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Study supporting the evaluation of the EU Animal Health Law

Final Report

Written by Ecorys, Wageningen University & Research, Arcadia International, and VetEffect

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Final Report

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Acronyms table

Acronym	Full Name
ABP	Animal By-products
ADIS	Animal Disease Information System
AHL	Animal Health Law
AMR	Antimicrobial Resistance
AMU	Antimicrobial Use
ASF	African Swine Fever
BRG	Better Regulation Guidelines
BRT	Better Regulation Toolbox
BT	Bluetongue
BTSF	Better Training for Safer Food
BVD	Bovine Viral Diarrhoea
CAGR	Compound Annual Growth Rate
CBA	Cost-Benefit Analysis
CfE	Call for Evidence
CJEU	Court of Justice of the European Union
CPs	Control Programmes
COMEXT	External Trade Database
CVO	Chief Veterinary Officer
DG Sante	Directorate General for Health and Food Safety
DVFA	Danish Veterinary and Food Administration
DOI	Digital Object Identifier
EAZWV	European Association of Zoo and Wildlife Veterinarians
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
FADN	Farm Accountancy Data Network
FMD	Foot-and-mouth disease
FVE	Federation of Veterinarians of Europe

Acronym	Full Name
HPAI	Highly Pathogenic Avian Influenza
GOE	Emergency Operations Group
IA and DA	Implementing and Delegated Act
IBR	Infectious Bovine Rhinotracheitis
IHN	Infectious Haematopoietic Necrosis
ISAV	Salmon Anaemia Virus
IT	Information Technology
LPAI	Low-pathogenic Avian Influenza
MS	Member State
NCA	National Competent Authority
NGO	Non-Governmental Organisation
OCR	Official Control Regulation
PCR	Polymerase Chain Reaction testing
PPR	Peste des Petits Ruminants
SGP	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
VHS	Viral Haemorrhagic Septicaemia
WAHIS	World Animal Health Information System
WOAH	World Organisation for Animal Health
WTO	World Trade Organisation

Executive Summary

The EU Animal Health Law (AHL), Regulation (EU) 2016/429, entered into force in 2016 and became applicable in April 2021. It represents a fundamental shift in the EU's animal health legal framework, moving from vertical legal acts, mainly directives, organised by diseases or specific topics such as intra-UE trade of certain animal species, to a horizontal overarching regulation accompanied by delegated and implemented acts to operationalise it. The AHL aims to protect animal health, support sustainable farming systems, safeguard public health, and maintain the effective functioning of the EU internal market.

This report aims to support the ex-post evaluation of the AHL and its delegated acts. This evaluation assists the European Commission in collecting quantitative and qualitative evidence on the Animal Health Law's performance and implementation, as mandated by Article 282 of Regulation (EU) 2016/429.

The evaluation has been conducted in line with the Better Regulation Guidelines and is guided by five core criteria: effectiveness, efficiency, coherence, relevance, and EU added value. Evidence for this assessment was collected through a combination of desk research, a public Call for Evidence, targeted surveys, interviews, focus groups, and validation workshops with stakeholders representing all EU Member States. The evaluation covers the period from 2016 to 2023, with a particular focus on the implementation phase from April 2021 to the end of 2023.

Key findings

Effectiveness

In terms of effectiveness, the AHL has been widely acknowledged as a significant step forward in harmonising the EU's approach to animal health, moving from a reactive to a preventive system. The current effectiveness of the AHL must be assessed in light of its ongoing implementation. Most Member States have not yet completed the alignment of their national legislation with the regulation, with some showing substantial progress (e.g. The Netherands, Italy and Spain). Delays are due to the complexity of national legal systems and administrative structures. In addition, the shift to the new logic introduced by the AHL will take time for all stakeholders to master, and therefore affect the perception of stakeholders regarding effectiveness and explain the progressive transition. In addition, the COVID-19 pandemic and delays in the adoption of delegated and implementing acts further delayed the transition.

The AHL has introduced a structured and science-based system for disease categorisation, listing transmissible animal diseases under five categories (A to E) based on their epidemiological profile, impact, and control feasibility. This categorisation enables proportional responses and prioritisation of resources, allowing Member States to tailor their surveillance and control strategies to national contexts. While stakeholders broadly support this approach, concerns have been raised about the system's responsiveness to emerging threats and the need for more frequent updates, particularly in light of climate-driven changes in disease dynamics.

The AHL also emphasises prevention through enhanced biosecurity. The regulation establishes clear responsibilities for operators and competent authorities, requiring the implementation of biosecurity measures at the farm level and across the production chain. While this has led to improvements in awareness and risk mitigation, implementation remains uneven. Larger, intensive operations have generally adapted to enhanced biosecurity measures more easily, while small-scale and remote farms face challenges due to limited resources and veterinary coverage. The lack of harmonised guidance and training has further complicated uptake in some Member States.

Another key feature of the AHL is the reinforcement of stakeholder roles and shared responsibilities. The regulation clarifies the duties of farmers, veterinarians, competent authorities, and other actors in the animal health chain. This has improved coordination and accountability, particularly in disease notification, surveillance, and outbreak response. However, the evaluation highlights the need for broader awareness and capacity-building, especially among smaller operators and non-authority stakeholders. Despite EU-level training initiatives as part of the Better Training for Safer Food activities, dissemination at the national level remains limited, and many stakeholders report difficulties in navigating the legal framework and understanding their obligations. In this regard, contingency planning and simulation exercises can also play a role in involving stakeholders and increasing awareness, but the alignment of national legislation is still ongoing.

In addition, delays in the alignment of national legislation have also led to differences in the application of certain new provisions, such as those on animal health visits, which, based on risk assessments, represent an important tool supporting disease prevention and early detection. Some Member States have integrated these visits into existing programmes, but the extent to which Article 25 is actually implemented remains difficult to assess due to a lack of official data. In addition, a lack of enforcement mechanisms or shortages in veterinary personnel, particularly in rural and remote areas, further undermine full compliance and the assessment of the effectiveness of such novelty.

The AHL also strengthens the EU’s capacity to control and eradicate diseases through structured eradication programmes and the recognition of disease-free areas, which are essential for maintaining trade and reducing the burden of

endemic diseases. However, the current variability in national implementation has limited their full potential. Importantly, the AHL has not led to a major disruption of trade flows during outbreaks thanks to the use of restricted zones. The AHL allowed Member States to apply targeted restrictions rather than blanket bans, enabling the safe movement of animals and products from disease-free zones. The AHL has also clarified the conditions under which vaccination can be used as a preventive or emergency measure. This has enabled more strategic deployment of vaccines, such as in the case of Highly Pathogenic Avian Influenza (HPAI), where targeted vaccination campaigns have helped reduce outbreak severity and limit economic losses.

The upgrade of digital tools such as TRACES for traceability and animal movements and ADIS for reporting and notification is seen as an improvement, although technical and interoperability issues persist.

While the implementation of the AHL has aimed to harmonise and simplify animal health requirements across the EU, some unintended effects have been observed, particularly for small-scale operators. In certain cases, the requirements introduced at the national level, which sometimes go beyond what is set by the AHL, have resulted in increased administrative and financial burdens. This has, in some instances, discouraged participation in disease control programmes. Additionaly, while the AHL does not regulate financial support, the lack of adequate compensation mechanisms has been noted by stakeholders as a barrier to effective implementation.

In conclusion, the AHL provides a strong and coherent foundation for a harmonised, preventive, and risk-based animal health policy in the EU. Its effectiveness is evident in areas where implementation has progressed, particularly in disease categorisation, risk-based surveillance, biosecurity, and eradication efforts. However, the overall current picture remains one of transition. Continued support for Member States, simplification of legal instruments, and broader stakeholder engagement will be essential to fully realise the regulation’s potential. As national systems continue to align with the AHL, a more comprehensive assessment of its long-term impact will become possible.

Efficiency

The evaluation of the AHL’s efficiency considers whether the costs incurred by Member States, stakeholders, and the European Commission have been proportionate to the benefits achieved since its implementation. However, a significant limitation of this study is that Member States have not yet fully aligned their national legislation with the AHL, nor have they fully utilised the flexibility offered by the AHL. As a result, it remains challenging for both the study team and stakeholders to disentangle the impact of the AHL from that of not fully aligned national legislation. Additionally, several years may be required before the effects of the AHL are reflected in actual changes to animal health status,

especially considering that external factors may also influence the epidemiological landscape.

Overall, the cost-benefit balance of the AHL is expected to be positive in the long term, though with important qualifications. In the short to medium term, the AHL has entailed substantial costs and administrative efforts for various stakeholders, and these upfront costs have in some cases been higher than initially expected. These costs and efforts are investments that are expected to yield clear future benefits in disease prevention and control, regulatory harmonisation, and trade facilitation. Such benefits are expected to grow over time. The AHL's emphasis on prevention (e.g. biosecurity measures and surveillance) is anticipated to reduce costly disease outbreaks in future years, leading to savings that justify the current expenditures. Indeed, survey feedback indicates a broadly positive outlook. Nonetheless, the efficiency gains are not yet fully realised, as the regulatory transition is still ongoing. In this early implementation phase, the AHL's benefits have materialised unevenly, while certain costs are front-loaded.

On the cost side, some National Competent Authorities have borne substantial one-off and ongoing costs to align national systems with the AHL. These include efforts to update or consolidate national legislation, upgrade IT systems (notably for disease notification and traceability), recruit or train personnel, and communicate new requirements to stakeholders. Many national authorities had to redirect significant resources to adapt their surveillance and reporting infrastructure. Economies have also faced new compliance costs. These stem from obligations such as enhanced disease surveillance and biosecurity protocols, record-keeping for animal movements, and, in some cases, requirements like periodic animal health veterinary visits and registrations of new establishments. However, depending on the specific measures, they were not entirely new to all stakeholders. For instance, some farmers in particular sectors and countries were already subject to animal health veterinary visits prior to the implementation of the AHL, either due to national legislation or participation in private certification schemes. Consequently, the extent to which the AHL has introduced new costs varies across stakeholders, sectors, and Member States.

The benefits observed or anticipated under the AHL include a more effective and efficient disease control and a more coherent regulatory environment. By replacing 38 legal acts with a single regulation, the AHL was designed to streamline rules and reduce legal fragmentation. In principle, this consolidation has given more legal certainty and should improve clarity and save administrative effort in the long term. Indeed, many stakeholders report that having a unified framework has improved coordination between authorities and stakeholders and facilitated a quicker, more unified response to transboundary disease threats. There is evidence that the AHL's measures (such as risk-based surveillance and regionalisation of disease restrictions) have helped contain recent animal disease incursions (e.g. avian influenza, African swine fever) more efficiently, thereby reducing the scale of culling, trade bans, and other costly emergency measures. Trade and internal market benefits have also been noted: by harmonising

standards and approaches across the EU, the AHL helps maintain trust in intra-EU trade of animals and animal products and prevents unjustified trade barriers during disease events (through the use of regional disease zoning rather than nationwide bans). These benefits, while harder to quantify immediately, contribute to a more stable and predictable operating environment for businesses and authorities. Taken together, these improvements suggest that the AHL is delivering value that should, over time, balance out the investments made.

Despite its long-term advantages, the implementation of the AHL by the MS and the alignment with their national legislation, stakeholders claim that the implementation has introduced administrative burdens, particularly in the initial stage. Stakeholders across the board have raised concerns about increased paperwork, the complexity of new procedures, and overlapping requirements between national and EU requirements. Certain target groups have been especially affected by administrative burdens. In particular, small-scale farmers and hobbyist animal keepers have reported that complying with the AHL's requirements (such as obtaining animal health certificates for animal movements, or meeting new record-keeping and biosecurity rules) is, in their view, onerous and disproportionate to the scale of their operations. Larger commercial operators also note some increased costs of compliance, but these tend to be more readily absorbed in bigger businesses; by contrast, very small operators feel the impact more acutely, perceiving some measures as bureaucratic overlaps with little direct benefit to animal health in their context.

The AHL is complemented by a number of Delegated and Implementing Acts, and some stakeholders report that information or obligations are spread across multiple pieces of legislation, making it challenging to navigate and get a clear overview.

The efficiency and cost-benefit experience of the AHL varies significantly between Member States and stakeholder groups. Member States that entered the AHL era with a developed veterinary infrastructure, advanced IT systems, and well-resourced administrations have generally managed the transition more smoothly and even capitalised on it. For example, countries such as Italy, which introduced a national computerised database for animal traceability, have reported improvements in surveillance and early detection capacity. In Austria, the integration of geographical coordinates into the veterinary registry supports rapid visualisation of outbreaks, enhancing epidemiological responsiveness. These examples highlight that where investment has been made in infrastructure and capacity-building, the AHL's operational efficiency can be realised more effectively. By contrast, Member States with more limited resources or less developed systems have faced steeper challenges and higher relative costs. Such disparities also affect stakeholders like farmers; for instance, if a country delays rolling out updated guidance, farmers and veterinarians in that country might struggle longer with confusing procedures.

Moreover, the distribution of costs and benefits among stakeholder categories also varies depending on the extent Member States use the flexibility granted by the AHL. In Member States that did not fully embrace a risk-based approach, the farming community felt a heavier burden. In other Member States that applied the flexibilities of the AHL to tailor measures to local risk (for example, exempting very small keepers from certain duties), the private sector's burden was relatively lighter. These policy choices, along with differing economic structures (large commercial farms vs. many smallholders), mean that the AHL's efficiency can be viewed differently from one country or sector to another.

The AHL maintained overall reporting obligations (yet for a reduced number of diseases subjected to EU rules, as by repealing Council Directive 92/65/EEC) with adjustments intended to enhance transparency and coordination across the EU. While the launch of the Animal Disease Information System (ADIS) has improved disease reporting at the EU level.

Coherence

The AHL largely demonstrates strong internal coherence, maintaining its structural and conceptual integrity despite minor inconsistencies primarily stemming from interpretation and implementation by MS. The AHL is also broadly aligned with other EU policy frameworks, including the Green Deal and the One Health approach. Its objectives reinforce those of the single market, public health, food safety, and environmental protection. Nonetheless, some inconsistencies remain. For instance, while the AHL integrates principles of animal health and food safety (even if Salmonella and TSE rules have not been modified by the AHL), no direct legal contradictions with animal welfare legislation were identified; however, perceptions of misalignment exist. Stakeholders, including non-governmental organisations, have raised concerns regarding issues such as animal transport and culling practices during outbreaks, particularly in intensive farming systems. These measures are based on risks and are intended to protect animal health while taking into consideration animal welfare. Such concerns, therefore, relate more to the implementation of temporary disease control measures and broader farming practices than to the legal provisions. In an ongoing update of the animal welfare legislation, these are likely to be clarified.

Relevance

The AHL's relevance remains high in the context of ongoing and emerging threats to animal health. Diseases such as ASF, Highly Pathogenic Avian Influenza (HPAI), and Bluetongue have continued to circulate in the EU, demonstrating the importance of a robust regulatory framework. The AHL has shown adaptability, particularly through its disease categorisation system, which allows for flexible responses based on risk. Nevertheless, some NCAs criticise the AHL for not being sufficiently dynamic to account for changes in epidemiological trends or the

emergence of new diseases. Stakeholders have called for a more responsive framework that can incorporate scientific advances more rapidly and adapt to the realities of climate change and its impact on disease vectors.

EU Added value

The AHL demonstrates its EU added value by strengthening mechanisms for coordinated responses across Member States, facilitating safe intra-EU trade and export continuity during outbreaks. By allowing regional restrictions rather than blanket national zero-risk measures, it reduces the costs significantly by minimising its negative impact on the single market. For instance, regionalisation strategies for poultry in France and compartmentalisation in aquaculture in Denmark have allowed trade to continue from disease-free zones or compartments during outbreaks. Also, the coordinated responses introduced by the AHL contributed to the acceptance of animal products in third countries.

Limitations

It is important to acknowledge the limitations of the present evaluation. Given that the AHL was only applicable from 2021, and full national alignment in a large number of MS is still ongoing, the evidence collected in this study reflects an early and transitional stage of implementation. As a result, it remains challenging to isolate AHL impacts from other external factors, such as the degree of alignment of national systems or external shocks like the COVID-19 pandemic and geopolitical developments and, at this stage, to quantify those impacts.

Overall conclusion

The AHL represents a strong foundation for a harmonised animal health policy in the EU. Its shift towards prevention, risk-based decision-making, and integration with broader EU goals marks a substantial improvement over the previous system. However, uneven implementation, complexity in legal instruments, and limited stakeholder understanding continue to pose challenges. With continued effort to promote simplification, build capacity, and enhance cooperation between Stakeholders, Member States and the European Commission, the AHL can fulfil its potential in safeguarding animal and public health, promoting sustainability, and supporting the competitiveness of the EU’s agri-food sector.

Résumé exécutif

Le Règlement (UE) 2016/429 relatif à la législation sur la santé animale (LSA) de l'Union européenne est entré en vigueur en 2016 et est devenu applicable en avril 2021.Cela représente un changement fondamental dans le cadre juridique de l'Union européenne en matière de santé animale, passant d'actes législatifs verticaux – principalement des directives par maladie ou par sujet spécifique (tels que les échanges intracommunautaires de certaines espèces animales) – à un règlement horizontal de portée générale, assorti d'actes délégués et d'actes d'exécution destinés à le mettre en œuvre. La LSA vise à protéger la santé animale, à soutenir des systèmes d'élevage durables, à préserver la santé publique et à garantir le bon fonctionnement du marché intérieur de l'Union.

Le présent rapport vise à appuyer l'évaluation ex post de la LSA et de ses actes délégués. Cette évaluation aide la Commission européenne à recueillir des données probantes quantitatives et qualitatives sur la performance et la mise en œuvre de la législation, comme le prévoit l'article 282 du règlement (UE) 2016/429.

L'évaluation a été conduite conformément aux lignes directrices du programme de l'Union européenne pour une meilleure réglementation. Elle s'appuie sur cinq critères fondamentaux: l'efficacité, l'efficience, la cohérence, la pertinence et la valeur ajoutée européenne. Les éléments probants ont été recueillis à travers une combinaison méthodologique incluant l'analyse documentaires, un appel public à contributions, des enquêtes ciblées, des entretiens, des groupes de discussion ainsi que des ateliers de validation réunissant les parties prenantes issues de l'ensemble des États membres de l'Union. L'évaluation couvre la période 2016 - 2023, en mettant particulièrement l' accent sur la phase de mise en œuvre entre avril 2021 et fin 2023.

Résultats clefs

Efficacité

En matière d'efficacité, la LSA est largement reconnu comme une avancée significative dans l'harmonisation de l'approche de l'Union européenne en matière de santé animale, marquant le passage d'un système essentiellement réactif à une approche davantage axée sur la prévention. L'évaluation de son efficacité actuelle doit toutefois être nuancée, dans la mesure où sa mise en œuvre demeure en cours. La majorité des États membres n'ont pas encore achevé l'alignement complet de leur législation nationale avec les dispositions du règlement, bien que certains aient enregistré des avancées notables, à l'instar de l'Italie et de l'Espagne. Les retards observés s'expliquent principalement par la complexité des systèmes juridiques et des structures administratives nationales. Par ailleurs, l'appropriation progressive, par l'ensemble des parties

prenantes, de la nouvelle logique introduite par la LSA requiert du temps, ce qui influence leur perception de son efficacité. En outre, la pandémie de COVID-19 ainsi que les retards dans l'adoption des actes délégués et d'exécution ont également contribué à ralentir cette phase de transition.

La LSA a instauré un système structuré, fondé sur des bases scientifiques, pour la catégorisation des maladies animales transmissibles. Celles-ci sont désormais classées en cinq catégories (de A à E), en fonction de leur profil épidémiologique, de leur impact potentiel, ainsi que de la faisabilité de leur prévention et de leur maîtrise. Cette catégorisation vise à permettre la mise en œuvre de réponses proportionnées et à faciliter la hiérarchisation des ressources, tout en offrant aux États membres la possibilité d'adapter leurs stratégies de surveillance et de lutte aux spécificités de leur contexte national. Bien que cette approche soit largement saluée par les parties prenantes, certaines préoccupations ont été exprimées concernant la capacité du système à réagir de manière adéquate aux menaces émergentes, ainsi que la nécessité d'actualisations plus fréquentes, notamment en réponse aux évolutions des dynamiques épidémiologiques liées au changement climatique.

La LSA accorde également une place centrale à la prévention, notamment par le renforcement des exigences en matière de biosécurité. Le règlement précise de manière explicite les responsabilités respectives des opérateurs et des autorités compétentes, en imposant la mise en œuvre de mesures de biosécurité tant au niveau des élevages qu'à l'ensemble de la chaîne de production. Si cette approche a contribué à une meilleure sensibilisation et à une réduction des risques sanitaires, sa mise en œuvre demeure hétérogène. Les éleveurs opérant dans des structures de grande taille, souvent plus intensives, se sont généralement adaptés plus facilement aux exigences accrues en matière de biosécurité. En revanche, les petits éleveurs, ainsi que ceux exerçant dans des zones isolées, rencontrent davantage de difficultés, en raison de ressources limitées et d'une couverture vétérinaire parfois insuffisante. Par ailleurs, l'absence de lignes directrices harmonisées et de formations adaptées a freiné, dans certains États membres, l'adoption effective de ces mesures.

Un autre volet essentiel de la LSA réside dans le renforcement du rôle des parties prenantes et des responsabilités partagées. Le règlement clarifie les obligations respectives des éleveurs, des vétérinaires, des autorités compétentes, ainsi que d'autres acteurs intervenant tout au long de la chaîne de la santé animale. Cette clarification a contribué à améliorer la coordination et la responsabilisation, notamment en ce qui concerne la notification des maladies, les activités de surveillance et la gestion des foyers épidémiques. Toutefois, l'évaluation met en évidence la nécessité de renforcer la sensibilisation et les capacités, en particulier auprès des petits opérateurs et des parties prenantes qui ne relèvent pas des autorités officielles. Malgré les initiatives de formation mises en œuvre au niveau européen dans le cadre du programme « Better Training for Safer Food », leur diffusion au niveau national demeure limitée. De nombreux acteurs rencontrent encore des difficultés à s'orienter dans le cadre juridique et à

comprendre pleinement leurs obligations. À cet égard, les plans de contingence et les exercices de simulation peuvent également jouer un rôle important pour mobiliser les parties prenantes et renforcer leur sensibilisation, bien que l'harmonisation des législations nationales soit encore en cours.

Par ailleurs, les retards observés dans l'alignement des législations nationales ont entraîné des disparités dans l'application de certaines dispositions nouvelles, telles que les visites sanitaires. Fondées sur une évaluation des risques, celles-ci constituent un outil essentiel pour la prévention des maladies et leur détection précoce. Si certains États membres ont intégré ces visites dans leurs dispositifs nationaux existants, l'ampleur réelle de la mise en œuvre de l'article 25 demeure difficile à apprécier, en l'absence de données officielles consolidées. En outre, le manque de mécanismes de contrôle, conjugué à des pénuries de personnel vétérinaire, en particulier dans les zones rurales et isolées, continue de compromettre le respect effectif de ces dispositions ainsi que l'évaluation de leur efficacité.

La LSA renforce également la capacité de l'Union à prévenir, gérer et éradiquer les maladies animales au moyen de programmes d'éradication structurés et de la reconnaissance officielle de zones indemnes. Ces dispositifs constituent des outils clés pour le maintien des échanges commerciaux et la réduction de la charge liée aux maladies endémiques. Toutefois, les disparités persistantes dans la mise en œuvre au niveau national ont limité le plein potentiel de ces mécanismes. Il convient néanmoins de souligner que la LSA n'a pas entraîné de perturbations majeures des flux commerciaux lors de foyers épidémiques, notamment grâce à l'application du principe des zones réglementées. Ce cadre a permis aux États membres d'imposer des restrictions ciblées plutôt que des interdictions généralisées, facilitant ainsi les mouvements sécurisés d'animaux et de produits en provenance de zones reconnues indemnes. Par ailleurs, la LSA a clarifié les conditions dans lesquelles la vaccination peut être utilisée, tant à titre préventif qu'en situation d'urgence. Cette clarification a favorisé une utilisation plus stratégique des vaccins, comme en témoigne la réponse à l'influenza aviaire hautement pathogène (IAHP), où des campagnes de vaccination ciblées ont contribué à atténuer la gravité des foyers et à limiter les pertes économiques.

La modernisation des outils numériques, notamment TRACES pour la traçabilité et les mouvements d'animaux, ainsi qu'ADIS pour le signalement et la notification des maladies, est globalement perçue comme une avancée importante. Toutefois, des difficultés techniques persistent, en particulier en matière d'interopérabilité entre systèmes, ce qui limite encore leur efficacité opérationnelle.

Un effet non intentionnel de la mise en œuvre de la LSA, lié aux exigences introduites au niveau national, a été, dans certains cas, la démotivation des petits opérateurs à participer aux programmes de lutte contre les maladies. Bien que la LSA ne régisse pas directement les dispositifs d'aide financière, l'absence de

mécanismes d'indemnisation jugés adéquats a été fréquemment signalée par les parties prenantes comme un obstacle majeur à la mise en œuvre effective des mesures prévues.

En conclusion, la LSA constitue une base solide et cohérente pour le développement d'une politique de santé animale harmonisée, préventive et fondée sur l'évaluation des risques à l'échelle de l'Union. Son efficacité est particulièrement visible dans les domaines où la mise en œuvre a enregistré des avancées notables, tels que la catégorisation des maladies, le renforcement de la biosécurité et les programmes d'éradication. Néanmoins, l'ensemble du dispositif demeure en phase de transition. La concrétisation du plein potentiel de la LSA dépendra d'un appui continu aux États membres, d'une simplification progressive des instruments juridiques, ainsi que d'une mobilisation accrue des parties prenantes. À mesure que les systèmes nationaux s'aligneront sur les exigences du règlement, une évaluation plus complète et plus précise de ses effets à long terme pourra être envisagée.

Efficience

L'évaluation de l'efficience de la LSA vise à déterminer si les coûts supportés par les États membres, les parties prenantes et la Commission européenne sont proportionnés aux bénéfices générés depuis son entrée en application. Toutefois, une limite majeure de cette analyse réside dans le fait que les législations nationales ne sont pas encore pleinement alignées sur le règlement, et que la flexibilité qu'offre la LSA, n'a pas été entièrement exploitée. Dans ce contexte, il reste difficile, tant pour l'équipe d'évaluation que pour les parties prenantes, d'isoler les effets spécifiques attribuables à la LSA de ceux découlant de l'absence d'harmonisation juridique. Par ailleurs, plusieurs années pourraient être nécessaires avant que les effets attendus de la LSA se traduisent concrètement par des améliorations durables du statut sanitaire, d'autant que la situation épidémiologique reste influencée par de nombreux facteurs extérieurs.

Dans l'ensemble, le rapport coûts-bénéfices de la LSA devrait s'avérer positif à long terme, bien que cette perspective doive être nuancée. À court et moyen terme, sa mise en œuvre a généré des coûts administratifs et des charges opérationnelles significatifs pour de nombreuses parties prenantes, ces coûts initiaux s'étant parfois révélés supérieurs aux estimations préalables. Ces dépenses doivent toutefois être interprétées comme des investissements destinés à produire, à terme, des bénéfices tangibles en matière de prévention et de maîtrise des maladies, d'harmonisation réglementaire et de fluidification des échanges. Ces bénéfices devraient croître progressivement avec le temps. L'accent mis par la LSA sur la prévention — notamment à travers les mesures de biosécurité et les dispositifs de surveillance — devrait permettre de limiter la survenue d'épidémies coûteuses, générant ainsi des économies susceptibles de compenser les investissements initiaux. Par ailleurs, les retours issus des enquêtes menées dans le cadre de l'évaluation font état d'une perception

globalement positive. Néanmoins, les gains d'efficience ne sont pas encore pleinement matérialisés, la transition réglementaire étant toujours en cours. Dans cette phase de transition, les bénéfices de la LSA apparaissent de manière inégale, tandis que certains coûts restent concentrés en amont.

Du point de vue des coûts, les autorités compétentes nationales ont supporté des charges ponctuelles et récurrentes pour adapter leurs systèmes aux exigences de la LSA. Cela a notamment impliqué la mise à jour ou la consolidation des législations nationales, la modernisation des systèmes informatiques (notamment pour la notification des maladies et la traçabilité), le recrutement ou la formation de personnel, ainsi que la diffusion des nouvelles obligations auprès des parties prenantes. Dans ce cadre, plusieurs autorités ont réaffecté des ressources pour ajuster leurs dispositifs de surveillance et de notification. Les acteurs économiques ont également été confrontés à de nouveaux coûts de conformité, liés à des obligations telles que le renforcement de la surveillance sanitaire, la mise en œuvre de protocoles de biosécurité, la tenue de registres des mouvements d'animaux, ainsi que, dans certains cas, des visites sanitaires périodiques ou l'enregistrement de nouveaux établissements. Toutefois, selon les mesures concernées, ces obligations ne constituaient pas nécessairement une nouveauté pour l'ensemble des opérateurs. Par exemple, certains éleveurs, dans certains secteurs ou États membres, étaient déjà soumis à des visites sanitaires dans le cadre de la législation nationale ou de schémas de certification privés. Ainsi, les coûts additionnels liés à la LSA varient selon les parties prenantes, les filières concernées et les contextes nationaux.

Les bénéfices observés ou anticipés dans le cadre de la LSA incluent une amélioration du contrôle des maladies animales et une plus grande cohérence du cadre réglementaire. En remplaçant 38 actes législatifs par un texte unique, la LSA avait pour objectif de simplifier les règles applicables et de réduire la fragmentation juridique. En principe, cette consolidation a permis d'accroître la sécurité juridique, de clarifier les responsabilités des acteurs concernés et de limiter les charges administratives sur le long terme. Plusieurs parties prenantes indiquent qu'un cadre réglementaire unifié a contribué à renforcer la coordination entre les autorités et les opérateurs, ainsi qu'à favoriser une réponse plus rapide et mieux structurée face aux menaces sanitaires, notamment en cas d'épidémies transfrontalières. Certaines données suggèrent que les mesures introduites par la LSA, telles que la surveillance fondée sur les risques ou la régionalisation des restrictions, ont contribué à contenir plus efficacement certaines récentes incursions de maladies animales, comme l'influenza aviaire ou la peste porcine africaine. Cela a permis de limiter, dans une certaine mesure, les abattages, les restrictions commerciales et d'autres mesures d'urgence. Des effets positifs ont également été relevés sur le commerce et le fonctionnement du marché intérieur : en harmonisant les approches au sein de l'Union, la LSA soutient la continuité des échanges intra-UE d'animaux et de produits d'origine animale, notamment en permettant le recours au zonage plutôt qu'à des interdictions générales. Bien que ces bénéfices soient encore difficiles à mesurer de manière précise, ils semblent contribuer à un environnement plus stable et prévisible pour les

autorités comme pour les acteurs économiques. Pris dans leur ensemble, ces progrès suggèrent que la LSA apporte une réelle valeur ajoutée qui, avec le temps, devrait compenser les investissements consentis.

Malgré les bénéfices attendus à long terme, la mise en œuvre de la LSA, ainsi que l'alignement progressif des législations nationales, ont entraîné, selon les parties prenantes, une augmentation de la charge administrative, en particulier lors de la phase initiale. Plusieurs acteurs ont exprimé des préoccupations concernant la complexité des nouvelles procédures, l'alourdissement des formalités administratives, ainsi que des situations de chevauchement entre exigences nationales et dispositions européennes. Certains groupes semblent plus concernés que d'autres par cette charge. En particulier, les petits éleveurs et les détenteurs d'animaux à des fins non commerciales considèrent que certaines exigences de la LSA, telles que l'obtention de certificats sanitaires pour les mouvements d'animaux ou le respect de règles renforcées en matière de traçabilité et de biosécurité, sont difficiles à mettre en œuvre et peu adaptées à la nature ou à la taille de leur activité. Les opérateurs commerciaux de plus grande taille signalent également une hausse des coûts de conformité, mais ces derniers peuvent être mieux absorbés au sein de structures organisées. À l'inverse, les très petits opérateurs ressentent plus directement l'impact de ces nouvelles obligations, qu'ils perçoivent parfois comme des contraintes administratives sans retombées sanitaires clairement perceptibles dans leur échelle.

La LSA est accompagnée de plusieurs actes délégués et d'exécution, qui précisent ses modalités d'application. Toutefois, certaines parties prenantes relèvent que les informations et obligations sont dispersées entre de nombreux textes juridiques, ce qui peut rendre l'ensemble difficile à appréhender et compliquer la navigation dans le cadre réglementaire.

L'expérience en matière d'efficience et de rapport coûts-bénéfices liés à la LSA varie sensiblement selon les États membres et les catégories de parties prenantes. Les États membres disposant, au moment de l'entrée en vigueur du règlement, d'infrastructures vétérinaires consolidées, de systèmes informatiques développés et d'administrations bien structurées ont, dans l'ensemble, mieux géré la phase de transition, certains en tirant même des avantages concrets. Par exemple, l'Italie, qui a mis en place une base de données nationale informatisée pour la traçabilité animale, a fait état d'améliorations dans la surveillance et la détection précoce des maladies. En Autriche, l'intégration des coordonnées géographiques au registre vétérinaire permet une visualisation rapide des foyers, contribuant ainsi à renforcer la réactivité en cas d'émergence épidémiologique. Ces exemples montrent que lorsque des investissements sont réalisés dans les infrastructures et les capacités administratives, la mise en œuvre de la LSA peut s'avérer plus fluide sur le plan opérationnel. À l'inverse, les États membres disposant de ressources plus limitées ou de systèmes moins développés ont rencontré davantage de difficultés, accompagnées de coûts relatifs plus élevés. Ces disparités se répercutent également sur les parties prenantes, notamment

les éleveurs: par exemple, lorsqu'un État membre tarde à diffuser des orientations actualisées, les éleveurs et les vétérinaires peuvent rester confrontés plus longtemps à des procédures complexes ou à des incertitudes réglementaires.

Par ailleurs, la répartition des coûts et des bénéfices entre les différentes catégories de parties prenantes dépend également du degré d'utilisation, par les États membres, des marges de flexibilité prévues par la LSA. Dans les États membres n'ayant pas pleinement mis en œuvre une approche fondée sur les risques, le secteur agricole a généralement supporté une charge plus importante. À l'inverse, dans ceux ayant utilisé cette flexibilité pour adapter les mesures aux risques locaux, par exemple en prévoyant des exemptions pour les très petits détenteurs d'animaux, la charge pesant sur le secteur privé s'est révélée plus limitée. Ces choix d'application, conjugués à des structures économiques nationales différenciées (présence dominante de grandes exploitations commerciales ou prédominance de petits éleveurs), contribuent à une perception contrastée de l'efficience de la LSA selon les contextes nationaux et sectoriels.

La LSA a maintenu les obligations générales de notification (mais pour un nombre réduit de maladies couvertes par les règles de l'UE, suite à l'abrogation de la directive 92/65/CEE du Conseil), tout en procédant à des ajustements destinés à améliorer la transparence et la coordination à l'échelle européenne. Bien que le lancement du Système d'information sur les maladies animales (ADIS) ait permis une amélioration de la notification des maladies au niveau de l'Union, des préoccupations subsistent quant à l'interopérabilité d'ADIS avec les systèmes nationaux, ce qui peut limiter l'efficacité globale du dispositif.

Cohérence

La LSA présente, dans l'ensemble, une cohérence interne satisfaisante, en maintenant une logique structurelle et conceptuelle claire. Quelques divergences ont toutefois été relevées, principalement en lien avec des différences d'interprétation ou de mise en œuvre entre États membres. Sur le plan externe, la LSA s'articule globalement de manière cohérente avec les principaux cadres stratégiques de l'Union européenne, notamment le Pacte vert pour l'Europe et l'approche « Une seule santé » (One Health). Ses objectifs complètent ceux du marché unique, de la santé publique, de la sécurité sanitaire des aliments et de la protection de l'environnement.

Néanmoins, bien que l'AHL intègre les principes de santé animale et de sécurité alimentaire (même si les règles relatives à la salmonelle et aux EST n'ont pas été modifiées par l'AHL), et qu'aucune contradiction juridique directe avec la législation sur le bien-être animal n'a été identifiée ; des perceptions de manque d'alignement existent.

Les parties prenantes, y compris les organisations non gouvernementales, ont exprimé des préoccupations concernant des questions telles que le transport des animaux et les pratiques d'abattage lors d'épidémies, en particulier dans les systèmes d'élevage intensif. Ces mesures sont fondées sur les risques et visent à protéger la santé animale tout en tenant compte du bien-être animal. Ces préoccupations concernent donc davantage la mise en œuvre de mesures temporaires de lutte contre les maladies et les pratiques agricoles générales que les dispositions juridiques elles-mêmes. Dans le cadre de la mise à jour en cours de la législation sur le bien-être animal, ces points devraient être clarifiés.

Pertinence

La LSA demeure pertinente dans le contexte actuel, marqué par la persistance et l'émergence de menaces pesant sur la santé animale. Des maladies telles que la peste porcine africaine, l'influenza aviaire hautement pathogène (IAHP) ou la fièvre catarrhale ovine continuent de circuler au sein de l'Union, soulignant la nécessité de disposer d'un cadre réglementaire structuré et adapté. La LSA a montré une certaine capacité d'adaptation, notamment à travers son système de catégorisation des maladies, qui permet de mettre en œuvre des mesures différenciées fondées sur l'évaluation des risques.

Néanmoins, certaines autorités compétentes nationales ont exprimé des réserves quant à la réactivité de la LSA, estimant que le cadre actuel n'est pas suffisamment flexible pour intégrer rapidement les évolutions des tendances épidémiologiques ou l'émergence de nouvelles maladies. Plusieurs parties prenantes soulignent la nécessité d'un dispositif plus agile, permettant une actualisation plus rapide sur la base des avancées scientifiques, ainsi qu'une meilleure prise en compte des effets du changement climatique, notamment en ce qui concerne l'évolution des vecteurs de maladies.

Valeur ajoutée européenne

La LSA illustre sa valeur ajoutée européenne en renforçant les mécanismes de réponse coordonnée entre les États membres, tout en facilitant la continuité des échanges intra-UE et des exportations, y compris en période d'épizootie. En autorisant l'application de restrictions régionales plutôt que des mesures nationales fondées sur une logique de « risque zéro », elle contribue à limiter les effets économiques négatifs sur le marché intérieur. Par exemple, les stratégies de régionalisation mises en œuvre dans le secteur avicole en France, ainsi que la compartimentation appliquée à l'aquaculture au Danemark, ont permis de maintenir les échanges commerciaux depuis des zones ou compartiments reconnus indemnes lors de foyers épidémiques. Par ailleurs, les réponses coordonnées introduites par la LSA ont également favorisé la reconnaissance,

par certains pays tiers, des garanties sanitaires applicables aux produits animaux en provenance de l'Union.

Limitations

Il convient de souligner certaines limites de la présente évaluation. La LSA n'étant applicable que depuis 2021, et l'alignement complet des législations nationales étant encore en cours dans la majorité des États membres, les données recueillies s'inscrivent dans un contexte de mise en œuvre encore partiel et transitoire. Dans ces conditions, il demeure difficile d'isoler les effets directement imputables à la LSA de ceux résultant d'autres facteurs externes, tels que le degré d'alignement des systèmes nationaux, la pandémie de COVID-19 ou les évolutions géopolitiques récentes. L'impact de la LSA ne peut donc être pleinement quantifié à ce stade.

Conclusion générale

La LSA constitue une base structurée pour le développement d'une politique de santé animale harmonisée à l'échelle de l'Union européenne. Son orientation vers la prévention, la prise de décision fondée sur les risques, ainsi que son articulation avec les objectifs plus larges de l'Union, représente une évolution notable par rapport au cadre réglementaire antérieur. Toutefois, la mise en œuvre demeure hétérogène entre les États membres, et la complexité des instruments juridiques, combinée à une compréhension encore partielle de certaines dispositions par les parties prenantes, continue de poser des difficultés. Dans cette perspective, des efforts soutenus en matière de simplification, de renforcement des capacités et de coopération entre les parties prenantes, les États membres et la Commission européenne seront nécessaires pour permettre à la LSA de déployer pleinement son potentiel, tant en matière de protection de la santé animale et publique que de durabilité et de compétitivité du secteur agroalimentaire européen.

Zusammenfassung

Das EU-Tiergesundheitsrecht (Animal Health Law – AHL), Verordnung (EU) 2016/429, trat im Jahr 2016 in Kraft und ist seit April 2021 anwendbar.

Es stellt einen grundlegenden Wandel im Rechtsrahmen der EU im Bereich Tiergesundheit dar, indem es die bisherigen Regelungen, die vertikal nach Krankheiten oder spezifischen Themen, wie z.B. dem innereuropäischen Handel mit bestimmten Tierarten, gegliedert waren, durch ein horizontales, umfassendes Regelwerk ersetzt, welches durch delegierte Rechtsakte und Durchführungsrechtsakte konkretisiert wird.

Das AHL verfolgt das Ziel, die Tiergesundheit zu schützen, nachhaltige landwirtschaftliche Systeme zu fördern, die öffentliche Gesundheit zu wahren und das reibungslose Funktionieren des EU-Binnenmarkts sicherzustellen.

Dieser Bericht dient der Unterstützung der Ex-post-Bewertung des AHL und seiner delegierten Rechtsakte.Diese Evaluierung hat zum Ziel, die Europäische Kommission bei der Erhebung quantitativer und qualitativer Nachweise zur Wirksamkeit und Umsetzung des AHL zu unterstützen, wie in Artikel 282 der Verordnung (EU) 2016/429 vorgesehen.Die Evaluierung wurde im Einklang mit den Leitlinien für bessere Rechtsetzung durchgeführt und basiert auf fünf zentralen Bewertungskriterien: Wirksamkeit, Effizienz, Kohärenz, Relevanz und EU-Mehrwert.

Die für diese Bewertung herangezogenen Erkenntnisse wurden mittels Literaturrecherchen, eines öffentlichen Aufrufs zur Stellungnahme, gezielter Umfragen, Interviews, Fokusgruppen und Validierungsworkshops mit Interessenträgern aus sämtlichen EU-Mitgliedstaaten gewonnen.Die Bewertung erfasst den Zeitraum von 2016 bis 2023, wobei der Schwerpunkt auf der Umsetzungsphase von April 2021 bis Ende 2023 liegt.

Zentrale Befunde

Wirksamkeit

In Bezug auf die Wirksamkeit wird das AHL allgemein als ein bedeutender Fortschritt bei der Harmonisierung der Herangehensweise der EU an Themen der Tiergesundheit anerkannt, der den Übergang von einem reaktiven zu einem präventiven System darstellt. Die aktuelle Wirksamkeit des AHL muss im Kontext seiner fortlaufenden Umsetzung bewertet werden. Die meisten Mitgliedstaaten haben ihre nationalen Rechtsvorschriften bislang noch nicht vollständig an das AHL angepasst, wenngleich in einigen Ländern – etwa in Italien und Spanien – deutliche Fortschritte erzielt wurden. Verzögerungen sind vor allem auf die Komplexität der nationalen Rechtssysteme und Verwaltungsstrukturen zurückzuführen. Darüber hinaus erfordert die Umstellung auf die neue Logik des

AHL eine gewisse Eingewöhnungszeit für alle Beteiligten und Betroffenen, was sich wiederum auf ihre Wahrnehmung der Wirksamkeit auswirkt und den schrittweisen Übergang erklärt. Die COVID-19-Pandemie sowie Verzögerungen bei der Annahme delegierter und Durchführungsrechtsakte haben den Übergangsprozess zusätzlich erschwert.

Das AHL hat ein strukturiertes und wissenschaftlich fundiertes System zur Kategorisierung von Tierkrankheiten eingeführt. Übertragbare Tierkrankheiten werden anhand ihres epidemiologischen Profils, ihrer Auswirkungen und der Kontrollmöglichkeiten in fünf Kategorien (A bis E) eingeteilt. Diese Kategorisierung ermöglicht verhältnismäßige Reaktionen sowie eine Priorisierung von Ressourcen und erlaubt es den Mitgliedstaaten, ihre Überwachungs- und Bekämpfungsstrategien an nationale Gegebenheiten anzupassen. Obwohl diese Herangehensweise von den Interessenträgern überwiegend unterstützt wird, wurden Bedenken hinsichtlich der Reaktionsfähigkeit des Systems gegenüber neu auftretenden Bedrohungen sowie des Bedarfs an häufigeren Aktualisierungen geäußert – insbesondere im Hinblick auf klimabedingte Veränderungen in der Krankheitsdynamik.

Das AHL legt zudem ein besonderes Augenmerk auf Prävention durch verstärkte Biosicherheitsmaßnahmen. Die Verordnung definiert klare Zuständigkeiten für Betreiber und zuständige Behörden und schreibt die Umsetzung von Biosicherheitsmaßnahmen auf Betriebsebene sowie entlang der Produktionskette vor. Dies hat zwar zu einer verbesserten Sensibilisierung und Risikominderung geführt, jedoch ist die Umsetzung weiterhin uneinheitlich. Größere und intensiver wirtschaftende Betriebe konnten sich in der Regel leichter an die verschärften Anforderungen anpassen, während kleinere oder abgelegene Betriebe mit Herausforderungen aufgrund begrenzter Ressourcen und unzureichender tierärztlicher Versorgung konfrontiert sind. Das Fehlen harmonisierter Leitlinien und entsprechender Weiterbildung hat die Umsetzung in einigen Mitgliedstaaten zusätzlich erschwert.

Ein weiteres zentrales Merkmal des AHL ist die Stärkung der Rolle und der geteilten Verantwortung der Akteure entlang der Tiergesundheitskette. Die Verordnung präzisiert die Pflichten von Landwirten, Tierärzten, zuständigen Behörden und weiteren Beteiligten. Dies hat die Koordination und Verantwortungszuweisung – insbesondere bei der Meldung und der Überwachung von Krankheiten sowie bei der Bekämpfung von Ausbrüchen – verbessert. Die Bewertung zeigt jedoch auch, dass ein größerer Bedarf an Aufklärung und Kapazitätsaufbau besteht, insbesondere bei kleineren Betrieben und nicht-behördlichen Akteuren. Trotz EU-weiter Weiterbildungsinitiativen im Rahmen von „Besseres Training für sicherere Lebensmittel“ ist die Verbreitung dieser Maßnahmen auf nationaler Ebene nach wie vor begrenzt, und viele Beteiligte berichten von Schwierigkeiten beim Verständnis des rechtlichen Rahmens und ihrer konkreten Pflichten. In diesem Zusammenhang können auch Notfallpläne und Simulationsübungen dazu beitragen, die Einbindung der Akteure zu stärken und deren Sensibilisierung zu fördern. Dennoch ist der

Prozess der Angleichung der nationalen Rechtsvorschriften weiterhin nicht abgeschlossen.

Zudem haben Verzögerungen bei der Anpassung der nationalen Gesetzgebung zu Unterschieden in der Anwendung bestimmter neuer Bestimmungen geführt, beispielsweise im Hinblick auf Tiergesundheitsbesuche. Diese stellen – basierend auf Risikobewertungen – ein wichtiges Instrument zur Krankheitsprävention und Früherkennung dar. Einige Mitgliedstaaten haben solche Besuche in bestehende Programme integriert. In welchem Umfang Artikel 25 tatsächlich umgesetzt wird, lässt sich jedoch mangels offizieller Daten nur schwer beurteilen. Darüber hinaus wirken sich das Fehlen wirksamer Durchsetzungsmechanismen sowie Engpässe beim tierärztlichen Personal, insbesondere in ländlichen oder abgelegenen Regionen, negativ auf die effektive Umsetzung dieser Bestimmungen und die Bewertung ihrer Wirksamkeit aus.

Das AHL stärkt auch die Fähigkeit der EU zur Bekämpfung und Tilgung von Tierkrankheiten, insbesondere durch strukturierte Tilgungsprogramme und die Anerkennung seuchenfreier Gebiete. Diese sind entscheidend für die Aufrechterhaltung des Handels und die Eindämmung endemischer Krankheitslasten. Die derzeit bestehenden Unterschiede in der nationalen Umsetzung schränken jedoch das volle Potenzial dieser Instrumente ein. Von besonderer Bedeutung ist, dass das AHL während Krankheitsausbrüchen nicht zu größeren Handelsunterbrechungen geführt hat – dank der Möglichkeit, begrenzte Sperrzonen statt pauschaler Handelsverbote anzuwenden. So konnten Tiere und Erzeugnisse aus seuchenfreien Gebieten weiterhin sicher bewegt werden. Darüber hinaus hat das AHL die Voraussetzungen für den Einsatz von Impfungen zu Präventions- oder Notfallzwecken klar definiert. Dies hat eine strategischere Anwendung von Impfstoffen ermöglicht, etwa im Fall der hochpathogenen aviären Influenza (HPAI), wo gezielte Impfkampagnen zur Minderung der Ausbruchsintensität und zur Begrenzung wirtschaftlicher Schäden beigetragen haben.

Die Weiterentwicklung digitaler Instrumente wie TRACES für die Rückverfolgbarkeit und Tierbewegungen sowie ADIS für die Meldung und Berichterstattung von Krankheiten wird als Fortschritt gewertet, auch wenn weiterhin technische Probleme und Interoperabilitätsfragen bestehen.

Ein unbeabsichtigter Effekt der Umsetzung des AHL besteht darin, dass die von den Mitgliedsstaaten eingeführten Anforderungen – insbesondere für kleinere Betriebe – in einigen Fällen abschreckend wirkten und die Teilnahme an Programmen zur Krankheitsbekämpfung behinderten. Auch wenn das AHL keine finanzielle Unterstützung regelt, wurde von Interessenträgern das Fehlen geeigneter Entschädigungsmechanismen als Hindernis für eine wirksame Umsetzung hervorgehoben.

Zusammenfassend lässt sich feststellen, dass das AHL eine solide und kohärente Grundlage für eine harmonisierte, präventive und risikobasierte

Tiergesundheitspolitik in der EU bildet. Wo die Umsetzung bereits fortgeschritten ist, zeigt sich seine Wirksamkeit insbesondere in den Bereichen Krankheitskategorisierung, Biosicherheit und Tilgungsbemühungen. Insgesamt befindet sich das System jedoch weiterhin in einer Übergangsphase. Eine vollständige Ausschöpfung des Potenzials des AHL erfordert fortgesetzte Unterstützung der Mitgliedstaaten, eine Vereinfachung der Rechtsinstrumente sowie eine stärkere Einbindung der Interessenträger. Mit der fortschreitenden Angleichung der nationalen Systeme mit dem AHL wird auch eine umfassendere Bewertung seiner langfristigen Auswirkungen möglich sein.

Effizienz

Die Bewertung der Effizienz des AHL bezieht sich auf die Frage, ob die von den Mitgliedstaaten, den Interessenträgern und der Europäischen Kommission getragenen Kosten in einem angemessenen Verhältnis zu den seit der Einführung erzielten Vorteilen stehen. Eine wesentliche Einschränkung dieser Evaluierung besteht jedoch darin, dass viele Mitgliedstaaten ihre nationalen Rechtsvorschriften noch nicht vollständig an das AHL angepasst haben und die im AHL vorgesehene Flexibilität nicht vollständig ausschöpfen. Daher ist es sowohl für das Evaluierungsteam als auch für die Interessenträger schwierig, die Auswirkungen des AHL klar von jenen der unvollständigen Rechtsangleichung abzugrenzen. Zudem kann es mehrere Jahre dauern, bis sich die komplette Umsetzung des AHL zu konkreten Verbesserungen der Tiergesundheit führen wird – insbesondere unter Berücksichtigung externer Faktoren, die die epidemiologische Lage ebenfalls beeinflussen können.

Insgesamt wird erwartet, dass das Kosten-Nutzen-Verhältnis des AHL langfristig positiv ausfallen wird – wenngleich unter bestimmten Vorbehalten. Kurz- bis mittelfristig hat das AHL erhebliche Kosten und Verwaltungsaufwand für verschiedene Interessenträger verursacht, wobei die anfänglichen Ausgaben in einigen Fällen höher waren als ursprünglich angenommen. Diese Kosten und Aufwände stellen Investitionen dar, die zukünftig klare Vorteile in Bezug auf Krankheitsprävention und -bekämpfung, regulatorische Harmonisierung und Erleichterung des Handels bringen sollen. Es wird davon ausgegangen, dass diese Vorteile im Laufe der Zeit zunehmen. Der präventive Ansatz des AHL – etwa durch Biosicherheitsmaßnahmen und Überwachung – dürfte künftig zur Reduzierung kostspieliger Krankheitsausbrüche beitragen, wodurch sich die aktuellen Ausgaben rechtfertigen lassen. Rückmeldungen aus Umfragen deuten bereits auf eine insgesamt positive Einschätzung hin. Dennoch sind die Effizienzgewinne bislang nicht vollständig realisiert, da sich das Regelwerk noch im Übergang befindet. In dieser frühen Umsetzungsphase treten die Vorteile ungleichmäßig auf, während ein Großteil der Kosten zu Beginn anfällt.

Auf der Kostenseite haben die zuständigen nationalen Behörden erhebliche einmalige sowie laufende Ausgaben getragen, um ihre Systeme an das AHL anzupassen. Dazu gehören Maßnahmen zur Aktualisierung oder Konsolidierung

nationaler Rechtsvorschriften, die Modernisierung von IT-Systemen (insbesondere für Krankheitsmeldungen und Rückverfolgbarkeit), die Einstellung oder Schulung von Personal sowie die Kommunikation neuer Anforderungen an die Interessenträger. Viele nationale Behörden mussten beträchtliche Ressourcen umschichten, um ihre Überwachungs- und Meldesysteme entsprechend anzupassen. Auch die Wirtschaft hat neue Kosten zur Einhaltung der Vorschriften zu tragen, etwa durch verpflichtende Krankheitsüberwachung, Biosicherheitsprotokolle, die Dokumentation von Tierbewegungen sowie – in einigen Fällen – durch regelmäßige tierärztliche Gesundheitsbesuche oder die Registrierung neuer Betriebe. Je nach Maßnahme waren diese Anforderungen jedoch nicht für alle Akteure neu: So waren manche Landwirte in bestimmten Sektoren oder Mitgliedstaaten bereits vor der Einführung des AHL zu tierärztlichen Gesundheitsbesuchen verpflichtet, sei es aufgrund nationaler Regelungen oder privater Zertifizierungsprogramme. Infolgedessen variiert der Grad, zu dem das AHL neue Kosten verursacht hat, je nach Interessengruppe, Sektor und Mitgliedstaat.

Zu den im Rahmen des AHL beobachteten oder erwarteten Vorteilen zählen eine wirksamere und effizientere Bekämpfung von Tierkrankheiten sowie ein kohärenteres regulatorisches Umfeld. Durch die Ablösung von 38 bestehenden Regelwerken durch eine einheitliche Verordnung wurde das AHL so konzipiert, dass es Vorschriften vereinheitlicht und die Rechtszersplitterung verringert. Diese Konsolidierung hat im Grundsatz zu größerer Rechtssicherheit geführt und sollte langfristig zur besseren Verständlichkeit und zur Verringerung des Verwaltungsaufwands beitragen. Viele Beteiligte berichten, dass der einheitliche Rechtsrahmen die Koordination zwischen Behörden und Interessenträgern verbessert und eine schnellere, koordinierte Reaktion auf grenzüberschreitende Krankheitsbedrohungen ermöglicht hat. Es liegen Hinweise vor, dass Maßnahmen des AHL – wie die risikobasierte Überwachung und die Regionalisierung von Beschränkungen – dazu beigetragen haben, jüngste Seuchenausbrüche (z. B. Influenza bei Geflügel, Afrikanische Schweinepest) effizienter einzudämmen, wodurch das Ausmaß von Keulungen, Handelsverboten und anderen mit hohen Kosten verbundenen Notfallmaßnahmen reduziert wurde. Auch für den Handel und den Binnenmarkt wurden Vorteile festgestellt: Durch die Harmonisierung von Standards und Verfahren innerhalb der EU trägt das AHL zur Aufrechterhaltung des Vertrauens in den innergemeinschaftlichen Handel mit Tieren und tierischen Erzeugnissen bei und verhindert ungerechtfertigte Handelshemmnisse bei Krankheitsausbrüchen – insbesondere durch die Anwendung von regionalem Seuchenzonierungskonzepten anstelle landesweiter Verbote. Auch wenn diese Vorteile schwer sofort zu quantifizieren sind, tragen sie zu einem stabileren und planbareren Umfeld für Unternehmen und Behörden bei.

Trotz der langfristigen Vorteile berichten Interessenträger, dass die Umsetzung des AHL und dessen Anpassung an das nationale Recht mit erheblichen administrativen Belastungen verbunden war – insbesondere in der Anfangsphase. Über alle Gruppen hinweg wurden Bedenken hinsichtlich eines

erhöhten Verwaltungsaufwands, der Komplexität neuer Verfahren und überschneidender Anforderungen zwischen nationalen und EU-Vorschriften geäußert. Bestimmte Zielgruppen sind von dieser administrativen Belastung besonders betroffen. Insbesondere kleine landwirtschaftliche Betriebe und Hobbytierhalter gaben an, dass die Einhaltung der AHL-Vorgaben – wie z. B. die Beantragung von Tiergesundheitsbescheinigungen für Tierbewegungen oder die Einhaltung neuer Dokumentations- und Biosicherheitsvorgaben – für sie unverhältnismäßig und belastend sei. Während größere Unternehmen die gestiegenen Kosten für die Einhaltung der Vorschriften eher absorbieren können, trifft dies sehr kleine Betriebe besonders hart; sie empfinden manche Maßnahmen als bürokratische Doppelbelastung ohne erkennbaren Nutzen für die Tiergesundheit in ihrem spezifischen Kontext.

Das AHL wird durch eine Vielzahl delegierter und Durchführungsrechtsakte ergänzt. Einige Interessenträger berichten, dass Informationen und Pflichten auf mehrere Rechtsakte verteilt sind, was die Orientierung erschwert und eine klare Gesamtübersicht behindert.

Die Erfahrungen in Bezug auf Effizienz und das Kosten-Nutzen-Verhältnis des AHL variieren erheblich zwischen den Mitgliedstaaten und den Gruppen von Interessenträgern. Mitgliedstaaten, die bereits über eine ausgebaute veterinärmedizinische Infrastruktur, moderne IT-Systeme und gut ausgestattete Verwaltungen verfügten, haben den Übergang in der Regel reibungsloser vollzogen und konnten daraus sogar Nutzen ziehen. So berichtete beispielsweise Italien, das eine nationale, digitalisierte Datenbank zur Rückverfolgbarkeit von Tieren eingeführt hat, von Verbesserungen bei der Überwachung und Frühwarnung. In Österreich unterstützt die Einbettung geografischer Koordinaten in das Tierregister eine schnelle Visualisierung von Ausbrüchen und fördert die epidemiologische Reaktionsfähigkeit. Diese Beispiele zeigen, dass dort, wo in Infrastruktur und Kapazitätsaufbau investiert wurde, die operationelle Effizienz des AHL besser ausgeschöpft werden kann. Im Gegensatz dazu hatten Mitgliedstaaten mit begrenzten Ressourcen oder weniger entwickelten Systemen mit größeren Herausforderungen und relativ höheren Kosten zu kämpfen. Solche Unterschiede betreffen auch Interessenträger wie Landwirte: Wenn ein Land beispielsweise die Einführung aktualisierter Leitlinien verzögert, sehen sich Landwirte und Tierärzte in diesem Land über längere Zeit mit unklaren Verfahren konfrontiert.

Darüber hinaus variiert auch die Verteilung von Kosten und Nutzen zwischen den Gruppen von Interessenträgern, je nachdem in welchem Maße die Mitgliedstaaten die vom AHL eingeräumten Flexibilitäten nutzen. In Ländern, die keinen konsequent risikobasierten Ansatz verfolgt haben, wurde die landwirtschaftliche Gemeinschaft stärker belastet. In anderen Mitgliedstaaten hingegen, in denen die Flexibilitäten des AHL genutzt wurden, um Maßnahmen an lokale Risiken anzupassen – etwa durch die Ausnahmeregelung für sehr kleine Tierhalter –, war die Belastung für den privaten Sektor vergleichsweise geringer. Solche politischen Entscheidungen, kombiniert mit unterschiedlichen

wirtschaftlichen Strukturen (z. B. große industrielle Betriebe gegenüber vielen Kleinbetrieben), führen dazu, dass die Effizienz des AHL von Land zu Land oder von Sektor zu Sektor unterschiedlich wahrgenommen wird.

Das AHL hat die allgemeinen Meldepflichten beibehalten – jedoch infolge der Aufhebung der Richtlinie 92/65/EWG für eine geringere Zahl von Krankheiten, die fortan unter die EU-Vorschriften fallen. Die vorgenommenen Anpassungen zielen darauf ab, die Transparenz und Koordination auf EU-Ebene zu verbessern. Zwar hat die Einführung des Animal Disease Information System (ADIS) die Krankheitsberichterstattung auf europäischer Ebene verbessert, doch bestehen weiterhin Bedenken hinsichtlich der Interoperabilität zwischen ADIS und den nationalen Systemen.

Kohärenz

Das AHL weist insgesamt eine starke innere Kohärenz auf und bewahrt seine strukturelle und konzeptionelle Geschlossenheit – trotz geringfügiger Unstimmigkeiten, die hauptsächlich aus Unterschieden in der Auslegung und Umsetzung durch die Mitgliedstaaten resultieren. Darüber hinaus steht das AHL im Einklang mit anderen politischen Rahmenwerken der EU, wie z.B. dem Europäischen Grünen Deal und dem One-Health Ansatz. Seine Zielsetzungen ergänzen jene des Binnenmarktes, des Gesundheitsschutzes, der Lebensmittelsicherheit und des Umweltschutzes.

Obwohl das AHL die Grundsätze der Tiergesundheit und der Lebensmittelsicherheit integriert (auch wenn die Vorschriften zu Salmonellen und TSE durch das AHL nicht geändert wurden) und keine direkte rechtliche Widersprüchlichkeit mit der Tierschutzgesetzgebung festgestellt wurde, bestehen Wahrnehmungen eines mangelnden Gleichlaufs.

Interessenträger, darunter auch nichtstaatliche Organisationen, haben Bedenken zu Themen wie Tiertransporte und Tötungspraktiken während Seuchenausbrüchen geäußert, insbesondere in intensiven Haltungssystemen. Diese Maßnahmen sind risikobasiert und zielen darauf ab, die Tiergesundheit zu schützen, wobei der Tierschutz berücksichtigt wird. Diese Bedenken beziehen sich daher eher auf die Umsetzung vorübergehender Maßnahmen zur Seuchenbekämpfung und auf allgemeine landwirtschaftliche Praktiken als auf die rechtlichen Bestimmungen selbst. Im Rahmen der laufenden Aktualisierung der Tierschutzgesetzgebung dürften diese Punkte voraussichtlich geklärt werden.

Relevanz

Die Relevanz des AHL bleibt angesichts fortbestehender und neu auftretender Bedrohungen für die Tiergesundheit hoch. Krankheiten wie die Afrikanische Schweinepest (ASF), die hochpathogene aviäre Influenza (HPAI) und die

Blauzungenkrankheit zirkulieren weiterhin innerhalb der EU, was die Notwendigkeit eines belastbaren und wirksamen Regelwerks unterstreicht. Das AHL hat dabei Anpassungsfähigkeit bewiesen, insbesondere durch sein System zur Krankheitskategorisierung, das risikobasierte und flexible Reaktionen ermöglicht.

Dennoch kritisieren einige zuständige Behörden in den Mitgliedstaaten, dass das AHL nicht hinreichend dynamisch sei, um auf veränderte epidemiologische Entwicklungen oder das Auftreten neuer Krankheiten zu reagieren. Vonseiten der Interessenträger wird ein anpassungsfähigerer Rechtsrahmen gefordert, der wissenschaftliche Fortschritte rascher aufnehmen und sich besser an die Realität des Klimawandels und dessen Auswirkungen auf Krankheitsüberträger anpassen kann.

EU-Mehrwert

Das AHL erweist seinen europäischen Mehrwert durch die Stärkung koordinierter Reaktionsmechanismen zwischen den Mitgliedstaaten sowie durch die Ermöglichung eines sicheren innergemeinschaftlichen Handels und die Aufrechterhaltung von Exporten auch während Krankheitsausbrüchen. Durch die Zulassung regionaler Maßnahmen anstelle pauschaler landesweiter Null-Risiko-Maßnahmen werden Kosten erheblich reduziert und die negativen Auswirkungen auf den Binnenmarkt begrenzt. So konnten beispielsweise Regionalisierungsstrategien im Geflügelsektor in Frankreich oder die Anwendung von Kompartimenten in der dänischen Aquakultur den Handel aus seuchenfreien Zonen oder Betriebseinheiten während Ausbrüchen aufrechterhalten. Darüber hinaus haben die im AHL verankerten koordinierten Maßnahmen zur Akzeptanz von Importen tierischer Erzeugnisse durch Drittländer beigetragen.

Einschränkungen

Es ist wichtig, die Grenzen der vorliegenden Evaluierung in Betracht zu beziehen. Da das AHL erst seit 2021 anwendbar ist und die vollständige Angleichung der nationalen Vorschriften in einer Vielzahl von Mitgliedstaaten noch andauert, spiegeln die im Rahmen dieser Studie erhobenen Daten eine frühe und eine Übergangsphase der Umsetzung wieder. Folglich ist es derzeit schwierig, die Auswirkungen des AHL von anderen externen Faktoren – wie dem Grad der rechtlichen Angleichung, der COVID-19-Pandemie oder geopolitischen Entwicklungen – klar zu trennen und deren Wirkungen zuverlässig zu quantifizieren.

Gesamtschlussfolgerung

Das AHL bildet eine tragfähige Grundlage für eine harmonisierte Tiergesundheitspolitik in der Europäischen Union. Der Paradigmenwechsel hin zur Prävention, zur risikobasierten Entscheidungsfindung und zur Verknüpfung mit übergeordneten Zielen der EU stellt eine wesentliche Verbesserung gegenüber dem früheren System dar. Gleichwohl bestehen weiterhin Herausforderungen – insbesondere in Form einer uneinheitlichen Umsetzung, der Komplexität der Rechtsinstrumente sowie eines begrenzten Verständnisses auf Seiten einiger Interessenträger. Durch anhaltendes Engagement für die Vereinfachung, den Kapazitätsaufbau und die vertiefte Zusammenarbeit zwischen den Interessenträgern, den Mitgliedstaaten und der Europäischen Kommission kann das AHL sein volles Potenzial entfalten: zum Schutz der Tier- und der öffentlichen Gesundheit, zur Förderung der Nachhaltigkeit und zur Stärkung der Wettbewerbsfähigkeit des europäischen Agrar- und Lebensmittelsektors.

1. Introduction

The health of animals is threatened by various diseases, some of which are highly contagious, and others may spread to humans (zoonoses). Outbreaks of such diseases can, therefore, significantly impact not only animal health but also public health and food safety. Both the outbreaks of diseases and their control carry economic consequences, increasing costs for farmers, related industries, and the public sector. Moreover, animal movements and trade in animal products may be very seriously affected, with major socio-economic impact. Wildlife populations may also suffer, potentially affecting biodiversity and the environment ([1]). Given that animal diseases do not stop at borders, international standards and regulations are made both at the global (WOAH) level and within the EU. In the past, this was done by EU Directives and decisions, and, to a minor extent, regulations covering specific topics or diseases. Member states implemented national legislation based on these Directives.

An Impact Assessment published in 2013 examined the economic, social, and environmental aspects of the EU animal health policy in an integrated and proportionate way ([2]). Based on this assessment, in May 2013 the European Commission proposed the Animal Health Law (AHL). The AHL was part of a package of measures proposed by the Commission in May 2013 to strengthen the enforcement of health and safety standards for the whole agri-food chain ([3]). As such, it is closely linked to Regulation (EU) 2017/625 ("Official Controls Regulation") ([4]). The AHL is also a key output of the Animal Health Strategy 2007-2013, "Prevention is better than cure" ([5]).

The initial objective of the Strategy was to develop a ‘single regulatory framework for animal health with a greater focus on incentives than penalties, consistent with other EU policies and converging to international standards’ and to ‘define and integrate common principles and requirements of existing legislation’. The AHL legislative proposal aimed to replace the existing series of linked and interrelated policy measures with a single policy framework to become the unique legal vehicle to implement many principles of the Strategy. Other actions aimed towards a responsibility-and cost-sharing approach regarding the detection and the eradication of diseases, towards better handling of animal by-products and closer EU convergence to international standards and smoother international trade.

Therefore, the new AHL was introduced to support the EU livestock and aquaculture sectors by enhancing their competitiveness and ensuring a safe and efficient internal market for animals and their products. Its main aim was to consolidate multiple legal acts into a single, streamlined framework, providing

([1]) Leaflet: Animal health is your health 2022.
([2]) Impact assessment SWD(2013161 final) SANCO/7221/2010-EN (europa.eu).
([3]) ec.europa.eu/commission/presscorner/detail/en/ip_13_400
([4]) Regulation - EU - 2017/625 - EN - EUR-Lex
([5]) EU Animal Health Strategy 2007-2013 - European Commission

clearer and more accessible rules. This enables authorities and stakeholders to focus on core priorities, such as disease prevention and control, and clarifies the responsibilities of farmers, veterinarians, and others involved in animal health. In March 2016, Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law') was adopted. Most of its provisions became applicable on 21 April 2021, except for Part VI relating to the non-commercial movement of pets, which become applicable on 21 April 2026.

The law also promotes the use of new technologies for activities like pathogen surveillance and electronic animal identification, supporting early detection and management of diseases, including those linked to climate change. Vaccination has become a generally permitted disease control option. Moreover, the AHL allows for greater flexibility to adapt to local and emerging challenges and strengthens the legal basis for monitoring antimicrobial resistance, complementing existing regulations on veterinary medicines and medicated feed.

Compared to the legislation previously in force, the AHL adopts a broader scope. It applies to all animals, both terrestrial and aquatic, kept for commercial purposes, in addition to pet animals and animals kept in laboratories and zoos, as well as wild animals.

The AHL lays down rules for the prevention and control of animal diseases that are transmissible to animals or to humans. It applies to animals kept by humans, germinal products, products of animal origin and wild animals. It also extends to animal by-products (ABP) and derived products, and to facilities, means of transport, and equipment that may be involved in spreading transmissible animal diseases. Overall, it aims to improve animal health as well as to support sustainable production in the EU, the effective functioning of the internal market, the reduction of adverse effects of diseases, and measures for their prevention and control.

The AHL presents a more integrated approach by recognising the relevance of animal health to broader EU policy objectives such as food safety, environmental protection, and public health, supporting the One Health framework, but it is not fully integrated or aligned with all related policies (animal welfare, environmental legislation) . It also considers socio-economic, cultural, and environmental issues while ensuring compliance with international standards. Finally, the AHL aims to ensure an equal level playing field among Member States and therefore promote a well-functioning EU single market while ensuring its competitiveness. This shift aligns the EU's approach more closely with the 'One Health' concept.

The AHL's overarching objective is to establish a unified and adaptable legal framework for animal health across the EU. While many of its provisions consolidate and update existing legislation, several new elements have been introduced, including:

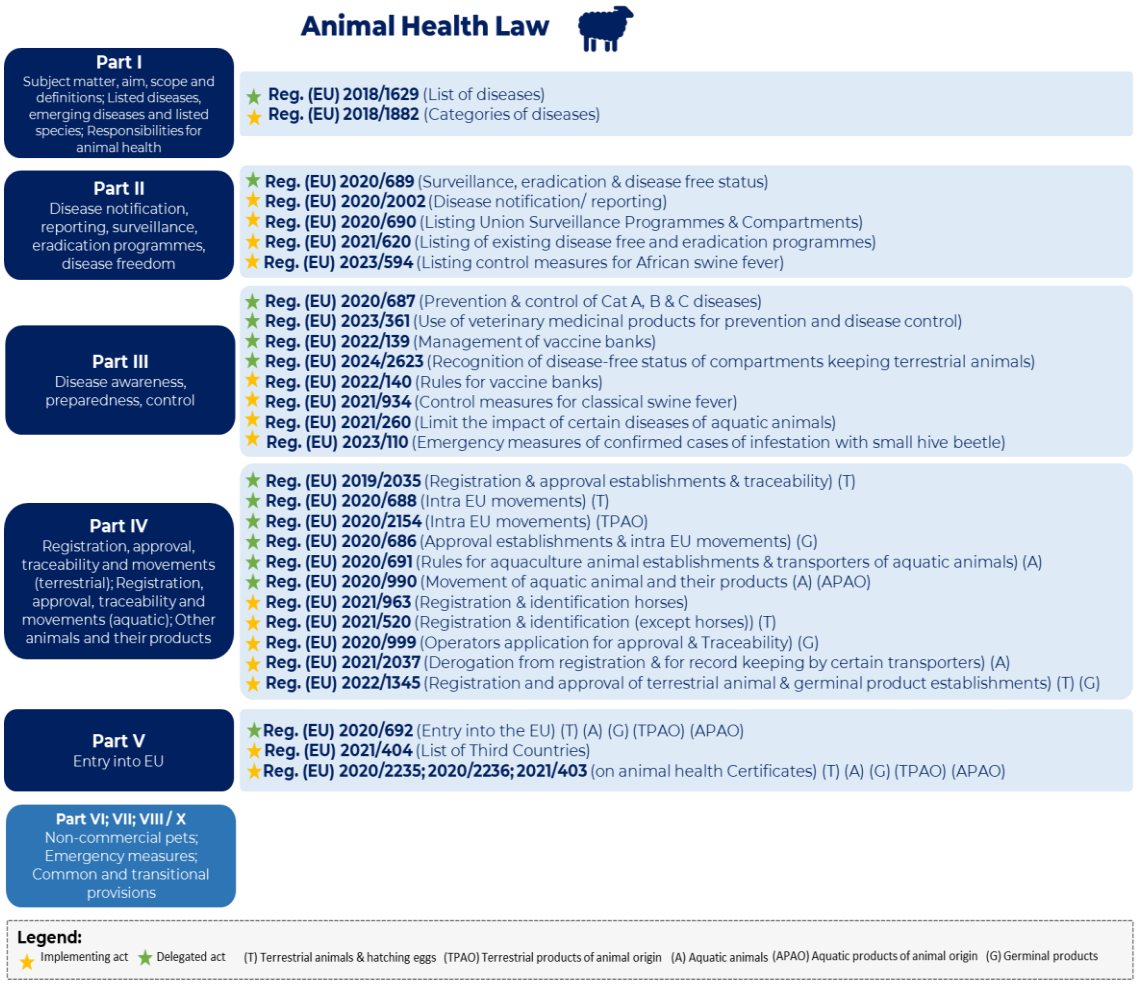
- Clear criteria for listing animal diseases that warrant different types of EU-level intervention and specifying applicable animal species covered under AHL (disease categorisation) ([6]);
- Clarification of the responsibilities for farmers, veterinarians, National Competent Authorities (NCAs), and others who deal with animals (e.g., requirements in relation to animal health, biosecurity measures, early detection and prevention of animal diseases, their surveillance, animal health visits, etc.) ([7]);
- Establishment of the Animal Disease Information System (ADIS), a new system for the notification and reporting of animal diseases in the EU (that replaces the previous ADNS). The objective of the system is to ensure rapid exchange of information on outbreaks of selected infectious animal diseases between the NCAs and the EC ([8]);
- The provision of measures for the prevention and control of emerging and listed diseases and sanitary measures in wild animals ([9]).

To operationalise the AHL, a series of delegated and implementing acts have been adopted. The law is structured into nine parts (Parts I–IX), each supported by corresponding tertiary legislation, as shown in Figure 1.

The AHL is directly applicable in all EU Member States as a regulation. However, Member States must align their national legislation by modifying or repealing existing legislation that conflicts with the new provisions. Additionally, MS are expected to establish several provisions, including the designation of the competent authorities responsible for enforcement and the sanctions for the violation of requirements established by the AHL, among others and to apply a risk-based approach to animal disease prevention and control measures, and in this way make the best possible use of the flexibility provided for in the legislation.

([6]) Articles 5, 7 and 8 of AHL.
([7]) Articles 11,12,13 ad 14 of AHL.
([8]) Article 22 of AHL.
([9]) Article 70 of AHL.

Figure 1 – Animal Health Law – Legal framework



Source: Consortium (adapted from Terms of Reference)

Animal disease situation in the EU in the period 2021-2023

Between 2021 and 2023, the animal health situation in the EU was marked by major transmissible animal diseases (TADs), such as highly pathogenic avian influenza (HPAI) and African swine fever (ASF), alongside the re-emergence of sheep and goat pox (SGP) and bluetongue (BT). These outbreaks occurred in parallel with strengthened disease prevention and control measures under the Animal Health Law (AHL), which provided a harmonised framework for surveillance, notification, control, and coordination among Member States. However, considering the growing concern of antimicrobial resistance (AMR) and the broader impacts of animal agriculture on One Health the overall situation remained complex and required continued vigilance.

African swine fever (ASF)

The number of EU Member States affected by ASF rose from 10 in 2019 to 14 in 2023. Indeed in that period ASF was reported for the first time in Germany, Italy, Croatia and Sweden and re-emerged in the Czech Republic and in Greece. Thanks to the prompt application of strict and tailored measures based on an appropriate evaluation of the epidemiological situation, Belgium (in 2020) and Sweden (2024) regained ASF-free status. The same approach was also applied in Germany and other Member States where a consistent improvement of the epidemiological situation was observed and restrictions could be lifted in certain areas of those Member States. Since 2023 no new Member States reported infections.

In general, since its first detection in the EU, in 2014, ASF is mainly detected in wild boars, with occasional incursions in the kept pig sector.

Sheep pox and goat pox (SGP)

After many years of absence from western Europe, sheep pox and goat pox (SPGP) re-emerged in the EU with outbreaks in Spain, in 2022–2023.

In total 30 outbreaks were recorded in two clusters (Andalusia and Castilla-La Mancha regions) in Spain that had been disease-free since 1968. Over 52,000 small ruminants were culled as part of a stamping-out policy. The last outbreak was reported on May 17, 2023, and Spain self-declared disease-free to WOAH in November 2023.

In 2023 Greece reported sporadic outbreaks (5) affecting nearly 2,000 animals in Central Greece and the island of Lesvos (North Aegean), 5 years after the last occurrence of SGP in its territory. On the same year Bulgaria experienced a single incursion in a border region (Burgas) 10 years after the last occurrence of SGP in its territory.

Blue tongue virus infections (BTV)

Bluetongue disease continued to pose significant challenges to animal health in the EU. BTV serotypes 1, 3, 4, 8, and 16 were reported across several Member States. BTV-4: Most widespread, with 146 outbreaks across 8 countries—Spain, Portugal, Italy, Greece, France, Romania, Croatia, and Bulgaria—affecting a total of 25,000 susceptible animals. BTV-8: was confirmed in France , Spain and Belgium (2,700 animals) and limited outbreaks some southern Member States of BTV-1 (Italy , Portugal and Spain) and BTV-16 (Greece). The vaccination policy differed between Member States. Some made it compulsory, others voluntary, and others prohibited vaccination.

HPAI outbreaks in the period 2021-2023

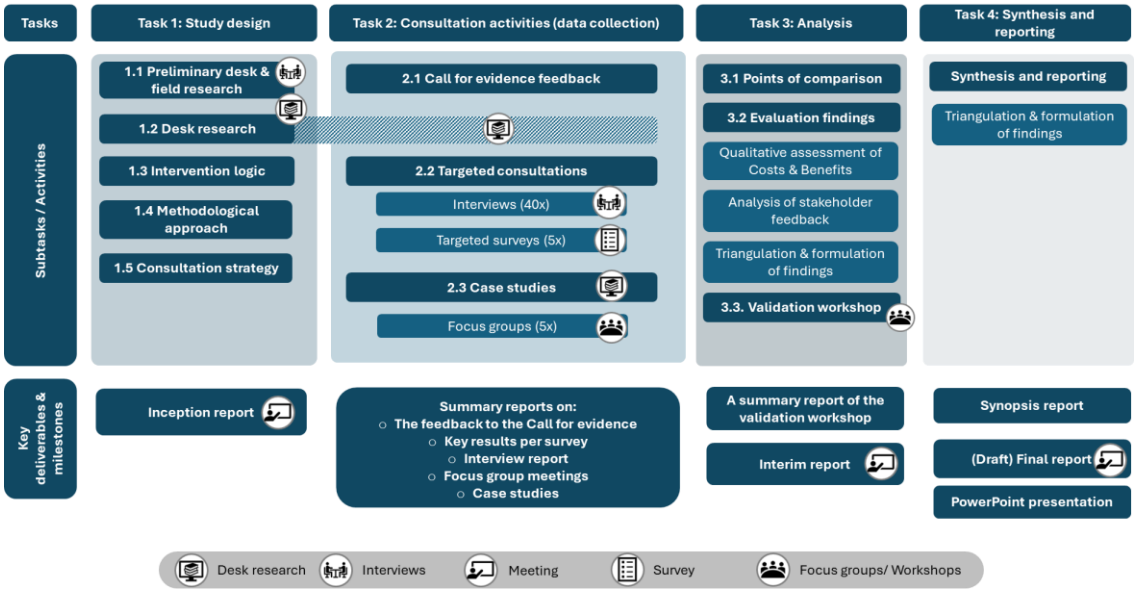
After the previous epidemic seasons being dominated by the circulation of H5N8 a major epidemic began in October 2021, driven mainly by H5N1, and affected wild birds, poultry, and captive birds in 25 Member States. Other subtypes (H5N8, H5N5) were continued to be detected only in limited areas of northern Europe. This epidemic extended into 2023, affecting 26 Member States. The 2022–2022 season was the most severe HPAI epidemic season ever in poultry in Europe, with 2,400 outbreaks and almost 50 million poultry affected in those outbreaks. France was the most affected EU Member State by outbreaks in poultry, with 1.400 establishments, mainly those keeping fattening ducks and geese. The recurrence of large number of outbreaks in France in the duck fattening sector has led to the decision to implement preventive vaccination against HPAI in this poultry sector. From October 2022, H5N1 was more frequently detected in mammals, including wild carnivores, fur-farmed species, marine mammals, and pets, though such cases remain rare. In the second half of 2023, the epidemiological situation improved in most Member States, but outbreaks in wild birds continued, particularly in the north. A new epidemic season began in October 2023, with common cranes among the most affected early cases, likely due to virus introductions by migratory birds.

2. Methodology and scope

2.1. Overall Methodological Framework

This evaluation has been conducted in a systematic way and provides an objective assessment of the AHL based on the Better Regulation Guidelines (BRG). The BRG define the evaluation criteria applied in this study and assess the extent to which the existing intervention has performed in terms of: effectiveness (i.e. meeting objectives and fulfilling expectations); efficiency (i.e. cost-effectiveness and the extent to which costs are proportionate to benefits); relevance in light of current and emerging needs; coherence, both internally and with other EU interventions; and EU added value (i.e. achieving results that would not have been attained by Member States acting alone). The following figure presents our interpretation of the BRG approach to evaluation. These criteria have guided the overall assessment.

Figure 2 – Overview of the overall approach to the evaluation



Source: Consortium

2.2. Scope

This report aims to support the ex-post evaluation of the Animal Health Law (AHL) (Regulation (EU) 2016/429) and its delegated acts. This evaluation assists the European Commission in collecting quantitative and qualitative evidence on the Animal Health Law's performance and implementation, as mandated by Article 282 of Regulation (EU) 2016/429. The results will be reported to the European Parliament and the Council by 22 April 2026.

The scope of the evaluation includes:

- **Time Scope**: The period from 2016 to 2023, focusing on 21 April 2021 (the date of the entry into application of the AHL) to 31 December 2023.
- **Material Scope**: All kept animals, including terrestrial and aquatic animals kept for commercial purposes, pets, and animals in laboratories and zoos.
- **Geographical Scope**: EU Member States, with references to the European Economic Area (EEA) and candidate countries.
- **Target Groups**: National competent authorities (NCAs) of EU Member States and accessing countries, international organisations and EU bodies and agencies, livestock and aquaculture farmers, veterinarians, animal farming and industry operators, SMEs and business associations, NGOs, Research institutes and Consumers.

2.3. Stakeholder consultation

This evaluation follows a mixed-method approach, combining desk research with several consultation activities to gather quantitative and qualitative evidence. The following consultation activities were conducted:

- Call for Evidence
- Scoping interviews
- A survey amongst relevant stakeholders (national competent authorities, representatives of the farming sector and livestock and aquaculture industries, veterinarians and scientists and NGOs)
- Interviews, focus groups and a validation workshop with representatives of the above-mentioned stakeholders

The **Call for Evidence (CfE)** was conducted through the European Commission's Have Your Say portal to collect open feedback and documentary evidence from citizens and stakeholders.

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 (BRT), 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 ([10]). 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 hobbyist organisations representing pet bird owners, *Kleindier Liefhebbers Nederland* and *Aviornis International Nederland,* 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

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

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.

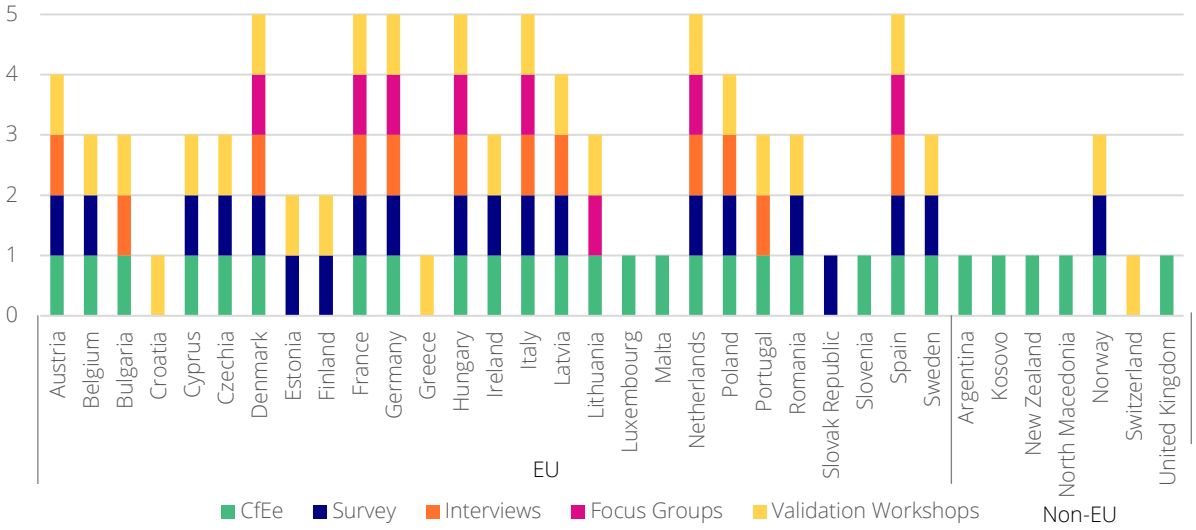
Targeted surveys were designed as the second consultation activity to collect stakeholders' views and inputs for evaluating the AHL. They were carried out via the EU Survey platform and designed to collect structured input from key stakeholder groups. Four specific questionnaires tailored to the specific stakeholder groups were shared to collect quantitative and qualitative inputs. A total of 91 participants responded, divided into four main categories: National Competent Authorities (23 respondents), livestock and aquaculture farmers and industry representatives (35), veterinary associations (14), and civil society, academia, and other organisations involved in animal health (18). 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, including frequency counts and percentage distributions across stakeholder categories. Qualitative insights from open-ended responses were analysed through systematic qualitative content analysis, which involved identifying and interpreting key themes, stakeholder perspectives, and illustrative examples. The **interviews** and **focus groups** were designed to address data gaps and explore specific challenges, experiences, and bottlenecks identified by stakeholders in greater depth. A total of 40 targeted interviews were conducted with stakeholders, including representatives from National Competent Authorities (21), livestock and aquaculture farmers and industry (9), veterinary associations (3), and civil society, academia, and other organisations involved in animal health (7).In addition, five focus groups were conducted with a total of 30 participants: National Competent Authorities (4), livestock and aquaculture farmers and industry (12), veterinary associations (8), and research organisations and academia (4). Both interviews and focus groups collected 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. A structured analysis matrix was developed, compiling all questions and corresponding responses. This allowed for systematic comparison of inputs across stakeholder groups and evaluation criteria, facilitating the identification of recurring themes, divergent views, and stakeholder-specific insights.

Finally, two **validation workshops** were organised to discuss the evaluation's preliminary findings; one was held online with NCAs and the other in person with other relevant EU stakeholder representatives. The first workshop gathered 48 participants, with national representatives from relevant ministries in charge of animal health policies and, in some cases, Chief Veterinary Officers participating.

Overall, representatives from 22 out of the 27 Member States ([11]) participated, as well as Switzerland, ensuring broad geographic representation. The second workshop gathered 12 participants, including EU-level representatives from farmers (4, including animal breeders), the industry sector (5, covering medicines, vaccines and pet care), a veterinarian association (1), an international organisation (1) and an EU agency ([12]). These activities provided additional insights and contributed to triangulating and validating the evaluation's findings.

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 3 provides an overview of the participation of EU Member States and several non-EU countries in the five stakeholder consultation activities.

Figure 3 – Country representation across the 5 stakeholder consultation activities



Source: Consortium

2.4. Desk research

Desk research was part of our data collection strategy to answer the different evaluation questions and inform the two case studies, and was composed of the following three elements:

([11]) Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Netherlands, Poland, Portugal, Romania, Spain, Sweden.

([12]) NGOs were also targeted as part of this stakeholder invitation. However, no stakeholder group representative was available to participate in the event.

Data research: analysis of trade figures based on External Trade Database (Comext) data. For 2010-2024, we studied the EU's exports and imports and intra-EU trade for live animals and animal products.

- **Literature research** (period 2016-2024)
    - Peer-reviewed research
    - Grey literature and official publications of Member States (including national evaluation reports)
    - Audit reports (Health and Food Audits from DG SANTE)
- **CJEU ruling case analysis**

Regarding the literature research, a search protocol was developed to be followed diligently to ensure a systematic and consistent approach to data collection across the whole project team. The literature search focused on literature published between 2016 and 2024. It resulted in a list of 509 articles and reports. Based on the title and abstract, it was decided whether or not the articles were included. When considered relevant, they were allocated to one or more of the study's evaluation themes.

These publications were further explored, and the findings of relevant articles were integrated into this report's findings (see Annexe 4—List of data sources).

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 interpretation of Regulation (EU) 2016/429, commonly known as the ‘Animal Health Law.’ 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.

3. Discussion on the limitations and findings

Assessing the effects of a policy after its implementation is a critical aspect of conducting evaluations. It is essential to establish a baseline (Tool #60), which acts as the initial reference point for comparison and provides a solid foundation for assessing the impact of policy changes. This baseline typically reflects a counterfactual situation wherein no policy changes have been introduced, incorporating relevant national, EU-level, and international measures assumed to remain in effect (see Tool #11).

However, as the findings presented in Section Effe 1.1 indicate, only a limited number of Member States have fully aligned their national legislation with the AHL. In cases where alignment has occurred, for instance, in Italy, new national legislation only entered into force in 2022. Consequently, insufficient time has passed for the full effects of the AHL to manifest in available data or for stakeholders to fully comprehend its implications. At the time of this study, data obtained through desk research or stakeholder consultations are, therefore, likely to provide only a partial understanding of the AHL's potential impacts.

Moreover, the AHL constitutes a horizontal regulation that consolidates 38 pre-existing legal instruments, as enumerated in Article 270. These instruments have been modernised to varying degrees and supplemented by four key novelties:

- The provision of clear criteria to list animal diseases warranting EU intervention, as well as animal species to which the AHL applies;
- Clarification of the responsibilities of farmers, veterinarians, MS competent authorities, and others who deal with animals (e.g., requirements in relation to animal health, biosecurity measures, early detection and prevention of animal diseases, their surveillance, animal health visits, etc.);
- The establishment of the Animal Disease Information System (ADIS), a new system for the notification and reporting of animal diseases in the EU;
- The provision of measures for the prevention and control of emerging and listed diseases and sanitary measures in wild animals.

Evaluating the effects of legal harmonisation and integrated frameworks on pre-existing national legislation poses significant challenges, especially when national pre-existing requirements continued to coexist with the AHL during the study period. Stakeholders such as farmers or frontline operators may not have experienced changes or are confronted with possible discrepancies between the AHL and national legislation that is still not updated.

The newly introduced provisions in the AHL reflect a paradigm shift towards a risk-based, preventive approach. This shift introduces substantial scientific complexity, as its intended outcomes, such as reducing disease incidence and outbreak severity, require long-term empirical validation. To this end,

epidemiological and economic models are currently the most viable methods for estimating the causal effects of various control strategies. These models facilitate the simulation of potential outcomes and offer insights into the effectiveness of preventive measures under differing scenarios. However, such modelling approaches necessitate comprehensive datasets and extended observation periods and thus lie beyond the immediate scope of this study.

Consequently, all indicators employed herein to assess the performance of the AHL remain susceptible to influence by external variables, including epidemiological trends and geopolitical developments that are outside the direct control of the EU or its Member States. Nevertheless, these indicators are presented with the aim of informing on potential impacts of the AHL, rather than delivering definitive conclusions.

This evaluation started at a moment where Member States are in different phases of implementation and alignment with national legislation. The reasons for this were multiple and varied between different Member States. For example, the following reasons were mentioned by the NCAs:

- Handling multiple outbreaks of contagious diseases such as HPAI, ASF, or BTV, staff and resources capacity constraints both for Ministries and implementing agencies in the Member States.
- Due to COVID-19 restrictions, national consultations with stakeholders were delayed
- The legislative process related to the alignment of national measures takes time.

These various implementation phases seriously impacted the availability and quality of the data available for analysis.

- The time period since the full or partial implementation was too short, or aspects of the implementation had not started to generate effects. Therefore, possible effects of the AHL on the selected impact indicators could not (yet) be observed.
- Stakeholders had problems disentangling the effects of the transition process from the effects of a fully implemented AHL and from what stems from national legislation versus the AHL.

As a result, the evaluation at this stage is more an assessment of the ongoing transition phase than an evaluation of a fully implemented AHL. Findings should be interpreted with this in mind.

4. Evaluation findings

4.1. Effectiveness

4.1.1. Effe 1.1 What were the main challenges in the implementing phase after April 2021? To what extent have these been addressed?

Key findings

- Alignment of national legislation with the AHL and full implementation at the Member States level is not yet complete. Progress is also uneven across the Member States.
- The transition period was hampered by external and internal challenges, including the COVID-19 pandemic and delays in adopting necessary EU-level acts. Despite EU support measures, most Member States were not fully prepared by April 2021.
- Implementation has proven resource-intensive and legally complex, with stakeholders highlighting difficulties in interpreting the layered legal framework and unclear interactions with related legislation.
- The European Commission actively supported Member States during the transition to the AHL through a combination of transitional legal measures, targeted guidance, and capacity-building through the Better Training for Safer Food (BTSF) programme
- The induced change in the underlying logic and institutional practice introduced by the AHL necessitates sustained investment in communication, training, and digital infrastructure to support full operationalisation and active stakeholder engagement.

Key limitations

- Due to the partial implementation of the AHL across the Member States, the challenges identified do not relate to persisting issues after April 2021, but are rather still related to ongoing implementation-related challenges.

The AHL represents a major milestone in the EU's approach to animal health. It entered into force in April 2016 and came into application in April 2021, replacing several previous directives and decisions with a single, harmonised legal framework. As an EU regulation, the AHL is a legally binding instrument that is directly applicable in all Member States, meaning that it does not require transposition into national law to take effect. As such, the AHL constitutes a major

simplification effort, reducing discrepancies typically associated with directive-based systems. However, while regulations have a direct effect, the practical implementation and enforcement remain the responsibility of each Member State. This includes, among others, establishing appropriate control systems, assigning responsibilities, and adapting existing structures to comply with the new legal framework.

Additionally, the shift from directives to regulation has introduced several transitional and legal challenges, particularly due to the legacy of previous national laws. Prior to 2021, animal health in the EU was primarily governed by directives, which allowed Member States considerable flexibility in how they implemented the rules. As a result, in the different MS, a range of national provisions and legal practices developed, some of which were not formally repealed or aligned when the AHL came into force. In some cases, these provisions are not completely in line with the AHL. The five-year transition period (2016-2021) was intended to allow Member States to implement the necessary changes to align their national legislation with the new framework. However, closer to the date, the European Parliament requested a postponement of the application date ([13]). Given the health crisis caused by COVID-19, Member States were not able to consult social partners on the application of the new rules, as required by the Regulation, and pointed out the risk of significant distortions in the implementation of the AHL ([14]). At the same time, the European Commission faced difficulties in adopting and implementing many delegated and implementing acts necessary for a full transition within the same period ([15]). While the European Commission acknowledged the concerns and issues related to the transition ([16]), no extension was granted because it would delay the implementation of animal health-related measures and their official control. The Commission enforced several measures to support the Member States in the implementation**.** Reinforced support was offered to Member States and stakeholders, including transitional measures for animal health and veterinary certificates for entry into the EU until October 2021, as well as new derogations for certificates related to intra-EU movements. Additionally, a more flexible approach to compliance and enforcement was foreseen, supported by the Better Training for Safer Food (BTSF) programme, aiming at NCAs, communication efforts, and supplementary documentation ([17]). Despite the fact that Member States have taken necessary action to address the alignment of their national legislations, it emerges that Member States are at different stages of implementation. The implementation of

([13]) European Parliament (2020) Question for written answer E-004906/2020, here.
([14]) European Parliament (2020) Question for written answer E-006355/2020, here.
([15]) European Commission (2021) Report on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law'). Available here.
([16]) European Parliament (2020) Parliamentary question - E-004906/2020(ASW). Available here.
([17]) Animal Health Advisory Committee (2021) State of play of the Animal Health Law – overview. Available here.

the AHL was for a number of Member States taken as an opportunity to revise and streamline their national legislation, including additional national measures, and update their contingency plans. For example, Spain has fully aligned its national legislation, while Germany is still facing delays, partially due to the legislative structure in the different Bundesländer. These differences were also confirmed during the validation workshops.

Box 1 and Box 2 illustrate the national legal changes undertaken in Austria ([18]) and Italy. NCAs in Austria acknowledge partial alignment of their national legislation with the AHL, but gaps remain. NCAs in Italy consider a full alignment of their national legislation with the AHL, except for the implementation of Article 25. The numerous legal acts adopted since the AHL's entry into force reflect the lengthy and complex process of alignment and demonstrate Italy's sustained efforts over the years to build a coherent national legal framework. It is worth highlighting that the new rules adopted by Italy have repealed previous legal provisions, some of which date back to the 1970s (see Article 22 of Decree 134/2022 and Article 32 of Decree 136/2022). This has resulted in a significant simplification and modernisation of the national animal health legislation, which was also mentioned by Italian NCAs consulted. However, while the legal framework has been streamlined, both the EU and Italian regulatory changes represent a substantial shift that will require time to be fully absorbed and implemented at all levels.

Box 1 – Austria's alignment with the AHL

2021: **Federal Law Gazette I No. 258/2021** - Amendment to the Animal Diseases Act (177/1909) to formally include the Veterinary Registry. The legal foundation of the register was also adapted to meet the current requirements of the AHL and the Official Control Regulation (OCR EU Reg 2017/625). Novelties include, for example, the geographical coordinates of the farm location and individual animals, which can be used to improve the visualisation of the exact location in the event of an epidemic.

2023: Control and Digitalisation Implementation Act (*Kontroll- und Digitalisierungs-Durchführungsgesetz – KoDiG)* Federal Law Gazette I No. 171/2023 – forms the legal basis, together with the AHL, for the Consumer Health Information System (*Verbrauchergesundheitsinformationssystem*, VIS), an electronic database that is available to the veterinary and food authorities. The VIS is divided into the areas of master data, farm data, animal data, inspection data and inspection data and entry obligations are laid down in the Animal Health Act (TGG, Federal Law Gazette I No. 53/2024) and the LMSVG (Federal Law Gazette I No. 3/2006). The major innovation introduced is that the official farm and control database is now also to be centralised in the food sector.

2024: **Animal Health Act, published in the Federal Law Gazette I No. 53/2024**. It directly implements the core provisions of the AHL and repeals:

([18]) Bericht 2024 über die Entwicklungen betreffend Lebensmittelsicherheit, Veterinärwesen und Tierschutz, here.

1. The Animal Diseases Act (*Tierseuchengesetzes*) RGBl. No. 177/1909
2. The Animal Health Act (*Tiergesundheitsgesetzes*), BGBl. I No. 133/1999
3. the Veterinary Law Amendment 2021 (*Veterinärrechtsnovelle*) BGBl. I No. 73/2021
4. the Bee Diseases Act (*Bienenseuchengesetzes*) BGBl. No. 290/1988

The law also addresses constitutional boundaries between the healthcare and veterinary systems in Austria, emphasising that animal health is governed separately under a distinct veterinary legal regime.

Box 2 – Italy's alignment with the AHL

2021:

- **Decree No. 27/2021** mainly addresses the **Official Control Regulation EU 2017/625 (OCR).**
- **Law No. 53/2021:** This represents the first step in the Italian legislation by which Italy adapts the legal provisions produced by the European Union into its domestic law. Article 14 allows the Italian government to implement Regulation 2016/429.

2022: on 27 September 2022, **a package to align national legislation to the AHL entered into force**. The package consists of three decrees covering the classification of diseases, early identification, notification and communication of the same, surveillance, eradication programmes and disease-free status, control measures, including in emergencies, the movement and traceability of animals, as well as the attribution of responsibilities in animal health matters. **More in detail,**

- **Decree No. 134: I&R Identification and Registration Decree (*Decreto I&R Identificazione e Registrazione*).** This decree repeals the old rules relating to the identification of animals, the registration of animal movements, the registration/recognition obligations of establishments where animals are kept and related obligations for their keepers. It also strengthens the information systems of the Ministry of Health by establishing a national computerised database (Banca Dati Nazionale, BDN) under the Ministry of Health that facilitates the traceability of animals by registering operators, establishments, and transporters involved in animal handling.
- **Decree No. 135: Exotic and Wild Animal Decree (*Decreto Esotici e Selvatici)*.** It addresses **trade, imports and conservation of wild and exotic animals**. It also focuses on the training of animal operators and professionals and outlines penalties for illegal trade in protected species.
- **Decree No. 136: Prevention Decree (*Decreto Prevenzione, here*).** This decree provides a new approach to the control, surveillance and eradication measures of animal diseases, through a general, cross-cutting legal framework. It covers a wide range of AHL provisions and aligns Italy's national legal system with the EU's AHL and related implementing and

delegated regulations. It designates the **competent authorities** and regulates several key areas of animal health management, including:

1. Assignment of responsibilities in animal health
2. Early detection, notification, and communication of diseases
3. Surveillance, eradication programmes, and disease-free status
4. Disease control and emergency measures
5. Registration and recognition of establishments and transporters
6. Movement and traceability of animals (including non-commercial), germinal products, and products of animal origin, both within the EU and across its borders

It also modifies the Ministerial Decree from December 2017, which established the ***appointed/designated veterinary***. Key changes include strengthening their involvement in the national animal health surveillance system. The decree requires a forthcoming Ministerial Decree to define the tasks, qualifications, and responsibilities of these veterinarians, particularly concerning operator surveillance obligations and animal health visits. It also extended the operational mandate of appointed veterinarians until 31 December 2025, ensuring continuity in official activities, and aims to tackle issues related to the shortage of company veterinarians, which does not allow for proper implementation of the ***ClassyFarm system.*** ClassyFarm is an integrated surveillance system developed by the Italian Ministry of Health to monitor and assess livestock farms, focusing on antimicrobial use (AMU), AMR, animal welfare, and biosecurity. The system collects and analyses data from various sources, including electronic veterinary prescriptions, on-farm assessments, and slaughterhouse inspections. The first version of the system was available in 2017, but Decree 136 further defines the procedures for data entry into ClassyFarm, including the use of digital checklists and the establishment of minimum frequencies for animal health visits based on risk assessments.

2023:

- **Decree No. 6 on Training:** it established the arrangements for the delivery of training programmes on the system of identification and registration of operators, establishments and animals for animal handlers and professionals, in accordance with the training requirements contained in Article 11 of Regulation (EU) 2016/429.
- **Ministerial Decree 7 March 2023:** provides supplementary measures to Decree No. 134 introduces an operational manual for managing and operating the **Identification and Registration (I&R) system** for operators, establishments, and animals. This manual aims to standardise procedures across Italy, enhancing traceability and control of animal movements.

2024:

- **Decree No. 220,** in force since February 2025, supplements and corrects provisions to Legislative Decrees 5 August 2022, n. 134, 135 and 136: Among others, it includes amendments to introduce the obligation for owners, holders or operators to communicate changes to the data in the database and foresees a penalty of a fine of 50 to 500 euros for each animal (Decree 134).

The revision of Decree 136 focuses on the **governance of the animal disease prevention system and response measures**. Key changes include the reorganisation of the National Centre for the Fight and Emergency Response, especially its Central Crisis Unit, and an updated structure for the Emergency Operations Group (GOE). Disease reporting procedures have been reinforced, and a new duty has been introduced for local health authorities: ensuring a timely and continuous exchange of information on suspected and confirmed zoonotic diseases within their organisations. Surveillance efforts have been expanded beyond Category D and E diseases, now also covering Categories A, B, and C, and for the first time, extending control measures to include wild animals, not just domestic terrestrial and aquatic species. Additional updates concern the roles of appointed veterinarians, company vets, and animal health laboratories.

- **Decree No. 236,** 8 October 2024, which establishes specific operational procedures for implementing **biosecurity measures in aquaculture**, as mandated by EU Regulation 2016/429 (Art.4 and 10). These measures are designed to prevent the introduction and spread of aquatic animal diseases and include structural protections like barriers and sanitation facilities, as well as hygiene management procedures for visitors, equipment, and vehicles.

In addition, specific measures have been introduced to **control the spread of ASF,** particularly through **Decree-Law No. 9 of 17 February 2022**, which was followed by further implementing acts. Notably, the **Ministerial Decree of 28 June 2022** strengthened national efforts by updating and consolidating **biosecurity requirements** for pig farms. This decree establishes **specific structural and operational standards** tailored to various types of pig establishments, taking into account several factors, such as whether pigs are kept indoors or outdoors and the **size or production capacity** of the farm (e.g., low or high-capacity holdings). The aim is to ensure that biosecurity measures are proportionate to the risk level of each establishment, thereby improving **early prevention and control** of ASF outbreaks across different farming systems.

NCAs consulted through the survey and interviews highlighted persisting challenges related to implementation. Survey replies to three questions related to implementation were limited, representing a limited sample relative to the total number of EU Member States (6). Most respondents (6 out of 9 responses to the question) report that there has been significant adaptation, with some areas still requiring attention, while very few consider the adaptation process complete (1 out of 9) or minimal (1 out of 9). These findings on the overall progress of the implementation should be interpreted with caution.

The degree and type of alignment have also been discussed during interviews with NCAs and the validation workshop (21 interviews with Ministries and chief veterinary officers (CVOs) in 13 Member States); while 22 Member States participated in the Validation workshop (for more details on the distribution, see the Synopsis Report). Two Member States have highlighted ongoing alignment

issues, while six others have reported that alignment is still in process. The reasons behind these delays can be different; for example, some Member States have mentioned issues in the repeal or integration of national legislation and its consolidation into a single law. A Member State stressed that they are still in the process of revising the legislation that was updated during the accession phase and aligned with previous EU directives to bring it in line with the AHL, requiring additional efforts and time.

In Spain, for example, NCA reported that changes to traceability systems and contingency plans were necessary. As part of this process, Royal Decree 787/2023 ([19]) (later modified by Royal Decree 1307/2024) introduced detailed provisions to regulate the identification, registration, and traceability of various terrestrial animal species in captivity, including cattle, pigs, sheep, goats, horses, camelids, deer, poultry, rabbits, fur animals, bees, and psittacines. This Decree aims to enhance clarity and effectiveness while ensuring consistency with EU Regulation (EU) 2016/429 and related national rules. The reform acknowledged the need for certain flexibility measures to accommodate specific species and regional contexts. As a result, amendments to earlier legislation were needed, including Royal Decree 479/2004, which governs the General Register of Livestock Holdings, and Royal Decree 728/2007, which oversees livestock movement and individual animal identification. Importantly, the reform allows Spain's autonomous communities and livestock farmers greater discretion in implementing identification obligations in a way that is tailored to their local realities. As for contingency plans, minor changes, particularly related to the acceptance of animals from other EU countries.

In other instances, NCAs reported that the adjustment to the AHL was relatively straightforward, requiring minimal to no changes to existing legislation. Findings from the case study countries confirmed differences in implementation.

Regarding challenges in the implementation after 2021, feedback received in the Call for Evidence highlights that legal and operational challenges further hinder the AHL implementation, as stakeholders report difficulty in interpretation due to limited guidance and excessive cross-referencing between multiple regulations. For example, public authorities and veterinarians have noted that regulations related to individual animal diseases that were addressed in one Directive in the past are now dispersed across multiple legal acts, including Delegated Regulations and Implementing Regulations, making it difficult for them to obtain a clear and comprehensive overview. Additionally, for them, the links between the AHL and Regulation (EU) 2017/625 on official controls remain unclear. Several NCAs have identified the perceived complexity of the AHL as one of the main issues hampering full alignment. In fact, although the aim of the AHL was to bring together existing EU rule on animal health into a single and simplified law and while this has been achieved, it also introduced a comprehensive legal framework covering all aspects of animal health: prevention, surveillance,

([19]) https://www.boe.es/diario_boe/txt.php?id=BOE-A-2023-22499

eradication, movements, traceability, and disease categorisation. In addition, the core AHL text is accompanied by multiple delegated and implementing regulations (see Figure 1) that provide detailed technical rules. These are in different documents, requiring users to cross-reference multiple legal acts to understand how the system operates in practice. This layering initially contributed to difficulty in accessing comprehensive, consolidated information. Others have reported that the initial rollout of the AHL and alignment of national legislation was time-consuming and resource-intensive, both in terms of personnel and financial investments, for example, in information systems. Member States have taken measures at the national level to overcome the challenges identified. For instance, in Bulgaria, a working group comprising policymakers, representatives from veterinary authorities, and other relevant stakeholders has been established. The working group ensures that the integration of the AHL meets national needs while ensuring compliance with EU law.

Policy officers and implementing authorities who used to work within the old structure and now needed to work with the new system encountered substantial challenges. Some Member States highlighted that the perceived complexity of the legal framework has also encountered resistance and required time for adaptation by all stakeholders, including veterinarians and animal keepers, who need to fully understand the rules and nuances and adopt a shift in the mindset. To navigate this challenge, Hungary has launched a comprehensive communication campaign to facilitate understanding and compliance with the new regulations.

4.1.2. Effe 1.2 To what extent has the AHL legislation achieved its general and specific objectives?

Key findings

- The implementation of the AHL in the MS has shown progress towards realising its general and specific objectives.

General objectives:

- The AHL has established a solid legal and operational framework for disease prevention and control. It builds on existing measures while placing a stronger emphasis on prevention. Stakeholders generally agree that the AHL provides a robust structure, but its full potential will only be realised once implementation is harmonised and enforcement is consistent across all Member States.
- The AHL successfully consolidated multiple pieces of previous legislation into a single, harmonised, and clearer legal framework, improving coherence and facilitating a more consistent application of animal health rules across Member States.
- There has been progress towards prevention and control of animal diseases. Since the AHL's entry into force, several Member States have achieved new or expanded disease-free statuses (e.g. BVD, IHN, VHS), showing tangible progress in disease control and eradication across the EU.
- Improved tools for prevention and preparedness: Mandatory animal health visits (Article 25) are intended to strengthen early detection and biosecurity but are inconsistently applied, especially in smaller or remote farms, due to legislative gaps, enforcement issues, veterinary shortages, and cost burdens. Contingency plans (Article 43) and simulation exercises (Article 45) have improved clarity of responsibilities and response speed, but some plans remain outdated or insufficiently detailed, and training gaps persist. In addition, enforcement and contingency plan updates remain inconsistent across MS.
- More flexible vaccination (e.g. HPAI in France) has helped to contain disease and limit negative effects, contributing to a higher overall animal health status.
- Strengthened traceability provisions and regionalisation/compartmentalisation measures have improved the ability to contain diseases and allow proportionate restrictions, although some market disturbances have occurred (e.g. ASF-related meat trade restrictions).
- Commission support, including transitional measures, detailed guidance and EU-level training such as BTSF, is widely valued for capacity building.

However, stakeholders highlight the need for more practical guidance, wider dissemination, greater inclusion of non-authority stakeholders and stronger assistance for NCAs to maintain knowledge, particularly among less frequent users of the AHL.

- Frequent delegated/implementing acts and derogations create uncertainty. Stakeholders need clearer, harmonised EU-level guidance on roles, procedures, and updates to ensure consistent application.

Specific objectives:

- **Simplification and clarity of the legal framework:** This has largely been achieved from a legislative standpoint, with clearer roles and responsibilities defined for all actors in the animal health chain. However, practical implementation has proven more complex. Many stakeholders, particularly farmers and veterinarians, report difficulties navigating the regulation due to its reliance on multiple delegated and implementing acts. While the AHL has improved clarity overall, the distribution of responsibilities is not always perceived as balanced, with some groups feeling disproportionately burdened.
- **Flexibility for new challenges including disease categorisation and prioritisation:** The AHL introduces general principles and a categorisation system that allow for a flexible response to emerging diseases. This system, which classifies diseases into five categories (A–E), is designed to ensure proportionate, science-based control measures. While stakeholders generally support this approach, concerns have been raised about its adaptability and the timeliness of updates. Some Member States have struggled with overly prescriptive measures, such as restrictions on vaccination in disease-free areas, which may not reflect local realities. There is a clear call for a more dynamic system that can respond to evolving epidemiological contexts and climate-related changes.
- Consistency with animal welfare and food safety: While no legal contradictions have been identified, stakeholder views on alignment vary, highlight the need for better communication and risk-based oversight.
- **Reducing socio-economic impact and trade disruption:** The AHL has contributed to reducing the socio-economic impact of animal diseases by enhancing disease awareness, preparedness, and response systems. Trade data indicates a strong recovery in intra-EU trade post-2021, despite ongoing outbreaks of diseases like ASF, HPAI, and BTV. Regionalisation measures have allowed Member States to maintain trade from unaffected areas, minimising disruptions. Stakeholders acknowledge that the AHL has strengthened the EU's export capacity and improved trust in disease-free declarations, although its impact on the internal market is seen as moderate.

Key limitations

- Due to the partial implementation of the AHL across the Member States, a full assessment of the AHL's general and specific objectives remains challenging, as many provisions are not applied or enforced yet.
- Assessment of the success of the AHL with regard to prevention requires the use of epidemiological and economic models, which fall outside the scope of this evaluation.

The general objectives of the AHL, as set out in Article 1, aim to prevent and control animal diseases, particularly those transmissible to other animals or humans. The aim is to improve animal health as a means of supporting sustainable agricultural and aquaculture production within the EU, ensuring the effective functioning of the Internal Market, and reducing the negative impacts that certain diseases can have on animal health, public health, and the environment.

Since most Member States are currently in the early phases of implementation of the AHL, it is difficult to assess to what extent the objectives of the AHL are fully achieved (see Section 3.0). Furthermore, assessing the effectiveness of disease prevention measures is also challenging because it involves evaluating the absence of an event which inherently lacks observable outcomes. Unlike outbreak response, which can be measured by clear indicators such as the duration, spread, or number of cases, prevention requires counterfactual assessments, i.e., estimating what would have happened without the measures in place. It remains difficult to determine the individual effect of different preventive and control strategies on the reduction or avoidance of outbreaks. While a general expectation is that effective prevention will lead to a lower incidence and reduced scale of disease outbreaks, proving this impact in practice is highly complex. Epidemiological and economic models are the only feasible option to get insight into the causal effects of different control strategies on outbreaks (see studies on Foot and mouth disease, Classical swine fever, Avian influenza) ([20]). In addition, the AHL has largely retained effective measures already in place from previous legislation, while introducing a stronger emphasis on prevention. However, quantifying the benefits of preventive action remains a scientific challenge. This is further complicated by the layered structure of animal

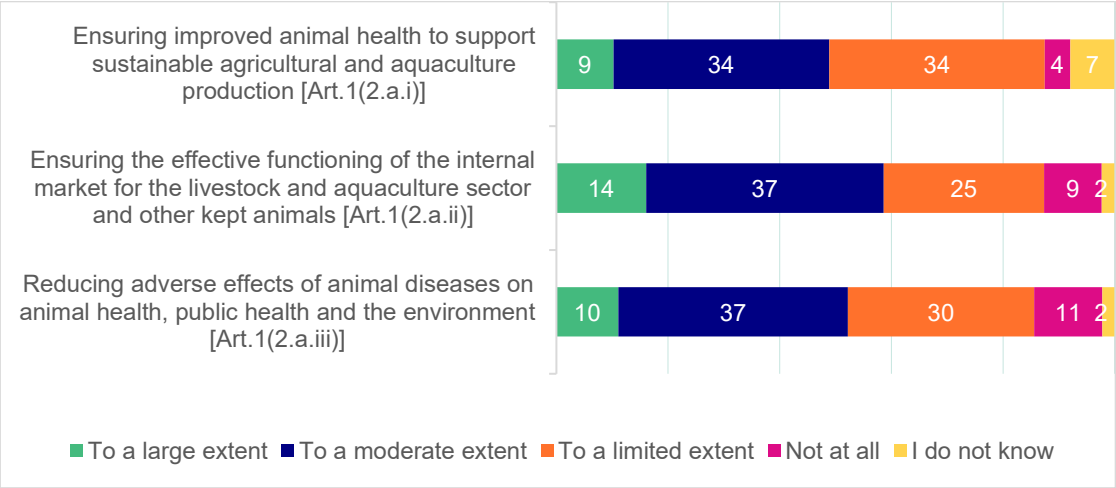
([20]) See for example: Backer, J. A., van Roermund, H. J. W., Fischer, E. A. J., van Asseldonk, M. A. P. M., & Bergevoet, R. H. M. (2015). Controlling highly pathogenic avian influenza outbreaks: An epidemiological and economic model analysis. Preventive Veterinary Medicine, 121(1-2), 142-150. https://doi.org/10.1016/j.prevetmed.2015.06.006 Bergevoet, R. H. M., & van Asseldonk, M. A. P. M. (2014). Economics of eradicating Foot-and-Mouth disease epidemics with alternative control strategies. Archivos de Medicina Veterinaria, 46(3), 381-388. https://doi.org/10.4067/S0301-732X2014000300006 Backer, J. A., Bergevoet, R. H. M., Fischer, E. A. J., Nodelijk, G., Bosman, K. J., Saatkamp, H. W., & van Roermund, H. J. W. (2011). Control of Highly Pathogenic Avian Influenza; Epidemiological and economic aspects. (LEI report; No. 2011-032). LEI. https://edepot.wur.nl/173727

health surveillance, encompassing diverse components such as on-farm biosecurity, active monitoring, and laboratory testing, each characterised by differing levels of data quality, consistency, and frequency across Member States. Additionally, disease dynamics are influenced by many external factors, including environmental changes, animal densities, wildlife interfaces, and trade patterns. These factors are only partially affected by legal instruments like the AHL. Major outbreaks such as the 2001 foot-and-mouth epidemic and the waves of highly pathogenic avian influenza in 2006 and again in 2021–2022 underscore the irregular nature of animal disease emergence. Furthermore, external shocks, such as geopolitical or economic disruptions, can significantly affect the outcomes of disease control and surveillance efforts, making it difficult to isolate the direct impact of the AHL on observed epidemiological trends. On the other hand, the effectiveness of control of animal diseases is more straightforward to assess. Nonetheless, as explained in EQ1.1, the following findings should be assessed considering early phase of the AHL implementation.

Findings suggest that the AHL has set a robust framework for disease prevention, but its full potential will only be realised once consistent implementation is completed across the 27 Member States and related enforcement fully implemented at the national level. This is demonstrated by stakeholders' opinions and indicators on disease-free areas, changes in animal health visits, the system in place for traceability, appropriate (preventive) measures for the movements of animals, including zoning, regionalisation and compartmentalisation, and the availability of training discussed below. The improved availability of implementing vaccination strategies and their flexibility, such as vaccination against Highly Pathogenic Avian Influenza (HPAI) in France and vaccination against Bluetongue (BT) in a number of Member States helped to contain the disease or minimise its negative effects. This has ultimately led to a higher overall animal health status. However, differences persist depending on the type of disease.

The different stakeholders surveyed acknowledge progress towards realising the general objectives of preventing and controlling animal diseases transmissible to animals or humans. More than half of the respondents noted positive effects on improving the Internal Market's functioning and reducing the adverse effects of animal diseases. Slightly less than half of the respondents acknowledge progress in ensuring improved animal health to support sustainable agricultural and aquaculture production.

Figure 4 – Survey replies to the question 'To what extent has the AHL been successful in achieving its general objectives?'



Source: Consortium (N=88, N=87, N=90)

As presented in Figure 2, Annexe 7, these views vary across the different types of stakeholders targeted, with most livestock and aquaculture farmers and industry representatives considering that the AHL has only been successful to a limited extent across all general objectives. Veterinarians hold a more optimistic view than farmers and industry representatives, recognising that the AHL has been a step forward in improving disease control and the effective functioning of the Internal Market, while more mixed views related to improved animal health for sustainable agricultural and aquaculture production**.** On the other hand, other stakeholders such as NCAs and civil society, academia, and other organisations involved with animal health have a more positive view of the contribution to preventing and controlling these diseases.

To realise its general objectives of prevention and control, the AHL introduced a set of interconnected mechanisms that together form the foundation of the EU's disease prevention and control system. These include provisions laid out in Part II on disease notification and reporting, surveillance, eradication programmes and disease-free status. As one of the main activities for proper surveillance, in addition to operators' obligations (Article 24) and the competent authority's surveillance obligation (Article 26), Article 25 introduced provisions regarding animal health visits by veterinarians with the aim to strengthen disease prevention and early detection mechanisms, potentially limiting the spread of infectious diseases and preventing outbreaks before they become unmanageable. The article requires operators to ensure that animal health visits are conducted at a frequency proportionate to the risk posed by the establishment concerned, based on, among other things, the type of establishment, species and categories of animals and the epidemiological situation in the zone and can be combined with visits for other purposes. Although veterinary visits are seen as one of the important elements contributing to early disease detection, biosecurity, and reduced antibiotic use, the frequency of such visits should be established

based on the risk proportionality. A study ([21]) carried out by the Federation of Veterinarians of Europe found that prior to the implementation of the AHL, 18 Member States already mandated regular animal health visits for some specific animal species. The introduction of the AHL should have implemented, harmonised and standardised such requirements across all animal species and operators by April 2021, but in practice, many Member States have not yet (fully) applied provisions related to Article 25 and continue to face challenges. Interviews with NCA indicate that national legislation regulating compulsory animal health visits is both incomplete and inconsistently enforced across the EU due to national legislative gaps, insufficient enforcement, veterinary workforce shortages, and limited farmer engagement, which remain key barriers to full implementation. In addition, while the AHL allows for flexibility for Member States to implement, some Member States authorities and veterinarians have expressed the need for guidance at the EU level on different aspects, such as clarification of roles and responsibilities and related payments, standardised procedures for conducting the visit and instructions on how to align animal health visits with existing surveillance and other visits. Some Member States, on the other hand, included visits to national veterinary programmes. While the AHL mandates that animal health visits be conducted using a risk-based approach, in practice, this is not always consistently implemented across Member States. As a result, some stakeholders from farmers ‘and industry organisations have expressed criticism toward the use of rigid, fixed-interval visit schedules in their MS, arguing that a risk-based approach would offer a more balanced and cost-effective way to meet the requirements than the currently applied schemes by a number of Member States. This could be overcome with clearer and harmonised EU-wide standards regarding health visits or improving knowledge in MS in the application of a risk-based approach.

These challenges related to animal health visits are particularly evident when comparing intensive, commercial farms with smaller holdings. In Ireland, for instance, while cattle farms undergo annual tuberculosis testing, providing some level of veterinary interaction, many remote and smaller (esp. sheep) farms receive no regular health visits. Although a voluntary programme exists to support biosecurity-focused visits, participation is optional, and there is no enforcement mechanism to ensure universal coverage. Similarly, in Romania, commercial pig farms are consistently monitored, but the country’s large number of backyard farms poses a major logistical challenge. While most of these holdings are visited at least once a year, it is not always possible to confirm adherence to biosecurity protocols, reflecting uneven standards of oversight. In the Netherlands, NCAs report that animal health visit practices have remained largely unchanged post-AHL: intensive farming sectors, such as pigs and poultry, often incorporate veterinary visits and biosecurity measures as part of industry-led quality systems. However, extensive sectors, such as sheep hobby farming, often lack the same level of structure and support, leading to less consistent veterinary engagement.

([21]) FVE (2021) Animal Health Visits FVE Survey on the Application of Art. 25 (last update November 2023).

There is also an ongoing debate across Member States regarding the role of private veterinarians in delivering these visits. Stakeholders have noted the financial burden such visits impose on small-scale farmers, as well as the limited availability of veterinarians in rural areas. As a result, compliance with Article 25 is often higher in large-scale operations, while small and remote farms face structural disadvantages (for a distribution of costs, see also Annexe 3).

Part III of the AHL on Disease awareness, preparedness and control lays out requirements for contingency plans (Article 43) and simulation exercises (Article 45). These play a big role in the prevention and preparedness capacity building of all stakeholders involved. Prior to the introduction of the AHL, contingency plans were covered by separate Directives for specific diseases ([22]), resulting in inconsistencies in planning, execution, and updates between Member States. Article 43 introduces a horizontal requirement for Member States to develop and maintain contingency plans for all Category A diseases, to ensure a more consistent and effective response to outbreaks of listed animal diseases. Stakeholders report clearer responsibilities, better prioritisation of animal diseases, and quicker responses to outbreaks thanks to this harmonised framework. However, some Member States continue to face challenges in keeping contingency plans updated and aligned with AHL requirements, particularly in light of regulatory changes and disease reclassification and expressed the need for continued training to support effective implementation according to AHL requirements. This is confirmed by audit findings (see Box 3) which found that some contingency plans remain outdated or insufficiently detailed. Deficiencies identified include outdated contingency plans and insufficient training of district veterinarians, which can have negatively impacted the timeliness, accuracy, and effectiveness of disease preparedness measures, showing Member States non-compliance with legal obligations and lack of proper enforcement. This lack of alignment with EU legislation further shows that full implementation of the AHL is still not complete. In the event of an outbreak, this can hinder the ability of authorities to respond effectively and in compliance with legal requirements, leading to the further spread of diseases.

([22]) Directive 2001/89/EC on African swine fever, Directive 2003/85/EC on foot-and-mouth disease and Directive 2005/94/EC on avian influenza

Box 3 – Examples of the implementation of contingency plans

Denmark: according to the audit report carried out in Denmark on controls on live aquatic animals ([23]), although **Denmark has a contingency plan for Category A aquatic animal diseases in place, it dates back to 2010 and does not yet reflect the latest requirements of the AHL**. An update is planned for 2024, which will include a revised format for epidemiological inquiries used by Team Aqua to investigate aquatic disease outbreaks. From a laboratory point of view, the DTU Aqua, the National reference laboratory for VHS and IHN, had its own laboratory contingency plan to respond to the expected additional demands in diagnostic capacity deriving from large IHN outbreaks.

Sweden: According to the audit report carried out in Sweden ([24]), the contingency plan for HPAI **had not yet been fully updated**, despite previous experiences, recent epizootics, and the persistent risk of incursions via wild birds. As such, the plan does not fully comply with Article 43(2) of the AHL. While the Swedish Board of Agriculture (SBA) has taken some steps to enhance response capacity, such as amending procedures to initiate carcass disposal preparations already at the suspicion stage, the overall plan is still under revision. To further strengthen preparedness, authorities plan to partially shift responsibility for carcass disposal to poultry operators, requiring them to develop establishment-specific contingency plans. On the laboratory side, the National Reference Laboratory (NRL) for HPAI has a generic contingency plan in place, outlining detailed procedures for scaling up testing capacity in the event of a sudden surge in diagnostic demand during an outbreak of Category A diseases like HPAI.

Contingency planning under Article 43 is directly tied to simulation exercises Article 45, simulation exercises which allow authorities to test the effectiveness of contingency plans under realistic conditions. They help identify weaknesses, gaps, or ambiguities in existing procedures before an actual outbreak occurs. Since the introduction of the AHL, exercises have also been carried out at the international level, within the WOAH framework. See, for example, in Czechia and Estonia ([25]) for Foot and Mouth disease in 2022 and in Czechia for Foot and Mouth disease, HPAI and ASF in 2023 ([26]).

([23]) Audit Report Denmark (2023).
([24]) Audit Report Sweden (2022).
([25]) WOAH Press releases (2022).
([26]) WOAH Press releases (2022).

Box 4 – Simulation exercises in Hungary

In the framework of the audit in Hungary for HPAI in 2023 ([27]), it was found that **three simulation exercises had been conducted**: one in September 2022 on depopulation methods and gas parameters, another in December 2022 focused on ASF and outbreak communication, and a third in November 2023 covering animal welfare during depopulation and cleaning/disinfection. However, **planned exercises in late 2021 and early 2022 were not carried out** due to an HPAI epidemic at the time. Auditors also assessed that the exercises conducted were **limited in scope**, addressing only specific aspects of outbreak response and **failing to cover essential components** such as epidemiological data collection, enquiries, censuses, and field investigations in restricted areas. Additionally, the **preparedness of local authorities** for these tasks was not verified, nor was the opportunity taken to share past lessons learned. As such, Hungary's approach **did not fully meet the requirements of Article 45 of Regulation (EU) 2016/429**. While the simulation exercises improved local authorities' knowledge, their **narrow focus limited their effectiveness** in addressing key weaknesses identified during recent HPAI outbreaks, as essential components of emergency response were deemed not covered.

While eradication programmes were already part of the animal health system before the introduction of the AHL, these were previously regulated under various disease-specific directives and decisions, rather than a single, harmonised legal framework. The AHL streamlined and harmonised these rules by bringing all disease surveillance, eradication, and disease-free status provisions under one umbrella, using a categorisation system (A to E) to determine which diseases require compulsory (for category B diseases) ([28]) or optional eradication programmes (for category C) as defined in Chapter 3 of Part II of the AHL. For example, Croatia has put forward a plan to eliminate enzootic bovine leukosis (EBL) and Ireland applied for approval of its programme to eradicate bovine viral diarrhoea (BVD). The purpose of the eradication programmes is to obtain disease-free status from that disease and to maintain that status once achieved. Changes in the number of areas declared disease-free of a specific animal disease within the EU are listed in Annex 14. These changes serve as tangible evidence that prevention and control measures are being successfully implemented and maintained by Member States Implementing Regulation (EU) 2021/620 has revised the lists of existing disease-free Member States, zones, and compartments and the existing approved eradication and surveillance programmes set out in Article 280 of the AHL. Based on the changes in disease-free status, it can be concluded that the AHL has supported meaningful progress in disease control and eradication across several Member States. Since the entry into application of the AHL and the adoption of Implementing Regulation (EU) 2021/620, there have been tangible improvements in the recognition of disease-free territories, as reflected in the multiple updates through successive

([27]) Audit Report Hungary (2023).

([28]) Approved compulsory eradication programmes for Category B diseases are available on the Commission website here.

regulations. These updates indicate that various Member States have successfully implemented prevention and control measures, resulting in new or expanded disease-free declarations for important pathogens such as BVD, Infectious Haematopoietic Necrosis (IHN) and Viral Haemorrhagic Septicaemia (VHS). While some Member States have not yet reported changes in disease-free status, the trend across the EU is one of gradual and demonstrable improvement. This suggests that, although uneven implementation persists, the AHL has established an effective legal and operational framework for monitoring progress and supporting coordinated disease control at the Union level.

Part IV of the AHL regulates registration and approval of establishments, traceability and movements. Two important tools for controlling and preventing the spread of animal diseases are animal traceability and (preventive) regionalisation (measures taken for the movements of kept animals). Chapter 2 of Part IV of the AHL (Articles 108-123) lays down the legal framework for the traceability of terrestrial animals and germinal products, including requirements for identification, registration, and movement reporting. Animals must be identified individually or in groups using approved methods (e.g. ear tags, electronic IDs), and their data is recorded in holding registers and national databases (record keeping). Member States' competent authorities are responsible for setting up, managing, and maintaining these databases pursuant to the AHL and to Delegated Regulation 2019/2035. These databases should be designed in a way to ensure interoperability integration and compatibility of the elements of the national system itself. In relation to EU – level, they should, to the extent appropriate, be adapted to EU-level systems, such as the computerised information system for Union notification and reporting and to TRACES, allowing for information sharing and coordinated disease response. Proper implementation of these provisions enables authorities to monitor animal populations, respond quickly to outbreaks, and reduce the risk of disease transmission between herds and across regions.The system of traceability is supported by EU-wide tools such as TRACES. Although not part of the AHL, it is regulated by Commission Implementing Regulation (EU) 2019/1715. The AHL explicitly encourages its use whenever possible (see, for example, Articles 153(2) and 163(2), meaning all the times that the system is operational. Stakeholders see TRACES as a useful tool for tracking animal movements at the cross-border level, but have also pointed out that the system has regularly unannounced updates, making it regularly inaccessible to users in Member States. The broader **IMSOC system** (Information Management System for Official Controls), which integrates tools like ADIS and TRACES, has been recognised as a step forward in simplifying procedures. Nonetheless, improvements are still needed, such as automatic preselection of certification requirements in TRACES based on official EU animal health statuses, to reduce the risk of human error during document issuance. In addition, an aquaculture representative stressed the importance of a consistent and correct use of TRACES across all stakeholders in this sector.

In addition, during consultations some farmers and industry stakeholders have specifically called for further digitalisation, proposing a global centralised animal

database integrating e-passports, residency, vaccination records, and health certificates to improve compliance and accessibility, but the feasibility of such a system depends on the existing level of digital infrastructure and integration in national competent authorities. The extent to which the current systems are efficient largely depends on the degree of digitalisation and data integration already observed within NCAs before AHL implementation and goes beyond the scope of the AHL.

Appropriate (preventive) regionalisation, whether across farms, regions, or national borders, is an essential component of the EU's disease containment strategy. Swift action is necessary to limit the spread of diseases and reduce their impact on animal health, public health, and trade. Table 1 in Annexe 2 of the AHL outlines the actions taken to apply restrictions to certain zones where diseases are detected, the so-called restricted zones. As defined in Article 4(41) of the AHL, these zones limit the movement of certain animals and animal products. Upon confirmation of a disease in kept animals, as per Article 60 of the AHL, NCA are mandated to implement immediate control measures, including the establishment of restricted zones, appropriate for the listed disease. Article 64 details the procedures for establishing restricted zones, taking into account the disease profile and epidemiological factors, while Article 65 outlines the specific disease control measures to be applied within these zones, such as movement restrictions, surveillance, and biosecurity enhancements. National examples include, among others, the restricted movement of animals in Greece, where a nationwide ban on sheep and goat movements was enacted in response to outbreaks of sheep pox and goat pox, and Spain, as outlined in Box 5. Similar movement controls were implemented in Romania to combat Peste des Petits Ruminants (PPR), while Box 7 outlines measures taken regarding ASF. These graduated restrictions introduced, including the establishment of restricted zones, movement bans, and requirements for clinical inspections and sanitary transport protocols, demonstrate a structured and risk-based approach to preventing the spread of disease. They also illustrate the agility of the system in enabling competent authorities to rapidly restrict movements, target surveillance and culling efforts, and apply biosecurity measures where they are most needed. Importantly, the ability to downscale or lift restrictions in areas where no new cases are detected underscores the role of real-time monitoring and the effectiveness of the interventions. The Spanish case also illustrates the flexibility within the AHL framework to accommodate exceptional circumstances (return of transhumant flocks caught in newly designated zones) while maintaining the integrity of the overall disease control system.

Box 5 – Sheep Pox and Goat Pox outbreak in Spain

Following the outbreak of **Sheep Pox and Goat Pox (SGP)** in Spain in 2022, a series of escalating measures were introduced following the establishment of restricted zones. Restrictions on movements were applied in February 2023, and especially in Castilla la Mancha **all movements were banned**, and sheep and goats were only allowed to exit to immediate slaughter. Movements from

fattening holdings were allowed exclusively to slaughterhouses, subject to prior clinical inspection of the source farm ([29]).

In April 2023, all movements from restricted zones to free areas required a clinical inspection of animals at least 24 hours before movement. The inspection is carried out in sealed trucks, which are checked for cleaning and disinfection ([30]).

In June 2023, Spain notified the EU Commission that some flocks moved in 2022 for transhumance ended up in areas later designated as Restricted Zones. These flocks now need to return to their origin. As a result, Spain requested an exceptional authorisation to allow their movement under a special sanitary protocol. The Commission proposed a one-off solution applicable only to the specific flocks concerned, without altering existing EU SGP zoning or control measures ([31]).

Box 6 – ASF and regionalisation

The European Union's approach to managing ASF has evolved with the implementation of Commission Implementing Regulations (EU) 2023/685 and 2023/594 and previous measures like Regulation (EU) 2021/605. This regulation establishes a structured framework for regionalisation, categorising areas into restricted zones (RZ) I, II, and III, based on the presence and spread of ASF. In addition, the persistence of ASF in wild boar populations continues to pose challenges in the control of the disease, with the European Food Safety Authority (EFSA) actively monitoring the evolving epidemiological situation. For instance, in 2024, several Member States, including Italy, Greece, and Poland, saw adjustments in their restricted zones to reflect the current ASF situation. Some regions achieved reductions in restricted zones due to effective control measures. Certain areas in Czechia and Germany were delisted or had their restrictions downgraded after prolonged periods without new ASF cases (see Annexe 2). By continuously adapting the demarcation of Restricted Zones I, II, and III in response to the evolving epidemiological situation, often on a monthly basis ([32]), proportionate and risk-based containment measures are ensured.

Stakeholders consulted generally see regionalisation and compartmentalisation as important benefits of AHL. However, an industry representative noted that in practice, these tools have not always delivered the expected results. In particular, during ASF outbreaks, regionalisation measures under the AHL have caused market disturbances. For example, in Germany, some regions refused to accept meat originating from ASF-restricted areas.

([29]) SGGP – Spain Presentation February (2023).
([30]) PAFF Summary Report April (2023).
([31]) PAFF Summary Report June (2023).
([32]) Chronology of main initiative taken or supported by the European Commission, here.

Box 7 – Compartmentalisation in Denmark ([33])

As part of its implementation of the **AHL** and Commission Delegated Regulation (EU) 2020/689, **Denmark** has adopted a **compartmentalisation strategy** to control aquatic animal diseases and facilitate safe trade within the EU and beyond. The Danish Veterinary and Food Administration (DVFA) has been actively conducting surveillance and sampling to **maintain national or compartment-level disease-free status** for key diseases affecting aquaculture, including Infectious Salmon Anaemia Virus (ISAV), Viral Haemorrhagic Septicaemia (VHS), and Infectious Haematopoietic Necrosis (IHN).

The audit team concluded that the Danish authorities apply an **effective system for notifying suspected aquatic disease cases**, including IHN. This system allows for the **swift application of containment measures** upon disease confirmation and has proven particularly effective within disease-free compartments. The authorities also maintain **up-to-date information on fish populations** and regularly update procedures based on **lessons learned from past outbreaks**, which has been crucial for the control of IHN. However, the presence of **multiple IHN outbreaks over the past three years**, including one in a previously free compartment, has made it **more difficult for Denmark to regain country-wide IHN-free status** in the near future. The current control strategy involves **differentiated approaches** based on the health status of individual establishments. Only the 27 IHN-free compartments are currently authorised to **dispatch consignments of live fish to other IHN-free areas**, while the rest remain under surveillance or specific eradication programmes. Where disease has been confirmed, the authorities have introduced **tailored restrictions**, which, although varying in scope, have been effective in **limiting the spread and persistence of the disease**.

The availability of training sessions and their effectiveness contribute to the prevention and control of animal diseases. At the EU level, the Better Training for Safer Food (BTSF) programme has been widely recognised by NCAs as a valuable tool for building capacity and harmonising practices. Table 2 in Annexe 2 lists the number of training sessions organised since 2021 in the framework of BTSF. Stakeholders consulted praised in-person BTSF courses for fostering informal knowledge exchange and practical discussion between participants. Study visits to Member States dealing with specific disease outbreaks, such as ASF, have also been highlighted as excellent hands-on learning opportunities. However, stakeholders have called for additional practical guidance, broader use of e-learning platforms for operators, greater inclusion of non-authority stakeholders in training initiatives and greater dissemination within the country to reach all stakeholders. Despite the availability of training sessions at the EU level (part of BTSF training), stakeholders expressed concerns about gaining and maintaining knowledge within NCAs, particularly among those who are not regular users of the AHL's legal framework.

([33]) Audit Report Denmark (2023).

The AHL uniform approach to disease management, while valuable for harmonisation, does not always reflect the biological diversity of specific diseases, which has led to the need for derogations under various delegated and implementing acts (DAs and IAs). Many stakeholders admitted uncertainty about how to interpret such exceptions or locate critical updates, leading to a risk that important legal or procedural changes may be overlooked. In most Member States, a comprehensive understanding of the AHL remains concentrated in a small group of legal or veterinary experts, underscoring the need for broader, ongoing training efforts and dissemination to support effective and inclusive implementation across the EU.

Specific objectives of the AHL

Alongside general objectives, **the specific objectives** of the AHL have been to:

1. Establishing a single, simplified, transparent and clear regulatory framework by providing a clear and balanced distribution of roles and responsibilities and introducing simplified procedures;
2. Introducing general principles that allow a simplified legal framework to be prepared for any new challenges, including disease categorisation and prioritisation;
3. Ensuring consistency among principles of animal health, animal welfare and food safety legislation;
4. Reducing the socio-economic impact of animal diseases on public health, animal welfare, economy and society while reducing the risks of trade disruption.

Establishing a single, simplified, transparent and clear regulatory framework by providing a clear and balanced distribution of roles and responsibilities and introducing simplified procedures

The first specific objective is to establish a single, simplified, transparent and clear regulatory framework by providing a clear and balanced distribution of roles and responsibilities and introducing simplified procedures.

As outlined in the introduction, the AHL simplified the previous animal health framework by consolidating numerous pieces of legislation into one comprehensive law. This replaced a complex and often inconsistent set of rules with a clearer, more harmonised approach across the EU by bringing together various requirements on disease prevention, control, and animal traceability into a single legal structure. From a regulatory and legislative standpoint, the AHL is largely seen as a simplification of the previous fragmented framework and as a more harmonised approach, bringing significant benefits for disease control and regulatory coherence. However, opinions diverge when it comes to practical implementation and usability, especially for end users such as farmers or frontline operators. While legislators may find the process more streamlined, users often

still face procedural complexity. Many report that implementation frequently requires navigating multiple delegated or implementing acts, making the law feel fragmented in practice. However, NCAs have also stressed that simplification will become more evident once full implementation of alignment is achieved. At the same time, several stakeholders, both representing NCAs (see EQ1.1), farmers and industry, report difficulties navigating the new regulation due to its complexity and cross-referencing alongside conflicting national regulations.

Moreover, the AHL aims to establish clearer roles and responsibilities by defining the obligations of all actors involved in the animal health chain, including competent authorities and veterinarians, animal keepers, transporters, and operators. By setting out who is responsible for prevention, detection, notification, and response, the AHL ensures a more coordinated and accountable system. This clarity should support quicker decision-making and more effective disease control, as each party understands their specific duties within the broader framework. The law also reinforces the principle of shared responsibility, ensuring that all stakeholders contribute actively to safeguarding animal health, biosecurity, and public safety. Stakeholder consultations show that the AHL has contributed to increasing clarity across actors regarding their roles and responsibilities. Nearly all respondents to the Call for Evidence acknowledged that the AHL clarified roles established by the AHL. Most stakeholders who have replied to the surveys (81%, N=69) acknowledge that the AHL has generally contributed to clearly delineating roles and responsibilities. However, the low percentage of ‘very clear’ responses (4%) and the presence of ‘not clear at all’ (6%) indicate that certain gaps remain. In particular, lower levels of clarity have been reported by livestock and aquaculture farmers and industry representatives, followed by veterinarians. On the contrary, the distribution of these responsibilities is not considered fully balanced. For example, farmers and industry claim that a disproportionate burden is placed upon them and veterinarians, who sometimes feel overburdened by compliance tasks.

Regarding better response mechanisms, the evolving epidemiological situation for HPAI, ASF, and BTV in recent years and recently FMD (even if outside the scope of the study) has placed considerable demands on authorities, operators, and other stakeholders. The number and distribution of outbreaks, as detailed in Annexe 2, reflect the scale of the challenge. As outlined in Box 6, and further evidenced by examples in Boxes 5 and 7, as well as vaccination strategies described earlier protocols in place ensure effective and rapid emergency measures, particularly within designated restricted areas and restricted movements of animals (see also Annexe 2 for restricted zones), the AHL enable swift establishment of restricted zones, movement controls, and targeted surveillance to contain outbreaks and limit socio-economic impacts.

The notification of diseases has also changed with the introduction of the AHL with the introduction of ADIS. The ADIS is seen as a significant improvement compared to the previous system, ADNS. Stakeholders consider the ADIS transparent, provided that timelines are respected. Timely reporting of a disease

is essential, as it allows the international system to be informed and to act accordingly, and this requires strengthened awareness and consistent engagement from operators in the sector. Disease notification should not be viewed as a mere bureaucratic obligation but as a critical tool for informing stakeholders of potential risks. It should provide key information that informs risk assessment and surveillance. However, some issues still remain in the reporting of the scale of outbreaks, for example, regarding wild animals affected. While there is an obligation to report estimates of wild animal deaths during outbreaks, stakeholders claim that this data does not seem to be fully included in ADIS nor made publicly available Stakeholders have raised concerns that without accurate reporting, even for wildlife, it is more complicated to assess the full picture for risks to animal and public health. This could also be linked to significant disparities in testing practices.

In addition, several NCAs have stressed the need to enhance interoperability with the WAHIS, due to the current different reporting requirements. This integration will represent a positive advancement as it will establish a single notification system and harmonise notification rules between the two platforms.

Introducing general principles that allow a simplified legal framework to be prepared for any new challenges including disease categorisation and prioritisation

The second specific objective is to introduce general principles that allow a simplified legal framework to be prepared for any new challenges, including disease categorisation and prioritisation. Findings generally underscore the introduction of general principles, but some stakeholders have raised concerns that its broad, general approach can overlook local disease dynamics and practical realities. For example, in the case of *Brucella melitensis*, the law allows for tailored responses such as selective or whole-herd slaughter, but some Member States continue to apply systematic culling, mirroring older legislation. According to stakeholders, this has led in a number of cases to disproportionate measures, such as mass culling despite low infection rates, with national authorities often viewing this as the only viable solution due to the absence of clearer guidance. Similarly, the AHL's cessation of vaccination in disease-free areas for a number of diseases (mainly category C and D diseases) is seen as overly prescriptive. Article 36(3) states that vaccination in disease-free Member States, zones, or compartments may be carried out only under specific conditions, to ensure that such vaccination does not compromise the disease-free status. This requirement is in line with WOAH international trade standards, which link the recognition of disease-free status to the absence of vaccination for certain diseases. While supporting market access and trade stability, some stakeholders reckon that specific risk-based circumstances in the different countries should allow for more flexibility. Vaccination has been a critical tool for controlling and containing diseases, including BVD, and an integral part of eradication programmes. Removing this option could not only undermine

progress done towards disease-free status but also increase the risk of re-emergence, economic loss and the costly prospect of restarting the eradication process, which is already lengthy and demanding This is particularly the case for Member States sharing a border with third countries which are not free from that disease and where farm operations on both sides of the border create potential risks.

The categorisation and prioritisation system is a cornerstone of the AHL as it introduced a list of relevant diseases based on specific criteria to ensure that disease control measures across the EU are science-based, proportionate, and risk-focused. The classification determines which diseases are to be listed at the EU level and how they are to be managed based on their epidemiology, impact, and control feasibility. The aim is to enable effective and harmonised responses that are aligned with both animal health priorities and trade considerations. The assessment methodology is outlined in EFSA's scientific opinion ([34]) and was conducted against the criteria set out in Articles 5, 7, 8, and Annexe IV of the AHL. It relies on a detailed disease-specific data collection framework, including information on routes of transmission, morbidity and mortality rates, zoonotic potential, societal and economic impact, and the existence of diagnostic and control tools, such as vaccines or treatments. The evaluation also considers the feasibility and cost-effectiveness of control measures such as vaccines or treatments. This resulted in five disease categories (A-E). The system also introduces a prioritisation mechanism, where the categorisation informs how urgently and intensively a disease should be addressed. For instance, Category A diseases trigger the highest alert level and resource mobilisation, whereas Category E diseases remain under monitoring unless epidemiological trends change. The aim was to enable EU and national authorities to allocate resources more effectively, maintain flexibility in response, and ensure regulatory consistency. It also facilitates better communication with stakeholders by providing a clear rationale for disease management strategies and fosters mutual trust among Member States.

Interview inputs generally support the categorisation system, highlighting its role in improving disease management and early disease detection. However, some issues still exist. A number of NCAs seem to be more critical of the prioritisation of some diseases, citing concerns over BTV, Johne's disease, or low-pathogenic avian influenza (LPAI), which, although categorised as lower-category diseases, remain problematic in several Member States. In addition, regional and sector-specific discrepancies also pose challenges to the effectiveness of the

([34]) EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), More S, Bøtner A, Butterworth A, Calistri P, Depner K, Edwards S, Garin-Bastuji B, Good M, Gortázar Schmidt C, Michel V, Miranda MA, Nielsen SS, Raj M, Sihvonen L, Spoolder H, Stegeman JA, T hulke HH, Velarde A, Willeberg P, Winckler C, Baldinelli F, Broglia A, Candiani D, Gervelmeyer A, Zancanaro G, Kohnle L, Morgado J and Bicout D, 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**

categorisation system. The categorisation system provides a harmonised approach that enables Member States to address target diseases of national and local importance. This flexibility, combined with EU-level coordination, is widely regarded as essential for ensuring targeted implementation and minimising discrepancies across the Union. In the absence of such coordination, Member States have previously adopted their own measures, which led to inconsistencies in disease control strategies and trade disruptions both within the EU and with third countries (see also EQ4.2). Challenges identified by some stakeholders relate not to the flexibility itself, but to the timeliness of coordination and the EU level and adoption of the EU act for emerging diseases. Interviews with NCA representatives indicate that responses to emerging threats, such as COVID-19 infections in mink and BT in ruminants, could be improved by reducing the time needed to approve EU acts that allowed Member States to take action.

In addition, stakeholders interviewed tend to be more sceptical about the adaptability and regular updates of the categorisation system based on scientific information and emerging diseases, underlining the need for a revision due to changes in the epidemiological situation, emerging diseases, and vector-borne diseases (see also EQ4.2), also due to the impact of climate change on vectors, as outlined by the aquaculture sector. This was also confirmed in the validation workshop, where most NCAs stressed the need for the system to be dynamic, allowing diseases to shift between categories based on the epidemiological context. In addition, a few farmers' representatives highlighted that while the system is helpful for competent authorities from a risk management perspective, it can be challenging for operators to navigate.

The AHL has also made progress in the incorporation of new scientific insights for disease detection, control and eradication, as well as innovation in diagnostic techniques. The emergence of new diseases has underscored the need for modern tools, including vaccines, and continued innovation is key to ensuring sustainability and competitiveness. Stakeholders acknowledged improvements in the clarity of EU rules for emergency vaccination under the AHL. However, concerns persist around the timeliness and flexibility of vaccine evaluation and authorisation. While veterinary medical products are regulated by Regulation (EU) 2019/6, part III of the AHL regulates the use of veterinary products for disease prevention and control and the establishment of Union antigen, vaccine and diagnostic reagent banks. Industry representatives highlighted the need for clearer guidance on research priorities for the pharmaceutical sector, earlier alerts and clearer procurement signals to ensure timely production and for more agile coordination between national authorities, the European Commission, and vaccine producers to ensure rapid deployment in crisis scenarios.

Ensuring consistency among principles of animal health, animal welfare and food safety legislation

The third specific objective aims to ensure consistency with principles of animal health, animal welfare and food safety legislation. As detailed in Section 0, findings reveal that no direct legal contradictions were identified, but some stakeholder feedback shows contrasting views on the alignment of animal welfare in the AHL with other legislation, ranging from good alignment to significant gaps. While some progress has been acknowledged, major challenges persist in areas such as animal transport, managing disease outbreaks, and culling practices. For instance, it has emerged that during HPAI outbreaks, biosecurity measures require animals to be kept indoors. Although such temporary measures are permitted under EU law and aim to protect animal health and welfare in the long term,in cases of prolonged outbreaks, animals may remain confined for extended periods, conflicting with public expectations for outdoor access as a key aspect of animal welfare, thus highlighting the need for transparent communication on risk and proportionality. Additionally, NGOs have raised concerns over intensive farming systems, which, in their opinion, contribute to disease spread due to high animal densities and a lack of welfare standards, for example, disincentivising outdoor access for animals. Although these aspects fall outside the direct scope of the AHL and do not relate to contradictions in its requirements, these farming systems could represent a higher inherent risk for the emergence and spread of infectious diseases. High-density environments can facilitate pathogen transmission and complicate containment measures. While the AHL does not regulate farming system design, its risk-based approach means that establishments with higher risk profiles, including intensive farms, could be subject to more frequent monitoring and stricter biosecurity requirements. In this way, the AHL indirectly addresses some concerns by adapting surveillance and control measures to reflect the risk posed by different production systems. Regarding the One Health approach, NGOs noted that while it is not explicitly referenced in the AHL, its adoption has increased thanks to the law's implementation, reflecting a gradual shift toward a more integrated approach to animal, human, and environmental health.

To reduce the impact of animal diseases on animal and public health, animal welfare, economy and society as far as possible by enhancing disease awareness, preparedness, surveillance and emergency response systems at national and EU level

The fourth specific objective regards the AHL's contribution to reducing the socio-economic impact of animal diseases on public health, animal welfare, the economy, and society while reducing the risks of trade disruption.

Trade flows between Member States and third countries are among the quantifiable indicators selected for this evaluation. The COMEXT dataset allows for the analysis of trends before and after 2016, starting with the 'EU trade of live

animals and animal products', as shown on Figure 5, the adoption of the AHL (2016) and its entry into force in 2021.

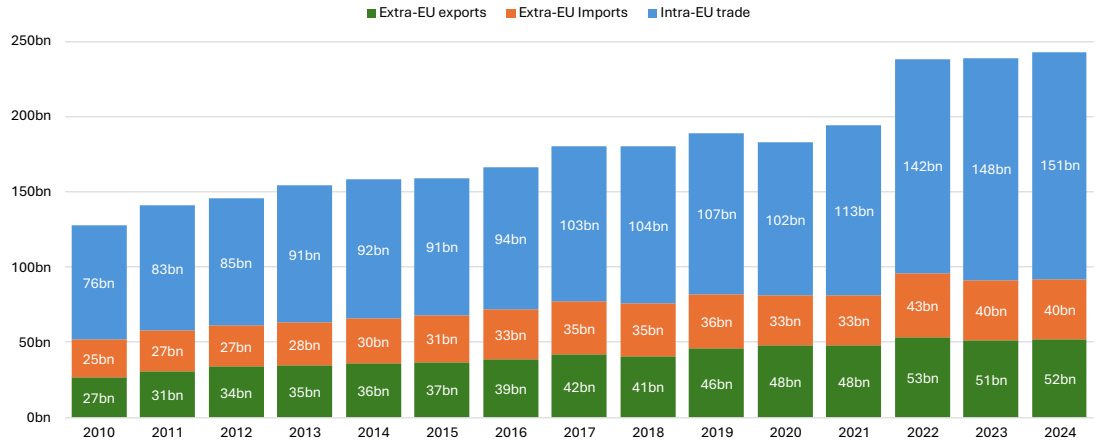
Exports in monetary terms to third countries have almost doubled since 2010, while intra-EU trade shows a slight decrease in 2020 (due to COVID). Analysing the period from 2010 to 2015, the Compound Annual Growth Rate (CAGR) for Intra-EU trade was 3.67%, while exports to countries outside the EU27 grew faster at 6.50% ([35]), and .4% for imports from countries outside the EU27. However, from 2016 to 2020, growth slowed across all categories, with intra-EU trade achieving a modest CAGR of 2.06%, exports to non-EU27 countries at 5.33%, and imports from outside the EU27 stagnating at 0%. Notably, between 2021 and 2024, intra-EU trade rebounded strongly with a CAGR of 15.60%, while exports growth to non-EU27 countries slowed to 4.08% and non-EU27 imports grew by 10.1% during this period. This highlights a strong post-2021 recovery, particularly within the EU27. Trade flows, particularly in terms of value, may have been influenced by several external factors, including inflation, global demand, and changes in market access.

In terms of the number of live animals exported (see Figure 6), EU exports to third countries have remained relatively stable. However, greater fluctuations are observed within the EU internal market. While the trade of sheep and goats increased significantly until 2021, a downward trend followed thereafter. A similar, though less pronounced, pattern is evident for bovine trade.

These trends may be attributed to several factors. First, there may have been a shift from the trade of live animals to processed products. Second, the livestock population has been declining, particularly for sheep and goats, in recent years (see Annexe 2). As a result, the intra-EU market may have become more constrained, potentially explaining the increase in trade value alongside a decrease in the volume of live animal trade.

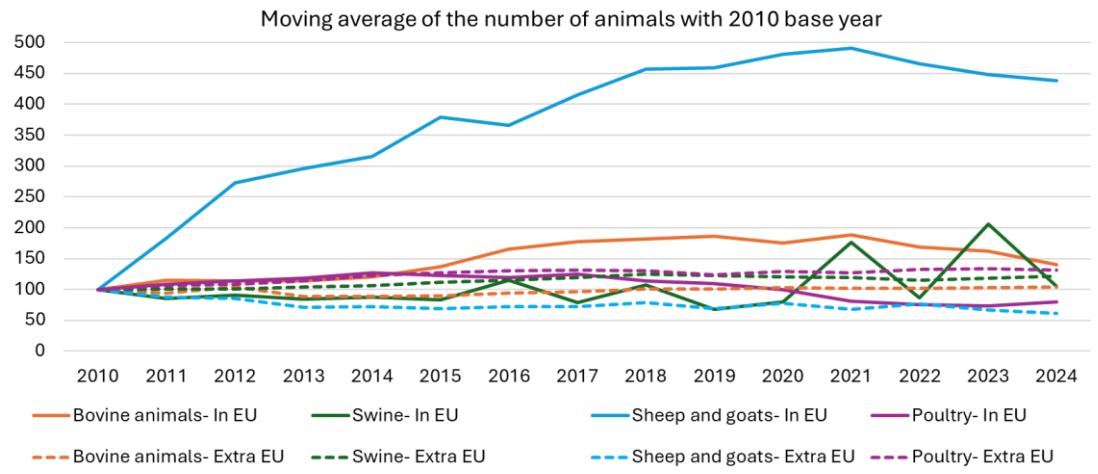
([35]) The main driver of the export to third countries is the export of pig meat to China due to the large outbreaks of ASF in China.

Figure 5 – EU Trade of live animals and animal products (EUR)



Source: Consortium based on COMEXT

Figure 6 – Volume Index of EU exports of live animals



Source: Consortium based on COMEXT

Based on the available data and the phased implementation of the AHL, it is not possible to determine its precise impact of the AHL on competitiveness. However, the EU market has demonstrated a degree of resilience in the face of several major disease outbreaks since 2016. ASF, for example, spread extensively across Eastern Europe between 2016 and 2020, resulting in a significant increase in infections among wild boar and the introduction into domestic pigs. BTV circulated continuously in France and neighbouring countries between 2016 and 2018, prompting Germany to launch vaccination campaigns in 2019. And the epidemic spread of BTV-3 starting in the Netherlands in 2022-2024 caused trade disruptions of bovine and sheep.

According to the case studies (see Annexe 11), in France, regionalisation has enabled quicker trade from non-contaminated regions during outbreaks, helping maintain trade flows during disease management situations. Furthermore, most EU Member States experienced recurrent seasonal outbreaks of HPAI during the

same period. Despite these challenges, there were no major shortages of meat or egg products within the EU. According to stakeholder feedback, the AHL has strengthened the EU's export capacity by streamlining trade procedures and reinforcing trust in the disease-free status of its livestock. Despite the fact that 3rd countries still have specific requirements for MS from which they import. Nonetheless, stakeholders report only a moderate effect on the internal market, particularly from the perspective of farmers and industry representatives. Moreover, while not directly linked to the AHL, some stakeholders argue that external markets often operate under less stringent regulations.

The ongoing outbreaks of diseases like ASF, HPAI and BTV, each of which restricts trade in infected regions did not result in excessive drops in the total number of animals traded between MS. The application of regionalisation enables MS in which infections occurred to continue to trade from non-affected regions, whereas in the past in the trade of the whole MS was disrupted.

4.1.3. Effe 1.3 How do these results compare with the initial expectations?

Key findings

- The AHL provides a flexible and coherent legal framework that enables Member States to tailor disease prevention and control measures to national contexts while maintaining alignment with EU legislation. Its harmonised approach has supported internal market stability and reduced trade disruptions.
- The AHL marks a shift towards a proactive, risk-based and preventive approach, moving away from eradication as the primary strategy. This has enhanced preparedness, improved coordination across Member States, and strengthened outbreak response capacities.

Key limitations

- While the AHL framework is robust, alignment of national legislations has been more complex than expected, resulting in current delays and inconsistencies in implementation across Member States.

According to the Impact Assessment accompanying the Proposal for the AHL, published in 2013, the flexible general legislative framework option was deemed to be the most likely to deliver a good level of effectiveness, efficiency, and coherence with EU objectives. It would allow clarity and coherence while leaving flexibility for particular circumstances, in particular, Member States or regions and adapting to rapidly changing circumstances.

Since its implementation, the AHL has introduced a risk-based approach that has been widely welcomed by stakeholders. In the Call for Evidence, 13 respondents explicitly supported this shift, noting that the AHL replaced the previous model, which focused heavily on eradication, with a framework centred on prevention and control. This is in line with the goals of the EU Animal Health Strategy 2007–2013 and has contributed to improved preparedness and responsiveness.

Importantly, despite concerns raised by some stakeholders regarding specific movement restrictions, particularly for non-commercial cross-border movement, no significant trade disruptions have been directly linked to the AHL. In fact, the structured and harmonised approach introduced by the legislation has enhanced the EU's capacity to manage disease risks while maintaining the functioning of the internal market. While the epidemiological landscape continues to evolve, driven by external factors such as climate change, increased animal movements, and changing wildlife dynamics, which are outside the direct control of the AHL, the situation today reflects an improvement compared to the beginning and mid-2000s when large-scale, difficult to manage outbreaks caused significant animal losses and trade instability. The AHL has created a wide legal backbone for

coordinated disease control, enabling faster responses, better communication among Member States, and more consistent application of biosecurity and surveillance measures.

Another notable achievement is the shift toward prophylactic (like biosecurity and vaccination) and risk-based strategies, which not only reduce the reliance on emergency eradication (e.g., mass culling) but also encourage long-term disease management planning. However, alignment with national legislation has proven more complex than anticipated, leading to delayed or partial implementation in some policy areas.

4.1.4. Effe 1.4 What are the strengths and weaknesses of the AHL, in particular in relation to specific provisions, regarding: clearer responsibilities, priorities for EU intervention, and prevention, including biosecurity and surveillance?

Key findings

- The AHL has clarified roles across actors (e.g., Member States competent authorities, veterinarians, operators), improving coordination and legal certainty during disease management, as well as increased awareness, especially for veterinarians and authorities. However, gaps remain in stakeholder engagement and consistent communication.
- The AHL prioritises interventions based on risk, enabling rapid and targeted responses. Disease categorisation and regionalisation support EU-level risk-based interventions, minimise trade disruptions while maintaining control measures. Delays in implementation and limited stakeholder coordination in EU-level prioritisation at the Member States level sometimes lead to mistrust or perceived top-down decisions.
- The AHL has reinforced biosecurity, especially in intensive sectors like pig and poultry farming. However, implementation across sectors and Member States remains inconsistent. Small-scale and aquaculture producers face challenges in compliance, enforcement, and accessing tailored support.
- The AHL has harmonised and modernised the EU's animal health legal framework, enabling the use of tools such as vaccination and harmonised eradication programmes. Positive examples include HPAI and BTV vaccination campaigns, which have supported disease control and safeguarding trade.
- Regionalisation measures under the AHL have proven effective in maintaining operations and trade in disease-free areas during outbreaks.

Key limitations

- The lack of staff at the NCA in a number of MS dedicated to the implementation of the AHL leads to delays in implementation and the co-existence of non-updated old legislation alongside the AHL.
- The lack of knowledge to apply risk-based prevention in the MS leads to a lack of effectiveness in the implementation of the AHL.

The AHL represents a major step forward in the harmonisation of previous EU animal health legislation, offering a more unified and consistent legal framework for disease prevention, control, and trade across Member States. Its ability to modernise and restructure national legislation without drastically altering existing frameworks. In several cases, the AHL has also served as a catalyst for regulatory improvement, prompting Member States to revise outdated frameworks and align with new, science-based evidence. While it is still too early to fully assess the long-term impacts of the AHL, its partial implementation in a number of MS has already shown promise. Demonstrating the effectiveness of prevention is inherently difficult, but there is broad agreement amongst consulted stakeholders that the AHL has enhanced control measures, particularly through facilitating the use of tools like vaccination, which were not systematically available under previous legislation, and harmonised (optional) eradication programmes. Successful vaccination campaigns include the one against HPAI (see Box 8) and Bluetongue Virus (BTV) (see Box 11), both of which demonstrate the law's support for targeted disease control measures. These efforts have proven essential not only in containing outbreaks but also in ensuring the continuity of production and trade. Vaccination has also been mentioned during the validation workshop, where stakeholders acknowledged improvements in the clarity of EU rules for emergency vaccination under the AHL, but where concerns were raised about becoming too reliant on fast turnaround times for the availability of vaccines. The pharmaceutical industry expressed the need for their earlier involvement in the sense of earlier alerts and clearer procurement signals to ensure timely production, and highlighted the current lack of systematic regulatory foresight or pre-authorisation of relevant vaccines. Clearer roles and responsibilities, especially in managing vaccine banks, with some asking for a stronger coordination role of the European Commission, as per Article 48.

Furthermore, mechanisms such as regionalisation have proven highly valuable during outbreaks. The EU has been facing many diseases in the evaluation period. However, these allow disease-free zones or regions to continue operations and trade, minimising disruption while maintaining strong biosecurity standards.

As described in EQ1.2 and in Section 4.4, greater stakeholder awareness has been highlighted as a positive aspect of the AHL, since the responsibility of the different actors is clearer. However, despite improvements, gaps in coordination still emerge during outbreaks, particularly where operational responsibilities

overlap or remain unclear at local level. For example, during avian influenza events, there was uncertainty around the responsibility of removing wild bird carcasses between farmers and the municipality, leading to inefficiencies and delayed responses. This issue appears to stem from shortcomings in local operational planning and coordination rather than from the AHL framework itself, showing that full implementation is not complete, as well as highlighting the need for further operational clarity and improved coordination mechanisms at all levels.

In addition, the emphasis on applying biosecurity measures has been greatly reinforced; the increase in biosecurity on farms (legal responsibility) leads to a reduction in the incidence and spread of diseases. Nevertheless, the different types of stakeholders interviewed provided diverse perspectives on the level of improvement of prevention, biosecurity and surveillance, highlighting that improvements have taken place, though with challenges in implementation, harmonisation and enforcement across Member States and across different sectors. The study by FVE ([36]) confirms that biosecurity implementation varies by sector, with pig and poultry farms being the most compliant, while dairy, beef, sheep, and goat farms lag behind. At the same time, stakeholders interviewed in aquatic animal sectors see little benefit from the AHL, calling for stronger enforcement mechanisms to address sector-specific concerns. The AHL has further increased awareness and adherence to biosecurity measures, particularly in response to some diseases like HPAI and ASF. Some countries report enhanced biosecurity protocols, risk-based surveillance, and better alignment of national measures. However, implementation remains uneven between MSs and livestock sectors. There is a lack of consensus among Member States regarding the definitions and approaches to biosecurity and health visits. This divergence reflects the challenge of balancing the EU's minimal legislative measures, the autonomy of individual Member States, and the imperative to maintain free trade. In addition, small-scale and family-run farms face resource shortages and a lack of veterinary visits, making compliance difficult, especially in remote farms. Strict biosecurity measures have led to a decline in small-scale and backyard farms in some areas due to compliance challenges and costs. In regions where illegal informal animal exchanges, persist, biosecurity risks are higher, especially in cross-border areas. Another common concern is the lack of tailored biosecurity measures for diverse farming systems. Some stakeholders find requirements either too general or too rigid, leading to confusion. In aquaculture, industry stakeholders frequently mentioned Inconsistent enforcement, unclear guidelines, and gaps in aquatic species biosecurity.

Stakeholders stress the need for stronger EU-level guidance to ensure effective and uniform biosecurity implementation. While the AHL represents an improvement, further support, harmonised guidelines, and training programmes (e.g. BTSF) that are also open for farmers and other business operators are necessary to bridge existing gaps. Training in coordination with international

([36]) FVE (2021) Animal Health Visits FVE Survey on the Application of Art. 25 (last update November 2023).

organisations such as the WOAH can also be useful in increasing knowledge and awareness.

Box 8 – Vaccination against HPAI in ducks in France ([37])

Since 2020, France, like most other EU Member States, has faced recurrent large outbreaks of HPAI in domestic poultry. These outbreaks led to the mass culling of poultry (see also Figure 4 in Annexe 2) and triggered the need for significant financial compensation from both national and EU sources to support affected livestock farmers. Duck farms, in particular, were shown to play a notable role in the epidemiology of the disease.

Table 1 – Impact of HPAI outbreaks in France

Season	2015/2016	2016/2017	2020/2021	2021/2022	2022/2023	Total
Outbreaks poultry	81	488	492	1377	402	**2480**
Millions of poultry killed (*inc. preventive culling*)	0.35	4.5 (2.5)	3.3 (2.2)	22 (6)	10 (3.5)	**40.15**
State/EU compensation for livestock farmers (million EUR)	136	175	158	621	552	**1 642**

In response to the scale and persistence of outbreaks, France initiated a **vaccination campaign**, following a national vaccination roadmap approved in July 2022. After experimental trials conducted in 2022, mandatory vaccination began in October 2023, specifically targeting duck farms with at least 250 birds, limited to ducks not intended for trade with other Member States or third countries.

By the end of September 2024, a total of 61.57 million ducks across 2,317 establishments had been vaccinated. The vaccination strategy was complemented by **reinforced passive surveillance** and **active surveillance** measures implemented by farmers and official veterinarians, including intensive **sampling** of vaccinated flocks. The total costs of the campaign in 2023-2024 amounted to EUR 100 million, of which 85% were borne by the state and 15% by the farmers.

The results were significant: the number of HPAI outbreaks in poultry dropped from **402** in 2022–2023 to just **10** in 2023–2024, with only 2 outbreaks occurring on vaccinated farms. Based on predictive modelling using data from previous outbreaks, the expected number of outbreaks in the absence of vaccination would have been much higher. The analysis indicates a **95.9%**

([37]) Olivier Debaere, Best practices in France Experience with Poultry Vaccination Olivier DEBAERE, BEST PRACTICES IN FRANCE EXPERIENCE WITH POULTRY VACCINATION, CHALLENGES AND OPPORTUNITIES, presentation at IABS conference 25 March 2025).

reduction in outbreaks attributable to vaccination. These findings suggest that vaccination effectively mitigated the HPAI H5 outbreak in France ([38]).

The AHL's effect on reaction times is mixed. Some stakeholders noted improved response times, citing standardised surveillance, more consistent and coordinated responses, reporting protocols, and better coordination among national authorities, veterinary services, and farmers. In some countries, this has supported faster containment of emerging or exotic diseases. The mandatory notification of an outbreak by the MS to the other MS by entering relevant information in ADIS within 24 hours after detection plays a key role in timely action, and the involvement of the Commission is seen as more efficient. Where strong response protocols existed before the AHL, there has been little to no need for change. Some NCAs noted that the AHL has not significantly reduced the incidence of major diseases like ASF or avian influenza, but some improvements have been noted, due to the increased responsibility of operators in the notification, leading to less spread and smaller outbreaks. Others suggest that farming organisations and staffing levels have a stronger influence on reaction time improvements compared to the AHL itself.

While the AHL is built on the principle of shared responsibility among all actors in the animal health system, the national implementation of the AHL has not always translated into balanced stakeholder engagement in the implementation of the AHL in a number of MS, with veterinarians having the highest level of involvement, while farmers and livestock/aquaculture farmers feel significantly less engaged. Additionally, a high number of respondents across all stakeholder groups indicated that they 'do not know' how effectively the AHL engages with them, suggesting gaps in communication and awareness. The importance of including farmers more actively in the decision-making process as a way to enhance the effectiveness and acceptability of control efforts has been stressed by NGOs and farmers' representatives who raised concerns about the top-down implementation of certain measures without sufficient stakeholder engagement in a number of MS.

While all changes to disease categorisation and prioritisation are based on EFSA's scientific opinion (see also EQ1.6), fish farmers highlighted the removal of certain vector species from implementing regulations, which they felt occurred without consultation or clear scientific communication. In a number of MSs, the lack of opportunity for feedback or public consultation before the regulation entered into force left stakeholders unprepared for the policy shift and raised concerns about risk being underestimated. A positive example is Sweden's collaborative approach to brucellosis management, which highlights the benefits of farmer inclusion. At the individual MS level, when measures are imposed

([38]) Guina C. et al, Promising effects of duck vaccination against highly pathogenic avian influenza, France 3 2023-24, here.

without consultation, it often leads to inefficiencies and resistance. Lower engagement from the different stakeholders regarding training has also been mentioned in EQ1.2. Moreover, NGOs have pointed out that the involvement of smaller stakeholders could be increased alongside the involvement of NGOs and experts such as ethologists and animal welfare specialists in the decision-making process. This should apply particularly during health emergencies and culling to ensure humane and legally compliant measures, as well as during vaccination campaigns.

The implementation of the AHL at the national level and related compensation schemes, as well as the reduction in emergency financial support, has led to an increase in the financial burden placed on farmers, particularly for some diseases like ASF and related visits and implementing biosecurity measures like fencing requirements. These financial strains are further worsened by the lack of consistent veterinary oversight across Member States, leading to disparities in disease control effectiveness. Farmers are also required to implement additional biosecurity and eradication-focused approaches, which, in case of outbreaks, such as HPAI, require animals to be kept indoors. In case of prolonged outbreaks, animals may remain confined for extended periods, and these practices often conflict with certain extensive farming systems (like organic farming) and animal welfare.

These measures can undermine sanitary resilience and lead to unintended consequences, such as farmers choosing not to declare diseases to avoid strict culling requirements. However, such avoidance behaviour does not stem from or characteristic of the AHL but rather is a common issue for any measures associated with any self-declaration system where those making the declaration may face negative consequences as a result.

4.1.5. Effe 1.5 What are the main shortcomings that need to be addressed?

Key findings

- Stakeholders highlighted insufficient support for farmers in understanding and applying biosecurity measures and disease detection protocols. Training and awareness programmes are not consistently implemented across Member States, affecting compliance and effectiveness.
- While the AHL does not regulate financial support, stakeholders consistently identified the absence of robust funding mechanisms, both at the national and EU levels, as a major barrier to effective disease prevention and emergency response.
- Stakeholders suggest that more balanced cost-sharing mechanisms involving the broader value chain (e.g. food industry, pharma) could enhance sustainability and encourage proactive prevention, improving overall implementation of the AHL.

Key limitations

- Due to the current partial implementation of the AHL across Member States, it remains difficult to fully assess which shortcomings require targeted action, as many provisions have not yet been applied or enforced in practice. This limits the ability to distinguish between issues arising from the Regulation itself and those stemming from delayed or uneven implementation.

Based on stakeholder consultations, the first issue is the lack of clear guidance and support for farmers, particularly regarding their biosecurity responsibilities and disease detection protocols, which was observed in a number of MS. Educational campaigns and training programmes are essential to bridge knowledge gaps, yet they are not consistently implemented across Member States. In addition, other stakeholders, like veterinary practitioners or livestock traders, have also mentioned the need for increased guidance to help them navigate the AHL.

This also links to the second issue identified, which is the lack of adequate financial mechanisms at the national level and the EU level. Although the AHL does not regulate financial support for prevention, stakeholders consulted have often mentioned the lack of financial support as a major challenge negatively impacting the effectiveness of disease prevention and emergency management. NCAs and industry representatives are also highlighting the decrease in co-financing for emergencies. Additionally, funding for emergency disease response remains a major concern, with decreased financial support mechanisms in place to help farmers and national authorities respond effectively to outbreaks.

Box 9 – Emergency co-financing

Before the entry into force of the AHL, the EU's financial support to eradicate, control and prevent various animal diseases was regulated by Regulation (EU) No 652/2014, covering the whole food chain, with a budget of almost EUR 1.9 billion covering the period 2014-2020, with funding priorities in the area of food and feed. **65% of the overall budget was allocated to implement animal health measures**. Co-funded measures included the **National Veterinary Programme** and **Emergency measures** ([39]). For the latter, grants could be awarded to EU countries in case of emergency measures taken as a result of the confirmed occurrence of a number of listed diseases (listed in Annexe I of Regulation (EU) No 652/2014). Regulation (EU) 652/2014 has been repealed by Regulation 2021/690, which established the **Single Market Programme (SMP)**. The SMP covers several aspects related to the Single Market and the allocated budget between 2021 and 2027 is EUR 4.2 billion, including food safety. At the same time, the European Health and Digital Executive Agency (HaDEA) has taken over the Food Safety funding, but DG SANTE remains responsible for Emergency funding for animals and plants ([40]).

Under **Regulation 652/2014**, Articles **5 and 6** detailed the co-financing conditions for **emergency measures** following outbreaks of specific diseases listed in **Annexe I**. These were tailored to animal health needs, and **grants could be awarded swiftly**, often at **up to 100% co-financing**, provided actions were prompt and compliant with EU law.

With the SMP, key changes include a shift from a dedicated to a more general Programme, possibly reducing the visibility and prioritisation of animal health funding. SMP Article 12: actions referred to in Annexe I, points 1 and 2, the co-financing rate applied shall be

1. 50 % standard rate
2. 75% for cross-border activities implemented together by two or more Member States in order to control, prevent or eradicate plant pests or animal disease
3. 100% for the activities benefiting from the Union contribution concern the prevention and control of serious human, plant and animal health risks for the Union (Article 12(5)(c))

While both regulations technically allow for 100% co-financing, Regulation 652/2014 provided a clearer, more automatic, and animal-health-specific pathway for emergency outbreak funding. Under the SMP, the process is more generalised, where 100% co-financing is still allowed, but only when risks affect the Union as a whole (Art. 12(5)(c)), making support less direct and predictable.

Due to over-demanding the budget, the EU co-financing for a number of diseases, like HPAI, has been reduced to 35%.

([39]) https://food.ec.europa.eu/horizontal-topics/funding-procurement-grants/food-chain-funding/funding-animal-health-measures_en

([40]) PAFF meeting HaDEA presentation, November 2021.

While the AHL does not regulate financial support, stakeholders consistently identify the lack of adequate financial mechanisms as a key barrier to effective implementation. Current compensation schemes remain largely reactive, offering limited support for preventive measures. A more balanced cost-sharing model, engaging actors across the value chain, such as processors and pharmaceutical companies, could strengthen financial sustainability. Examples like the Dutch Animal Health Fund and Germany's *Tierseuchenkasse* illustrate how such models can support disease control. Without clearer funding frameworks and proactive incentives, the burden on farmers may hinder timely reporting and weaken the overall impact of the AHL.

4.1.6. 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?

Key findings

- The AHL's risk-based approach effectively allows for tailored disease control to specific risks related to disease type, species, region, or farming system. By focusing on high-risk situations, it enables more efficient resource use. This approach is widely supported by stakeholders for its practicality, scientific foundation (notably from EFSA), and adaptability to national needs.
- While the AHL's categorisation system was built to guide proportional responses, stakeholders raised concerns that some widely present diseases like ASF and HPAI are no longer feasible to eradicate, suggesting a need to shift from eradication to long-term management.
- Stakeholders have called for more frequent updates to disease categories and increased flexibility, particularly for vector-borne and emerging diseases affected by climate change.

Key Limitations

- Due to the current partial implementation of the AHL across the Member States, a full assessment of the effectiveness of the risk-based approach remains challenging as many provisions are not applied or enforced yet.

The risk-based approach under the AHL focuses on tailoring disease prevention, surveillance, and control measures according to the level of risk posed by a specific disease, species, or farming system rather than applying a uniform, one-size-fits-all approach. This method prioritises high-risk diseases and regions, ensuring that resources and interventions are directed where they are most needed. It also seeks to reduce unnecessary burdens in lower-risk situations while maintaining effective disease control.

Decisions are based on veterinary risk assessments and cost-benefit analysis, ensuring they remain practical and suited to regional needs. At the EU level, EFSA plays a crucial role by providing scientific risk assessments, disease testing requirements and evidence-based recommendations to guide disease prevention, control, and policy decisions at the EU level. EFSA contributed to the categorisation of diseases (see EQ1.2) and provides continuous support in the assessment of evolving epidemic diseases. In addition, cases of differentiated approaches based on the health status of individual establishments were taken in Denmark (see Box 7) or Hungary's response to HPAI. During an audit ([41]), it emerged that authorities implemented a risk-based control system that prioritised surveillance and inspections in establishments based on size, compliance

([41]) Audit Report Hungary (2023).

history, and past outbreak records. This targeted approach was seen as a positive development in ensuring resources are focused where they are most needed. Similarly, the Hungarian Poultry Product Board's establishment of a working group to assess the feasibility and implications of HPAI vaccination highlights the use of risk-based planning in coordination with EFSA's scientific opinions and third-country trade considerations. This suggests that risk-based frameworks under the AHL are actively shaping national-level decision-making. Responses to the Call for Evidence also praised the AHL's risk-based approach, which has been widely praised for its scientific basis, allowing NCAs to apply measures to specific regional and sectoral needs. In addition, the focus on preventive measures that reflect actual disease risks ensures that resources and interventions are allocated more efficiently.

While acknowledging the value of disease categorisation based on risk assessment, concerns were raised during the stakeholders' consultation regarding disease categorisation, regulatory flexibility, and implementation challenges. While Category A diseases follow clear eradication strategies, Category B and C diseases present greater complexity/more flexibility of MS for a risk-based response.

Stakeholders have questioned the feasibility of eradicating certain Category A diseases, which are now widely present across the EU (e.g. HPAI and ASF). This has led to calls for a shift towards long-term management strategies for these diseases, as eradication may no longer be practical or sustainable. Some NCAs have also expressed doubts about some diseases being classified in another category/downgraded ([42]). Changing from a uniform approach to an MS-specific approach makes it more difficult for NCA to apply restrictive measures only based on the AHL. A widely mentioned example is bluetongue, which, due to its categorisation, does not foresee an EU-eradication plan, but requires alternative strategies at the MS level to maintain effective disease management. This has been further complicated by the fact that the disease has been difficult to manage under current regulations, as it does not fit neatly within existing disease control categories (see also case study in Annexe 11). The categorisation of BTV as Cat C requires individual Member States to manage their own policies, leading to differences in control across the Member States, with the potential to challenge the level playing field for intra-EU trade (for instance, compensation of farmers for BT vaccination and damage differed between Member States). As a solution, some NCAs suggested that reclassifying bluetongue as a Category D or E disease would provide greater clarity on trade and vaccination measures, ensuring that disease control efforts do not compromise disease-free status or restrict necessary biosecurity actions. Whereas others call for an EU-wide uniform control approach.

([42]) Whereas the categorisation of diseases in the AHL is not intended to be a grading of disease but to express importance and need for eradication and control either at the MS or EU level, a number of stakeholders consider placing a disease into another category as upgrading or downgrading of the disease.

Several countries have also highlighted the need for more flexibility in categorising vector-borne diseases, especially as climate change influences disease spread. Other stakeholders also believe that the categorisation framework has not been updated frequently enough, limiting its ability to address evolving epidemiological risks. Non-commercial breeders and conservationists struggle with rigid disease classifications that limit flexibility in genetic conservation and species reintroduction efforts.

4.1.7. Effe 1.7 Does the AHL enhance transparency in decision-making processes related to animal health?

Key findings

- The AHL has fostered greater transparency and openness in decision-making; however, limitations remain in the deeper and more consistent involvement of stakeholders.

The findings of the case studies and the validation workshops show that the AHL has acknowledged improved transparency in decision-making, enabling better engagement from the farming community. However, deeper stakeholder involvement in the different MS is needed to enhance transparency, along with ongoing education on processes to ensure clarity and accessibility. The lack of clear biosecurity guidelines has been mentioned as one example where transparency could be improved in cases where national authorities launch compliance checks without transparent criteria, creating uncertainty and inconsistency in enforcement. Moreover, the challenge remains in translating this into actionable insights for those directly affected on the ground. While NCAs report being well involved from the outset, thanks to regular AHAC meetings with other stakeholders, this level of engagement does not always extend effectively to those on the ground.

4.1.8. Effe 1.8 Does the AHL enhance the resilience of animal health systems?

Key findings

- 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.
- Although concerns were raised about cross-border movement restrictions, particularly for non-commercial activities, no significant trade disruptions have been directly linked to the AHL. On the contrary, the law has generally facilitated the safe movement of animals and products by enabling disease control without halting commerce.
- 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.

During the Call for Evidence, respondents expressed doubts regarding the promotion of the free internal market due to the restriction of cross-border movements for non-commercial purposes. However, as described in EQ1.2, no trade disruption can be directly attributed to the AHL. In fact, the AHL has generally contributed to minimising trade disruption despite the epidemiological situation, particularly through its structured zoning, compartmentalisation and traceability systems, which have helped to safeguard the safe movement of animals and products within the EU during outbreaks.

The resilience of animal health systems has also been enhanced thanks to enhanced monitoring and response mechanisms. Stakeholders noted that these measures have improved the EU's overall ability to detect, contain, and respond to disease outbreaks more effectively than under previous legislation. Nevertheless, some stakeholders interviewed reckon that the current system is not suitable to timely address new emerging diseases, highlighting the need for constant adaptation to address evolving challenges stemming from, among others, climate change and support mechanisms.

The AHL's emphasis on eradication, such as the mandatory culling of animals for Category A diseases, may be effective in containing outbreaks but, from an animal NGO's perspective, overlooks long-term impacts on animal welfare, farmer livelihoods, and systemic sustainability. However, they may be unaware that CAs should take these elements into account, as mentioned in Article 1(2)(b): *"animal welfare, including the sparing of any avoidable pain, distress or suffering*" and "*the environment, including biodiversity and valuable genetic resources, as well as the impact of climate change".* NGOs have recognised the AHL's value in achieving and maintaining disease-free status, but also see an opportunity to use

this success as a platform to promote transition toward more resilient, sustainable farming models.

4.1.9. Effe 1.9 What were the unexpected or unintended effects which have occurred during implementation?

Key findings

- While the AHL has brought significant legal simplification and harmonisation, its implementation has required substantial administrative effort and resources. The process has been slower than anticipated, with ongoing challenges in aligning national laws and fully operationalising flexibility mechanisms.
- Tools such as regionalisation are not always applied or recognised consistently between Member States. This lack of coordination reduces the effectiveness of the AHL's safeguards for trade continuity during outbreaks and may weaken confidence in intra-EU animal health management systems.

Key limitations

- Due to the partial implementation of the AHL across the Member States, a full assessment toward the AHL general and specific objectives remains challenging as many provisions are not applied or enforced yet.

Implementing the AHL has led to some unexpected or unintended effects, impacting farmers, authorities, and overall disease control efforts. Based on the information gathered, the following effects are identified.

The AHL represents a major step forward in regulatory simplification, consolidating multiple fragmented and outdated regulations into a single, coherent legal framework. This harmonisation has significantly improved clarity and consistency, reducing the previously complex patchwork of rules that varied across Member States. For this, the implementation process has required significant effort and resources, with many aspects still ongoing. The change of the legislation, combined with administrative burdens, has led to delays and inconsistencies between the AHL and non-revised national legislation across Member States, making full enforcement at the moment challenging. Furthermore, these efforts to align national legislation in several Member States have taken more time than anticipated, also partly due to the timing coinciding with the COVID-19 pandemic, which compounded the challenges of achieving full and uniform implementation of the AHL and related implementation of the flexibility mechanisms introduced by the AHL.

Secondly, as from former disease prevention regulations or such regulations in third countries, the AHL relies to some extent on self-declaration from farmers. Article 42 regulates the suspension, withdrawal and restoration of disease-free

status based on EU-level epidemiological assessment and risk zones, stakeholders noted that when a disease is detected in any part of a region with disease-free status, all farms in that zone temporally automatically lose their status, even if they are geographically distant or well-isolated from the outbreak. This approach may discourage farmers from participating in disease programmes in a collective manner, as they perceive the process as unfair and overly burdensome. This has the unintended effect of farmers choosing to only obtain disease-free status on their farms, rather than including the surrounding waterways, which would improve security. Additionally, efforts to preserve specific disease-free statuses (in existing zones) are now at risk due to these rigid measures. While the AHL provides valuable tools like regionalisation to minimise trade disruptions during outbreaks, their effectiveness depends on consistent acceptance and implementation across Member States. Divergences in how restrictions are recognised and applied can undermine these mechanisms, leading to unintended economic consequences and reduced confidence in intra-EU trade.

This financial responsibility between the State and the private sector, and the decision of NCAs on the extent to which farmers will bear compliance costs, can discourage farmer participation in disease prevention programmes or, worse, from reporting diseases, particularly when the economic costs at farm level is high as it is often the case with eradication and biosecurity measures. Disease reporting can result in mandatory culling or costly containment measures, leading some farmers to withhold information to avoid financial losses or operational disruptions. This poses a risk to disease control efforts, as underreporting undermines early detection and containment strategies. Finally, financial pressures have emerged as a key issue, with high costs associated with compliance, biosecurity measures, and disease management. Farmers, particularly small-scale producers, struggle with the financial burden of implementing AHL requirements on biosecurity, while Member States face challenges in sustaining emergency response funding due to the reduced EU co-financing rate.

4.2. Efficiency

4.2.1. 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?

Key findings

- Findings from desk-based research show that preventive, cross-sector approaches improve efficiency and cost-effectiveness. By focusing on prevention and collaboration across sectors, the AHL optimises resources, avoids redundant efforts, and enhances overall health outcomes while lowering long-term costs. In particular, biosecurity measures are low-cost for high-value animals, but emergency responses, like culling during outbreaks, result in significant financial burdens.
- Implementation costs for AHL, such as animal movement, traceability, and disease control measures, have been noted as significant by stakeholders, especially for smaller farms.
- The focus on disease prevention through clearer rules and responsibilities has led to better health management in some sectors, but challenges remain in aligning global practices with EU regulations.
- Compliance costs vary based on production scale and animal type. Small-scale farmers and those in aquaculture face higher burdens. Key cost drivers include biosecurity investments, veterinary visits, record-keeping, and compliance training.
- Specific examples illustrate potential benefits of the AHL, even if broad effects are not yet widely felt. For instance, early detection of diseases (like avian influenza) has improved in certain regions, which can mitigate the impact of outbreaks.
- Feedback from veterinarians indicates that while daily veterinary tasks and direct responsibilities did not change drastically, indirect compliance costs rose in areas such as training, staffing, and administration.

Key limitations

- There is a scarcity of published studies and hard data on the AHL's efficiency and impacts. Only a few formal studies or reports have been conducted so far. This means the evaluation had to work with limited empirical literature. The primary reason is that the AHL is relatively new (formally applied since 2021) and still in its implementation phase, so comprehensive data have not yet accumulated.

- Given the lack of extensive prior research, the analysis relies heavily on stakeholder consultation activities and case studies for evidence. The evidence from these consultations may not capture all nuances and often cannot be independently verified through external data.
- Quantifying the benefits of preventive actions is inherently difficult, and this is a limitation in the analysis.

The literature and reports on the AHL remain limited, with only a few studies and publications identified (see Section 2.4). Given the limited availability of existing sources and literature on the efficiency of the AHL, our analysis mostly relies on consultation activities and case studies. In particular, desk-based research on the efficiency and costs associated with the AHL remains scarce. The only ongoing implementation is most likely the main reason for this. Below, we summarise key insights drawn from the limited publications available, alongside a review of reports evaluating animal health programmes and measures at the Member State level.

A review of the economic value of, for example, One Health initiatives highlights important insights into their efficiency and cost-effectiveness. Health initiatives improve efficiency and cost-effectiveness through prevention and cross-sector collaboration. They optimise resources, reduce redundancy, and enhance health outcomes while lowering costs. Despite challenges in fully assessing their economic impact, these approaches consistently deliver substantial long-term benefits ([43]).

4.2.1.1. Assessment of the costs and benefits per stakeholder group

According to the findings from the Call for Evidence conducted in 2024, stakeholders indicated some activities/areas of the AHL to be the most costly. Specifically, the specific areas of the AHL for which stakeholders expressed concerns on costs included the movement of animals (86 out of 215) and additional general costs linked to the overall implementation of the AHL (69 out of 215). Only a few stakeholders raised concerns on the costs associated with traceability (4 out of 215), disease control measures (4 out of 215), and enforcement of rules (5 out of 215). Furthermore, the 215 respondents to the Call for Evidence highlighted additional costs as a concern for different groups of stakeholders, with the majority (167 out of 215) reporting that hobbyists were most impacted. Smaller numbers of farmers (6), NCA (2), economic operators other than farmers (3), and veterinarians (1) also noted additional costs. Since stakeholder groups' perceptions of the implementation's costs and benefits vary, we will present the main findings for each group in a separate section.

([43]) Auplish, A., Raj, E., Booijink, Y., de Balogh, K., Peyre, M., Taylor, K., ... & Häsler, B. (2024). *Current evidence of the economic value of One Health initiatives: A systematic literature review. One Health, 100755*. DOI: https://doi.org/10.1016/j.onehlt.2024.100755.

It is difficult to get insight into the benefits of preventive actions, the frequency and costs of disease outbreaks, and the impact of measures on actual data. This insight is further hampered by the fact that the ongoing implementation process in a number of Member States makes it very difficult both for stakeholders as well as for researchers to fully assess and quantify the benefits of the AHL. Therefore, the findings below should be seen as a first description of the stakeholders' perception of costs and benefits, where feasible cost estimates are derived from specific examples.

Farming sector

The findings suggest that the financial impact of AHL measures varies depending on production scale and animal value, affecting over four million farmers in the EU ([44]). Smaller farms, particularly in livestock and aquaculture, face a disproportionate burden when surveillance costs remain fixed regardless of size, while larger farms absorb these costs more easily. High-value animals, such as race and sport horses, justify biosecurity investments, whereas small-scale poultry producers face higher relative costs with fewer benefits. Cost categories include biosecurity measures (generally low for equines but variable for other species) and outbreak response costs (high, especially for disease events like HPAI, which lead to widespread culling, disruption of production and financial losses). Based on the survey results and the in-depth interviews, respondents reported several concerns regarding the financial implications of AHL measures, especially for farmers in the livestock and aquaculture sectors.

Costs

As shown in the cost-benefit analysis (Annexe 3), the implementation of the AHL has led to increased costs for both direct and indirect compliance across various livestock sectors and the aquaculture sector, with significant variation between Member States depending on national legislation, interpretation, and sectoral differences. According to survey results (Figure 7 – 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.Figure 7), most respondents perceive an increase in costs across several of the considered incremental cost categories. The category for which there is the highest perceived increase by this stakeholder group (22/35 respondents) is the additional investment in professional development (such as training). Supporting this result is the particular case of Italy, which, under the Decree of 6 September 2023 ([45])

([44]) Number of livestock holdings reported in the 2020 Farm Structure Survey, available in Eurostat: https://doi.org/10.2908/EF_LSK_MAIN

([45]) Defines the modalities for the delivery of training programmes on the system of identification and registration of operators, establishments and animals for animal handlers and animal professionals, in accordance with the training requirements contained in Article 11 of

from the Ministry of Health, introduces compulsory training for livestock and aquaculture ([46]) farmers and transporters. As per the decree, existing and new farmers must complete an 18-hour training every three years, covering legal aspects, major diseases, biosecurity, and related topics. The Decree also foresees a 30% reduction in the duration of the training depending on the maximum number of animals per establishment. Table 2 shows an estimation of the total cost supported by farmers, based on the most recent publicly available data (2020), per livestock species (see Annexe 3 for the detailed explanation on the quantification). The training fees range from 140 EUR to 200 EUR, depending on the provider and/or livestock type. The highest total cost would be attributable to bovine farmers, as they represent the highest share of livestock farmers in Italy, while the lowest cost estimation is observed for apiculture and swine. The total yearly cost for farmers of all estimated livestock species would be approximately EUR 47 million in Italy. In other MS costs for similar training might differ due to differences in content, method of delivery and duration of the training.

Table 2 – 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: Consortium

Several respondents also reported increasing costs related to biosecurity measures, mostly for enclosing and fencing, but also cleaning and disinfection, requiring additional staff or investment. However, the results from different consultation activities (surveys and interviews) show that these depend on

Regulation (EU) 2016/429. (23A05686) (OJ General Series No. 243 of 17-10-2023). Available at: https://www.gazzettaufficiale.it/eli/id/2023/10/17/23A05686/sg

([46]) Fee for aqualculture are not available online, but several courses are organised by University of Messina and Forma Consulting.

([47]) Whenever different providers offer different prices. Check Annexe 3 for more details.

([48]) Sources: Eurostat Structure of earnings survey, Labour Force Survey data for Non-Wage Labour Costs; International Standard Classification of Occupations (ISCO) 6 - Skilled agricultural and fishery workers

([49]) Values correspond to the number of holdings per animal species, in Italy, in 2020, retrieved from Eurostat. The assumption is that one holding = one farmer, also considering the relevant article from the Italian decree: *(24) 'operator' means any natural or legal person having animals or products under his responsibility, including for a limited duration of time, but excluding pet keepers and veterinarians.*

national legislation and sectoral requirements, with significant differences between Member States and livestock sectors. For example, for farmers who did not implement any biosecurity measures other than the standard management practice prior to national or sector-specific legislation (which is the case for the poultry and pig sectors), the impact on costs is approximately EUR10,000 (for items such as clothing, cleaning equipment, fences, cleaning products, window coverings, etc.) ([50]). However, it is important to highlight that there might be a case for policy invariance. Indeed, it is likely that farmers had already implemented equivalent biosecurity measures as part of their standard operating practices, motivated by the need to prevent disease outbreaks and protect revenue. For these operators, some of the biosecurity requirements were largely policy-invariant, resulting in negligible additional compliance costs. Secondly, national legislation prior to the AHL and after its adoption might be more or less stringent. Furthermore, farm type and size greatly impact biosecurity costs as well as the epidemiological situation.

Similarly, 19 out of 35 respondents report an increase in costs associated with the **required veterinary health visits** (Article 25 of the AHL), especially in the dairy, beef, and sheep sectors. Visits are more frequent, especially in places that place a greater burden on small-scale farmers and those without private quality assurance (QA) systems. In sectors where QA schemes mandate regular vet visits, such as in the poultry and pig sector in parts of Italy or the Netherlands, no additional costs are incurred, while costs are notably higher where such systems are absent. On average, visits cost around EUR 150-350 per year, depending on the number of visits, if the visit is combined with other purposes and with the location and remoteness of farms further influencing costs.

Over 50% of respondents (17 out of 35) reported higher costs associated with record keeping of animal movements, health status and treatments are higher. These changes are particularly relevant for operators that fall now under the scope of the AHL, where national authorities did not exert exemptions, and need to apply for registration (e.g. hobby farms- poultry); in Italy, where additional changes are reported due to the interpretation of Art. 4 (27) of the AHL, on the definition of establishment, and the improvement of Traces NT ([51]). Considering the particular case of the Netherlands, it was reported that a farmer would need an initial time investment of 1.5 hours to apply for the first registration ([52]) and develop animal health and treatment plans, and 10 hours per year for record keeping of treatments, updates and changes ([53]). As estimated in Table 3, this would represent a total cost of 36.3 EUR per farmer, for initial application for registration and development of animal health and treatment plans. Regarding yearly record keeping, a farmer of an average-sized farm in the Netherlands (198

([50]) Estimate based on information provided in an interview with a representative of a farm association.

([51]) Source: interviews with representatives of farm associations.

([52]) There is only one initial registration per farmer.

([53]) Source: interview with Dutch competent authority.

LSU/holding) would need approximately 10 hours, while for farms below and above the average size, we assume they would need 8 and 12 hours, respectively. This represents a total estimated cost of approximately EUR 7 million for Dutch farmers for yearly record keeping, representing 0.06% of the Duttch livestostock industry production value (around EUR 11 billion).

Table 3 – 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**

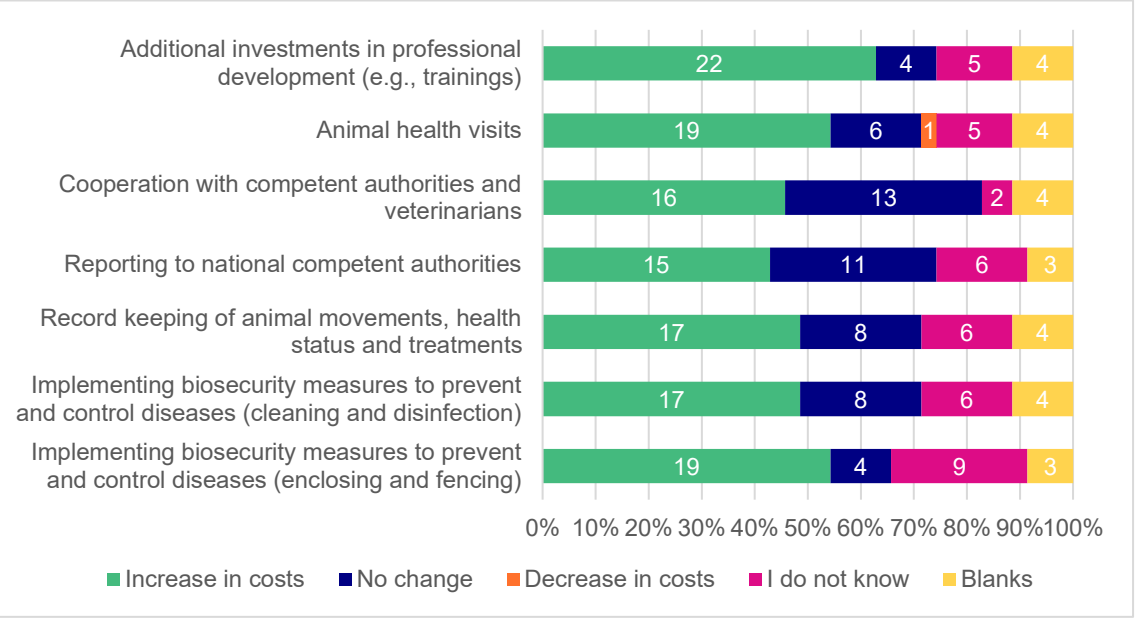
Source: Consortium

For the remaining two categories—cooperation with and reporting to national competent authorities—perceptions are more balanced between an increase or no change in costs after the implementation of the AHL, although the number of respondents for whom there was an increase still outweighs those for whom there was no change. Even though the results show that most Member States did not yet implement additional control measures due to ongoing alignment of national legislation, lack of staff and unclear definitions, there is increased information sharing across them, as well as discussions between farmers and NCAs.

(54) Sources: Eurostat Structure of earnings survey, Labour Force Survey data for Non-Wage Labour Costs; International Standard Classification of Occupations (ISCO) 6 - Skilled agricultural and fishery workers.

Figure 7 – 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.

The figure includes only adjustment and administrative cost categories.



Source: Consortium.

Benefits

According to our consultation activities, the introduction of the AHL has currently led to mixed or limited positive benefits across sectors and Member States, given the limited implementation of measures in some of them. Survey results (Figure 8) show that respondents in this stakeholder group mostly report that the implementation of the AHL had no impact on the assessed benefits.

Some clear improvements are reported (17 out of 35 respondents) for disease prevention and control due to clearer rules and responsibilities. One farm association in aquaculture reported cost savings of around 25%, while another notes that the benefits of Article 25, including increased veterinary visits, have contributed to lower antibiotic use and fewer endemic diseases.

For most of the benefit categories – simplified regime for crossing borders, market opportunities, better regional health status, reduced occurrence/effect of animal epidemics, better image of the sector – the perception of most respondents is that the implementation of the AHL has brought no significant change. However, there are some country and sector-specific highlights of improvement:

- Evidence of early detection in avian influenza is reported to improve the reduced occurrence and effects of animal epidemics, and one farm

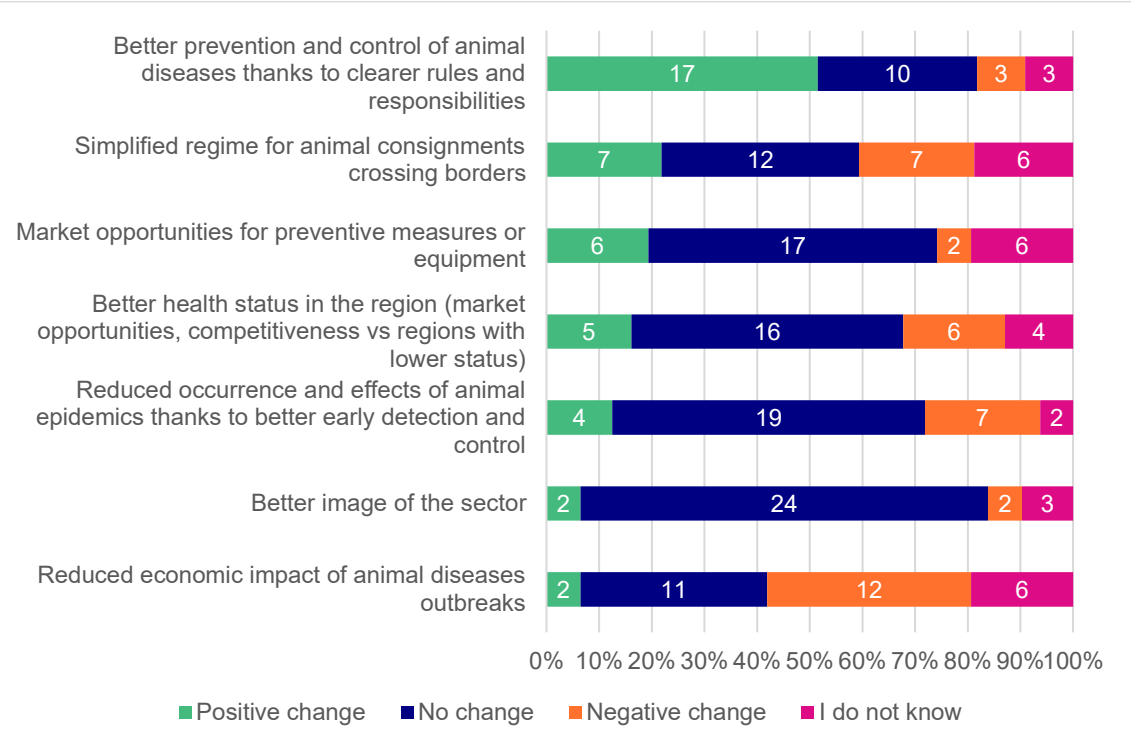
association of aquaculture reported +10-15% in terms of benefits/cost savings.

- Two operators estimate that better health status in the region leads to approximately 25% in cost savings, although respondents agree that it is very difficult to estimate these savings. It is additionally noted that, besides the effect of the absence of diseases due to the AHL, measures also contribute to improving general health.
- According to one animal transport association, the image of the sector improved by +15-20% in terms of benefit/cost-saving since the adoption of the AHL. Another stakeholder reported that the AHL has the potential to enhance the sector's image through its emphasis on prevention, including biosecurity, preventive vaccination, and improved surveillance. However, public scepticism about vaccination and the negative perception of animal disease outbreaks, such as avian influenza or African swine fever, remain relevant challenges.

The benefit category for which a particularly higher number of respondents (12 out of 35) reported a negative change is the reduced economic impacts of animal disease outbreaks. However, respondents were not able to quantify or provide further details on this category.

It is also worth mentioning that stakeholders underlined the advantages that animal disease control programmes (CPs) offer for animals, farmers, the industry, and consumers by enhancing general animal health and welfare, reducing antibiotic usage, and, in the case of zoonotic diseases, improving the safety of animal products. CPs help minimise both direct and indirect disease-related losses. While their implementation incurs costs for testing and administration, these expenses are typically seen as being outweighed by the overall benefits, although difficult to quantify.

Figure 8 – 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: Consortium.

Veterinarians

Costs

Veterinarians and veterinary associations interviewed reported that the implementation of the AHL resulted in minimal changes, with increased indirect compliance costs mainly related to professional development. As seen in Figure 9, out of 14 survey responses, 9 indicated increased costs. Different factors are indicated by some of these respondents that might justify this perceived increase in costs. A key concern is the lack of a unified training framework, particularly in critical areas like biosecurity, which forces professionals to seek their own learning solutions. Additionally, the transition to more complex compliance procedures—such as digital checklists and on-site IT systems—requires new skills and more staff, driving up labour and training costs. Expectations for continuous communication with stakeholders and the need to host regular information events further intensify the demand for qualified personnel.

In terms of maintaining detailed records of treatments, vaccinations, and other health interventions, results were mixed: 8 reported increased costs, and 6 reported no changes. This variation is largely due to the existing national requirements, as some Member States already had such obligations in place,

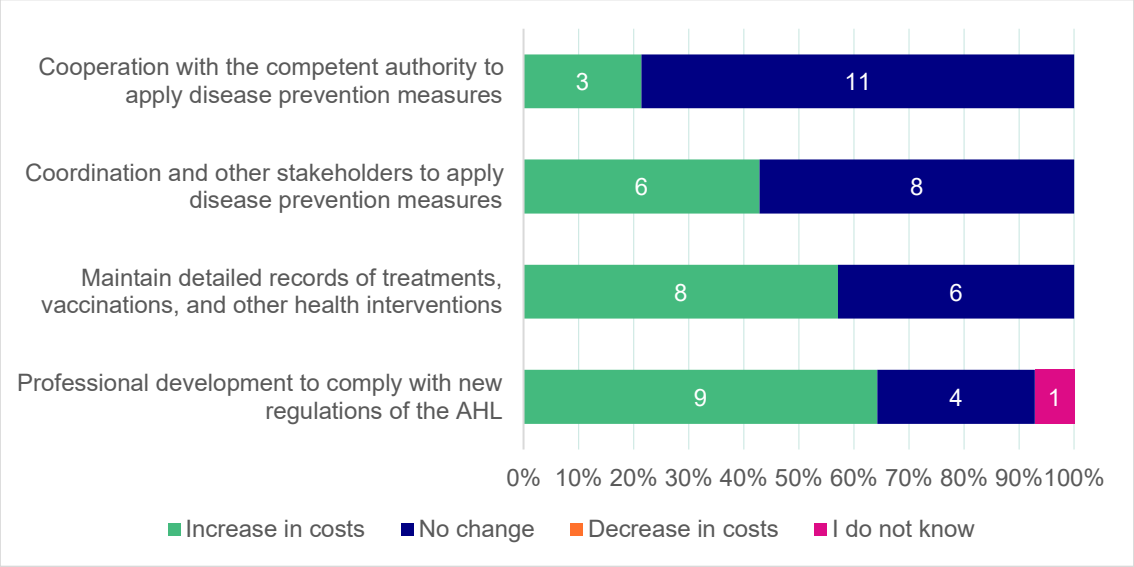
while others only introduced them following the AHL, thus generating additional costs.

Regarding direct compliance costs, coordination with stakeholders to apply disease prevention measures showed mixed findings, with some stakeholders reporting increased costs and others reporting no changes. Limited information was available on this topic. Similarly, cooperation with competent authorities and other stakeholders for disease prevention and control was largely reported to have remained unchanged, with 11 out of 14 respondents stating no increase in costs. However, the quality and extent of communication between national competent authorities, the farming sector, and veterinarians continue to vary between Member States.

Lack of staff to execute the farm visits was reported as a major challenge in most Member States. For remote areas, there were worries about the economic feasibility of executing these farm visits. The number of farms that can be visited per day is limited, and the cost per visit is therefore high, leading either to high costs for farmers or low revenues for veterinarians.

Figure 9 – 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: Consortium.

Benefits

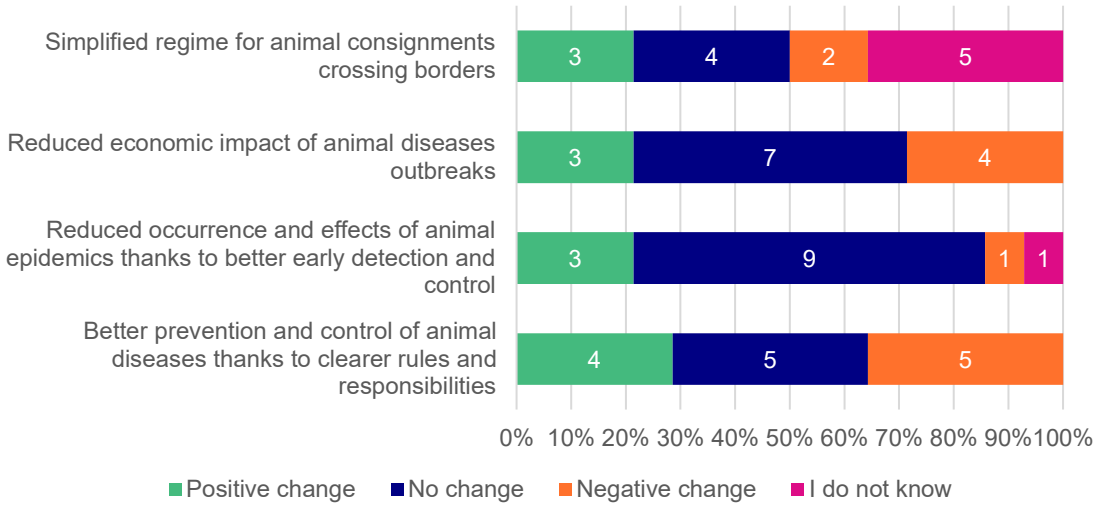
Veterinarians report a mix of positive and negative changes following the adoption of the AHL, with a similar number of respondents in each category related to the AHL implementation areas. Many noted no significant change, particularly in relation to the reduction in the occurrence and impact of animal epidemics through early detection and control, as well as the economic consequences of disease outbreaks. However, one interviewee noted that communication has been instrumental in ensuring alignment on early detection, control, and prevention measures. They noted that in Ireland, since the introduction of the AHL, there have been no animal epidemics. While a rise in tuberculosis (TB) rates is observed, they believe it is more likely attributable to the expansion of the dairy industry than linked to the AHL. In what concerns economic consequences, stakeholders in this group note that, while no changes are perceived for the overall sector, individual farmers bearing the economic costs of eradication measures are impacted negatively ([55]). One survey respondent highlights that improved international coordination has helped contain the financial consequences of regulated disease outbreaks. However, others note that shortcomings in the law—such as vaccination restrictions in Luxembourg—have directly contributed to severe outbreaks like BTV3, resulting in significant livestock losses. Additionally, ongoing concerns about endemic diseases, particularly those in categories D and E, reflect the persistent economic risks these pose to the farming sector.

Opinions are split regarding better prevention and control of animal diseases, with approximately the same number of respondents stating it led to positive, negative or no changes at all. One representative from a veterinary association states that the AHL led to the simplification of eradication efforts, particularly for diseases like BVD, by setting clear criteria that remove ambiguity. Others reported positive developments in international coordination and early detection. In contrast, several responses pointed to negative outcomes, arguing that unclear or fragmented responsibilities have worsened enforcement in diseases like ASF and American foulbrood. Some also noted that national and international legal systems still lack cohesion.

Additionally, several respondents expressed uncertainty about the effects, especially regarding cross-border regulations.

([55]) Source: Interview with representative of veterinary association.

Figure 10 – 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 veterinary associations.



Source: Consortium.

NCAs

Costs

The survey results (Figure 11) show that most respondents in this stakeholder group find that, in general, there were no changes in costs due to the implementation of the AHL, while some report an increase in several categories.

The number of respondents reporting no changes in administrative costs associated with crisis management in case of outbreaks is particularly high (13 out of 23), as well as for costs linked to reporting to the EC on simulation exercises when requested (14 out of 23) and coordination with other Member States and third countries (15 out of 23). The overall approach to managing disease outbreaks has not changed significantly in the Member States. However, outbreaks of diseases that had been absent for a long period prompted updates to contingency plans.

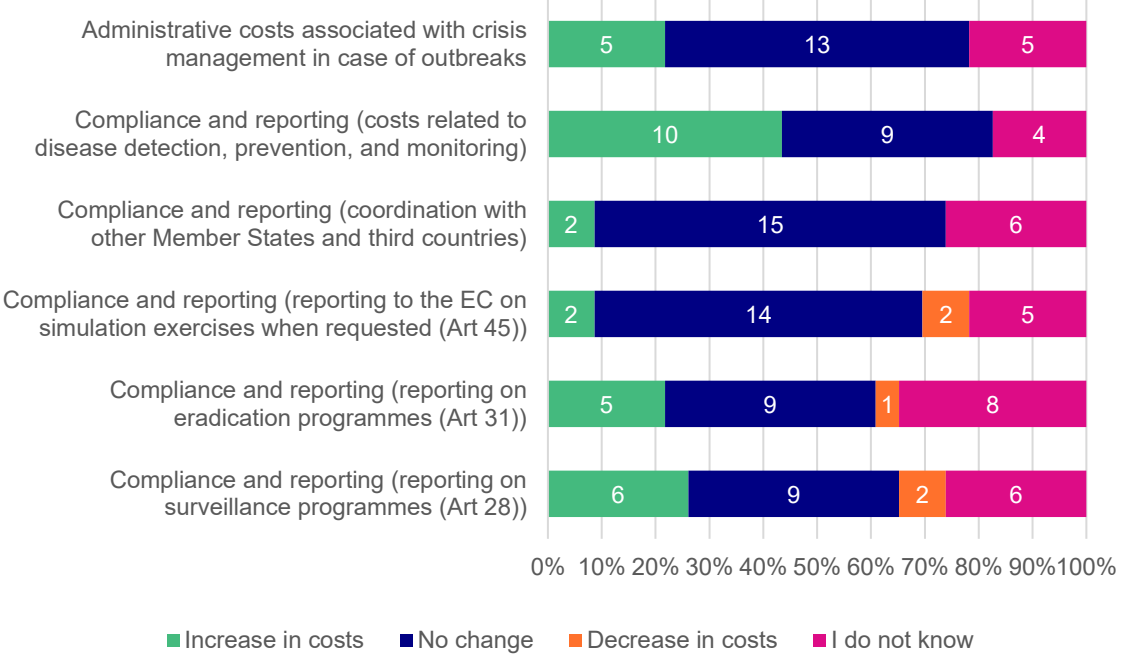
As for costs associated with reporting on eradication and surveillance programmes, opinions are more fragmented, with a higher number of respondents indicating uncertainty or an increase in costs. Italy highlighted that the reporting system has become more time-consuming and costly than initially anticipated due to HaDEA's administrative approach and the complexities of digitalisation, especially for co-financing surveillance and eradication programmes. Additionally, fragmented data collection processes created barriers, for example, during the efforts to eradicate ASF. By nature, surveillance costs are challenging to assess due to the involvement of multiple stakeholders

and fragmented systems. This complexity finds evidence in the surveillance strategies for different diseases, such as tuberculosis, HPAI, and ASF, each requiring tailored approaches. In addition, changes in the epidemiological situation are also a factor influencing costs, for example an NCA reported additional costs of 15% both for surveillance and eradication programmes to tackle outbreaks of ASF and HPAI, while another reportedthe need to hire one additional FTE for surveillance programmes.

The highest number of respondents indicating an increase in costs (10 out of 23) is observed for disease detection, prevention and monitoring. An NCA, in particular, reported higher administrative costs due to the registration of hobby farms. Additionally, stakeholders note that the AHL also introduced wildlife and pets monitoring requirements, leading to increased costs reported by numerous Member States. More specifically, since the AHL is based on a risk and prevention approach, the increased number of ASF and HPAI over the last years has led to higher costs; in fact, costs have been higher in terms of prevention and due to the recent disease outbreaks.

Figure 11 – 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: Consortium.

Benefits

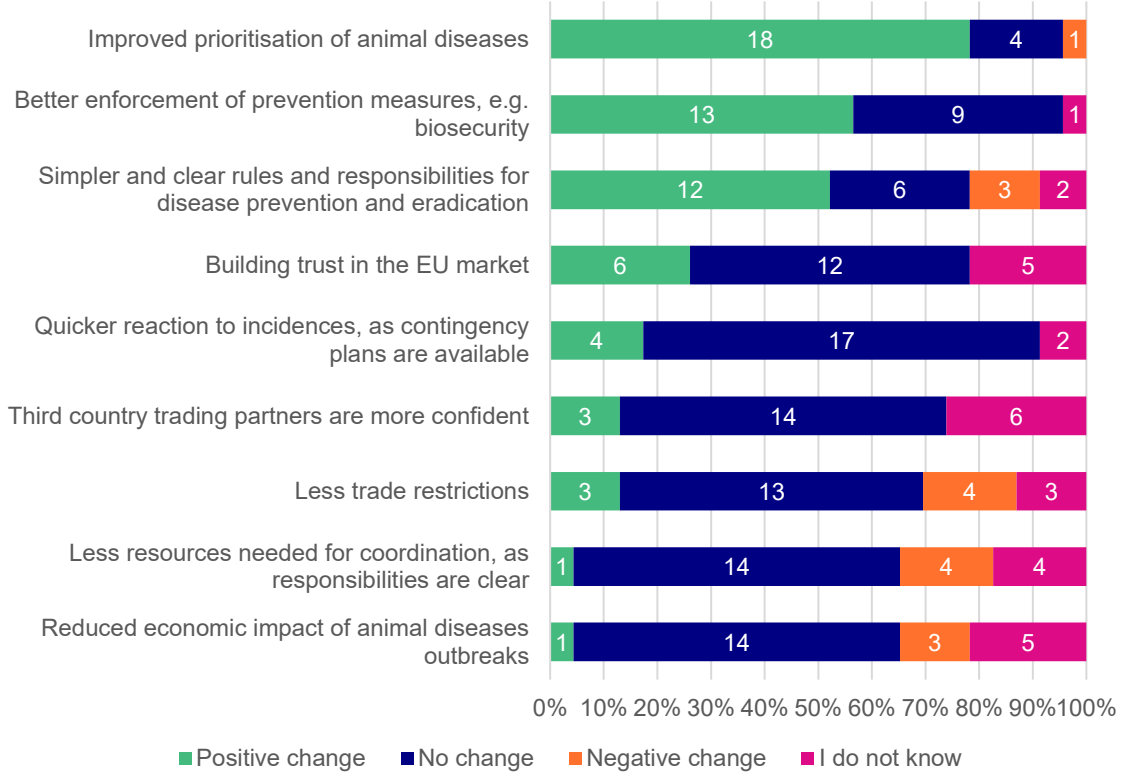
Despite the mentioned challenges, surveyed and interviewed NCAs find that the AHL has brought benefits, including better disease prioritisation, simplified rules, and a harmonised EU framework. These improvements have enhanced regional health status, clarified stakeholder responsibilities, and strengthened market trust, although financial responsibility for disease prevention remains significant. However, they note that it is very challenging to quantify these benefits.

Based on our survey findings (Figure 12), over half of the NCAs indicated that they observed positive change in several areas of animal health as a result of adopting the AHL. The majority of NCAs consider that the AHL contributed to improving the prioritisation of animal diseases, better enforcing prevention measures (e.g. biosecurity) and allowing for simpler and clearer rules and responsibilities regarding disease prevention and eradication**.** According to the findings from the in-depth interviews carried out, the AHL has been beneficial for the control and eradication of diseases like Infectious Bovine Rhinotracheitis (IBR) and Bovine Viral Diarrhoea (BVD), where farm-level 'disease-free' qualifications are possible. These qualifications offer commercial advantages, reduce disease losses, and enhance reputation, supporting trade and improving animal health. Previously, diseases regulated only at the Member State level, like BVD, now benefit from EU-wide standards.

For all of the other assessed benefits, however – building trust in the EU market, quicker reaction to incidences, strengthened confidence of third country trading partners, less trade restrictions, reduction in resources needed for coordination and lower economic impact of animal disease outbreaks – respondents generally agree that no changes are observed due to implementation of AHL. The highest consensus is observed for the reaction to incidences, with 17 out of 23 stakeholders sharing the opinion that no changes are observed. The limited evidence suggests that the reaction time is at least as good, if not better, than before, and that wildlife monitoring has also contributed to increased awareness. The reaction times to the Bluetongue Virus (BTV) outbreaks varied across Member States, with some responses being relatively quick, particularly in vaccine development and early detection. It is important to highlight that there is still limited evidence to assess precisely to what extent these benefits are impacted by the AHL, partly due to its early implementation stage in many Member States.

A few NCAs, however, indicate negative changes regarding the additional resources needed for coordination and rules and responsibilities for disease prevention and eradication, notably referring to navigating a new legislative framework.

Figure 12– 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: Consortium.

4.2.1.2. Assessment of the proportionality between costs and benefits per stakeholder group

When analysing the survey responses shown in Figure 13, the difference in perception regarding the proportionality between costs and benefits of the AHL is evident between stakeholder groups.

More than half of the surveyed farmers and industry representatives consider that the costs outweigh or far outweigh the benefits. Respondents particularly note the disproportionate costs they have to incur in the case of outbreaks, due to very complex and restrictive measures for some diseases, which impact trade for a long period of time and cause a great financial impact. Additionally, stakeholders complain about a greater administrative burden. Contrarily, those who report a balanced proportion between costs and benefits, or even that the latter outweighs the former, highlight the focus of the AHL in preventive measures, such as vaccination and early detection and monitoring, which are less costly and avoid outbreaks and overly expensive emergency responses. However, stakeholders in this group reiterate that, although the benefits are perceived as greater than the costs for the overall sector, this is not always the case at the farm level, where compensation is noted as not sufficient.

Veterinary associations reported more fragmented perceptions. The 5 out of 14 respondents in this group who report that the benefits of the AHL implementation outweigh the costs, or that there is proportionality between them, reflect a generally positive view of animal health visits and disease monitoring in aquaculture as key veterinary measures introduced by the AHL. The remaining respondents expressed concerns about increased indirect compliance costs, particularly related to professional development, record-keeping obligations, and administrative burdens associated with complex compliance procedures, as described in the previous section .

tWhile some respondents noted improvements in early detection and international coordination of disease prevention, others pointed out challenges such as fragmented responsibilities and lack of a unified training framework, which increase operational burdens. These respondents highlight increased regulatory burdens, especially compared to previous frameworks like the BALAI, with limited ([56]) practical consequences. They note additional costs without return on investment and the need to adapt a large number of national laws to comply with the AHL.

On the contrary, most NCAs feel that the AHL's costs are proportionate or outweighed by its benefits. However, most of them note that this is highly variable between Member States, farm structures, and types of measures. Some disclaim that the legislation is too rigid regarding outbreaks of A-listed diseases, in which cases the costs outweigh the benefits, in specific cases, these findings are not generalisable while others note that it is too early to accurately assess and quantify the costs and benefits of the AHL.

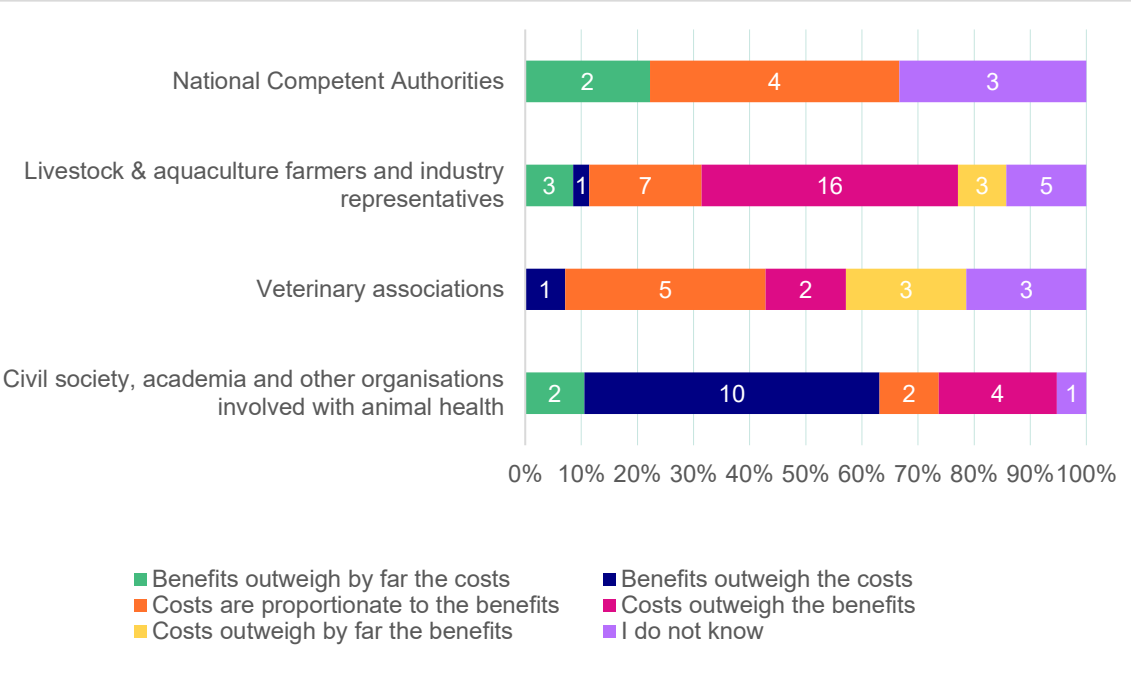
Most responses from academia and other organisations involved with animal health agreed that the initial costs of biosecurity, record-keeping, and reporting may seem high, but preventing disease outbreaks reduces overall costs by avoiding expensive interventions, minimising production losses, and maintaining market access. While the AHL has led to increased compliance costs—especially for small-scale farmers—it has also delivered benefits such as improved disease prevention, clearer rules, and stronger market trust. A large majority indicated positive changes due to the adoption of the AHL in improving human health and food safety, animal welfare, and animal health. Notably, no respondents reported any negative changes.

The AHL prioritises prevention, which leads to long-term savings in the livestock and aquaculture sectors. Although the AHL adds costs, they are justified by the investment in a healthier, more resilient farming system. Since a large part of the measures were already implemented before the introduction of the AHL (by implementing the directives due to national legislation), the costs of implementing

([56]) Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC.

these measures were already present before the AHL and can be earned back over time through improved efficiency and welfare practices. The AHL also offers benefits, such as providing clear rules that help mitigate the impact of disease outbreaks by allowing border closures between EU Member States to be replaced with targeted movement bans within specific regions (regionalisation or compartmentalisation), thereby reducing the overall economic impact.

Figure 13 – 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: Consortium.

4.2.2. Effi 2.2 Were the costs and benefits distributed as expected and of the magnitude expected? Are there significant differences between Member States?

Key findings

- Costs and benefits of AHL implementation vary widely between EU countries, depending on national resources, existing animal health systems, and legislative readiness. Some invested early in extra staff and IT systems to handle new requirements, while others struggled with limited resources leading to uneven progress.The AHL has led to a redistribution of responsibilities, placing more accountability on industry stakeholders.
- Member States with previously weaker animal health systems see more benefit from the AHL. In contrast, Member States with robust pre-existing systems experience fewer marginal benefits but face additional administrative requirements.
- Many Member States used the AHL as a chance to modernise their animal health legislation.
- NCAs initially struggled to understand and apply some parts of the law. Not all NCAs fully realised ahead of time the needed change to adapt national rules or train stakeholders, indicating a learning curve that could take some years to overcome.The costs and benefits of the AHL are not evenly felt by different stakeholders. Small farms face relatively higher costs with few immediate rewards (making compliance hard), whereas larger farms or high-value producers can absorb expenses more easily and are likely to see long-term gains in health and trade.

Key limitations

- The implementation of AHL requirements varies across the EU , as Member States started from different levels of ability and used different approaches to include them in their national systems.
- Most Member States are still catching up, and experience different starting conditions and approaches, which makes it hard to assess overall progress uniformly.

The distribution of costs and benefits varies significantly among Member States, in part due to differing national circumstances and how each country implemented the AHL. Some countries, such as Denmark, Bulgaria, Austria, and the Netherlands, allocated additional staff to handle the changes. These upfront costs were significant and not uniform across the EU. Some countries also invested in new IT systems (for disease notification and traceability) to meet AHL reporting requirements. In other Member States, implementation had to be managed alongside regular tasks, leading to staff shortages, higher turnover (e.g. Sweden), or to partial implementation until this far (e.g. Germany).

The benefits of the AHL are more pronounced in Member States that previously lacked comprehensive animal health rules. For instance, the AHL introduced compulsory registration of many animal holdings and Animal Health visits in all Member States. Member States that already had strict surveillance and farm biosecurity rules (like the Netherlands or Germany) experienced less marginal benefit, but still must shoulder new administrative tasks. In contrast, Member States with less developed systems expect greater disease prevention gains from the AHL, albeit after investing in capacity building.

The perceived distribution of costs across Member States is also influenced by epidemiological developments and therefore the unequal distribution of disease outbreaks, such as HPAI and BT. For some Member States, a large part of these costs for regulatory changes and updates of e.g. contingency plans occurred already before the implementation of the AHL since they were confronted with outbreaks in the recent past, whereas others encountered outbreaks after the introduction of the AHL. Outbreaks of HPAI, ASF and BTV were the most predominant in the last few years. As a result, Member States experiencing larger outbreaks face stricter control measures, leading to significantly higher costs for breeders and transporters.

Costs

Findings from the evaluation of regulated diseases and the impact of the AHL in France ([57]) revealed that the AHL only moderately changes the management of regulated diseases in France. Most diseases covered by the previous regulations remain under the scope of the AHL. However, its implementation presents an opportunity to redesign the governance of animal health in France, which has traditionally been largely controlled by the State. The AHL places more responsibility on stakeholders for the execution and oversight of health management, while the State retains its role of control. The AHL is generally supported by the industry, as it emphasises prevention, offers potential improvements in health management, and encourages initiatives already underway in certain sectors. Some sectors, such as pig and poultry farming, are further ahead in collective management and disease prevention, and their experiences could be shared and adapted to less integrated sectors.

Spain experienced a relatively smooth transition, primarily due to pre-existing legislative structures and national control measures exceeding the EU's minimum requirements. In several Member States, the AHL was also seen as an opportunity to modernise animal health legislation. However, as most countries remain in the process of (partial) implementation, current costs are primarily borne by ministries and enforcement agencies, while farmers are yet to fully implement biosecurity and disease prevention measures.

([57]) Ministère de l'Agriculture et de la Souveraineté alimentaire (2024) Évaluation des coûts des maladies réglementées et de l'impact de la Loi Santé Animale. Available here.

Importantly, the implementation of the AHL has been integrated into broader national animal health strategies also in countries like Italy and the Netherlands. In these cases, the AHL served as a 'catalyst' for structured, extensive consultation between public authorities and industry stakeholders. The successful deployment of the AHL requires consultation between public authorities and industry representatives, as well as a clearer definition of procedures for each sector.

In Denmark, additionalresources are needed to understand and implement the AHL, with some sectors hiring full-time employees. Implementing the Animal Health Law, secondary national laws, and control systems, including IT structures for facilitation and documentation, required approximately 8-10 man-years of staff resources ([58]). According to survey findings, the Danish National Competent Authority mobilised 8 full-time equivalents (FTEs) in 2022, 6 FTEs in 2023, and 3 FTEs in 2024. This investment was needed given the importance of the livesock sectors for Danish economy, which employs around 43,000 people and generates a gross value added of EUR 1.8 billion.

Overall, while all stakeholders expressed support for the changes introduced by the AHL, at the start most NCAs did not fully comprehend the necessary amendments to national legislation, the opportunities presented by the AHL to tailor specific provisions to local contexts or particular actors, or the importance of raising awareness and providing training regarding the newly introduced measures or changed in the architecture. As some stakeholders noted, the sector is still at the early stages of a learning curve, and it may take up to a decade to fully assess the costs and benefits associated with the AHL.

Benefits

According to findings from consultation activities, cost distribution differs across stakeholders: small farms struggle with financial viability due to limited incentives for disease-free status, whereas larger operations and high-value sectors manage costs more efficiently. Emergency response expenses can be substantial, especially for livestock sectors reliant on intra-EU and international trade. Investments in animal health knowledge are considered beneficial, though smaller farms find them harder to justify.

While the AHL promotes harmonised practices across Member States, its benefits vary and require further guidance. For example, in the context of bluetongue disease management, there has been a shift of responsibility to the industry, specifically on the animal handler, yet the lack of structural support from public authorities hinders disease control efforts. Stakeholders emphasise the need for enhanced collaboration and assistance to mitigate these challenges.

([58]) Danish Veterinary and Food Administration (2021) *Implementation of AHL - Danish perspective*. Available here.

During interviews, one farm association reported that overall costs related to AHL have increased by +15%. According to the stakeholder, this increase in costs was attributed to biosecurity measures and time spent on recordkeeping, with overlapping IT systems creating administrative burdens. Benefits reported include improved disease prevention and control (+25%), fewer epidemics (+10–15%), and simplified cross-border consignment requirements (+25%). However, the broader economic impact, market opportunities, and sector image remain hard to quantify.

One transport association reports a +25% increase in costs related to reporting requirements on movement and identification (suggesting that better integration of TRACES with digital databases and linking documents like horse passports could reduce paperwork and delays). While some costs are unclear due to regional differences and outbreak frequency, regions with better health status report a +25% improvement. Benefits in preventive training and equipment sales rose by +10%, and the sector's image improved by +15–20%. More scientific data is needed to fully assess long-term impacts (see also the cost and benefits overview in Annexe 3).

In conclusion, the implementation of the Animal Health Law across EU Member States led to changes in the animal health governance. Despite increased costs and administrative burdens, especially for smaller operators, the AHL is widely seen as a step towards improved disease control, prevention and harmonised EU standards.

4.2.3. 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?

Key findings

- Stakeholders reported that the need to navigate multiple new EU regulations with which they are not yet familiar, and sometimes the need to understand the links with national legislations, creates administrative complexity and, in some instances, extra paperwork.
- The available flexibility to provide derogation or to base requirements on risk assessment granted by AHL is currently underused by NCAs
- A critical sentiment, especially from hobbyists and small farmers, is that the administrative measures of the AHL do not always scale to the level of risk or the size of operation.

Key limitations

- Implementation of the AHL has been inconsistent across the EU. Most Member States are still catching up, and experience different starting conditions and approaches, which makes it hard to assess regulatory burden.
- In several instances, EU AHL rules overlapped with national regulations, which have not yet been fully aligned, creating difficulty in attributing the burden.

Administrative burdens complexities

Stakeholders have reported various administrative burdens related to animal movement and general tasks associated with the implementation of the AHL. A major contributor to this increased workload is the need to become familiar with multiple delegated and implementing acts, as well as the obligation to provide extensive supporting evidence, such as tracing animal products from restricted zones during Highly Pathogenic Avian Influenza (HPAI) outbreaks. While these requirements have increased the administrative workload for both stakeholders and NCAs, they are indispensable for safeguarding animal health, containing the scale of an outbreak and preventing the spread of diseases.

In the Call for Evidence, hobbyists, bird keepers, and veterinarians expressed concerns about the administrative complexity of requirements. One particular point is the requirement for a TRACES health certificate for any cross-border movement of animals. Hobbyists find the TRACES documentation process burdensome and disproportionate to the scale of their activities. Many feel that filling out official certificates and navigating veterinary authority approvals is excessive when they are just exchanging a few animals as a hobby.

Box 10 – Additional costs for hobbyists and small-scale breeders

Based on the consultation activities (interviews), small-scale breeders face disproportionate regulatory and financial burdens when transporting animals (such as birds for exhibitions) abroad. Each individual movement, even of a single bird, requires separate veterinary checks and certification procedures that, in the Netherlands, seem disproportionate compared to other countries and require further administrative demands, such as a mandatory three-week stay at the same location before veterinary inspection. This often results in costs ranging between EUR 250 and EUR 400 ([59]) per shipment, depending on the destination. In contrast, in countries such as France and Spain, the costs are almost zero, highlighting a lack of harmonisation across Member States and a potential non-level playing field. Stakeholders called for exemptions or simplified procedures for a limited number of species (such as specific endangered bird species). It is important to highlight that EU legislation, such as Implementing Regulation 2022/1345, provides Member States with the possibility to derogate from registration requirements for establishments considered to pose a negligible risk. The core of the problem, however, is twofold: on one hand, hobbyist breeders of poultry or bees may believe their activities are risk-free, whereas national authorities often take a more cautious view based on disease prevention responsibilities. On the other hand, some Member States choose not to apply the available derogations, although EU law permits them.

Despite flexibility mechanisms within the AHL, some stakeholders stated that the AHL lacks a way to account for local circumstances. This introduces a more uniform approach that can overlook regional structures and specific needs, making implementation more difficult in certain contexts. In particular, stricter registration requirements for small-scale activities, such as poultry or beekeeping, create significant hurdles for hobbyists, many of whom struggle to meet these standards. Paradoxically, this may hinder rather than help disease control efforts, as informal or unregistered operations fall outside the official monitoring system.

Farmers and other animal businesses also reported general administrative burden from AHL implementation. They pointed to routine tasks – registering establishments, maintaining updated animal health plans, record-keeping of treatments, reporting animal movements or suspicions of disease – as areas where the AHL either introduced new obligations or expanded existing ones. While many of these tasks were pre-existing to the introduction of AHL, and at the same time deemed fundamental to disease prevention, stakeholders feel the AHL has layered an extra burden. For instance, farmers in some Member States must ensure regular “animal health visits” by a veterinarian and keep detailed records of those visits, which is a newer requirement under the AHL framework. Even though basic record-keeping and disease notification existed before, the AHL’s enhanced requirements mean additional scheduling and paperwork that farmers must manage. However, as discussed in section Effi 2.1, AH visits are

([59]) Estimate based on information provided in an interview with a representative of an animal hobbyists association.

not a new requirement for all farmers. In some Member States, specific sectors were already subject to veterinary visits, as some farmers enrolled in certification schemes.

Moreover, there is an overlap between AHL and national rules. Some Member States supplemented the AHL or did not change national provisions (e.g., additional biosecurity measures or record-keeping standards). Stakeholders indicated that where EU and national requirements "layer" on top of each other without full alignment, it creates confusion and duplication of effort. For example, an operator might have to report similar data in two systems because of parallel obligations. Such inefficiencies were flagged as areas where better integration or clarity could reduce unnecessary workload.

A critical sentiment, especially from hobbyists and small farmers, is that the administrative measures of the AHL do not always scale to the level of risk or the size of operation. Hobbyist keepers argue that rules designed for commercial farms (like TRACE certificates or limits on animals kept) are being applied to them as well, even though, according to them, a backyard breeder with a handful of animals poses minimal risk compared to an industrial farm. Against these arguments, scientific literature shows that while industrial farms pose a greater risk for large-scale outbreaks due to high animal density and interconnectivity, small farms or hobbyists may initiate outbreaks or act as disease reservoirs, especially if animals are kept in close contact with humans or other species. Therefore, scientific literature recommends the integration of small-scale operations in animal health policy([60]),([61]),([62]).

Farmers echoed a similar point regarding certain procedures: for instance, the process to declare a herd or area disease-free (for diseases like bovine tuberculosis or brucellosis) now follows uniform EU rules under AHL. Some farmers reported that this process is too rigid and does not account for local disease conditions, making it lengthy or unnecessarily strict for regions with better status. The strict uniform criteria can translate into more paperwork or waiting time for farmers without a clear added health benefit in areas that are already low-risk.

([60]) Donaldson AI, Alexandersen S. Reflections on the foot and mouth disease epidemic of 2001: a United Kingdom perspective [Internet]. Paris: World Organisation for Animal Health (WOAH); 2022 [cited 2025 Jun 30]. Available from: https://www.woah.org/en/reflections-on-the-foot-and-mouth-disease-epidemic-of-2001-a-united-kingdom-perspective/

([61]) University of Exeter. Could intensive farming raise risk of new pandemics? ScienceDaily. 16 Jul 2024 [cited 2025 Jun 30]. Available from: https://www.sciencedaily.com/releases/2024/07/240716202247.htm

([62]) Bartlett H, Holmes MA, Petrovan SO, Williams DR, Wood JLN, Balmford A. Understanding the relative risks of zoonosis emergence under contrasting approaches to meeting livestock product demand. Royal Society Open Science. 2022;9:211573. doi: 10.1098/rsos.211573 [Accessed 30 Jun 2025].

Some stakeholders pointed out that while there has been more clarity in certain disease control procedures, weaknesses have emerged, particularly in relation to gaps in the epidemiological network and monitoring mechanisms. For example, in Belgium, simplification of procedures was reported to have led to deficiencies in disease surveillance within the aquaculture sector. The reduction in surveillance frequency and veterinary visits hindered effective epidemiological reporting. This was largely due to the recategorisation of certain diseases, especially those in Category C, which introduced ambiguity around the implementation of voluntary control measures.

Challenges for NCAs

These views were echoed by NCAs participating in in-depth interviews. While acknowledging certain improvements under the AHL, NCAs emphasised that significant challenges remain. As mentioned above, the core issue for them is the complexity of navigating multiple delegated and implementing acts, especially when detailed evidence is needed for disease outbreak tracing. For instance, in the case of ASF, despite falling under the general rules of AHL, the EC introduced Implementing Regulation (EU) 2021/605 (now updated by 2023/594), which lays down “special disease control measures for ASF.” This ASF-specific regulation establishes zones (I, II, III) and movement restrictions on top of the general AHL rules. This was pointed out as a kind of parallel measure which “contradicts the philosophy of cross-cutting approaches” of the AHL and essentially reverts to the vertical (disease-by-disease) model2. This regulation creates “restriction zones even in areas not affected by the disease (Zone I), undermining the system’s reliability” and confusing trading partners.

Although procedural streamlining has been introduced at the EU level, such as clearer delineation of responsibilities and platforms like TRACES and the Animal Disease Information System (ADIS), these benefits have been limited by the burdens of national-level implementation and legislative adaptation. In practice, both farmers and NCAs continue to face heavy workloads. One NCA shared that the process of cleaning up and reassessing legislation to align with the AHL demanded considerable time, resources, and staffing. Although additional personnel were hired, budget constraints forced a reprioritisation of tasks, leading to delays in other projects, backlogs, staff stress, and sick leave. These issues were exacerbated by concurrent disease outbreaks such as Newcastle disease or ASF, leaving the authority behind on legislative updates and continuing to request further support from the ministry.

Administrative burdens related to compliance and reporting obligations have varied across Member States. In the context of surveillance programmes under Article 28, six out of seventeen NCAs reported cost increases, though these were primarily attributed to disease outbreaks such as ASF and HPAI, and to a lesser extent to the AHL. Austria experienced a 15% cost increase, while Poland reported a 50% rise, citing additional training needs, the implementation of IT

systems, and revised sampling protocols, alongside reduced financial support from the EU.

No major overall cost shifts were observed in most Member States for eradication programmes under Article 31. However, Austria and Poland again noted 15% and 50% increases, respectively, primarily due to the scale and duration of outbreaks they recently encountered in their Member States.

The AHL itself played only a minor role in the increase of costs in the different Member States, with new requirements such as reporting on wildlife outbreaks contributing to the increase in monitoring costs. Cost impacts were more mixed in the area of disease detection, prevention, and monitoring, with ten NCAs reporting increases and nine reporting no change. Increases were often linked to new requirements, such as registering hobby farms, as observed in the Netherlands, and expanded monitoring obligations for wildlife and pets. The increasing number of outbreaks significantly contributed to higher costs in monitoring and surveillance. The risk-based approach of the AHL is designed to manage resources efficiently; however, its potential to mitigate administrative burdens has not been fully implemented in all Member States.

4.2.4. Effi 2.4 Have any inefficiencies been identified? How do these impact different stakeholders?

Key findings

- The AHL broadened requirements to include many previously unregistered animal keepers (such as hobby breeders), and NCAs struggled to identify and register all these small keepers promptly. Many hobbyists were initially unaware of the new registration duties, making enforcement patchy and resource-intensive in the early phase of rollout.
- Farmers question the cost-benefit balance of new obligations. They acknowledge that many AHL-related tasks (vet care, disease monitoring) were already standard practice, but new elements have introduced extra costs. For example, mandatory Animal Health veterinary visits require time and money, and some feel these added costs have not yet delivered clear improvements in animal health.
- Stakeholders report long processing times for the electronic health certificates needed to move animals across borders.
- Veterinarians face a higher administrative workload. This increase in administrative tasks is seen as an inefficient use of a specialised workforce's time, potentially pulling veterinarians away from essential animal health work.

Key limitations

- Implementation of the AHL has been inconsistent across the EU. Most Member States are still catching up, and experience different starting conditions and approaches, which makes it hard to assess inefficiency.
- In several instances, EU AHL rules overlapped with national regulations, which have not yet been fully aligned, creating difficulty in attributing the burden.

The introduction of the AHL has triggered some challenges for NCA, as they faced the need to align and sometimes repeal national legislation. Broadly speaking, two strategies were adopted. In more than ten Member States, alignment was managed by hiring additional staff or establishing dedicated project teams. While this approach required significant investment, it also offered an opportunity to modernise national frameworks and improve alignment with the AHL. In contrast, other Member States relied on existing staff to implement the necessary changes alongside their regular duties. This strategy proved more challenging and led to inefficiencies. Given the increasing frequency of disease outbreaks, the legislative alignment process was often delayed. These delays, in turn, hampered the ability to respond efficiently to outbreaks, as the lack of fully aligned legislation led to uncertainty and ambiguity in the interpretation of the

regulations due to the parallel implementation of both national legislations and AHL and therefore limited the efficiency of AHL efforts.

While some NCAs, such as those in Austria and Denmark, initially expected the AHL to simplify procedures, its implementation has instead introduced additional complexity. One of the main challenges identified is that both civil servants and stakeholders—who share responsibility, often in specific areas—require time to fully understand the shift introduced by the AHL. In particular, the transition from disease-specific (vertical) regulations to a horizontal framework governing overall animal health, supplemented by secondary legislation for specific aspects, has proven difficult to grasp. Based on the consultation activities, it appears that this systemic shift and its broader implications have not yet fully reached all stakeholders, partly due to delays in aligning national legislation. As a result, the AHL is perceived by some stakeholders as more burdensome, especially in the context of ongoing disease outbreaks.

Another challenge noted by NCAs is ensuring compliance across the scope of AHL. The law expanded certain requirements (like requiring registration of many previously unregistered animal keepers, such as hobby breeders). Several NCAs found it difficult to identify and register all these small keepers promptly, which is an operational hurdle. Some hobbyists themselves admitted they were unaware of new registration duties. This indicates an inefficiency in rollout—the effort to bring every smallholder into compliance has been resource-intensive, and in the interim, enforcement is uneven.

While farmers acknowledged that many AHL-related tasks were already part of previous regulations or business as usual (e.g., veterinary care, disease monitoring), new elements of the AHL have introduced extra expenditures. The main perceived inefficiency stems from the perceived payoff between additional costs and perceived health benefits. A clear example is the mandatory AH veterinary visits for farms, where compliance can translate to notable time investment, which for a farmer is equivalent to money (either in veterinarian bills and/or in hours not spent on production and managing paperwork). Some farmers feel these added costs are not yielding clear improvements.

The TRACES document was another source of inefficiency for stakeholders. As mentioned earlier, hobbyists and small breeders saw long processing times for TRACES documents disrupting trade and exchanges. Even transport operators noted that if the electronic system or the authorities are backlogged, shipments can be held up waiting for paperwork, which is inefficient for trade.

Additionally, some farmers criticised the rigid disease-free status recognition process, arguing that uniform rules across large districts failed to account for local health conditions, creating economic challenges. In areas that have been historically disease-free, authorities and farmers found the one-size-fits-all process inefficient, possibly longer or more resource-intensive than necessary for their situation. This rigidity can slow down how quickly normal trade resumes after

an incident, or how quickly a farm can be certified to a certain health status, which has operational cost implications.

Finally, feedback from the veterinarian community suggests that their workload on administrative tasks has grown, which is an operational concern. For example, private veterinarians now must spend time filling out digital certificates, updating disease databases, and conducting routine farm visits mandated by AHL, beyond their usual clinical work. Official veterinarians similarly face more reporting duties and coordination meetings. If veterinarians are tied up with paperwork, this could be an inefficient use of a specialised workforce's time.

These factors have contributed to a range of operational challenges under the AHL, particularly concerning process efficiency—namely, the ability to maintain essential health safeguards without introducing undue delays, complexity, or rigidity. In instances where AHL procedures have proven cumbersome—such as slow certification processes or difficulties in ensuring compliance for smaller actors—stakeholders have been prompt in highlighting these issues.

4.2.5. 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?

Key findings

- Most issues identified relate not to amending the legal requirements of the AHL on reporting obligations or other simplifications, but to simplifying the implementation and operational aspects of the AHL at the national level.
- The AHL created a single EU-wide legal framework directly applicable in all Member States, which is a positive step for harmonisation. However, because Member States are still updating their pre-existing national laws (often narrower or even stricter than the AHL), there is now a layering of old and new rules that adds complexity – NCAs must ensure coherence between the AHL and national legislation, to minimise administrative workload for all stakeholders.
- NCAs see value in the AHL but want it to be applied more flexibly, while all stakeholders, including NCAs, stress that the AHL should maintain an equal playing field.
- Preventive measures prove cost-effective: stakeholders (e.g., farm associations) highlighted that investing in prevention yields major benefits in the long run. Coordinated vaccination programmes and other preventive measures are far more cost-effective than reactive responses to outbreaks.
- Stakeholders across the board called for better digital solutions to reduce administrative burdens under the AHL. They suggest upgrading systems like TRACES (the EU animal movement database) to auto-import farm data and pre-fill forms, and introducing user-friendly mobile apps for farmers and vets to report movements or suspicions of disease in real time. Improved interoperability between databases is another avenue.

Key limitations

- Implementation of the AHL has been inconsistent across the EU. Most Member States are still catching up, and experience different starting conditions and approaches, which makes it hard to assess inefficiency.
- In several instances, EU AHL rules overlapped with national regulations, which have not yet been fully aligned, creating difficulty in attributing the burden.

The positive impact of the AHL lies in its provision of legislation directly applicable across all member states. However, Member States are, in most cases, in the process of changing their pre-existing national legislations. While national laws may not conflict with the AHL, their scope is often narrower (for instance, sector or disease-specific) and, in some instances, exceeds the requirements of the

AHL. As a result, from the perspective of operators and NCAs, the layering effect created by this process introduces additional complexity and burden. Whereas in the past they could implement the disease directives in their national legislation, they now have to ensure coherence between the AHL and national legislation. The workload for local authorities can be overwhelming, as they are now tasked with managing multiple pieces of legislation.

During the Validation Workshop, NCAs mentioned several key potential areas for improvement. In particular, NCAs called for greater flexibility for Member States in managing disease outbreaks and conducting risk assessments, as well as simplification of disease surveillance requirements, such as allowing more adaptable approaches to routine sampling and official visits to reduce unnecessary disease risks. NCAs also stressed the need to clarify the relationship between the AHL and its delegated acts, streamline documentation through digital platforms, and harmonise disease notification forms used by veterinarians to improve efficiency and consistency across the EU.

Other stakeholders, such as farm associations, identified additional opportunities for simplification and cost reduction in the implementation of the AHL. Although not directly related to the simplification of obligations, they emphasised that preventive measures, such as coordinated vaccination programmes, are more cost-effective in the long term compared to reactive responses to disease outbreaks. For example, the French vaccination against HPAI (see Annexe 3 for more detailed information) has proved to be more cost-effective than previous reaction measures implemented following outbreaks. As shown in the table below, the total costs for the campaign amounted to around EUR 100 million, shared between the French government and farmers, with 85% and 15%, respectively. On the other hand, reactive measures during the HPAI crises in the 2020-2021 outbreak, total state aid (sanitary and economic) reached about EUR 1.1 billion to cover the catastrophic losses nationwide. While the upfront investment in vaccination was substantial, it remained a fraction of the cost incurred during past reactive responses to outbreaks. This highlights the value of shifting from crisis management to proactive disease prevention.

Table 4 – 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
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: Consortium.

Furthermore, the vaccination campaign not only helped prevent further outbreaks but also provided indirect benefits extending beyond the farm. For instance, an outbreak disrupts breeding cycles beyond the year of the crisis. The foie gras industry in France was notably affected, with sales and output remaining depressed years after the initial impact. The outbreaks triggered trade bans from key importers such as China, Japan, and the U.S., causing significant disruption throughout the entire poultry supply chain, from hatcheries to processors. This led to shutdowns and structural strain, particularly affecting smaller producers, and resulted in a significant decline in the national poultry population, especially ducks. Recovery has been slow, with long-term impacts on production capacity. Repeated culling, financial uncertainty, and the inability to protect flocks have led to psychological strain and moral fatigue among breeders, impacting mental health and long-term engagement in the sector. Continuous emergency response and mass culling operations have also placed sustained pressure on veterinary teams.

A major theme is leveraging digital tools to automate and simplify reporting. Many stakeholders called for upgraded digital systems to replace paper-based or manual processes. For instance, the TRACES platform could be further improved to autofill data (pulling farm registration information automatically) so that operators spend less time inputting forms. The use of mobile apps for farmers to

report suspicions or to notify of movements could make compliance easier. Enhanced interoperability between databases (e.g. linking livestock traceability systems with disease reporting systems) is another avenue, so that once a farmer or veterinarian enters data, it flows to all necessary channels.

On the same topic, veterinarians suggested that some administrative veterinary tasks could be delegated to para-professionals or digitised to free up their time. For example, routine data entry or checks could possibly be handled by certified veterinary technicians or through automated systems that alert veterinarians only when something is amiss. Stakeholders also mentioned exploring the use of risk-based inspection scheduling – i.e., focus animal health vet visits and controls where there are signals of problems, and lighten them where things have been consistently good. This risk-based approach is another way to allocate effort more efficiently.

It is also worth noting that some simplifications have already occurred during implementation. The European Commission, responding to stakeholder concerns, issued guidance clarifying that certain low-risk animal movements (like pets accompanying owners under specific conditions) fall under pet travel rules rather than commercial AHL rules, effectively streamlining those cases. Ongoing dialogue has identified where national implementation could be adjusted. For example, a few Member States decided to waive fees for hobbyist certificates to address the issue of disparate TRACES fees, a national simplification that reduces the cost impact for citizens.

4.3. Coherence

4.3.1. 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 coherently?

Key findings

- The AHL demonstrates overall structural and conceptual coherence, with identified inconsistencies largely stemming from divergent interpretation and implementation across EU Member States rather than from flaws in the legislation itself.
- The AHL and its Delegated and Implementing Acts are generally coherent, though targeted technical refinements could further enhance legal clarity and operational effectiveness.

To date, the AHL has demonstrated a satisfactory level of internal coherence, as evidenced by a triangulated analysis of the surveys, interviews, and case studies carried out during its evaluation. Although some minor inconsistencies were identified, these do not compromise the overall structural and conceptual integrity of the legislation under examination.

Stakeholders broadly perceive the AHL as structurally and conceptually consistent, with most contradictions arising from its interpretation and/or implementation. Surveys indicate that many NCAs and approximately half of the surveyed farmers and veterinarians did not identify internal contradictions within the legislation. Where concerns were raised, these related to specific gaps or ambiguities—for example, the exclusion of hatching eggs from traceability requirements, or the unclear scope of permissible activities for 'other veterinarians' under Article 14.1.c(i). Similarly, issues were raised concerning the complexity of control programmes and disease-free status criteria. This is particularly the case for Category C diseases such as IBR (e.g. ban on the use of vaccines in the two years preceding recognition of IBR-free status), where disease categorisation, though conceptually helpful, can complicate implementation due to differing disease dynamics.

Interviews corroborate these findings, with NCAs consistently affirming the law's overall coherence while noting the need for greater clarity in the legal language and guidance from the European Commission.

Observed inconsistencies are largely attributable to differences in interpretation and implementation across EU Member States and third countries, rather than flaws in the AHL itself. Stakeholders frequently emphasised that challenges stem from divergent applications at the national level. Several respondents from

industry and veterinary associations reported that inconsistencies often arise during implementation, where national authorities apply the same provisions differently. This variability undermines harmonisation and contributes to legal uncertainty, particularly for businesses engaged in cross-border trade. Civil society and academia similarly pointed to delays in the development of certain provisions (e.g. those to be elaborated by the European Commission regarding compartmentalisation pursuant to Art. 37) and to the lack of clear definitions for key aspects or issues(e.g. ‘disease prevention’, ‘terrestrial animals’), which may contribute to inconsistent national practices.

In addition, linguistic discrepancies in translated versions of the AHL affect consistent application but do not indicate conceptual incoherence within the legislation. Case studies highlighted issues arising from divergent translations of key terms such as ‘confined establishment’, which in some Member States is interpreted to include pasture-based systems. These discrepancies impact the practical implementation of the AHL but are not intrinsic to the legal text itself.

The absence of interpretative jurisprudence from the Court of Justice of the EU (CJEU) further limits the harmonisation of interpretations across national jurisdictions. Although the EFTA Court's ruling in *Case E-8/24 Nordsjø Fjordbruk* provides some judicial guidance, it is not binding on EU Member States. The national legal proceedings originated from an action brought by an aquaculture company (Nordsjø Fjordbruk) against the Norwegian authorities because of the refusal of the latter to approve the company’s operating plan, which involved the movement of fish within the national territory between two different aquaculture establishments.

The AHL and its delegated and implementing acts are generally coherent, though certain provisions would benefit from technical refinement to enhance clarity and enforceability. Survey responses and interviews reveal limited concerns regarding misalignment between the AHL and tertiary legislation. Most stakeholders did not identify major contradictions. However, approximately half of the surveyed veterinarians reported the existence of provisions that appeared inconsistent, suggesting difficulties with technical interpretation rather than systemic incoherence. Isolated concerns were raised about the alignment of Implementing Regulation (EU) 2023/594 on African Swine Fever, but these were considered exceptions requiring targeted adjustments rather than evidence of broader legislative dissonance.

Inputs to the Call for Evidence confirm that while amendments—particularly to Delegated and Implementing Regulations 2020/686 and 2020/692—have improved coherence, opportunities remain for further alignment. Stakeholder recommendations focused on refining definitions and improving the categorisation of pathogens to reflect contemporary scientific understanding.

In conclusion, while from an outside eye the EU legal framework encompassing the AHL and its associated Delegated and Implementing Acts may be perceived

as complex, it is structured in a way that guarantees legal clarity and comprehensiveness and does not reveal any substantial legislative incoherence. However, while the broad structural and conceptual coherence of the AHL framework is evident, targeted refinements could enhance legal clarity and operational effectiveness, as identified inconsistencies are limited and primarily stem from interpretative divergences and/or implementation challenges rather than legislative flaws.

4.3.2. C 3.2 Is this legislation coherent with other related EU pieces of legislation and policies?

Key findings

- The AHL demonstrates strong alignment with EU food safety and disease prevention objectives, contributing to enhanced control systems and reduced antimicrobial reliance. Nonetheless, occasional operational inconsistencies arise during implementation, particularly in the coordination of sanitary and food safety measures and maintaining compliance under climate-related constraints.
- The AHL shows moderate coherence with other relevant EU legislation and policies, including animal welfare frameworks and EU financing instruments. Stakeholders have indicated that the future development of animal welfare legislation, particularly the Animal Transport Regulation, will need alignment with the AHL.
- The AHL presents a mixed level of coherence with other related EU legislation and policies. This encompasses both areas of substantial alignment and domains where opportunities for enhanced harmonisation are present.

The evaluation indicates that the AHL's coherence with other related EU legislation and policies is moderate overall. While there is substantial alignment in specific domains, most notably in food safety and disease prevention, opportunities for enhanced harmonisation remain with other key frameworks, particularly those related to animal welfare and EU financing instruments. This reveals a mixed picture, highlighting both strong convergence and areas where further regulatory synergy could be explored. In relation to food safety legislation, the AHL demonstrates a high degree of coherence. This is consistently confirmed by NCAs, farmers, veterinarians, and industry representatives. Stakeholders acknowledged that the AHL’s focus on disease prevention and biosecurity supports food safety objectives, particularly by reducing reliance on antimicrobials and enhancing control systems. However, some respondents, namely farmers and civil society organisations, reported occasional operational inconsistencies between food safety requirements and the AHL implementation. These include challenges in coordinating sanitary and food safety measures and maintaining compliance under climate-related constraints.

The coherence between the AHL and animal welfare legislation is assessed as partial. Across all sources of information, stakeholders , particularly NCAs and NGOs, identified practical issues where disease control measures, such as those for listed A diseases, including culling procedures and movement restrictions may conflict with animal welfare considerations . However, these concerns stem not from legislative incoherence within the AHL but rather from the distinct legal mandates and objectives of the AHL and Animal welfare framework, In addition, a few veterinarians are of the view that animal welfare principles or provisions are lacking within the AHL, despite acknowledging the intrinsic link between animal health and welfare. Additionally, NGOs raised further concerns regarding the compatibility of certification systems, such as TRACES, with welfare standards, citing a lack of clarity and functionality that has, in some cases, resulted in inefficiencies and the misclassification of animal types during transport. However, these challenges are primarily practical implementation issues, not legislative incoherence. Desk research, including the *Study supporting the Impact Assessment accompanying the revision of the EU legislation on the welfare of animals during transport*, also identified inconsistencies within the current Animal Transport Regulation. While a concept ([63]) for a new transport regulation, currently open for stakeholder feedback, seeks to address many of these shortcomings. Stakeholders highlight the need for future animal welfare legislation, notably the Animal Transport Regulation, to be aligned with the AHL. This alignment is considered important for ensuring regulatory coherence. Coherence with EU financing measures, including Regulation (EU) 2021/690, was assessed as partial. While the AHL promotes proactive risk-based approach to disease prevention and control , the co-financing regulation is largely reactive, offering support for disease losses rather than prevention strategies. Stakeholders, including NCAs and civil society, highlighted the need for better integration between the AHL and financial instruments, alongside clearer eligibility and funding guidelines although no specific examples or proposals were provided to illustrate how this could be achieved. A more coherent integration of the AHL's disease prevention model into EU funding programmes, particularly under Regulation (EU) 2021/690, could ensure the animal health system is more efficient and resilient in the long term.

Despite that, AHL has introduced a well-structured, risk based approach for animal disease control, its coherence with pre-existing, non-Lisbonised legislation—particularly the TSE Regulation (Regulation (EC) No 999/2001)—remains partial. Stakeholder input, particularly from competent authorities, has highlighted that maintaining separate legal frameworks for TSEs and other zoonotic diseases has resulted in regulatory fragmentation and implementation difficulties.

TSEs not being included in the AHL's disease categorisation process results in confusion among operators and authorities, it complicates disease prioritisation, influences co-financing decisions and weakens communication of health risks.

([63]) EUR-Lex - 52022SC0328 - EN - EUR-Lex

Addressing these inconsistencies would support both legislative coherence and more efficient allocation of disease-related EU funding.

In conclusion, this study reveals that the AHL presents a mixed level of coherence with other EU legislative and policy instruments. While it fully aligns with food safety and disease-specific legislation, certain aspects—such as those related to animal welfare, and EU financing mechanisms—would benefit from improved coordination and greater alignment. Enhancing clarity, strengthening cross-sectoral guidance, and considering targeted adjustments where appropriate could support a more consistent and integrated application of the AHL within the broader EU policy framework.

4.3.3. C 3.3 To what extent has the implementation of the AHL put in place a coherent animal health 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?

Key findings

- The AHL established a coherent EU-level legal framework, but its implementation across EU Member States has been uneven due to differing national legal systems, institutional capacities, and starting points. Some countries required minimal adjustments to their national systems, while others needed substantial legal changes, reflecting their diverse starting points and institutional contexts.
- National legal and institutional frameworks are still being adapted by most EU Member States to align with the AHL's provisions. This indicates that full coherence between the AHL and national frameworks has not yet been achieved across the EU.
- The AHL presents a mixed level of coherence with other related EU legislation and policies (TSE, zoonoses). This encompasses both areas of substantial alignment and domains where opportunities for enhanced harmonisation are present.

Key limitations

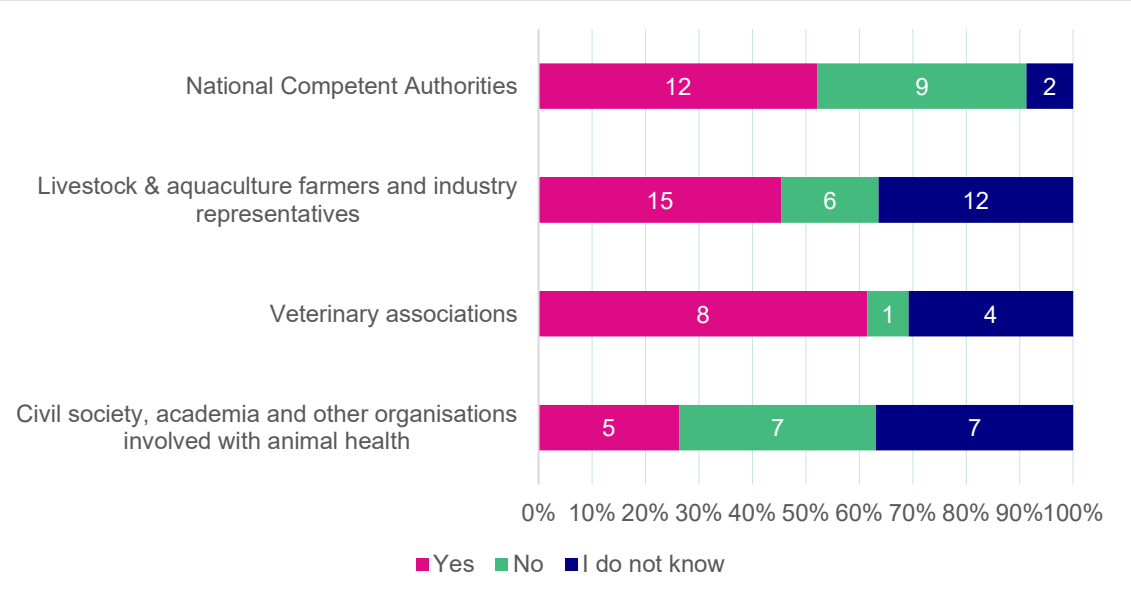
- The findings on the AHL's implementation reflect an evolving landscape, as several EU Member States were still in the process of adapting their national legal and institutional frameworks at the time of data collection. Therefore, this evaluation may not yet capture the Regulation's full effect on coherence across the EU

The implementation of AHL aims to establish a harmonised and risk-based approach to animal health management across the EU. However, as previously noted (EFFE 1.1), the national implementation has taken place unevenly, with significant variations between EU Member States. According to the input

provided by NCAs, most EU Member States are still in the process of aligning national frameworks with the AHL's provisions, which signals that full coherence has not yet been achieved. A few NCAs(e.g. Italy, Spain, and Latvia) reported no significant delays in the adoption of national measures associated with the AHL, insofar as aligning national laws with the AHL required minimal legislative adjustments. Conversely, several other NCAs (e.g. Bulgaria, Austria, Hungary, and Denmark) reported that substantial revisions were necessary, including the repeal of outdated legislation and comprehensive legal restructuring.

Largely in line with the observations referred above, evidence from the survey indicates that approximately half of the 91 respondents have identified diverging provisions, interpretations, or application issues between the AHL and national animal health measures and systems (Figure 14). Notably, several NCAs specifically reported that interpretations of certain AHL provisions differ among experts, creating uncertainty in their implementation. Additionally, a few stakeholders noted that legislation has not been fully adopted yet.

Figure 14 – 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: Consortium (N = 91)

These findings underscore that, while the AHL has introduced a coherent and comprehensive legal architecture at the EU level, its practical integration into the legal and institutional frameworks of Member States is somewhat partial and still underway. Consequently, a fully coherent Union-wide animal health policy is still in process of being realised , with a certain degree of variability persisting in the interpretation and enforcement of the AHL at national level across EU Member States.However, external inconsistencies persist with older legislation—such as the TSE and zoonoses frameworks—which were kept in force when the AHL was adopted in 2016 (see recital 17 of the AHL). In general, the lack of full EU-level

coherence continues to generate operational inefficiencies. A comprehensive review of such legacy legislation would help strengthen the integration and effectiveness of the EU's animal health policy framework and reduce administrative burden.

4.3.4. C 3.4 To what extent does the AHL facilitate international collaboration on animal health to address global challenges and promote harmonisation of standards?

Key findings

- The AHL is generally recognised as a valuable framework for tackling global animal health challenges and aligning with international standards, particularly among NCAs, civil society, and farmers. However, its perceived effectiveness beyond EU borders remains moderate, primarily due to varied uptake by third countries.
- While the AHL has demonstrably influenced legislative alignment in neighbouring regions and export-oriented sectors — especially for accessing the EU market — its broader promotion of harmonised animal health standards outside the EU is considered limited.

The AHL has been generally recognised as a valuable framework in the context of international collaboration to address global challenges and promote harmonised standards. However, its effectiveness remains contingent upon the consistency of its implementation across EU Member States and its perception and uptake by third countries.

Based on the responses gathered through in-depth interviews, NCAs generally tend to agree that the AHL represents a useful instrument for tackling global animal health challenges, besides being well aligned with international standards, such as those of the World Organisation for Animal Health (WOAH). A few NCAs (e.g. Portugal, Austria) highlighted that the AHL facilitates harmonised rules for the entry of animals and products of animal origin, encouraging non-EU countries to align with EU standards, particularly in the context of international trade. However, one NCA (Hungary) considers the AHL framework as a useful, yet moderately effective, instrument for addressing global animal health challenges. This is because some third countries have a limited understanding of the AHL and perceive it rather as a trade barrier..

Also, civil society, academia, and NGOs generally regard the AHL as a technically robust and valuable framework for addressing global animal health concerns, namely in areas such as disease prevention, zoonotic risk reduction, and antimicrobial resistance. .. Farmers echo this overall positive view, acknowledging that the AHL provides a beneficial framework for addressing global animal health challenges, at least to some extent. Conversely, industry operators perceive the AHL as having limited effectiveness beyond EU borders.

Global effects are considered unlikely except for those non-EU producers who adapt specifically to the regulation to access the EU market. This stakeholder group notes that third countries tend to prioritise national regulations of individual Member States rather than EU-wide legislation. Also, while they acknowledge that the EU has in place a harmonised import framework, export procedures remain fundamentally subject to the regulations and requirements imposed by third countries. These challenges are not directly attributable to shortcomings within the AHL itself, but rather stem from international trade policy.. As regards the veterinarians who were surveyed, this stakeholder group has opposing opinions. On the one hand, the AHL's structure is perceived as being less effective than the preexisting EU legal framework, and, as such, its adoption by third countries would not significantly contribute to solving global animal health challenges. On the other hand, for others, it is important to have a European framework that is useful and well done. Therefore, although the AHL is widely seen as an effective model of regional governance, its practical impact is limited due to inconsistent implementation within the EU and low visibility outside its borders.

The AHL has had a measurable, albeit moderate, influence on legislative developments outside the EU. According to most NCAs, the AHL inspires or influences the legislation of non-EU countries to some extent. Particularly, those countries engaged in trade with the EU have shown interest in aligning their national legislation with elements of the AHL, especially in areas relating to the entry and export of animals and animal products. This alignment is most evident in the requirements coordinated at the EU level, which third-country exporters must meet to access the EU market. One NCA refers, for instance, that there is a very close bilateral exchange with Switzerland due to its agreements with the EU. This country has closely harmonised its legal framework with the EU, including the AHL. On the other hand, the opinion of the industry operators is different. One industry operator reports that at the moment, there are no significant trade benefits, as from the outside, the EU is not yet seen as a unified bloc by third countries. Another industry operator states that some non-EU producers are adapting to the AHL for export purposes to the EU. For civil society, academia and other organisations, it may take some time before the full impact of the AHL globally is felt, but in the geographical area surrounding the EU, including the Balkans, measures to control ASF have already been implemented or are currently in the process of adoption. While there is evidence that the AHL has inspired legislative convergence in neighbouring states and among export-oriented sectors, its broader international influence remains modest.

The AHL, while intended to reinforce the EU internal coherence in animal health governance and align with international standards such as those of the WOAH, has nevertheless prompted mixed reactions among the EU's trading partners. Opinions gathered through in-depth interviews with NCAs reflect a lack of consensus on the extent to which the AHL raises concerns among third countries. Two of the NCA interviewees stated that AHL does not raise concerns from EU trading partners, as the requirements are aligned with WOAH. From this

perspective, the AHL is viewed as a legitimate, science-based framework that supports transparency and predictability in the context of multilateral trade rules (notably, within the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organisation). Conversely, two other NCAs mentioned that some third countries expressed concerns. This is the case of Turkey, which expressed reservations regarding the management of Bluetongue (BT) by the EU, and the USA, which stated objections concerning the vaccination strategy for highly pathogenic avian influenza (HPAI).

In 2023, a third country raised concerns regarding SPS within the WTO in response to the EU's import restrictions on ostrich meat due to HPAI. In 2024, the EU raised several SPS concerns related to AHL: i) 5 concerns regarding import restrictions due to ASF; ii) 2 concerns related to import restrictions because of HPAI; iii) 1 concern involving import restrictions on products of animal origin connected to BT ([64]). These instances reflect the concrete impact of the AHL on international trade relations.

Based on our findings, the AHL has supported international collaboration on animal health and contributed to the harmonisation of standards beyond the EU to a limited extent. It is recognised as a strong model of regional governance, but its overall impact is reduced by uneven implementation within the EU and limited acceptance in third countries. While it has influenced neighbouring regions and export-focused sectors, concerns about trade barriers persist. Strengthening internal consistency and external engagement will be key to increasing its global relevance.

([64]) World Trade Organisation (2024) Trade Concerns Database. Available here.

4.3.5. C 3.5 To what extent does the AHL promote cooperation with relevant international organisations, the exchange of information and joint response measures?

Key findings

- The AHL has strengthened the EU's role in international standard-setting bodies, particularly WOAH, and improved global information exchange on transboundary animal diseases. This is largely driven by commercial imperatives and active EU participation in relevant fora.
- The AHL's contribution to international cooperation is largely indirect and often secondary to broader EU external policy and trade objectives. Additional efforts to promote awareness and provide technical support could help reinforce the visibility and application of the AHL among international stakeholders.

The implementation of the AHL has played a significant role in fostering cooperation with international organisations, though the degree and nature of this cooperation remain somewhat nuanced.

Evidence from in-depth interviews and stakeholder inputs suggests that the AHL is broadly aligned with the EU's external engagement strategy in international standard-setting bodies. NCAs consistently acknowledge that the EU plays an active and influential role in shaping international standards through its participation in global and regional fora. This includes contributions to the development of international standards, particularly within the framework of the WOAH. This participation allows the EU to promote its animal health system within these forums, notably through its influence and proactive engagement in such discussions. Additionally, an NCA pointed out that the EU's engagement with third countries, especially in the context of trade, is pivotal. These countries must comply with the EU's AHL rules to export to the EU, creating a platform for international cooperation, which is largely driven by commercial interests.

Several respondents, including industry operators and civil society actors, noted that while cooperation—particularly with the WOAH—is evident and ongoing, it is driven more by the EU's external policy and trade imperatives than by the AHL's legal architecture itself. Thus, should the EU intend to inspire greater cooperation, it must take a more proactive stance, for instance, by actively promoting, publicising, and providing training on the AHL to international stakeholders.

The implementation of the AHL has had a positive, albeit uneven, impact on international information exchange and joint responses to emerging transboundary threats. According to interviewed NCAs and civil society stakeholders, one of the most notable contributions of the AHL has been the enhanced transparency and sharing of scientific and technical information, particularly through mechanisms involving the European Food Safety Authority (EFSA), which plays a crucial role in disseminating scientific opinions. Moreover,

the AHL has facilitated improved information exchange concerning transboundary threats, including joint responses to animal disease outbreaks. However, the full integration of the Animal Disease Information System (ADIS) with the World Animal Health Information System (WAHIS) has not yet been achieved. Nonetheless, it is anticipated that this integration will improve over time, enabling more effective and timely sharing of data. Several examples demonstrate the effectiveness of this exchange, such as the constant flow of information between the EU and WOAH on issues like HPAI, in terms of continuous information sharing on strains, vaccination strategies and containment measures; ASF in terms of collaboration on standard-setting and mutual enrichment of surveillance and response protocols; 'Sheep pox and goat pox' in terms of prompt information sharing leading to the revision of WOAH technical documents following outbreaks in Spain and Greece; 'Peste des Petits Ruminants' and also vaccination standards.

In conclusion, the AHL has contributed to fostering cooperation with international organisations, particularly WOAH, through active participation and commercial-driven exchanges. However, further efforts are required to strengthen the proactive promotion of cooperation and to enhance the integration of information exchange systems.

4.3.6. C 3.6 To what extent does the intervention comply with the 'do no significant harm' principle?

Key findings

- The AHL was not designed with the 'Do No Significant Harm' principle as a primary objective, but it generally has a neutral effect on the environment .Its interaction with EU biodiversity and circular economy objectives is limited.
- The AHL supports disease prevention in wildlife, contributing to biodiversity protection, but measures like mass culling for disease control can conflict with conservation and rewilding efforts.

Key limitations

- Our study encountered a somewhat limited scope of responses from participants concerning the AHL's interactions with circular economy principles, biodiversity, habitat conservation, and broader environmental and climate strategies. This might affect the comprehensive capture of all nuances related to these specific interplays.

The AHL's alignment with the objectives of the EU's Circular Economy Action Plan (COM/2020/98 final) is likewise limited. One NCA acknowledged opportunities for circularity through enhanced disease monitoring systems. Civil society and academic stakeholders highlighted that the AHL's implementation remains largely disconnected from broader circularity goals.

The AHL demonstrates a mixed interaction with EU biodiversity and habitat conservation goals. NCAs noted that the AHL contributes to preventing disease outbreaks that could threaten wild fauna. However, measures like mass culling for Category A diseases (e.g., African Swine Fever, Avian Influenza) can create tensions with species conservation efforts. Farmers and environmental stakeholders highlighted practical inconsistencies where restocking or rewilding efforts meet strict AHL biosecurity protocols. Furthermore, AHL's wildlife monitoring requirements present implementation challenges, as managing diseases like HPAI in wild bird populations often demands resources beyond feasible capacity. These interactions underscore the need for integrated planning, as the AHL can influence biodiversity outcomes through wildlife disease surveillance and culling but does not define conservation priorities or directly address habitat restoration.

In conclusion, the AHL was not designed with the 'Do No Significant Harm' principle as a primary objective, but it generally has a neutral effect on the environment . Therefore, its coherence with this principle can be considered limited. While its foundational objectives do not inherently cause environmental harm, the law's implementation has not been systematically designed to support broader EU environmental and climate strategies.

4.3.7. 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 environmental health?

Key findings

- The AHL is broadly aligned with key EU policy frameworks, including the European Green Deal, the Farm to Fork Strategy, the One Health approach and the Long-Term Vision for Rural Areas. However, stakeholder perceptions of this alignment differ. Civil society organisations, academia, and animal health actors view the AHL as contributing significantly to these objectives. In contrast, veterinarians, NCAs, farmers, and industry representatives perceive its contribution as more limited, due to ongoing challenges in implementation and practical integration.
- The AHL supports the functioning of the internal market by enabling the safe movement of animals and harmonising animal health rules across Member States. This contributes to the competitiveness of the EU agri-food sector.
- The AHL reflects a clear legislative commitment to the One Health approach, integrating animal, human, and environmental health considerations. Stakeholders acknowledge this foundation while also noting that practical implementation is still evolving, particularly with regard to environmental health and cross-sectoral collaboration.

From the evaluation, AHL exhibits a meaningful alignment with the broader strategic policy objectives of the EU, including the European Green Deal, the Farm to Fork Strategy, the One Health approach, and the Long-Term Vision for Rural Areas. However, the extent of its practical alignment and operational effectiveness is perceived differently by various stakeholder groups and is marked by both strengths and persisting challenges in implementation and integration.

Survey data indicate that civil society organisations, academia, and other entities involved in animal health largely perceive the AHL to contribute to a large or moderate extent to the European Green Deal, the Farm to Fork Strategy, and the One Health principle. These actors underscore the relevance of the AHL in fostering sustainable agricultural practices, improving disease prevention, and enhancing the resilience of the EU food system. In contrast, veterinarians, national NCAs, livestock and aquaculture farmers, and industry representatives generally assess the AHL's contribution to these policy areas as moderate or

limited. While these groups recognise the regulatory structure's utility, particularly in establishing a unified framework for animal health and disease management, their feedback suggests that implementation challenges temper the law's overall impact. The survey also reveals that only half of farmers and industry stakeholders believe that AHL contributes to the Long-Term Vision for Rural Areas. This suggests that although the AHL supports market functions and biosecurity, its benefits are not consistently felt in rural contexts or by small-scale operators who are central to rural vitality.

NCAs consulted during an in-depth interview stressed that the AHL facilitates the safe movement of animals across the EU, which is fundamental to maintaining a competitive internal market. However, different levels of implementation across EU Member States create challenges in maintaining safe animal movement. Similarly, the farmers and industry operators interviewed stated that the AHL framework contributes to the single market and competitiveness. However, one farmer highlighted that differences in implementation standards and the absence of consistent equivalence between EU and non-EU trade partners threaten the integrity of the internal market and create uneven conditions for competitiveness. On the other hand, one veterinarian stated that he is not sure because there is a contradiction between free trade and safely moving animals. Civil society, academia and other organisations involved with animal health show different points of view with respect to the contribution of AHL to the current and emerging EU policies for the long-term competitiveness of the EU agri-food sector. One interviewee noted that the AHL framework contributes to the single market insofar as EU Member States are more confident in the intra-EU movements of animals. Another one stated that a good economic assessment is needed to evaluate the competitiveness and contribution of AHL to a single market. Finally, another interviewee mentioned that the unification and harmonisation of AHL and animal welfare legislation into a more coherent legislative framework would simplify compliance for operators, reduce administrative burdens and create a fairer market.

Regarding the One Health approach, the NCAs interviewed mentioned that AHL embodies the One Health concept and continues to be relevant to the macro-objectives of this concept, but its effective implementation remains a challenge, despite the presence of some gaps. Civil society, academia and other organisations involved with animal health expressed different opinions on the extent to which the AHL contributes to reinforcing the One Health approach. One respondent mentioned that the One Health principle is now present in the list of diseases and on the emergency diseases, which was not the case before. Another interviewee stated that, with the AHL, there has been some progress toward a risk-based approach to disease detection, and the adoption of the One Health principles is an ongoing process. Finally, another argues that the One Health approach could have been stronger, as it lacks significant multidisciplinary inclusion of human and environmental health aspects, especially environmental ones.

In conclusion, the AHL demonstrates a strong degree of conceptual alignment with the EU strategic policy objectives, notably the European Green Deal and the Farm to Fork Strategy framework. It also contributes to the competitiveness of the agri-food sector by strengthening health standards and facilitating the safe movement of animals within the internal market.

However, the AHL was not designed to directly address environmental objectives or to support the goals outlined in the Long-Term Vision for Rural Areas, As a result, its contribution to these areas remains limited.With regard to the One Health approach, the AHL reflects a solid commitment at the legislative level to integrating animal, human, and environmental health concerns. Nonetheless, its practical implementation is still insufficiently developed. As such, while the AHL sets an important foundation, its operationalisation of the One Health approach remains incomplete and requires further integration, particularly with regard to environmental health and cross-sectoral collaboration.

4.4. Relevance

4.4.1. R 4.1 Is the AHL fit and relevant to current and emerging needs regarding Animal health?

Key findings

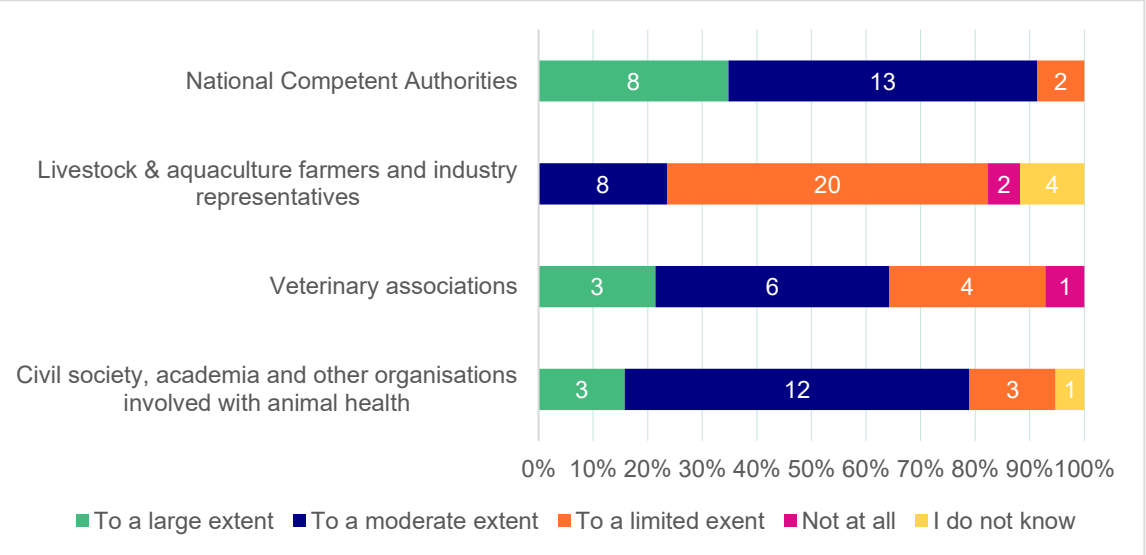
- The AHL is fit and relevant to current and emerging needs regarding Animal health. It leads to a level playing field and improves the possibilities of trading between Member States.
- The categorisation of diseases is seen as an improvement
- The AHL is, to a large extent, able to adapt and adequately reply to evolving threats and challenges in animal health by using a harmonised approach
- For the quickly spreading vector-borne disease, such as BT, the room to adapt to local circumstances resulted in control measures (i.e. vaccination policies) that differed between MS leading to challenges in trade and transport between MS.
- Despite the wealth of training provided by the BTSF programme, the relevant sector representatives and business operators are not well reached by NCAs in disseminating the acquired knowledge to relevant stakeholders, leading to suboptimal awareness of sector obligations

Key limitations

- The implementation of animal health visits by veterinarians is not detailed in the AHL, IAs, or DAs, which carries a risk of unequal fulfilment in MS. This may lead to uneven emphasis on disease prevention in farm practices, with risks of a higher disease burden or an unnecessary burden for a specific group of farmers.
- The implementation of biosecurity measures is not detailed in the AHL, IAs, or DAs, which creates a risk of unequal fulfilment in MS. This may lead to enhanced risks of disease outbreaks or an unnecessary burden for a specific group of farmers.
- There is no distinction in the AHL, IAs or DAs between varying animal production systems (i.e. organic, intensive, small-holder farm, industrial enterprises), which challenges the implementation of risk-based prevention measures.

From our study, we find that the AHL is fit and relevant to current and emerging needs regarding Animal health. This is based on stakeholder opinions from surveys, interviews and focus groups, as desk-based research on relevance associated with the AHL remains scarce. From the survey, most NCAs indicate that existing challenges in animal health can, to a large or moderate extent, be managed within the framework of the AHL and that supplementary legislation has been further developed in line with the experiences gained. These views are also shared by many livestock and aquaculture farmers, industry representatives and veterinarians (see Figure 15). In addition, all stakeholder groups emphasise the need for greater flexibility to respond to newly emerging diseases or variants.

Figure 15 – 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: Consortium (N= 91).

The AHL has not yet been fully implemented and national legislation adapted to the new AHL across all Member States; consequently, its implementation currently cannot be considered harmonised. Where the AHL is fully implemented, evidence from interviews and focus groups indicates that national implementation aligns well with the overarching objectives of the AHL. However, variations exist in practical implementation and enforcement among Member States, particularly concerning the risk-based approach in animal health visits and biosecurity measures.

A risk-based approach to preventing and managing animal diseases has been developed in several EU Member States (e.g., Ireland, Germany, France, Italy, and the Netherlands). In others, such as Lithuania and Hungary, it remains under development. Regarding stakeholder responsibility for preventing outbreaks through enhanced biosecurity and early disease detection, interview and focus group participants largely agreed that responsibilities are now more clearly defined. Many stakeholders perceive this increased clarity as potentially

contributing to the mitigation of major disease outbreaks and helping to limit disease spread.

However, the design and application of biosecurity measures are largely left to the discretion of Member States and operators, resulting in varied approaches across the EU.

Moreover, full enforcement of biosecurity measures at the farm level is still evolving. In many Member States, discussions are ongoing regarding the technical requirements that NCAs can enforce, how to involve practising veterinarians in improving biosecurity, and how to raise farmers' awareness and understanding of biosecurity principles. Pig and poultry farmers, especially those managing large numbers of animals, tend to be more advanced in implementing biosecurity measures. This is often due to existing national frameworks preceding AHL implementation and a higher level of awareness. In contrast, cattle farmers, extensive farmers, and smallholders tend to lag behind.

Some good practices in the implementation of biosecurity measures have been identified. For instance, veterinarians in Germany and Italy have been providing biosecurity training to farmers. In March 2025, the Netherlands enacted legislation ([65]) requiring poultry farmers to develop a farm-specific biosecurity plan in accordance with the AHL, demonstrating that enforcement of AHL provisions is still progressing. In Latvia, the ASF situation resulted in strong emphasis on implementing and enforcing biosecurity measures in pig farms.

Stakeholders, consulted in interviews and focus groups, considered that the AHL was mainly based on rules set out in various pre-existing Union Acts. The AHL builds upon lessons learned from past experience, updates of international standards, modern epidemiological approaches, as well as scientific progress, WOAH standards, epidemiological data, and EFSA opinions. The new approach in the AHL is therefore relevant to current and emerging needs because requirements for disease prevention and preparation for possible outbreaks are now brought together in one legal framework, together with requirements for identification and registration of animals, for entry of animals into EU and their movements in EU, and for disease control and eradication, aspects that are further detailed in supplementing DAs and IAs.

Previously, there was a specific directive for each disease or topic. In contrast, the AHL now serves as an overarching framework, with information organised by topic rather than by disease. Stakeholders from NCAS and the sector acknowledged initial difficulties in locating relevant legal text for particular diseases; they valued bringing most of the EU rules into a simpler law with a better focus on the key priorities in tackling diseases. In this respect, most respondents in all consultation activities expressed a desire for further guidance in navigating the new AHL.

([65]) https://zoek.officielebekendmakingen.nl/stcrt-2025-6633.html

In relation to the extent to which the AHL fosters training, Article 11 of the Regulation stipulates that operators and animal professionals must possess adequate knowledge of animal health. The Commission has developed the Better Training for Safer Food (BTSF) programme to support this requirement, primarily targeting official veterinarians in Member States. However, during focus groups, sector representatives expressed a desire for broader access to BTSF training modules, particularly those covering biosecurity and related measures, for farmers and other stakeholders. Such access, they argued, would enhance awareness and understanding of the regulatory requirements.

NCA representatives reported high levels of satisfaction with the BTSF programme, which engages NCAs from multiple Member States. Although the BTSF is primarily designed for training national authorities, it operates on a 'train-the-trainer' model., it is therefore incumbent upon NCAs to disseminate the acquired knowledge to relevant stakeholders, NCA participants suggested that the programme would be more effective if training materials were made available in national languages and accessible to farmers' organisations However, initiatives to do so train relevant stakeholders are still lacking in most MS. Moreover, national trainers should ensure that dissemination activities incorporate national legislation enacted to align domestic law with the AHL.

A clear consensus emerged that categorising animal diseases is an essential tool for harmonising and rationalising the prevention and control of diseases (as indicated by the CfE responses, surveys, interviews, and focus groups). Stakeholders and scientific experts agree on the criteria for categorising and prioritising. NCAs view this categorisation as a valuable instrument for streamlining efforts to prevent and control animal diseases. Furthermore, the criteria for addressing emerging diseases are in place.

Since the adoption of the AHL, improvements have been made to the categorisation, particularly concerning category C vector-borne diseases. However, some stakeholders have suggested that certain vector-borne diseases would benefit from more consistent and clearly defined regulations (see Box 11).

Overall, stakeholders consider the AHL to be relevant and fit for purpose. Responses from all consultations indicate that the AHL has enabled the establishment of clearer rules, which support both public authorities and the farming sector in preventing and eradicating diseases. Additionally, the delineation of roles and responsibilities among relevant stakeholders is clearly defined (as reflected in the surveys, interviews, and focus groups).

Box 11 – Bluetongue virus

Bluetongue virus (BTV) is present in several Member States. In 2023, an outbreak of BTV-3 emerged in the Netherlands, severely affecting the sheep population and also causing morbidity and mortality in cattle ([66]). In Spain, BTV-1 and BTV4 occurred, and in Belgium and Germany BTV-3 outbreaks led to withdrawal of the BTV free status ([67]).

BTV is classified as a Category C disease under the Animal Health Law (Regulation (EU) 2016/429). Category C diseases are those of concern to some Member States, necessitating measures to prevent their spread to disease-free areas or those with eradication programmes. This classification permits competent authorities to implement optional eradication programmes aimed at controlling all known serotypes (1 to 24) ([68]). Consequently, various Member States have adopted differing measures to curb disease spread.

Building upon these varied national strategies, challenges have emerged in the context of intra-EU animal movement. Commission Delegated Regulation (EU) 2020/688 governs such movements and allows for specific derogations, enabling the destination Member States to accept animals under mutually agreed health conditions. To implement these derogations, the destination MS must notify both the European Commission and other Member States of the authorised movement criteria. However, due to differences in national approaches, including vaccination and disease control policies, these health conditions often vary not only between destination and origin Member States but also across transit Member States. This variation has led to regulatory inconsistencies, resulting in confusion and trade disruptions.

During stakeholder consultations, many expressed the need for a harmonised EU-wide approach to managing BTV. Opinions varied on whether this should involve reclassifying BTV (specifically BTV-3) or all 24 serotypes or implementing uniform pre-transportation health requirements.

([66]) M. Holwerda, I.M.G.A. Santman-Berends, et al. Emergence of bluetongue virus serotype 3, the Netherlands, september 2023 Emerg. Infect. Dis., 30 (8) (2024), pp. 1552-1561, 10.3201/eid3008.231331.

([67]) https://food.ec.europa.eu/horizontal-topics/committees/paff-committees/animal-health-and-welfare_en#meetings_2023

([68]) https://food.ec.europa.eu/animals/animal-diseases/surveillance-eradication-programmes-and-disease-free-status/bluetongue_en

4.4.2. R 4.2 To what extent is the AHL able to adapt and adequately reply to evolving threats and challenges in animal health?

Key findings

- The AHL is, to a large extent, able to adapt and adequately reply to evolving threats and challenges in animal health by using a harmonised approach.
- The AHL can address new disease threats with uniform minimum requirements for diseases listed in categories A and B, or with more flexibility for disease prevention and control measures in EU MS for diseases listed in categories C, D, and E.
- Separate EU legislation exists to manage diseases such as Salmonella and TSEs. Consequently, these diseases did not undergo the same process of listing, categorisation, and subsequent prevention and control measures as outlined by the AHL. To simplify compliance and implementation, it would be beneficial to create a unified legal framework encompassing all farm-impacting diseases, including Salmonella and TSEs.
- Member States are required to align national programmes for diseases of national importance with the provisions outlined in the AHL.

Key limitations

- Depending on the categorisation, flexibility for disease prevention and control measures for diseases listed in categories C, D, and E can lead to a heterogeneous distribution of mitigation measures, which are beneficial for controlling the disease in the Member States but can impact intra-EU trade.

The AHL establishes a harmonised framework for the control and eradication of listed diseases. While it ensures uniform minimum requirements for diseases listed in categories A and B, its application to categories C, D, and E remains less straightforward. One of the principles of the AHL is the risk-based approach when dealing with animal disease outbreaks. Member States can implement measures based on their specific epidemiological contexts, financial resources, and national priorities. This means that the Member States have a margin for manoeuvre when adopting disease prevention and control measures. Flexibility is therefore needed. This flexibility has led to the heterogeneous distribution of mitigation measures, which are beneficial for controlling the disease in the Member States but can impact intra-EU trade ([69]). Variations in national approaches to disease

([69]) Roch, F. F., & Conrady, B. (2021). Corrigendum: Overview of Mitigation Programs for Cattle Diseases in Austria. Frontiers in veterinary science, 8, 822386.

control, such as differing responses to BTV, have been cited by stakeholders, including NCAs, farmers' organisations, and trade associations, as a source of trade disruption.

The structure of the AHL, with the mechanisms of delegated and implementing acts, facilitates the timely updating of measures in response to evolving threats and challenges. New measures are implemented based on scientific evidence and lessons learned, for example during outbreaks. An example was amending Delegated Regulation (EU) 2020/687, in which control measures were made proportionate to the risks involved ([70]).

The large-scale outbreaks of HPAI in a number of Member States (e.g. FR and NL) and the increasing cost needed for the eradication and control called for additional measures to be implemented. The implementation of vaccination for BTV in a number of MS and HPAI (see Box 8) is an example of the ability of the AHL to respond to evolving threats and challenges. While the AHL provides a comprehensive framework for managing a wide range of infectious diseases, separate EU legislation exists to manage certain major diseases such as Salmonella and TSEs. Consequently, these diseases did not undergo the same process of listing, categorisation, and subsequent prevention and control measures as outlined by the AHL. This results in a misalignment with the AHL's core approach and may lead to disproportionate surveillance and control. For example, in 2024, the Netherlands allocated EUR 4.2 million (22% of its monitoring budget) to BSE and TSE surveillance, with costs rising due to testing (a 20% rise in BSE testing costs) linked to Bluetongue virus three outbreaks(BTV-3) ([71]). To simplify compliance and implementation, it would be beneficial to create a unified legal framework encompassing all farm-impacting diseases, including Salmonella and TSEs.

[70] http://data.europa.eu/eli/reg_del/2020/687/2023-05-03

([71]) JAARVERSLAG VAN HET MINISTERIE VAN LANDBOUW, NATUUR EN VOEDSELKWALITEIT (XIV) EN DIERGEZONDHEIDSFONDS (F) 2024, here.

TSEs and the AHL

Current 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 ([72]).

- A detailed instruction for the MS on how to act in case of the occurrence of a TSE
- Also detailed instructions (not risk-based) on monitoring of the population at risk

Substantial costs associated with transmissible spongiform encephalopathies (TSEs) in the Member States are significant. For instance, the Netherlands allocated EUR 4.2 million (22% of its monitoring budget) for bovine spongiform encephalopathy (BSE) and TSE monitoring in 2024. A considerable portion of this budget was dedicated to the testing of each deceased bovine sent to rendering plants. In 2024, there was a notable increase in the number of ruminants that died and required testing, primarily attributable to outbreaks of Bluetongue virus 3 (BTV-3)([73]). This uptick has resulted in a 20% rise in BSE testing costs.

WOAH -Classical versus atypical BSE

There is a distinction to be made between these two forms:

- **Classical BSE** occurs through the consumption of contaminated feed (see section 'transmission and spread'). Whilst classical BSE was identified as a significant threat in the 90s, its incidence has markedly decreased over the past years, as a result of the successful implementation of effective control measures, and is now estimated to be extremely low (close to 0 cases/year worldwide).
- **Atypical BSE** refers to naturally and sporadically occurring forms, which are believed to occur in all bovine populations at a very low rate, and which have only been identified in older bovines when conducting intensive surveillance.

In the early 2000s, prions causing atypical BSE were identified as the result of enhanced surveillance for transmissible spongiform encephalopathies. The yearly incidence of atypical BSE is estimated to be negligible. Indeed, whilst to date there is no evidence that atypical BSE is transmissible, recycling of the atypical BSE agent has not been ruled out, and therefore, measures to manage exposure risk in the feed chain continue to be recommended as a precautionary measure.

The TSEs and the other zoonotic diseases covered by Regulation No 999/2001, Directive 2003/99/EC and Regulation No 2160/2003 have not undergone the same process that led to the listing and categorisation of all other diseases covered by the AHL and its subsequent delegated and implementing acts, including a complete scientific review by EFSA. The current rules on TSEs also have a major influence on the EU legislation on animal by-products. The decision to keep the abovementioned legislation on TSEs in place when the AHL was adopted almost ten years ago (see recital n.17) could

find several valid justifications at that time. However, in the light of all new scientific knowledge, experienced gained on TSEs and their impact on human health and evolution of international standards, it appears appropriate to review at least the existing rules on TSEs to ensure their full coherence with the principles and criteria established in the AHL, first of all to ensure that the administrative burden related to their implementation is proportionated to the health risks posed by the diseases in question.

Member States are required to align national programmes for diseases of national importance with the provisions outlined in the AHL.

Respondents welcomed the structured approach to disease prevention and control in the AHL. However, some respondents have raised concerns about certain emerging diseases, such as LPAI and BT, regarding their categorisation. Some respondents from academia mention that this can have negative socio-economic impacts. (e.g., the risk of reassortment of human and poultry influenza strains potentially leading to a new pandemic). Additionally, the uniform approach for diseases in Cat A (e.g. ASF, foot-and-mouth disease (FMD), HPAI) has implications for disease management, especially in Member States with pre-existing contingency plans developed after previous outbreaks and tailored to their local circumstances (e.g. NL and DK).

From the study, no examples of AHL, DA, or IA having adopted new diseases were identified. However, regarding the need to include new contagious animals and zoonotic diseases under the AHL, stakeholders view that the flexibility requested by NCAs often represents a positive aspect, as it allows measures to be adapted to specific risk conditions. This logic is valid when applied to the identification, assessment, and management of risks. However, such flexibility has likely weakened or diminished transnational coordination mechanisms, which are crucial for addressing diseases and phenomena without borders, such as those involving vectors and wildlife (e.g. BTV). The fragmentation resulting from differing strategies and logic among Member States can lead to significant challenges in achieving consistency and uniformity among Member States.

The AHL seeks to provide a coherent expression of the ‘One Health’ concept, addressing the interconnections between animal and public health, wildlife, the environment, food and feed safety, animal welfare, food security, economic factors, and social and cultural issues. However, the AHL does not cover all diseases to the same extent. For example, it addresses Salmonella and other specified food-borne zoonotic agents, as well as transmissible spongiform encephalopathies (TSEs), only insofar as specific regulations are not already established in other Union legislation (Recital 17, AHL).

([72]) https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001R0999
([73])JAARVERSLAG VAN HET MINISTERIE VAN LANDBOUW, NATUUR EN VOEDSELKWALITEIT (XIV) EN DIERGEZONDHEIDSFONDS (F) 2024, here.

However, according to the public health officials interviewed, the logic behind disease categorisation is not entirely sufficient for a fully integrated One Health approach. New emerging zoonotic diseases, besides the ones mentioned above, which necessitate a transnational and interdisciplinary approach, are frequently excluded from national intervention and control priorities. The existence of wildlife reservoirs and the associated control and monitoring cross-border challenges underscore the need for coordinated strategies across animal health, human health, and environmental health, which are currently lacking. Wildlife surveillance now predominantly targets diseases specified in the AHL, along with its DA and IA, such as ASF, rabies or avian influenza. The EU is already setting up a coordinated surveillance system under the One Health (OH) approach for new or emerging cross-border pathogens that threaten the Union, such as the ENETWILD programme to improve surveillance in the EU for zoonoses in the environment, and the methods for surveillance of these pathogens in the environment ([74]).

([74]) https://www.efsa.europa.eu/en/supporting/pub/en-8241

4.4.3. R 4.3 Are there issues that arose after the adoption of the Regulation that would require further attention in view of the objectives pursued?

Key findings

- For quickly spreading vector-borne diseases, such as BT, the room to adapt to local circumstances resulted in different approaches between Member States, which led to trade obstructions.
- COVID-19 in mink and BT in ruminants were two issues that arose after the adoption of the Regulation and were addressed in the EU MS affected. MS learned to work with the AHL in this challenging situation. To a large extent, the AHL, including DA and IA, worked according to expectations.
- Improved biosecurity in pig farms leads to less endemic disease and less antibiotic usage in those farms, which requires further attention for prevention on cattle (veal) and poultry farming.

Key limitations

- The initial notification process in ADIS requires comprehensive information, which may be burdensome in urgent situations.

Regarding the assessment of the appearance of new emerging diseases and pathogens, two main examples were mentioned during the consultation activities: 1) COVID-19 in mink and 2) BTV in ruminants, which were discussed in previous sections.

Limiting antimicrobial resistance is also an objective of the AHL. Regarding assessing the development and spread of resistance to antimicrobial agents post-AHL implementation, literature shows that increased biosecurity in pig farms leads to less endemic disease and less antibiotic usage in those farms ([75]),([76]). Regarding prudent antibiotic use, there may be a risk that too rigid protocols for reducing AB usage could undermine veterinarians' professional judgment. Regarding animal health and welfare, there should remain flexibility to effectively treat sick animals, for which professional veterinary judgment should remain a priority, not limited to 'exceptional circumstances'.

The initial notification process in ADIS requires comprehensive information, which may be burdensome in urgent situations. A more efficient approach could

([75]) Postma, M., Backhans, A., Collineau, L., Loesken, S., Sjölund, M., Belloc, C., ... & Dewulf, J. (2016). The biosecurity status and its associations with production and management characteristics in farrow-to-finish pig herds. Animal, 10(3), 478-489.

([76]) Dhaka, P., Chantziaras, I., Vijay, D., Bedi, J. S., Makovska, I., Biebaut, E., & Dewulf, J. (2023). Can improved farm biosecurity reduce the need for antimicrobials in food animals? A scoping review. *Antibiotics*, *12*(5), 893.

involve a pre-notification system (as soon as laboratory confirmation is available), allowing Member States to report confirmed cases promptly. This would be followed by an update with additional details as they become available. Such a system would enhance ADIS's responsiveness.

Consultations with various stakeholders revealed no significant concerns regarding animal health, the functioning of the internal market, or any adverse effects on animal health, public health, or the environment following the adoption of the AHL that would require further attention. Nevertheless, some aspects related to external coherence were raised and are discussed in Section C 3.2.

Besides the possibility to vaccinate against HPAI and BTV, no evidence was found to support the adequacy of the AHL in implementing new technological developments that could be evaluated. This might be because, since the implementation of the AHL, besides vaccination against HPAI and BTV, no new cost-effective developments that support animal disease prevention, monitoring, and control have been implemented. The developments in vaccine production are under the responsibility of the European Medicines Agency (EMA).

No evidence was found to evaluate new potential risks from pre-accession countries or third countries.

4.5. EU added value

4.5.1. EUAV 5.1 EU AHL has added value compared to what could have been reasonably achieved by Member States acting alone

Key findings

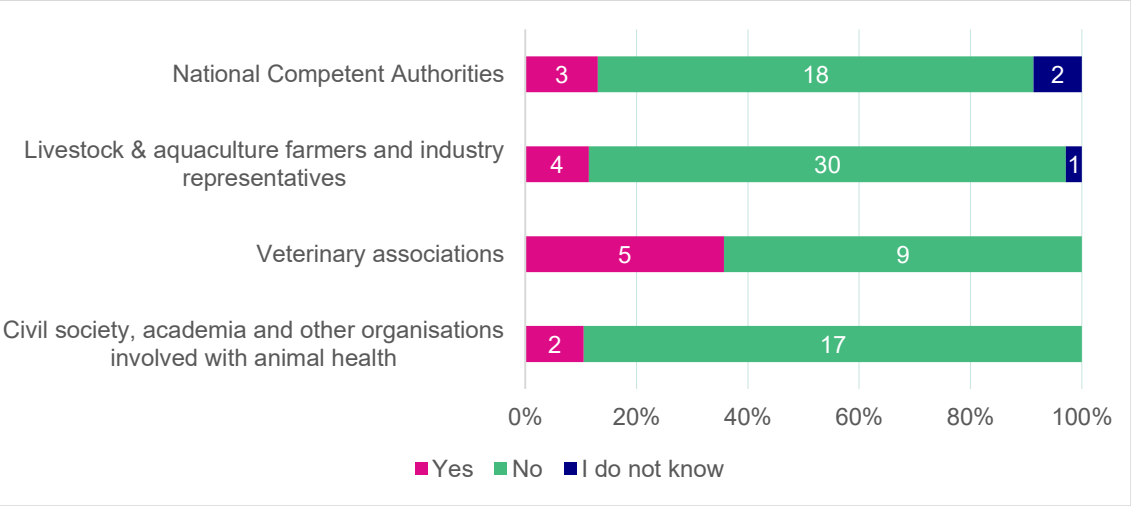
- The AHL has contributed to improved coordination of animal disease prevention and control measures within the EU.
- The AHL has added value: harmonised rules for preventing and controlling critical List A and B animal diseases across the EU, resulting in overall efficiency gains, a level playing field, and improved intra-EU trade.

Key limitations

- Lack of detail in prescribing the requirements for animal health visits and biosecurity in the AHL, DA and IA leaves the implementation of these elements at the discretion of the MS and has led to difference in advancement of these measures across EU MS.

From the Surveys, we identified clear evidence that all stakeholders clearly found that the same results would not have been achieved by national animal health measures and systems alone without an EU AHL (see Figure 16). Most stakeholders agree that maintaining the same levels of animal movements and trade of animal products (without increased risks of disease introduction or outbreaks) between Member States would not be feasible without the AHL.

Figure 16 – 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: Consortium (N= 91)

The AHL has shifted the focus from reactive to proactive animal health measures, marking a significant change from prior legislation that primarily addressed existing threats rather than anticipating new issues. The major benefit observed due to the implementation of the AHL is the more streamlined approach. Prior to the AHL, animal health regulations were often seen as cumbersome and difficult to navigate, but the AHL has simplified procedures. With the AHL, there is a clearer framework for cooperation among Member States, compared to earlier legislation, where responsibilities were less defined. This clarity supports more effective disease control measures across borders. Before the AHL, the regulatory landscape was fragmented, leading to inconsistencies in disease management practices across Member States.

Given the epidemiological developments in Europe since 2021, particularly regarding ASF, BT, EHD, SPGP, HPAI, and more recently FMD, the EU has shown a degree of resilience. Whether this resilience is directly linked to the AHL remains unclear, and only long-term data will establish a causal relationship between the AHL and animal health or trade.

Nonetheless, some stakeholders have reported discrepancies in the implementation and enforcement of regulations across Member States, complicating the movement of animals across borders (see Box 11). This issue, however, is not specific to the AHL and can arise with any EU legislation that allows for flexibility at the Member State level to accommodate local circumstances (especially for diseases in categories C and D).

However, most survey respondents (30 out of 35) and all interviewees indicated that it would not be feasible to maintain the same levels of animal movements and trade of animal products between the EU and third countries without the AHL. The large majority indicates that the AHL facilitates trade with third countries by reducing administrative burdens for both sides in the import and export processes. The EU's added value also lies in its monitoring systems (ADIS), which are seen as a significant achievement. These systems provide essential data for effective control.

The AHL has contributed to improved coordination of animal disease prevention and control measures within the EU. Prior to its adoption, existing EU regulations already provided rules for responding to animal health emergencies. However, the AHL placed greater emphasis on prevention and on farmers' responsibilities for maintaining animal health. The gradual implementation of regular animal health visits, biosecurity measures, and enhanced training for farmers and sector representatives on biosecurity has fostered better coordination for animal disease prevention and control in EU Member States. This improvement can, at least partially, be attributed to the AHL.

Before the implementation of the AHL, wildlife disease monitoring was not homogeneous in the EU, and often restricted to certain pathogens, regions, and/or population compartments. Efforts were made to develop wildlife disease

monitoring programmes, which are a component of general animal health surveillance systems in many countries. Including wildlife in the AHL ensures that disease surveillance and monitoring in wildlife are implemented in all MS, despite the fact that resources available and monitoring strategies applied differ between MS. The biology and characteristics of pathogenic agents, as well as fluctuations in wildlife populations and changes in their management, will result in regional differences between monitoring schemes([77]). Monitoring in wildlife as regards rules for the prevention and control of animals affected by category A diseases is therefore an important part of the contingency plans as described in Delegated Regulation (EU) 2020/687.

An example of the role of the AHL in facilitating trade with 3rd countries is the reduction of existing trade restrictions on the importation of unvaccinated live poultry from France and unvaccinated live ducks from the APHIS-recognized European Poultry Trade Region (EPTR), as well as Iceland, Switzerland, Liechtenstein, and Norway to the USA. The evaluation by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service of France's HPAI vaccination program supports the conclusion that APHIS can maintain safe agricultural trade with reduced restrictions on these unvaccinated poultry and poultry products/byproducts derived from non-vaccinated flocks. This conclusion aligns with the World Organisation for Animal Health (WOAH) standards regarding the impact of HPAI vaccination on trade. Vaccinated poultry (including hatching eggs and day-old ducklings derived from vaccinated poultry) and products/byproducts derived from vaccinated poultry will remain ineligible for import. Vaccinated birds may not show signs of HPAI infection, which could lead to the export of infected live animals or virus-contaminated products to the United States ([78]).

([77]) Cardoso, Beatriz, et al. *Stepping up from wildlife disease surveillance to integrated wildlife monitoring in Europe*. Research in Veterinary Science 144 (2022): 149-156.
([78]) USDA Reduces HPAI Restrictions on Poultry from France and the European Union | Animal and Plant Health Inspection Service

4.5.2. EUAV 5.2 To what extent did this intervention strike a balance between action at EU level and national action? Is it proportionate?

Key findings

- The AHL has balanced coordination at EU level and national action by providing different categories of diseases (Lists A-E) that differ in the required uniformity of interventions at EU and national levels.
- The balance between actions at EU and national levels is overall proportionate, but it can be challenged notably for diseases categorised under lists C-E when multiple MS are faced with outbreaks and implement different control strategies. In such cases, more EU intervention might improve uniformity in disease prevention and control measures.
- The harmonised framework to control outbreaks for category A and B diseases with AHL and its DA and IA ensures a uniform approach between MS. For category C-E diseases and non-listed diseases, MS have substantial flexibility to take into account local circumstances.

There is broad consensus among survey, interview, and focus group participants on the necessity of a harmonised framework for animal health standards across the EU. Respondents underscore that uniform implementation by all Member States is vital to ensure the effectiveness of the AHL. While proportionality and flexibility are central to successful enforcement, achieving an optimal balance remains challenging.

While flexibility in applying the AHL allows Member States to tailor measures to local risk conditions, particularly in risk identification, assessment, and management, this adaptability may have inadvertently weakened cross-border coordination mechanisms. Given that diseases, especially vector-borne and wildlife-related ones, do not respect national boundaries, divergent strategies among Member States can lead to inconsistencies, undermining uniformity.

Several NCAs consider EU legislation to be excessively stringent and lacking in flexibility. While alternative measures that achieve equivalent sanitary objectives could be explored, in their opinion, the legislative change hinders Member States' capacity to respond promptly to emerging challenges. Moreover, several NCAs have proposed improving the responsiveness and efficiency of the Union by ensuring more timely updates to EU legislation, particularly in relation to disease categorisation and prioritisation.

The current AHL framework does not prevent NCAs from going beyond EU standards. Member States with high livestock densities and significant trade volumes, such as the Netherlands and Denmark, continue to apply stricter national standards to mitigate disease risk and ensure trade continuity. The

existence of such national measures within an EU framework highlights the complementary role of local adaptations rather than a substitution for EU-level regulation. One aquaculture industry representative noted that compared to the pre-AHL system, rules are not stricter, for example on the management of occurrence of listed diseases. Member States have retained more control and flexibility over the application of exemptions to the prior authorisation.

In countries characterised by diverse farming systems, including extensive free-range pig and poultry production, stakeholders stress the importance of regulatory flexibility. For example, current national interpretations of biosecurity rules by NCAs are perceived as overly uniform. Farming sector representatives advocate for differentiated approaches supported by appropriate policy instruments and social measures. The study shows that, given growing societal support for free-range farming, developing targeted guidelines and assessment tools is increasingly important. A 2023 review across 28 countries (15 EU Member States) identified 74 different biosecurity assessment methods, varying in objectives, evaluators, data collection, and feedback mechanisms. While this diversity reflects differing epidemiological and production contexts, it also poses challenges for cross-country comparability([79]). While the study team observed that current research and national approaches tend to focus on biosecurity implementation in intensive farming, an exception is the University of Ghent's BIOCHECK tool, which also assesses biosecurity in small-scale and outdoor farming ([80]).

([79]) Duarte, F., et al., (2025). *Methods to assess on-farm biosecurity in Europe and beyond*. Preventive Veterinary Medicine 239: 106486.
([80]) https://biosecure.eu/

4.5.3. EUAV 5.3 What adaptations could increase the additionality of EU-level action?

Key findings

- Clear, structured guidance from EU towards more streamlined national, regional and local uniformity in approaches for disease prevention and control for public and private stakeholders would enhance understanding and accessibility of the regulatory measures and support compliance
- EU support for tailored, sector-specific guidance improves regulatory clarity and can increase additionality of EU-level action
- National, regional and local standards may vary in content to accommodate regional variation, but should lead to a more consistent level of risk-prevention in MS
- Sharing good practice in biosecurity requirements and strategic use of the veterinary workforce would strengthen implementation capacity in EU MS.

Key limitations

- Knowledge to apply a risk based approach varies between MS NCA's. In some cases this leads to overly strict measures for example related to the application of biosecurity measures. Education of current and future CA in applying risk based approaches may lead to improvements.

Several targeted adaptations should be considered to increase the additionality of EU-level action, particularly in relation to regulatory clarity, workforce capacity, and standard harmonisation.

Clear, structured guidance for public and private stakeholders would enhance accessibility and support compliance. Consultation feedback highlighted the need for topic-specific tools—such as roadmaps—to help occasional users navigate complex legislation, particularly in areas like disease control. Regularly updated guidance would improve both usability and accuracy, making EU law more accessible to a wider range of stakeholders. This has a direct link with the BTSF programme. Although a task of NCA guidance by the Commission is appreciated by stakeholders.

Tailored, sector-specific guidance improves regulatory clarity and could be expanded to other domains. The European Association of Zoo and Wildlife Veterinarians' AHL handbook demonstrates the value of bespoke resources for specialised stakeholders. Similar instruments—developed for artificial insemination centres, animal traders, or aquaculture operations—could facilitate compliance by providing clear, sector-relevant interpretations of legal obligations.

Standards must balance clarity with sufficient flexibility to accommodate regional variation. While flexibility is necessary for local authorities to adapt measures to specific conditions, overly broad definitions risk inconsistent interpretation among Member States. Unambiguous definitions, coupled with the capacity for local adjustment, would reduce complexity. The development of detailed guidelines at the national, regional or local level —with possible support from the EU and input from EU reference institutes—could lead to a more consistent level of risk-prevention in MS.

Harmonised biosecurity requirements and strategic use of the veterinary workforce would strengthen implementation capacity. Stakeholders have emphasised the importance of minimum biosecurity standards for animal keepers, alongside clear instructions for NCAs in assessing compliance. EU reference institutes could coordinate establishing such standards, promoting consistency across Member States. In parallel, the effective implementation of the AHL is hindered in some regions by budget constraints and a lack of human resources among CAs. Allowing private veterinarians and other duly trained professionals and technicians to undertake certain official duties—under appropriate oversight—could ease these pressures and encourage professionals to work in underserved rural areas. Sharing good practice in biosecurity requirements and strategic use of the veterinary workforce would strengthen implementation capacity in the EU MS.

5. Conclusions

5.1. Effectiveness

The alignment of national legislation with the AHL across the 27 Member States has not yet been fully completed and, in several cases, remains partial or ongoing. This is largely due to the complexity of repealing, integrating, and consolidating existing national laws in line with the AHL, despite the significant resources allocated to the process and the support provided at the EU level. Moreover, this alignment process has taken place during a challenging transition period, marked by the COVID-19 pandemic, which diverted administrative capacity and delayed legislative reforms. In parallel, the continuously evolving epidemiological situation, including outbreaks of diseases such as ASF and HPAI, required urgent response measures, further stretching national resources. These external pressures have contributed to delays in national transposition and have complicated efforts to fully absorb and operationalise the new legal framework.

The AHL represents a major step forward, shifting from a reactive eradication model to a prevention-focused and risk-based approach. It has significantly simplified and harmonised the EU's legislative framework by replacing a fragmented set of rules with a single, coherent and wider system, improving clarity and consistency for authorities and stakeholders alike. However, the transition to this broader framework has proven challenging. The complexity of the AHL and its numerous Implementing and Delegated Acts has made national alignment and practical application difficult in some cases. This shift also demands a change in mindset, requiring authorities and operators to move from prescriptive, rule-based compliance toward flexible, risk-based decision-making.

The AHL has simplified the legal framework and demonstrated progress toward its objectives of preventing and controlling animal diseases, particularly those transmissible to other animals or humans, and has not caused any trade disruptions despite the epidemiological situation. It has strengthened disease prevention and control by introducing a risk-based approach across key areas such as disease categorisation, surveillance, and vaccination strategies, and through clearer role definitions for competent authorities. These changes have improved early detection mechanisms and enabled more rapid responses by Member States, contributing to better control of outbreaks and overall improvements in animal health. However, uneven implementation and differences in local capacities and contexts continue to hamper the full and consistent application of the AHL across the EU.

Despite notable progress, uneven implementation across Member States, particularly in the implementation and enforcement of mandatory animal health

visits and biosecurity measures, continues to limit the full potential of the AHL. In some countries, visits are well integrated into national programmes and carried out regularly, while in others, enforcement remains inconsistent due to gaps in legislation, limited veterinary capacity, or lack of awareness among farmers. Similarly, while biosecurity requirements have been strengthened at the EU level, their interpretation and practical application vary significantly across regions and farming systems. This lack of uniformity undermines the AHL's objectives of harmonisation.

Continuous training, guidance, and knowledge sharing will be essential to ensure that the principles of the AHL are fully understood, accepted, and effectively applied at all levels. More effective dissemination of knowledge to all stakeholders, veterinarians, operators, and control authorities, together with greater involvement of stakeholders in the early stages of implementation, will

The AHL has improved clarity around roles and introduced more structured procedures for disease prevention and control. However, the distribution of responsibilities is sometimes perceived as imbalanced, with certain stakeholders (such as small-scale farmers) facing disproportionate financial burdens, and veterinarians reporting increased administrative workloads. These pressures have, in some cases, led to resistance or reduced engagement and cases of underreporting. The reduction of emergency budget and proper financial support at the Member State level have also emerged as pressing issues hampering the full potential of the AHL.

Despite the benefits of the risk-based approach, the current disease categorisation system faces practical challenges, particularly regarding its flexibility and responsiveness. This requires more regularly updated classifications that better reflect the epidemiological realities on the ground and allow for more tailored responses.

5.2. Efficiency

Based on our efficiency analysis, we found that while the Animal Health Law has led to mixed outcomes, it has significantly shaped animal health governance across the EU. On the positive side, the AHL has contributed to improved disease prevention, the establishment of clearer rules, and enhanced trust within the market. However, it has also brought about increased compliance costs—particularly for small-scale farmers—and introduced additional administrative burdens, notably for hobbyists and operators in Member States with limited resources.

The multiple delegated and implementing acts have further complicated compliance, often resulting in inefficiencies and delays in aligning national legislation. Stakeholders, especially smaller operators, have highlighted disproportionate impacts, with particular challenges arising from the use of the

TRACES system([81]). There have been widespread calls for streamlining procedures and simplifying documentation to alleviate these burdens and improve overall efficiency.

Key findings from desk-based research indicate that conducting a comprehensive economic analysis of the AHL remains difficult. This is largely due to the complexity of estimating both direct and indirect costs, as well as assessing broader environmental and social impacts. Prevention has proven to be more cost-effective than reactive disease measures, with coordinated vaccination programmes demonstrating notable long-term savings. Biosecurity measures, while relatively low-cost, offer significant protection for high-value animals. In contrast, emergency responses—such as culling during outbreaks—impose substantial financial burdens.

The cost of implementing the AHL, particularly in relation to animal movement, traceability, and disease control, has been identified by stakeholders as significant, especially for smaller farms. While the AHL's emphasis on disease prevention through clearer roles and responsibilities has improved health management in certain sectors, difficulties persist in aligning global practices with EU regulatory frameworks. The financial burden of compliance has not been evenly distributed. Smaller farms face considerable challenges in meeting requirements, whereas larger and more structured sectors are generally better equipped to manage implementation demands. Furthermore, the AHL has led to a redistribution of responsibilities, placing greater accountability on industry stakeholders.

A majority of stakeholders, particularly hobbyists, report excessive bureaucracy associated with AHL implementation, including the administration of health certificates and the TRACES system. Several Member States have also indicated that aligning national legislation with the AHL has demanded considerable resources.

5.3. Coherence

The analysis confirms that AHL, along with its delegated and implementing acts, demonstrates a high level of internal coherence, both structurally and conceptually. Identified inconsistencies are limited and primarily result from divergent interpretations, translation issues, and implementation challenges at the Member State level, rather than from flaws in the legislation itself. Stakeholder input—via surveys, interviews, and case studies—reinforces the AHL's overall integrity, while highlighting areas where targeted refinements could improve legal clarity and operational effectiveness. Although recent amendments have

([81]) Note: TRACE is linked with the Council Regulation (EC) N. 1/2005 on animal welfare during transport.

strengthened alignment, particularly in key delegated and implementing regulations, further adjustments are needed to strengthen coherence, reduce legal uncertainty, and support consistent implementation across the EU. Regarding the coherence of the AHL with other related EU legislation and policies, our study reveals a mixed picture. While there is substantial alignment in specific domains—most notably in food safety and disease prevention—coherence with other EU policies—such as those on animal welfare, and EU financing instruments remains limited, stemming from the distinct scope of these separate policy areas.

The AHL exhibits a high degree of alignment with EU food safety legislation, particularly through its emphasis on disease prevention and biosecurity. This coherence has been consistently acknowledged by a broad range of stakeholders, including NCAs, veterinarians, farmers, and industry representatives. Conversely, the coherence between the AHL and EU animal welfare legislation is assessed as limited. A significant proportion of stakeholders, including NCAs, NGOs, and veterinary professionals, identified substantive regulatory gaps and inconsistencies, particularly in the areas of transport documentation and the interaction between disease control measures and animal welfare objectives. Furthermore, the alignment between the AHL and EU financial instruments—particularly Regulation (EU) 2021/690—is assessed as partial. While the AHL prioritises proactive prevention measures, current financing mechanisms remain largely reactive, with limited support for preventive actions. Stakeholders highlighted the need for improved integration between legal and financial frameworks, as well as clearer guidance on eligibility and funding modalities. Overall, stakeholders agree that the challenges to the coherence of the AHL lie in its interface with transport and animal welfare legislation. In contrast, the alignment with food safety legislation is broadly considered effective. To enhance the overall coherence of the AHL within the EU policy framework, targeted efforts should be undertaken to improve inter-legislative coordination, clarify operational guidance, and address the identified regulatory gaps, particularly in the domains of animal welfare and EU co-financing instruments. These measures would strengthen the legal consistency, operational effectiveness, and policy integration of the AHL across the Union.

While stakeholders consistently acknowledge the benefits of a harmonised regulatory framework under the AHL, its implementation across Member States remains uneven. Significant variations persist in the extent to which national frameworks have been adjusted, with some requiring only limited adjustments and others undertaking extensive legislative changes. Moreover, divergent interpretations of certain provisions continue to hinder uniform implementation across the Union. These findings highlight that, although the AHL provides a unified legal basis for animal health management at the EU level, its effective and coherent implementation across the Union is still in progress. Continued coordination and targeted guidance remain essential to fully realise the objectives of the AHL and to ensure its uniform application across all Member States.

The AHL is broadly recognised by stakeholders as a valuable and technically sound framework for addressing global animal health challenges and promoting alignment with international standards, notably those of the WOAH. It has facilitated harmonised rules within the EU and has inspired some legislative convergence in neighbouring countries and among trade-oriented sectors. However, its potential as a global benchmark remains constrained by inconsistent implementation across Member States and limited uptake or understanding by third countries. While certain NCAs and civil society actors acknowledge its role in enhancing international cooperation and sanitary transparency, industry operators and some veterinarians question its practical utility and recognition by non-EU partners. Moreover, concerns raised by third countries regarding specific disease management strategies further illustrate the challenges of broader international acceptance. To enhance the AHL's global relevance and impact, clearer guidance, reinforced coherence within the EU, and a more strategic approach to external engagement and communication will be essential.

It is recognised that AHL has played a constructive role in advancing the European Union's international cooperation efforts, particularly by supporting transparency, promoting the exchange of scientific information, and aligning with global standards. Through active engagement in international standard-setting bodies such as the WOAH, and through technical dialogue facilitated by EFSA and platforms like ADIS—despite the ongoing process of full integration with WAHIS— the EU has strengthened its position in global animal health governance. However, the impact of the AHL in this domain is largely underpinned by the Union's broader external policy and trade objectives, rather than by specific legal obligations embedded in the AHL itself. While stakeholders acknowledge the EU's effective role in promoting coordination and knowledge-sharing, they consistently highlight the need for a more formalised, strategic, and forward-looking approach to international cooperation.

The AHL's interaction with EU biodiversity and circular economy objectives is limited. While the law supports disease prevention in wildlife, thereby contributing to biodiversity protection, measures such as mass culling for disease control can conflict with conservation and rewilding efforts. In conclusion, the AHL complies with the 'Do No Significant Harm' principle only to a limited extent; while its foundational objectives do not inherently cause environmental harm, the law's implementation has not been systematically designed to support broader EU environmental and climate strategies. The evaluation confirms that the AHL demonstrates meaningful alignment with the European Union's strategic policy objectives, including the European Green Deal, the Farm to Fork Strategy, the One Health approach, and the Long-Term Vision for Rural Areas. However, the extent of its practical alignment and operational effectiveness is perceived differently by various stakeholder groups and is characterised by both notable strengths and persistent challenges in implementation and integration. In particular, it was acknowledged that the AHL contributes to a safe and smooth functioning of the internal market for live animals and animal by-products. Nonetheless, it also highlighted the need for greater coherence in implementation

across Member States to ensure consistent outcomes. Regarding the One Health approach, the AHL reflects a clear legislative commitment and remains relevant to its overarching objectives. Despite this, its effective application continues to face gaps, especially in the integration of environmental health and cross-sectoral collaboration. Stakeholders hold mixed views on its impact, with consensus indicating a limited to moderate contribution in practice. Thus, while the AHL establishes a robust and well-aligned conceptual framework with EU strategic priorities, its full potential remains curtailed by fragmented implementation and the incomplete realisation of the One Health approach. Further efforts are required to enhance coherence, strengthen multidisciplinary integration, and better align with the long-term goals of sustainable competitiveness and rural development.

5.4. Relevance

From our study, we find that the AHL is fit and relevant to current and emerging needs regarding Animal health. Existing challenges in animal health can, to a large or moderate extent, be managed within the framework of the AHL, and supplementary legislation has been further developed in line with the experiences gained.

The AHL has not yet been fully implemented and national legislation adapted to the new AHL across all Member States; consequently, its implementation cannot currently be considered harmonised. Where the AHL is fully implemented, national implementation aligns well with its overarching objectives. However, variations exist in practical implementation and enforcement among Member States, particularly concerning the risk-based approach in animal health visits and biosecurity measures.

Stakeholder responsibility for preventing outbreaks through enhanced biosecurity and early disease detection is now more clearly defined, contributing to the mitigation of major disease outbreaks and helping to limit disease spread.

However, the design and application of biosecurity measures are largely left to the discretion of Member States and operators, resulting in varied approaches across the EU. Full enforcement of biosecurity measures at the farm level is still evolving.

Previously, there was a specific directive for each disease or topic. In contrast, the AHL now serves as an overarching framework, with information organised by topic rather than by disease. Stakeholders from the NCAS and sector acknowledged initial difficulties in locating relevant legal text for particular diseases; they valued bringing most of the EU rules into a simpler law with a better focus on the key priorities in tackling diseases. In this respect, most respondents in all consultation activities expressed a desire for further guidance in navigating the new AHL.

The Commission has developed the Better Training for Safer Food (BTSF) programme to support adequate knowledge of animal health, primarily targeting official veterinarians in MS. Although the BTSF is primarily designed for training national authorities, it operates on a 'train-the-trainer' model. It is therefore incumbent upon NCAs to disseminate the acquired knowledge to relevant stakeholders.

A clear consensus emerged that the categorisation of animal diseases is an essential tool for harmonising and rationalising the prevention and control of diseases. Since the adoption of the AHL, improvements have been made to the categorisation, particularly concerning category C vector-borne diseases. However, certain vector-borne diseases would benefit from more consistent and clearly defined regulations.

The TSEs and the other zoonotic diseases covered by Regulation No 999/2001, Directive 2003/99/EC and Regulation No 2160/2003 have not undergone the same process that led to the listing and categorization of all other diseases covered by the AHL and its subsequent delegated and implementing acts, including a complete scientific review by EFSA. it appears appropriate to review at least the existing rules on TSEs to ensure their full coherence with the principles and criteria established in the AHL.

One of the principles of the AHL is the risk-based approach when dealing with animal disease outbreaks. Member States can implement measures based on their specific epidemiological contexts, financial resources, and national priorities. This means that the Member States have a margin for manoeuvre when adopting disease prevention and control measures. Flexibility is therefore needed.

The AHL seeks to provide a coherent expression of the 'One Health' concept, addressing the interconnections between animal and public health, wildlife, the environment, food and feed safety, animal welfare, food security, economic factors, and social and cultural issues.

The logic behind disease categorisation is not entirely sufficient for a fully integrated One Health approach. New emerging zoonotic diseases, which necessitate a transnational and interdisciplinary approach, are frequently excluded from national intervention and control priorities. The existence of wildlife reservoirs and the associated control and monitoring cross-border challenges underscore the need for coordinated strategies across animal health, human health, and environmental health, which are currently lacking.

5.5. EU added value

There is a broad consensus on the necessity of a harmonised framework for animal health standards across the EU. Uniform implementation by all Member States is vital to ensure the effectiveness of the AHL. While proportionality and

flexibility are central to successful enforcement, achieving an optimal balance remains challenging.

The AHL has shifted the focus from reactive to proactive animal health measures, marking a significant change from prior legislation that primarily addressed existing threats rather than anticipating new issues. The major benefit observed due to the implementation of the AHL is the more streamlined approach. With the AHL, there is a clear framework for cooperation among Member States, which supports more effective disease control measures across borders.

Given the epidemiological developments in Europe since 2021, particularly regarding ASF, BT, EHD, HPAI, and most recently FMD, the EU has shown a degree of resilience. Indeed, available data show that, despite these outbreaks, the volume of trade in animals and animal products between EU Member States increased. However, whether this resilience is directly linked to the AHL remains unclear.

As regards international trade, it would not be feasible to maintain the same levels of animal movements and trade of animal products between the EU and third countries without the AHL. The AHL facilitates trade with third countries by reducing administrative burdens for both sides in the import and export processes. Systems such as TRACES provide essential data for effective control.

The AHL placed greater emphasis on prevention and on farmers' responsibilities for maintaining animal health. The gradual implementation of regular animal health visits, biosecurity measures, and enhanced training for farmers and sector representatives on biosecurity has fostered better coordination for animal disease prevention and control in EU Member States.

Including wildlife in the AHL ensures that disease surveillance and monitoring in wildlife are implemented in all Member States, despite the fact that resources available and monitoring strategies applied differ between Member States.

Standards must balance clarity with sufficient flexibility to accommodate regional variation. While flexibility is necessary for local authorities to adapt measures to specific conditions, overly broad definitions risk inconsistent interpretation among Member States. Unambiguous definitions, coupled with the capacity for local adjustment, would reduce complexity.

Harmonised biosecurity requirements and strategic use of the veterinary workforce would further strengthen implementation capacity.. In parallel, budget constraints and workforce shortages hinder the effective implementation of the AHL in some regions.

To increase the additionality of EU-level action, several targeted adaptations could be considered, particularly in relation to regulatory clarity, dependence on human resources (many MS CAs complain about scarce human resources) and

modern technologies (such as use of sensors, drones, AI), and harmonisation of standards. Clear, structured guidance would enhance accessibility and support compliance. These standards must balance clarity with sufficient flexibility to accommodate regional variation. While flexibility is necessary for local authorities to adapt measures to specific conditions, overly broad definitions risk inconsistent interpretation among Member States. Harmonised biosecurity requirements and strategic use of the veterinary workforce would strengthen implementation capacity.

Although not the primary objective of the AHL, its implementation led to a facilitation of trade with third countries of individual MS by reducing existing trade restrictions, e.g., the importation of unvaccinated live poultry from France and unvaccinated live ducks to the USA.

5.6. Study team recommendations

General implementation of the AHL

The Animal Health Law (AHL) is a key output of the EU Animal Health Strategy 2007–2013, 'Prevention is better than cure', which emphasises a risk-based approach to animal health management. Such an approach requires a robust understanding of the local epidemiological context, especially in a continuously evolving environment. Knowledge gaps in this area often lead to precautionary, zero-risk policy interventions, which may result in significant public and private costs. Within the EU's multilevel governance framework, it is therefore essential that continuous learning is fostered both from the bottom up and top down.

To address this, in each MS, NCA and stakeholders of the public and private sectors should provide systematic guidance on the application of risk assessments. These assessments must account for the evolving nature of risk, which is often context-dependent and time-sensitive.

NCAs expressed the need for EU-level guidance on biosecurity requirements, especially for extensive farming systems. Dedicated training should also be developed at the national level for small-scale operators, who often perceive the associated costs as disproportionate to the scale of their operations.

A flexible, risk-based approach that adapts to the local context is only justifiable if it is underpinned by robust surveillance systems. The study team therefore recommends:

- Enhancing national-level surveillance networks and ensuring alignment with EU-level indicators to maintain a level playing field across Member States.
- Establishing a national platform to foster trust and transparency in disease control measures, particularly for regionally targeted actions such as those for vector-borne diseases. Mutual recognition between regions is crucial to preventing disruptions in animal movements. Representatives of these national platforms should also engage in regular exchanges with their EU counterparts.
- There is also an opportunity to strengthen alignment between the AHL and animal welfare legislation, particularly with respect to Category A diseases. Ensuring that the Animal Welfare Transport Regulation([82]) (currently under revision) is coherent with the AHL would enhance compliance and reinforce the effectiveness of the AHL as the legal framework for the prevention and control of animal diseases..

([82]) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of animals during transport and related operations, amending Council Regulation (EC) No 1255/97 and repealing Council Regulation (EC) No 1/2005.

Knowledge transfer and training

Accordingly, the study team recommends the systematic integration of training and guidance materials for all stakeholders involved in the handling of animals. Several non-exclusive options have been identified to support this:

- Greater emphasis on the relevance and practical application of the AHL, including risk-based assessments of biosecurity, should be incorporated into training and continuous education of stakeholders in MS (NCA, private veterinarians and other stakeholders, including in veterinary curricula).
- Stakeholders have indicated the need for increased awareness and targeted training to effectively navigate the AHL and its accompanying Implementing and Delegated Acts (IA and DA).
- While the Better Training for Safer Food (BTSF) programme targets national competent authorities (NCAs), the spillover effects do not sufficiently reach occasional users of the AHL. Within the MS, key users/AHL experts could be identified to support these occasional users.

To support implementation of the AHL in MS, the study team recommends the establishment of a cooperation framework at the national level. This framework could offer joint training sessions for key stakeholders—including veterinarians (public and private), competent authorities, and operators—to clarify roles and responsibilities. It could also promote the long-term benefits of preventive measures such as vaccination and biosecurity. Additionally, such a framework could serve as a platform for sharing implementation challenges, such as those encountered in the roll-out of vaccination campaigns or the need for vaccine banks.

As detailed in Section 3, the AHL has not yet been fully implemented at the Member State level. Consequently, this evaluation may have been premature in providing robust evidence of its impacts. The study team recommends that this evaluative exercise be repeated only when sufficient data have become available.

A future evaluation can be facilitated when vital data are collected and reported to the CI on a regular basis. Sources of information can be audit reports, but foremost, reports of the MS to the commission on the progress and results of the AHL. The indicators that are of relevance for this future evaluation that could be routinely collected and reported by MS are presented in Annexe 1()

The next multi-annual plan (2026–2030) of the Directorate-General for Health and Food Safety could prioritise the implementation of controls (audits) to ensure that national authorities are meeting their legal obligations under the AHL. These audits will not only provide insights into the degree of implementation but also assess the effectiveness of enforcement measures, which are currently lacking. Audit findings may be complemented by research and other scientific data.

Currently, there is a notable paucity of peer-reviewed evidence assessing the effectiveness of these interventions. More evidence base for future policy evaluations and inform cost-effective, evidence-based decision-making could be provided. Developing a robust body of evidence is essential not only for policy refinement but also for fostering stakeholder trust in the regulatory framework.

The intervention logic provides indicators that give insights into the progress of implementation and effectiveness of the AHL. Monitoring by the Member States and reporting progress in MS annual reports based on these indicators would facilitate monitoring progress and success.

Annexes

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