significant harm' principle?	3.6.1 To what extent is the AHL coherent with the EU efforts to fight climate change? 3.6.2 To what extent is the AHL coherent with EU policies that	3.6.1. Degree of alignment between AHL and EU efforts to fight climate change. 3.6.2 Degree to which the AHL limits or supports the implementation of circular economy approaches and solutions (food waste and efficient use of resources)	3.6.1 Evidence collected from literature and stakeholders	- Interviews (with NGO and science/academia)	The AHL was not specifically designed to address the "Do No Significant Harm" principle, but overall it has a largely neutral environmental impact. It shows limited direct alignment with EU policies on climate change, circular economy, and environmental sustainability.
			3.6.2 Evidence collected from literature and stakeholders	- Interviews (with NGO and science/academia)	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	support circularity? 3.6.3 To what extent is the AHL coherent with EU policies to prevent biodiversity loss and conservation of habitat and species? 3.6.4 To what extent is the AHL coherent with the EU policies on environmental pollution and unsustainable management of water and marine resources?	3.6.3 Degree of alignment between the objectives of AHL and EU policies on the prevention of loss of biodiversity and protected habitats and species 3.6.4 Degree of alignment between the objectives of the AHL and EU policies on environmental pollution and unsustainable use of water and marine resources	3.6.3 Evidence collected from literature and stakeholders 3.6.4 Evidence collected from literature and stakeholders	- Interviews (with NGO and science/academia) - Interviews (with NGO and science/academia)	The AHL contributes positively to biodiversity protection through disease prevention, including in wildlife. However, certain measures, such as culling for disease control, may at times conflict with conservation and rewilding objectives. Overall, coherence with environmental policies is partial and indirect, and the assessment is constrained by limited stakeholder feedback on these aspects. External study, p.142

C 3.7 To what extent is the intervention coherent with the EU sustainable development goals? How does the AHL relate to and contribute to strategic policy objectives, among others One Health, Green Deal, a Long-Term Vision for Rural Areas and the sustainable competitiveness of the agri-food sector? In particular, does the AHL strengthen the integration of a One Health approach that recognises the interconnectedness of human, animal, and	3.7.1 To what extent does the AHL contribute to the objectives of the EU Green Deal and the Farm-to-Fork Strategy? 3.7.2 To what extent does the AHL contribute to reinforcing the One Health approach? 3.7.3 To what extent does the AHL contribute to the Long-Term Vision for Rural Areas? 3.7.4 To what extent does the AHL contribute to the current and emerging EU policies on long-term competitiveness of the EU agri-food sector?	3.7.1 Degree of alignment between the objectives of AHL, EU Green Deal and Farm-to-Fork Strategy 3.7.2 Degree of alignment between the objectives of AHL and One Health approach 3.7.3 Degree of alignment between the objectives of AHL and Long-Term Vision for Rural Areas 3.7.4. Degree of alignment between the objectives of AHL and current and emerging EU policies on long-term competitiveness of the EU agri-food sector	3.7.1-of 4 Evidence collected from literature and stakeholders, namely on social, economic and environmental dimensions.	- Surveys - Desk research - Interviews	The AHL is broadly aligned with key EU policy frameworks, including the Green Deal, Farm to Fork Strategy, One Health approach, and the Long-Term Vision for Rural Areas. It supports the internal market by harmonising animal health rules and enabling safe animal movements, thereby contributing to the competitiveness of the EU agri-food sector. The AHL reflects a clear commitment to the One Health approach by integrating animal, human, and, to a lesser extent, environmental health considerations. However, its practical implementation and cross-sectoral integration are still evolving. Stakeholder perceptions vary: civil society and academia see a strong contribution, while veterinarians, NCAs, farmers, and industry consider it more moderate due to ongoing implementation challenges. External study, p.143

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
environmental health?					

Relevance

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
Relevance					
R 4.1 To what extent is the AHL fit and relevant to current and emerging needs regarding Animal health?	4.1.1 Is implementation of the AHL harmonised and streamlined across MSs? 4.1.2 Are the responsibilities of stakeholders (farmers, veterinarians, MS competent authorities, and others) still up to date with current needs?	4.1.1 Stakeholders perceive a more harmonised approach 4.1.2 Delineation of roles and duties of relevant stakeholders is clear 4.1.3 The availability and offer of trainings for veterinarians, animal handlers, and staff is adequate 4.1.4 Criteria to address emerging diseases are in place	4.1.1 Degree of agreement of stakeholders on the level of harmonisation	- Surveys	The AHL is overall fit and relevant to current and emerging animal health needs, providing a harmonised and adaptable framework that supports disease control, facilitates trade, and ensures a level playing field across Member States. The disease listing and categorisation system is considered a clear improvement and remains appropriate to current challenges. The AHL also broadly defines stakeholder responsibilities and supports training (e.g. through BTSF), although dissemination to operators remains uneven, leading to gaps in awareness.
			4.1.2 Degree of understanding and agreement in roles and responsibilities of relevant stakeholders among MS	- Surveys	
			4.1.3 Proportion of veterinarians, animal handlers and staff involved with animal health and biosecurity ve acquired knowledge through formal education or training regarding animal health, disease prevention and their responsibility	- Interviews - Case studies - Desk research: FVE reports on art. 25	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	4.1.3 To what extent is the AHL fostering training for veterinarians, animal handlers and staff involved with animal health? 4.1.4 Are the criteria for listing of diseases still up to date with current needs?		4.1.4 Diseases that cannot be adequately listed	- Interviews - Case studies	However, implementation is not yet fully harmonised across Member States, with differences in national approaches and use of flexibility leading to inconsistent application, as seen for example in responses to vector-borne diseases. In addition, limited detail on key elements such as biosecurity and animal health visits, as well as the lack of differentiation between production systems, creates risks of uneven implementation and effectiveness. Overall, while the framework is fit for purpose, its full potential is not yet realised due to ongoing implementation challenges. External study, p.146
R 4.2 To what extent is the AHL able to adapt and adequately reply to evolving threats and challenges in animal health?	4.2.1 Are there examples where AHL, DA or IA have adopted new diseases (including new threats and emerging diseases)?	4.2.1 Degree of responsiveness of the legislation in including new animal diseases 4.2.2 Stakeholders/scientific experts agree with the criteria of categorisation and prioritisation of animal diseases	4.2.12 Incorporation of zoonosis, new emerging animal diseases in AHL, DA or IA	- Focus group: academia and NCAs	The AHL is largely able to adapt to evolving animal health threats through its harmonised and flexible framework, with appropriate disease categorisation and the ability to address new and emerging diseases. Systems like ADIS support monitoring and information exchange.
			4.2.3 Number of large-scale disease outbreaks and of animals culled due to eradication measures	- Focus group: academia and NCAs	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	4.2.2 Does the AHL currently consistently cover all diseases (including zoonosis, new food safety threats and emerging diseases)? 4.2.3 Are the animal diseases categorised and prioritised correctly? 4.2.4 Is the Animal Disease Information System (ADIS) adaptable to emerging diseases?	4.2.3 Degree of responsiveness of ADIS in including new animal diseases	4.2.4 Stakeholders' opinion/proposal on criteria for categorisation and prioritisation	- Interviews - Surveys	However, separate legislation for some diseases (e.g. Salmonella, TSEs) creates fragmentation, and flexibility in certain categories can lead to divergent national measures, affecting consistency and intra-EU trade. External study, p.151
			4.2.4 Examples of inadequate uptake of new diseases in ADIS	- Case studies	
R 4.3 Are there issues that arose after the adoption of the Regulation	4.3.1 How well adapted is the AHL to:	4.3.1 Adequacy of evaluation of whether new contagious animal and zoonotic diseases need to	4.3.1 Adjustments of diseases listed in Reg 2018/1629	- Interviews - Focus groups	Some issues were identified to require further attention. Flexibility in addressing fast-spreading diseases has led to

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
that would require further attention in view of the objectives pursued?	- The animal health situation that occurred after 2021? - The effective function ing of	be included in the AHL, including DA and IA 4.3.1 Adequacy of the AHL to support the functioning of the internal market 4.3.1 Adequacy of the AHL to reduce the adverse effect on animal health, public health and the environment?	4.3.1 Reduction of disturbed transport due to discrepancies or gaps in national legislation that necessitate EU-level action perceived by stakeholders 4.3.1 Reduction of adverse effects on animal health, public health and the environment due to inadequate EU legislation	- Interviews - Focus groups - Interviews - Focus groups	divergent national approaches and trade disruptions. While the AHL worked broadly as expected in crises (e.g bluetongue), gaps remain, including uneven biosecurity improvements across sectors and burdensome notification requirements in urgent situations., External study p.156

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	the internal market? - Reduction in the adverse effects on animal health, public health and the environment? 4.3.2 How well adapted is the AHL to technological developments that have appeared since its introduction?	4. 3.2 Adequacy of the AHL incl. DA and IA to implement new technological developments that have appeared since its introduction	4.3.2 Evidence of the implementation technological developments, e.g. updates of TRACES, data collection methods, digitalisation, detection methods, vaccines, transport	- Interviews	

EU added value

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
Eu added value					
EUAV 5.1 What has been the EU added value of the AHL compared to what could have been reasonably achieved by Member States acting alone?	5.1.1 T What are the major benefits observed due to the implementation of the AHL? 5.1.2. What are the observed positive and/or negative impacts of the AHL on animal health and trade? 5.1.3 Could the same results have been achieved by national animal	5.1.1 Identifiable evidence that the AHL's effects could have been achieved without EU intervention 5.1.2. Observed positive and negative impact of AHL 5.1.3 Identifiable evidence that Member States acting alone met equivalent results to the ones of the AHL	5.1.1 Stakeholder opinion on the extent to which the effects of the AHL could have been achieved without EU intervention without updating of the AHL	- Surveys	The AHL has clear EU added value by strengthening coordination of animal disease prevention and control across Member States and establishing harmonised rules, particularly for major (List A and B) diseases. This has contributed to greater efficiency, a level playing field, and improved intra-EU trade, while supporting more consistent and effective responses to animal health risks. These results could not have been achieved by Member States acting alone, as national approaches would likely remain fragmented, leading to inconsistent measures and weaker coordination, especially for cross-border and emerging diseases.
			5.1.2. Identified positive and negative impacts of AHL	- Surveys	
			5.1.3 Stakeholder opinion on the need for EU-level coordination	- Surveys	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
	health measures and system alone? 5.1.4 To what extent has the AHL contributed to coordination for better animal disease		5.1.4. Identified differences in measures for the prevention and control of emerging and listed diseases and sanitary measures in kept terrestrial and aquatic animal MS in EU MS prior to the implementation of the AHL	- Interviews - Case studies	Overall, the AHL has enhanced alignment and cooperation across the EU, although some variation in implementation persists, particularly due to limited detail on biosecurity and animal health visits, which are left to national discretion. External study p.158

	prevention and control measures in EU MS? 5.1.5. Would measures for the prevention and control of emerging and listed diseases in kept terrestrial and aquatic animals be differently applied in EU MS without AHL? 5.1.6 Could measures for the prevention and control of emerging and listed diseases in kept terrestrial and aquatic animals and sanitary measures in wild animals be differently applied in EU MS without AHL?		5.1.5 Identified differences in measures for the prevention and control of emerging and listed diseases and sanitary measures in wild animals in EU MS prior to the implementation of the AHL	- Interviews - Case studies	
EUAV 5.2 To what extent did	5.2.1 To what extent does the	5.2.1 Degree of responsiveness of the	5.2.1 Degree of responsiveness of the	- Interviews	The AHL strikes an overall proportionate balance between EU-

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
this intervention strike a balance between action at the EU level and national action? Is it proportionate?	AHL provide sufficient flexibility to adapt rules to local circumstances? 5.2.2 Are there any efficiency/effectiveness gains of EU-level action compared to national action?	legislation in including new animal diseases 5.2.2 Identifiable evidence that the AHL ensures efficiency/effectiveness gains compared to national actions	legislation in including new animal diseases		level coordination and national action. It provides a harmonised framework for major diseases (categories A and B), ensuring consistent measures across Member States, while allowing flexibility for other diseases (categories C–E) to adapt to local circumstances. This approach enables efficiency and effectiveness gains compared to purely national action, particularly through coordinated responses, improved disease control, and support to the internal market. However, for diseases where flexibility is higher, different national measures can lead to inconsistencies, suggesting that in some cases stronger EU-level coordination could further improve uniformity. External study p.161.
			5.2.1 Stakeholder opinion on the flexibility provided by the AHL to adapt rules to local circumstances	- Interviews	
			5.2.2 Identifiable evidence that the AHL ensures efficiency/effectiveness gains compared to national actions	- Inputs from efficiency/effectiveness	
			5.2.2 Stakeholder opinion on efficiency/effectiveness gains driven by the AHL compared to national actions	- Inputs from efficiency/effectiveness	

Evaluation Question	Sub question	Judgement criteria	Indicators	Data sources	
EUAV 5.3 What adaptations could increase the additionality of EU-level action?	5.3.1 Can adaptations be identified that may increase the additionality of EU-level action?	5.3.1 Suggestions for improvements put forward that justify (further) EU-level action	5.3.1 Stakeholder suggestions for improvements justifying EU-level action	- Surveys - Inputs from previous criteria	EU added value could be strengthened through clearer and more structured guidance to support more consistent implementation across Member States, including tailored, sector-specific guidance to improve clarity and compliance. Greater sharing of best practices (e.g. biosecurity, veterinary workforce) and stronger capacity in applying risk-based approaches would further enhance consistency and effectiveness, while maintaining flexibility for local conditions. External study p.163.

Annex IV. Overview of benefits and costs

Table 1. Overview of costs and benefits identified in the evaluation

	Citizens/Consumers		Businesses		Administrations	
	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Cost or Benefit description:						
Key area 1: Prevention and control of transmissible animal diseases;	**Recurrent and one-off:**	Estimation of potential product increasement of 0 - 5% to offset business additional cost in producing food.	**Direct benefit:** Less risk of sickness from animals and their products. **Indirect benefit:** Lower use of antimicrobials contributing to less AMR **Indirect Cost:** Potentially a slight increase in pricing of goods.	Estimates are that benefits of healthy animals far outweigh the economic impact. For example, an average pig farmer earns 5.753.700 euro per year, who can face losing profits depending on infected animals. Profit loses from death of animals affect profits: ranging from 10% dead	**Direct benefit:** Less risk of diseases destroying farms. **Indirect benefit:** Less farms destroyed, more products on market giving macroeconomic benefits. Additionally, less environmental impacts for farmers if other farms get sick. **Direct compliance cost:** Adjustment to	National authorities estimate an increase in 10% burden (on all total key areas). This is offset due to the indirect benefits such as healthier population, animals and less administrative works for incidence.	**Direct benefit:** Less administrative work from disease incidents due to less duplications.

				animals (575.370 euro) to 90% (5.178.330 euro) dead ones. Animal deaths are unpredictable, but loss of animals far outreach administrative burdens on farmers, as disease outbreaks cause financial ruin.	new requirements. Estimate slight adjustment 5-10%. **Enforcement cost:** Inspection of animals health are still happening, no cost change here.		
Key area 2: Prioritisation and categorisation of animal diseases of Union concern	**Recurrent:**		**Not applicable**	Farmers indicate an additional burden on 5 to 10% extra, depending on their size. This is offset by quicker identification of animal diseases that lowers risk of further	**Direct benefit:** Proportionate measures to prevent and control animal diseases, avoid focussing on too many diseases **Indirect benefit:** Common knowledge on diseases in regions aids	National authorities estimate an increase in 10% burden (on all total key areas). This is offset due to the indirect benefits such as healthier population, animals and	**Direct benefit:** Easier administrative work on identification **Enforcement cost:** Monitoring and updating the list. No cost change due to

				animal deaths and infections.	better and focussed earlier treatment.	less administrative works for incidence.	part of their agencies work.
Key area 3: Animal disease Surveillance, early detection, notification, and laboratory confirmation; eradication programmes and disease–free status.	**Recurrent and one off:**		**Direct benefit:** Consumer knowing product is disease-free. **Indirect benefit:** Not becoming infected from other people.	Estimation of a 5 – 10% increase, depending on the size of the farmer. This is offset by quicker identification of animal diseases that lowers risk of further animal deaths and infections.	**Indirect benefit**: Label of "disease free" status is marketable. **Direct cost:** Implementation fees (one off). **Enforcement cost:** Surveillance, testing, disease control measures	National authorities estimate an increase in 10% burden (on all total key areas). This is offset due to the indirect benefits such as healthier population, animals and less administrative works for incidence.	**Direct benefit**: **Direct cost:** Implementation fees (one off). **Enforcement cost:** Reaction to notification, and laboratory confirmation of diseases.

Key area 4: Biosecurity and responsibilities of operators and competent authorities	**Recurrent:**		**Not applicable**	Farmers indicate an additional burden on 5 to 10% extra, depending on their size from small to large. This is offset by actions to minimize introduction of harmful organism.	**Indirect benefit:** Prevention of introducing harmful organism reduces risk of disease outbreaks. **Enforcement cost:** Actions to minimize risk of introduction of harmful organisms.	National authorities estimate an increase in 10% burden (on all total key areas). This is offset due to the indirect benefits such as healthier population, animals and less administrative works for incidence.	**Indirect benefit:** Prevention of introducing harmful organism reduces enforcement cost through less notifications and laboratory checks. **Enforcement cost:** Actions to minimize risk of introduction of harmful organisms.
Key area 5: Disease eradication, awareness, preparedness and control	**Recurrent:**		**Indirect benefit:** Awareness allows consumer to make better choices when buying products.		**Direct benefit:** Better farmer's awareness, easier knowledge of animal diseases severity. **Indirect benefit:** Disease eradication can long term lead to	National authorities estimate an increase in 10% burden (on all total key areas). This is offset due to the indirect benefits such as healthier	**Indirect benefit:** Disease eradication can long term lead to better competitiveness on a macroeconomic scale.

					less usage of certain drugs.	population, animals and less administrative works for incidence.	
Key area 6: Identification, traceability, and movements of animals and germinal products	**Recurrent:**		**Indirect benefit:** Ensuring trust of consumers when buying products and animals from thrustful sources.		**Direct benefit:** ensured traceability of animals less risk of diseases destroying farms. **Indirect benefit:** Ensuring trust in national and international trade **Direct compliance cost:** Adjustment to new requirements. **Enforcement cost:** Inspection of animals health are still	National authorities estimate an increase in 10% burden (on all total key areas). This is offset due to the indirect benefits such as healthier population, animals and less administrative works for incidence.	**Enforcement cost:** Bigger administrative burden due to new and lengthier tasks.

					happening, no cost change here.		
Key area 7: Registration and approval of establishments and operators.	**One off:**		**Indirect benefit:** Ensuring trust of consumers when buying products and animals from thrustful sources	Farmers expect slightly longer registration and approval.	**Indirect benefit:** Ensuring trust in national and international trade **Direct cost:** Applying to register takes a little time.	National authorities estimate an increase in 10% burden (on all total key areas). This is offset due to the indirect benefits such as healthier population, animals and less administrative works for incidence.	**Enforcement cost:** Approval of operators, though already a part of their work.

Key area 8: Animal health requirements for movements in the Union of terrestrial and aquatic animals.	**One-off / Recurrent:**		**Not applicable**	Farmers expect requirements to move increases burdens for 10-15% of the cost.	**Direct cost:** Filling out forms to meet requirement takes a little time.	National authorities estimate an increase in 10% burden (on all total key areas). This is offset due to the indirect benefits such as healthier population, animals and less administrative works for incidence.	**Enforcement cost:** National authorities have to check applications and judge them.
Key area 9: Animal health requirements for entry conditions for into the Union of animals, germinal products and products of animal origin into the Union and the export of such consignments from the Union.	**One-off / Recurrent**	**Indirect benefit:** Better health requirement and proof of entry means less diseases spread to house pets or hobby farmers.		Farmers who already follow requirements expects no additional costs.	**Direct benefit:** Knowing your animal is healthy reduces risk of selling unhealthy products. **Indirect benefit:** equal level playing ground between intra Union requirements for animals and their	National authorities estimate an increase in 10% burden (on all total key areas). This is offset due to the indirect benefits such as healthier population, animals and	**Indirect benefit:** Checking animals health increase environmental, social and has wider economic impact on EU. **Enforcement cost:** Continuous cost to check

					products and those imported from outside the Union **Direct cost:** Showcasing requirements for entry takes little time. Takes no time, if papers are done previously.	less administrative works for incidence.	requirement for conditions of entry for animals. Nothing new, so no cost change.

Annex V. Stakeholder consultation - Synopsis report

This annex summarises all stakeholder consultation activities carried out for the evaluation of Regulation (EU) 2016/429 (the Animal Health Law – AHL). It builds on evidence collected through the supporting study (RfS SANTE/2024/G2/007) and complements the analysis presented in Section 4 of the Staff Working Document.

1. Consultation strategy

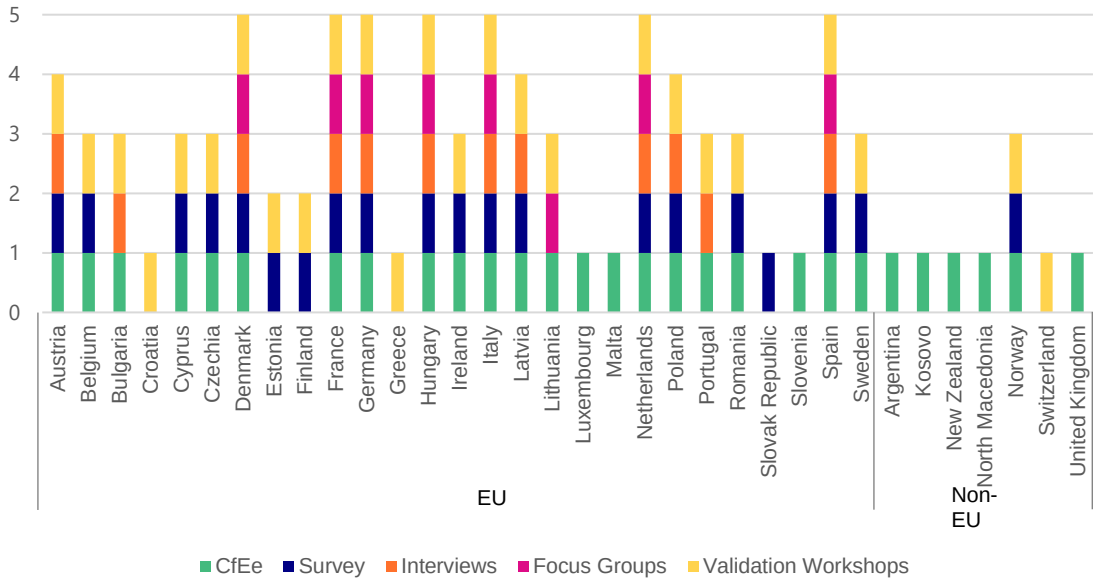
1.1 Objectives of the consultation

The stakeholder consultation was designed as a central component of the evaluation of the Animal Health Law (AHL), supporting the collection of evidence on the law's implementation and performance across the EU. It aimed to gather insights from a wide range of stakeholders directly affected by the AHL, including National Competent (NCAs), farmers and industry representatives, veterinarians, civil society, academia and other organisations and citizens. The consultation complemented the desk research by ensuring that practical experiences, challenges, and stakeholder recommendations informed the assessment of the AHL's effectiveness, efficiency, relevance, coherence, and EU-added value.

The first activity conducted was the **Call for Evidence (CfE),** gathering feedback from citizens and organisations from 6 March to 3 April 2024. **Four online targeted surveys** were then conducted between October and November 2024, targeting National Competent Authorities (NCAs), livestock and aquaculture farmers and industry representatives, veterinary associations, civil society, academia, and other organisations involved in animal health. Consequently, **40 targeted interviews** were conducted from November 2024 to January 2025 to complement the information received. They targeted national and EU-level stakeholder representatives to provide a comprehensive overview of the AHL across the EU. In addition, five **focus groups** were held between December 2024 and January 2025 with participants from selected Member States, focusing on national implementation practices and cross-border movement issues. Finally, two **validation workshops** were organised in February 2025 to discuss preliminary findings and gather feedback on the evaluation's draft conclusions. One workshop was held online with NCAs and the other in person with a broader group of stakeholders including farmers, industry, veterinarian representatives as well as international and EU organisations/agencies.

The consultations have achieved broad representation across EU Member States, non-EU countries, and EU-level organisations. Across the five consultation activities, contributions were received from stakeholders in all EU Member States, ensuring comprehensive geographical coverage. Figure 1 provides an overview of the participation of EU Member States and several non-EU countries in the five stakeholder consultation activities.

Figure 1 – Country representation across the 5 stakeholder consultation activities



Source: External study.

Table 1 provides an overview of the final outreach achieved per stakeholder consultation activity

Table 1 – Overview of the stakeholder consultation activities performed and final outreach ([68])

	NCAs (including CVOs)	Farmers rep.	Industry rep.	Veterinarians	NGOs, Research organisations and academia, others	International organisation (IO) and EU agency	Citizens
Call for Evidence	18 NCAs	26 business associations 10 businesses			37 NGOs 3 Research organisations/ Academia 50 Other (hobbyists, consumer org., trade union)	-	428 EU citizens 1 non-EU citizen
Targeted surveys (4)	23 NCAs	16	19	14	11 NGOs 2 Trade Union 1 Research organisation / Academia 4 Other	1 International organisation	-
Targeted interviews (40)	21 NCAs	5	4	3	2 NGOs 2 Research organisation / Academia	2 International organisation 1 EU agency	-
Focus groups (5)	6 NCAs	4	8	8	4 Research organisations/ Academia	-	-
Validation workshops (2)	48 NCAs	4	5	1	-	1 International organization 1 EU agency	-

([68]) The numbers of responses indicated in this table include the valid responses received. More information on the number of responses excluded (campaigns and duplicates) is presented in the following Section.

1.2 Methodology

This evaluation follows a mixed-method approach, combining desk research with several consultation activities to gather quantitative and qualitative evidence. The **CfE** was conducted through the European Commission's *Have Your Say* portal, to collect open feedback and documentary evidence from citizens and stakeholders, which required a specific approach when handling responses.

Identification of duplicates and campaigns, and specific approach to analyse the CfE's inputs

All consultation inputs were systematically analysed and cleaned to ensure unique responses. The CfE required some thorough checks throughout the responses submitted. While 942 responses were initially submitted for the CfE, 369 responses were excluded from the analysis as they were identified as either duplicates (61 responses) or part of an organised campaign (308 responses). In line with the Better Regulation Toolbox, these answers were separated from the analysis when submitted by the same respondent (duplicates) or when their content was substantially the same across more than 10 responses.

Three distinct campaigns were identified among the responses and excluded from the final analysis ([69]). The first campaign was conducted by a bird breeding association and gathered 17 responses. The second was published by two Federations of Associations for the protection of nature and animals and gathered 191 responses. The third campaign was published by two hobbyists organisations and gathered 100 responses. All three campaigns, while providing distinct instructions on the organisations' respective websites, raised as a main concern the high costs and excessive bureaucracy associated with TRACES certificates for hobbyists.

After cleaning the responses, 573 valid responses remained for the analysis of the CfE. All valid replies were then scanned through automated tools and contributions categorised across themes relevant to the AHL intervention logic. A coding system was developed to capture the main themes discussed and structure the inputs provided by respondents. As some responses addressed multiple issues, they contributed to one or more themes, allowing for a quantification of the number of respondents expressing views on specific topics.

Targeted surveys were designed as the second consultation activity to collect stakeholders' views and inputs for evaluating the AHL. They were carried out via the EU Survey platform and designed to collect structured input from key stakeholder groups. Four specific questionnaires tailored to the different stakeholder groups were shared to collect quantitative and qualitative inputs. The survey's responses were extracted, cleaned and analysed to identify general trends and quantify the proportion of respondents expressing specific views. Closed-ended questions enabled statistical analysis, while open-ended responses were examined to capture additional qualitative insights.

([69]) A dedicated paragraph on their contribution is included in Annex 1 of the Summary Report for the Call for Evidence.

The **interviews** and **focus groups** were designed to address data gaps and explore specific challenges, experiences, and bottlenecks identified by stakeholders in greater depth. Both interviews and focus groups collected qualitative insights on the implementation, enforcement, and reporting of the AHL and potential challenges encountered. All discussions were transcribed and carefully reviewed to identify common challenges and perspectives shared across stakeholder groups.

Finally, two **validation workshops** were organised to discuss the preliminary findings of the evaluation; one was held online with NCAs and the other in person with other relevant EU stakeholder representatives. These activities provided additional insights and contributed to the triangulation and validation of findings for the evaluation.

2. Results of the consultation activities

2.1 Effectiveness

Risk-based approach

The AHL's shift to a risk-based approach was overall praised by NCAs, allowing for more focused disease prevention and control measures to address animal diseases (validation workshop, interviews, CfE). NCAs indicated that this approach enabled better resource prioritisation for higher-risk areas, improving strategic decision-making and preparedness (surveys). Several NCAs also noted that increased transparency in rules and procedures has supported more open decision-making and built trust among stakeholders (validation workshop). However, a few NCAs pointed out limitations in applying the risk-based approach, noting the need for greater flexibility to adapt measures to local contexts, especially during outbreaks of diseases categorised as C, D or E (validation workshop, interviews).

Farmers and industry representatives also recognised the value of the risk-based framework for implementing biosecurity measures, but stressed the need for sector-specific guidance to help implement it at the farm level. Several farmers argued that the current framework does not account for the diversity of production systems, with varying biosecurity requirements across intensive, extensive, and organic farms (interviews). They called for more tailored risk-based measures that reflect these differences and are manageable for smaller farmers (validation workshop).

Industry stakeholders highlighted the importance of their early involvement in risk-based planning, especially regarding vaccine development and outbreak preparedness. Several of them also expressed the importance of EFSA's early involvement in monitoring emerging diseases and the pharmaceutical industry's involvement in developing vaccines. Some noted that the industry was often engaged too late in the process, calling for earlier dialogue between EU agencies and industry to ensure timely information sharing (validation workshop).

Veterinarians supported the risk-based approach but reported challenges such as uneven application in different sectors and Member States, training gaps, and unclear operational procedures, which limit the AHL’s effectiveness (interviews). A few veterinarians also highlighted that inadequate training and a lack of communication between veterinarians,

farmers, and authorities in some regions further exacerbated inefficiencies in managing animal health and preventing disease outbreaks (focus groups).

While civil society and research organisations also supported the focus on prevention, they emphasised the need to include animal welfare in the risk-based model to ensure it does not prioritise economic or health risks over animal well-being (interviews). They called for broader stakeholder involvement in risk assessment processes to improve transparency (surveys, interviews).

Categorisation system for diseases

NCAs generally supported the AHL's disease categorisation system for enhancing disease management and early detection (CfE, validation workshop, interviews). Several NCAs noted that the system has helped prioritise diseases based on their risk and impact, enabling more targeted surveillance and control (surveys). However, some NCAs suggested that the system should be made more dynamic, allowing quicker adaptations based on changing epidemiological situations (validation workshop). A few NCAs also noted that the flexibility provided to Member States in managing certain animal diseases listed under categories C, D and E can lead to inconsistencies in disease control measures across the EU, which in turn can create disruptions to intra-EU trade (validation workshop, interviews).

Farmers expressed mixed views. While some acknowledged the usefulness of the categorisation, others found it challenging to apply. They noted operators would benefit from more prescriptive guidance in specific disease situations, rather than interpreting broad categories of legislative measures (surveys, validation workshop).

Industry stakeholders supported the categorisation but stressed the need for greater flexibility, especially for emerging and vector-borne diseases. They called for clearer guidance on how responsibilities should be shared between operators and authorities in managing these risks (validation workshop).

Veterinarians generally agreed that categorisation supports better planning but noted that its impact is limited if not accompanied by clear, harmonised procedures and adequate training (surveys, interviews). They also highlighted that discrepancies in categorisation between diseases with different transmission patterns (e.g., vector-borne versus infectious diseases) create operational challenges (surveys).

Civil society and research organisations supported the categorisation system for harmonising disease management across the EU (CfE). However, they called for regular reviews to ensure its relevance to emerging diseases (interviews, surveys).

Roles and responsibilities of stakeholders

A large majority of NCAs reported that the AHL has clarified the roles and responsibilities of stakeholders involved in animal health (surveys, interviews, CfE). Many noted that the roles of competent authorities and operators are now more clearly defined than in previous frameworks (interviews). However, a few considered that farmers in their Member States are not sufficiently involved and could take more responsibility from NCAs to ensure greater accountability. In contrast, a few NCAs point out that in their Member States, farmers already have greater responsibility for

maintaining biosecurity and preventing disease outbreaks, which is viewed as a positive change (interviews, validation workshop).

Farmers acknowledged the clearer definition of responsibilities under the AHL but noted that, in practice, their level of responsibility has not changed significantly compared to the previous system (interviews). Some also highlighted the need for continuous dialogue with competent authorities and veterinarians to ensure responsibilities are understood and implemented effectively at the farm level (validation workshop).

Industry representatives generally agreed on the clearer allocation of roles (interviews, surveys). However, they emphasised the importance of strong collaboration between authorities and operators. They suggested that involving industry more in decision-making, particularly on disease control measures and biosecurity standards, could improve implementation and make responsibilities more realistic (interviews).

Veterinarians provided mixed feedback. Some noted improvements in role clarity, while others pointed to limited changes in practice due to varying structures of veterinary services across Member States (interviews). A few veterinarians highlighted that unclear responsibilities in some countries lead to gaps in health visits and diseases prevention (focus groups).

Civil society and research organisations recognised the clearer distribution of roles (CfE) but called for more involvement of additional stakeholders, such as NGOs and animal welfare specialists, especially in emergency responses and control measures (interviews). Including a broader range of expertise could balance disease control with broader animal welfare considerations.

Implementation and challenges

Overall, NCAs reported that the legal framework provided by the AHL has made it easier for authorities to manage outbreaks and enforce disease control measures, leading to faster, more coordinated responses (interviews). However, many NCAs also highlighted significant challenges linked to the complexity of the legislative framework (surveys, interviews, focus groups). In particular, several NCAs underlined that the large number of delegated and implementing acts, combined with the length and technical detail of the legislation, make it difficult for authorities and stakeholders to navigate, interpret, and apply the rules effectively (CfE, interviews, focus groups, validation workshop, surveys). It was noted that the complexity stems from the structure of the AHL, where specific provisions are scattered across delegated and implementing acts, making the legislation harder to read and understand (surveys). Additionally, a few NCAs pointed out difficulties in aligning the AHL with existing national legislation, with some countries having to invest additional time and resources while others have integrated the AHL more smoothly (interviews, focus groups).

Farmers' representatives reported positive changes in disease management practices and improved biosecurity efforts (surveys, interviews). However, they echoed concerns about the AHL's complexity. A few indicated that the transition from a disease-based organisation to a topic-based structure has made the framework more complicated, creating difficulties in understanding and applying the provisions in practice (validation workshop).

Industry stakeholders also expressed concerns about implementation, pointing out that differences in the pace and approach across Member States have led to inconsistent application of the rules. This creates trade barriers and distorts competition within the internal market, particularly concerning disease status recognition and certification procedures (interviews, focus groups).

Veterinarians observed that the AHL has led to more effective disease control efforts but pointed to gaps in harmonisation across Member States, particularly regarding the organisation of veterinary services and the enforcement of health visits (interviews, focus groups). A few veterinarians also highlighted insufficient training and guidance for field-level professionals, which limits the effective application of biosecurity measures and other preventive actions (interviews). Additionally, a few veterinarians noted that limited awareness of the AHL among pet owners, a lack of input from field practitioners, and insufficient integration of research findings further complicate the practical implementation of the law (surveys).

Civil society, research organisations, and other stakeholders acknowledged the improvements brought by the AHL but stressed that gaps in implementation remain, particularly in cross-border cooperation and harmonisation of enforcement practices. They also pointed to a need for stronger enforcement and oversight to ensure that the law is applied consistently across the EU (interviews, CfE). Additionally, they suggested that establishing dedicated forums for stakeholder engagement and better integrating cross-disciplinary research into practice could help address these implementation gaps and support more effective application of the AHL (surveys).

2.2. Efficiency

Benefits

The AHL was perceived by NCAs as instrumental in improving animal health management across the EU. Most NCAs acknowledged the benefits of the AHL's harmonised approach, which has enhanced coordination and communication between Member States. According to them, the AHL has made it easier to respond to cross-border disease outbreaks and has ensured that disease control measures are consistently applied across the EU (surveys, interviews).

Several farmers and industry representatives largely agreed that the AHL has improved disease control and market stability. According to them, the AHL has helped ensure the smooth functioning of the internal market by setting clear expectations for animal health standards and biosecurity measures, therefore reducing barriers to trade and protecting public health. Some industry stakeholders saw the harmonisation of health standards as a key benefit of the law, as it facilitates safe trade and ensures consistency across the EU (interviews, surveys).

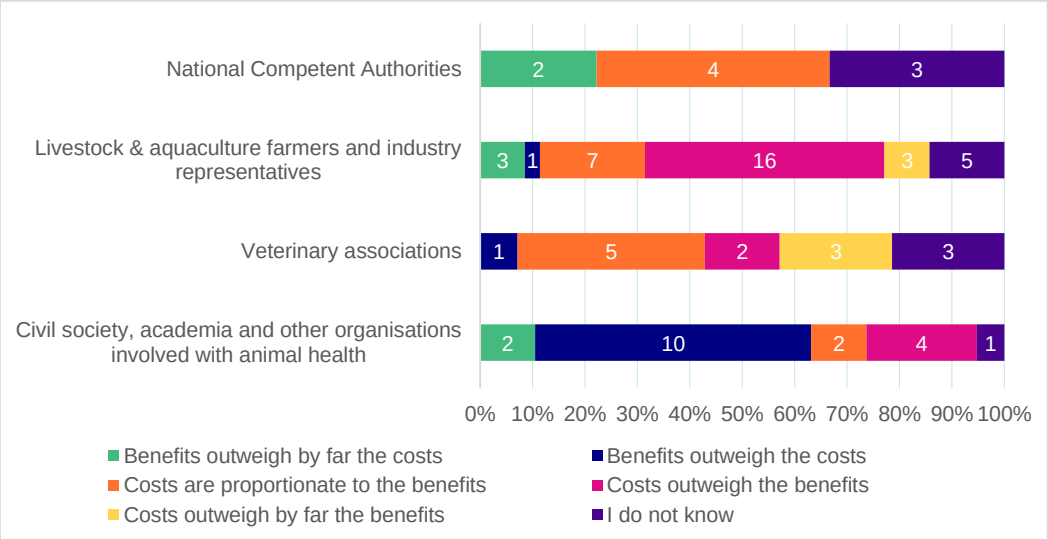
Veterinarians acknowledged the positive impacts of the AHL, such as clearer responsibilities, improved early detection, and better disease prevention measures, which contributed to reducing outbreaks and economic losses on farms. (surveys, interviews).

Civil society and research organisations recognised that the AHL has had positive effects on the public's trust in food safety and animal health practices. The law is seen as a step

towards greater transparency and accountability in how diseases are managed, contributing to the EU's overall public health goals (interviews).

Regarding the proportionality between the costs and benefits of the AHL, many stakeholders considered the benefits to be proportionate to the costs involved. A significant number of respondents - particularly among NCAs, veterinarians, civil society organisations, and other relevant organisations - considered that the benefits of the AHL clearly outweigh the costs or are at least proportionate. Conversely, a smaller group of stakeholders, mainly from the livestock and aquaculture sectors, raised concerns that the costs of compliance and administrative requirements may outweigh the benefits. These findings are reflected in the survey results presented in Figure 2.

Figure 2 – To what extent do you consider the overall costs of the AHL proportionate to the benefits?



N=77 ([70])

Source: External study.

Costs

While the benefits of the AHL were widely acknowledged, stakeholders noted that it has introduced certain costs. Some NCAs reported that the costs of implementing the law, including staff recruitment, training, and IT infrastructure, have placed a financial burden on public authorities (interviews, focus groups). A few NCAs also noted additional costs and time required to adapt and harmonise national standards to comply with EU requirements (survey, interviews).

Farmers and industry representatives expressed concerns about compliance costs, especially regarding biosecurity measures, health checks, and certification processes. While they recognised that these costs are necessary for preventing disease outbreaks, many indicated that they disproportionately impact smaller farms, which lack the financial capacity to meet the regulatory requirements (interviews, surveys). A few

([70]) Survey responses.

farmers also mentioned that the costs of complying with certain provisions, such as implementing animal health surveillance programmes, have not always been offset by tangible health benefits, especially in sectors that do not face high disease risks (validation workshop).

Veterinarians indicated that the costs of training and the additional time spent on administrative tasks (such as health certifications and disease reporting) have added to their workload. While these activities are essential for maintaining the law's effectiveness, they argued that these additional responsibilities take time away from their core activities of direct animal care (interviews, surveys).

Civil society and research organisations pointed out that the financial burden on smaller operators and public authorities may limit the law's effectiveness and could reduce the law's overall efficiency. They stressed that sufficient financial and technical support should be provided to help smaller operators comply without compromising animal health and welfare standards (interviews).

Administrative burden

NCAs reported that managing the complex requirements of the AHL, including reporting, disease monitoring, and compliance checks, has significantly increased their workload. This was particularly the case during the transition from previous systems, which required amending or repealing national legislation often coinciding with major disease outbreaks, further exacerbating the challenges. In addition, the need to coordinate across multiple national and EU-level bodies while ensuring compliance with various regulations was seen as time-consuming and resource-intensive (focus groups, interviews).

Farmers and industry representatives also expressed concerns about the administrative demands, particularly for record-keeping. Some suggest that the AHL could be more efficient if it incorporated more risk-based flexibility in reporting and certification requirements (validation workshop).

A few veterinarians also noted that the AHL has increased their administrative workload, with additional reporting obligations, such as consolidating regulatory requirements and completing paperwork, adding to their responsibilities. This includes tasks like filling out disease notification forms, which were reported to require harmonisation across agencies, as well as paperwork related to compliance with sector-specific legal requirements (e.g. in aquaculture). This administrative burden has reduced the time available for hands-on veterinary work, potentially affecting the quality of animal health care (interviews, surveys). Civil society and research organisations emphasised that while these administrative requirements are important for ensuring compliance, they can often create inefficiencies. They suggested that a more streamlined digital approach to reporting could reduce administrative burdens while maintaining high standards of animal health (interviews).

Opportunities for simplification

Several NCAs suggested that the process could be made more efficient by harmonising reporting requirements, specifically addressing issues such as reporting overlaps and the proportionality of time invested versus the potential benefits gained. In addition, aligning national procedures with EU-wide standards and providing clearer guidance and more

targeted training for national authorities are also perceived as ways to help streamline the application of the law (interviews, focus groups).

Farmers and industry representatives recommended reducing the complexity of animal movement reporting and certification processes. Digital tools such as e-certificates and integrated traceability systems were mentioned to simplify compliance and improve the speed of reporting, reducing the burden on both farmers and authorities (surveys, interviews). They also proposed introducing more flexibility in how disease surveillance and biosecurity measures are applied, particularly for low-risk areas, to avoid unnecessary costs and paperwork (validation workshop).

Veterinarians highlighted that digitalisation could be a key tool in simplifying reporting and reducing the administrative load, without further specifying. A more integrated system for health certifications and disease reporting, linked with existing veterinary databases, could save time and improve data accuracy (surveys, interviews). They also stressed the importance of ongoing training for veterinary professionals to ensure efficient and effective application of the AHL (focus groups).

Civil society and research organisations also advocated for simplifying the AHL's implementation by reducing redundant or overlapping requirements. A few organisations highlighted that the fragmentation of animal health and welfare legislation across the EU leads to duplicated procedures, inconsistent rules between Member States, and increased administrative burdens—particularly for operators involved in cross-border activities. They proposed that the AHL should be more flexible and adaptable to the needs of different farming systems, allowing for a more targeted approach to disease management (interviews, surveys). Regular reviews and updates to the AHL could also help keep it aligned with emerging challenges without overcomplicating implementation.

2.3 Relevance

Addressing current and emerging needs

Most NCAs considered the AHL fit and relevant to current and emerging animal health needs. They noted that its harmonised approach ensures that public authorities and the livestock sector can effectively tackle disease outbreaks across Member States (surveys, interviews). A few NCAs also emphasised that the law is flexible enough to accommodate the rapid evolution of specific diseases and public health threats, such as African Swine Fever and Avian Influenza (validation workshop, interviews).

Farmers and industry operators expressed mixed views on the AHL's capacity to address current and emerging needs. They noted that delegated and implementing acts allowed for quicker adjustments, while changes to the basic regulation are more complex and take longer, making it challenging to update measures when needed (interviews).

Veterinarians generally agreed that the AHL is relevant to address current animal health needs but pointed out that certain sectors, such as aquaculture, face difficulties in adapting the AHL's broad framework to their specific requirements. They noted that while the AHL is effective for broader disease management, further sectoral adaptations are necessary for full implementation (surveys, interviews).

Civil society and research organisations recognised the AHL's role in addressing global animal health challenges but stressed the need to improve the framework. A few international organisations and NGOs pointed out that the AHL has legal mechanisms for emergency responses but that improvements are needed to increase preparedness for climate-related risks (interviews, surveys).

Adaptability to evolving threats and challenges

The AHL's ability to adapt to new and evolving threats was widely seen as a strength across stakeholders. NCAs particularly appreciated the flexibility provided by the AHL's risk-based approach, which allows for targeted responses to emerging risks and evolving disease patterns (validation workshop, surveys).

Farmers and industry representatives also valued the AHL's adaptability but express concerns about the speed at which the framework can respond to rapidly spreading diseases. For example, during recent Bluetongue outbreaks, differences in approaches across Member States led to trade disruptions and complications in disease control (validation workshop, interviews).

Veterinarians highlighted that while the AHL's risk-based approach is generally effective, delays in its application to newly emerging diseases have been a challenge. They suggested that more proactive scanning and earlier detection of potential threats could enhance the system's responsiveness (surveys).

Civil society and research organisations echoed such concerns, mentioning the need for more frequent updates to remain effective in managing the risks posed by new diseases and evolving environmental challenges, including climate change and biodiversity concerns (interviews).

Flexibility for local adaptation and resulting challenges

There was consensus among all stakeholder groups that the flexibility of the AHL to adapt to local circumstances is both necessary and beneficial, particularly for addressing regional disease risks and outbreaks. However, stakeholders also agreed that this flexibility must be balanced with the need for harmonised implementation to avoid inconsistencies that could undermine the effectiveness of disease control and disrupt cross-border trade. While adaptation to national contexts is important, they emphasised that it should not compromise the AHL's core objective of ensuring coherent and effective disease management across the EU (validation workshop, interviews, surveys).

2.4 Coherence

Internal coherence

There was overall consensus among all stakeholder groups that the AHL is coherent within its framework, with only minor inconsistencies. While some NCAs, farmers, industry representatives, veterinarians, and civil society organisations acknowledged practical challenges such as the complexity of the legal language, varying implementation across Member States, and differences in interpreting certain measures, these issues were generally seen as manageable and not undermining the AHL's objectives (validation workshop, interviews, surveys).

External coherence

A large majority of NCAs agreed that the AHL aligns well with key EU policies, particularly those related to food safety and trade. The law's emphasis on disease prevention and biosecurity complements EU food safety regulations, enhancing cross-border disease management and ensuring the stability and safety of trade in animals and animal products.

Farmers representatives generally agreed that the AHL is coherent with animal welfare legislation but expressed concerns about its coherence with environmental policies. While they valued the AHL's flexibility and risk-based measures, they noted challenges in balancing food safety, sanitary requirements, and climate-related objectives, such as maintaining safety standards while minimising environmental risks. (interviews, surveys).

A few industry representatives highlighted that while the AHL aligns with the Official Control Regulation, its connection to animal transport and welfare regulations remains unclear, leading to inconsistencies in definitions and application. Similarly, farmers raised concerns about unresolved trade barriers despite internal harmonisation tools like regionalisation and compartmentalisation. They called for a more flexible approach to facilitate global trade (validation workshop, interviews).

Veterinarians supported the AHL's coherence with food safety policies, particularly its contribution to reducing the need for antibiotics and improving animal welfare. They also pointed out that while the AHL strengthens biosecurity, it could better align with EU environmental policies, especially those addressing climate-related impacts on animal health (surveys, interviews).

Civil society and research organisations supported the AHL's alignment with EU animal welfare and food safety regulations but called for a more integrated approach with environmental policies. They argued that the AHL should better address environmental sustainability, especially in the context of climate change and biodiversity. They recommended a closer integration with EU climate strategies, the European Green Deal and the Farm to Fork Strategy, to ensure that animal health management contributes to both immediate health goals and long-term environmental sustainability (interviews, surveys, CfE).

Addressing global challenges and fostering international cooperation

NCAs recognised that the AHL has contributed significantly to enhancing international cooperation by providing a framework for managing animal health that is globally recognised. According to them, the law has facilitated better engagement with international organisations, such as the World Organisation for Animal Health (WOAH), helping tackle global animal health challenges and ensuring the EU's compliance with international disease control standards. Several NCAs also noted that the AHL has strengthened the EU's ability to collaborate with neighbouring countries on cross-border disease management, improving disease control and preventing outbreaks in both the EU and surrounding regions (surveys, interviews, CfE, validation workshop).

Farmers acknowledged the benefits of international cooperation fostered by the AHL, particularly in maintaining access to international markets. The harmonisation of animal

health standards and the recognition of disease-free zones within the EU has facilitated trade relationships with non-EU countries (interviews, surveys, CfE). Industry representatives, in particular, emphasised the role of the AHL in raising the EU's standards for animal health, which are recognised globally. A few industry representatives also suggested that more focus should be placed on improving collaboration with low and middle-income countries, particularly in disease surveillance and capacity building (surveys, focus groups, validation workshop).

Veterinarians highlighted that international cooperation, especially with WOAH and other regional organisations, has helped align the EU's disease control efforts with global standards. This collaboration has further strengthened the EU's position in global animal health governance. However, some veterinarians suggested that international cooperation could be enhanced through joint training programmes and data-sharing initiatives to tackle emerging global threats more effectively (surveys, interviews, CfE).

Civil society and research organisations strongly supported the AHL's role in fostering international cooperation, particularly in addressing global health challenges such as zoonotic diseases. They stressed that the EU should continue to lead in global health diplomacy, ensuring that its policies not only promote trade but also contribute to global health security (interviews, CfE). In addition, an international organisation pointed out challenges in interpreting key concepts, such as 'disease control' and 'prevention,' which differ between the AHL and WOAH standards.

2.5 EU added value

The added value of an EU-Level framework

There was a consensus among all stakeholder groups on the added value of the EU-level framework provided by the AHL. Stakeholders agreed that harmonised rules at EU level are essential for effective disease prevention and control, facilitating trade, and ensuring a coordinated response to cross-border and global animal health threats.

Most **NCAs** recognised that the **EU-level framework** provided by the AHL has been essential in harmonising **disease prevention** and **control measures** across the EU. The AHL ensures **consistent standards**, which facilitates **trade** and the **movement of animals** within the EU, a benefit that national measures alone would likely not have achieved according to NCAs (validation workshop, surveys). Several NCAs highlighted that the **EU-wide approach** has proven particularly useful in managing **global disease threats** and maintaining a **level playing field** for Member States (surveys, interviews).

Farmers and industry representatives valued the EU-level action for its uniformity in trade and disease management. They recognised that the AHL's harmonised rules simplify compliance with both internal and external trade requirements, thereby strengthening the EU's position in international trade (interviews, surveys).

Veterinarians agreed that **EU-level action** is critical, particularly in avoiding fragmented rules and supporting **uniform disease management**. They stressed that without EU-level action, many **Member States** would struggle to implement effective **disease prevention** and **biosecurity measures** (surveys, interviews).

Civil society and research organisations generally echoed the positive views on EU-level action, acknowledging that national systems alone could not have achieved the same **harmonisation** and **cross-border coordination** necessary for effective disease control (surveys, interviews). Several organisations mentioned that the EU's actions ensure uniform standards, effective cross-border countermeasures, and uniform health regulations, which are crucial for managing animal health in the integrated European market (survey).

Suggestions to further strengthen EU-added value

Stakeholders across the board suggested several measures to **enhance EU-added value** under the AHL. **NCAs** proposed that the EU could provide more **guidance** and **resources** for national adaptation, particularly regarding **disease management** and **biosecurity standards**. This could include **dedicated training** and **capacity-building programmes** to ensure that **national authorities** are well-equipped to implement the law effectively (interviews, surveys).

Farmers and **industry representatives** recommended **streamlining documentation**, improving **digital tools**, and making the legislative structure less complex to make it easier for **small-scale farmers** to comply (interviews, surveys). In addition, several farmers' representatives recommended expanding the BTSF programme to include a broader range of stakeholders, as it is primarily designed for NCA and currently provides a limited snowball effect (validation workshop).

Veterinarians also recommended **further training** and **capacity building** to ensure that the veterinary profession is fully equipped to support the AHL's implementation. They suggested **more harmonised training programmes** and better **data-sharing** between **Member States** to improve **disease surveillance** and **biosecurity measures** (interviews, surveys). Additionally, a few proposed peer-to-peer training for animal keepers and veterinarians (validation workshop).

Annex VI Animal Health Law legal evolution and transitional phase (2016-2021)

In accordance with Article 264(3) of the AHL, the Commission reported in 2020 on the exercise of its delegated powers[71]. That report confirmed that substantial legislative development took place between 2018 and 2020, culminating in the adoption of delegated regulations forming the core of the secondary legal framework (see Table 1). By the date of application, the Commission had adopted 10 delegated acts supplementing non-essential elements of the AHL and 13 implementing acts laying down detailed technical provisions. These acts established the operational framework required for uniform application across Member States

Table 1: Delegated Regulations containing the specific measures adopted under the relevant empowerments in Regulation (EU) 2016/429.

Delegated Act	Empowerments in Regulation (EU) 2016/429
Commission Delegated Regulation (EU) 2018/1629 of 25 July 2018 amending the list of diseases set out in Annex II to Regulation (EU) 2016/429 of the European Parliament and of the Council on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')	Article 5(2) and (4)
Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs	Articles 3(5), 87(3), 94(3), 97(2), 101(3), 106(1), 118(1) and (2), 119(1) and 122(2), Articles 271(2) and 279(2)
Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals	Articles 94(3), Article 97(2), Article 101(3), Article 106(1), Article 122(1) and (2), Article 131(1), Article 160(1) and (2), Article 161(6), Article 162(3) and (4), Article 163(5), Article 164(2), Article 165(3) and Article 279(2)
Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs	Article 3(5), Article 125(2), Article 131(1), Article 132(2), Article 135, Article 136(2), Article 137(2), Article 140, Article 144(1), Article 146(1), Article 147, Article 149(4), Article 154(1), Article 156(1), Article 160, Article 162(3) and (4), Article 163(5)(b) and (c) and Article 164(2)

[71] COM(2021) 57final EUR-Lex - 52021DC0057 - EN - EUR-Lex.

Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases	Articles47(1), Article 53(2), Article 54(3), Article 55(2), Article 58(2), the first paragraph of Article 63, Article 64(4), the first paragraph of Article 67, Article 68(3), Article 70(3), Article 72(2), Article 73(3), Article 74(4), Article 76(5), Article 77(2) and Article 272(2)
Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases	Article 29, Article 31(5), 32(2), 37(5), Article 39, Article 41(3), Article 42(6) and Article 280(4)
Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals	Articles 176(4), 181(2), 185(5), 189(1) and 279(2)
Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin	Articles 234(2), 237(4) and 239(2)
Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health and certification requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals	Articles 192(2), 197(3), 201(3), 202(3), 205(2), 211(1), 213(1), 216(4), 218(3), 221(1), 222(3), 223(6), and 224(3)
Commission Delegated Regulation (EU) 2020/2154 of 14 October 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards animal health, certification and notification requirements for movements within the Union of products of animal origin from terrestrial animals	Articles 166(3), 168(3) and 169(5)

In its 2020 and its 2025 report[72] on the exercise of delegated powers, the Commission confirmed the continuation of delegated acts adoption covering areas such as Union antigen, vaccine and diagnostic reagent banks; the use of certain veterinary medicinal products for disease prevention and control; and rules for approval and recognition of disease-free status in compartments keeping terrestrial animals. By mid-2025, 85 of the 110 delegated powers conferred under the AHL had been exercised. The report concluded that the empowerments remained necessary to ensure flexibility, allow regular adaptation to scientific developments and address areas requiring further regulatory specification. On this basis, the Commission proposed extending the empowerments beyond the initial five-year period.

Moreover, Article 274 of the AHL obliged the Commission to adopt certain delegated acts and one implementing act by 19 April 2019. The Commission had partially met this obligation as only three of those acts were published in the official journal in 2019, while the rest, even if ready and adopted by the Commission earlier, were published only in 2020. The drafting and adoption of the delegated and implementing acts was intense and technically demanding with 60 expert group meetings between 2017 and 2019, and 41 in 2018 alone.

Scientific advice, including EFSA opinions and alignment with international standards, was translated into operational legal provisions across a wide range of disease areas. The transition to the AHL framework required Member States to adapt existing national systems and procedures to directly applicable Union rules and the delays in adopting certain delegated and implementing acts posed an additional challenge to Member States. To facilitate the adjustment, the Commission introduced transitional measures, issued guidance and organised technical exchanges alongside the legislative package.

[72] COM(2025) 316 final REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL.