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NOTE

From:	Commission services
To:	Delegations
Subject:	2026 Annual Progress Report on Simplification, Implementation and Enforcement (Health, animal health and welfare, plants and plant health, food and feed safety)

Delegations will find in annex the above-mentioned report.

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1. Introduction

- As Commissioner for Health and Animal Welfare, I was tasked to consolidate the European Health Union. I am also responsible for building on the One Health approach, which recognises the connection between people, animals, plants and their shared environment. This mission supports the Commission's priorities in two of the EU's most important economic sectors – health and food. In public health, the Commission helps Member States to manage and prepare for crises, improve public health and access to healthcare, and strengthen their health systems, while in food and feed safety, we ensure that EU rules are correctly applied and work to modernise and simplify them.
- This report presents the activities I have undertaken to implement the Commission's Simplification Agenda and its **Communication on implementation and simplification,** as well as the **Communication "A Simpler, Clearer and Better Enforced EU Rulebook"** (April 2026) in my portfolio areas. In respect of simplification, it sets out an overview of recent, ongoing and upcoming initiatives. This second annual progress report on simplification, implementation and enforcement covers the period from 1 August 2025 to 31 July 2026 and will be submitted to the relevant Parliamentary committees and Council configurations.

2. Executive Summary

- European Union action, in complement to national policies, aims at ensuring a high level of human health protection and improving public health. This includes ensuring a high level of protection of animal and plant health, and animal welfare and that food and feed are safe.
- In line with the ***Commission's 2025 Overview report on simplification, implementation and enforcement***[1], I continue to deliver on the Commission's simplification agenda including by simplifying our regulatory framework that will help better deliver the policy objectives. To this end, I put forward a series of proposals on 16 December 2025: 1) a **Food and Feed Safety Simplification Omnibus** package, with the aim of increasing competitiveness of the food and feed industry and of farmers and reducing administrative burdens related to marketing authorisations of products – while not compromising on safety; 2) a proposal for a European **Biotech Act** containing simplification measures in the area of health, for example through targeted amendments to the Clinical Trials Regulation. The proposal also contains targeted amendments to the General Food Law to accelerate the EU risk assessment process and the functioning of EFSA; and 3) a proposal to revise the rules on **medical devices** that is expected to enhance innovation in the sector as well as to enhance competitiveness by making the rules more proportionate, while maintaining the highest patient safety standards.
- We also continued to evaluate the performance of the **European Food Safety Authority (EFSA),** the **Animal Health Law** and launched a full evaluation of the **Biocidal Products Regulation**. The evaluations will provide a basis for identifying further opportunities for simplification in these sectors with the help of stakeholder views. The insights from the biocides implementation dialogue conducted in July 2025 directly fed into a call for evidence and a public consultation launched in December 2025 in the context of the Biocidal Products Regulation. In the context of the preparatory work on the impact assessment for **Food Contact Materials (FCM)**, a reality check is envisaged for end 2026 to gather feedback from stakeholders on possible simplification initiatives.
- In the areas of my portfolio, the Commission plays a pivotal role in the implementation of EU legislation by supporting Member States, addressing implementation gaps, deploying strategic initiatives, advancing digital solutions, and collaborating with EU regulatory agencies in matters of direct relevance to EU citizens and businesses.

[1] https://commission.europa.eu/publications/2025-overview-report-simplification-implementation-and-enforcement_en

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- To ensure that EU health and food safety laws are applied and enforced we work closely with Member States through a variety of both preventive and corrective tools. Regular follow-up and dialogue bolster the enforcement of EU public health and food safety rules and standards.

3. Delivering Results: Key Measures

A. Simplification and costs savings

As from 1 August 2025, the Commission continued to implement the simplification agenda in line with the Communication on implementation and simplification. In the area of health and food safety, and following the ongoing **stress-testing** and **regulatory deep cleaning** (referred to in Annex I of the Communication From Rules to Results: A Simpler, Clearer and Better Enforced EU Rulebook) of the EU acquis in the remit of my portfolio, the Commission adopted in December 2025 targeted revisions of a wide range of legislation to streamline procedures and foster innovation: the food and feed safety simplification omnibus, the revision of the medical devices legislation, and the Biotech Act.

First, the Commission adopted a proposal for a **Food and Feed Safety Simplification** Package as the tenth simplification omnibus. Stemming from the stress-testing of the health and food safety acquis, the initiative streamlines procedures, clarifies and modernises selected provisions across several pieces of EU food and feed safety legislation, and fosters agri-food innovation, while maintaining a high level of protection for human and animal health and the environment. The proposal aims to increase competitiveness of EU farmers and the food and feed industry via a stronger alignment of standards for pesticide maximum residue levels and to reduce administrative burden for Member States' authorities related to marketing authorisations of products, improve legal clarity and increase the efficiency of regulatory procedures. It aims to speed up market access for biocontrol pesticides, simplify and clarify regulatory requirements for other plant protection products - including their application by drones - as well as for biocidal products, fermentation products obtained with GMOs, feed additives, food hygiene and official controls, and to simplify the EU legal framework that applies to food and feed safety. The proposed simplifications in this package could save over €1 billion in administrative and compliance costs, including over €428 million annually for EU businesses (€227 million for SMEs), as well as €661 million annually for national and EU administrations. This includes annual administrative cost savings estimated at €939 million for both businesses and national administrations. Negotiations in the Council and in the Parliament started in the first part of 2026.

Second, the Commission adopted the proposal to revise current rules on **medical devices and *in vitro* diagnostic medical devices** to make them simpler, more effective, and innovation-friendly, while preserving a high level of public health and patient safety. This proposal, which is based on the targeted evaluation of the two Regulations completed in December 2025, along with tertiary legislative acts, aims at promoting competitiveness and innovation, creating a single, coherent regulatory framework for AI incorporating devices and introducing clearer timelines for conformity assessments to speed up access and ensure continuous supply of medical devices and in vitro diagnostics.

In sum, the revised regulatory framework proposes to eliminate the requirement for companies to re-certify devices every five years, reduce the frequency of Periodic Safety Update Reports (PSURs), and exempt well-established devices used safely for decades from requiring new clinical studies. The Commission continues to actively pursue the revision and support the ongoing discussions with the co-legislators. On 26 March 2026, a high-level conference bringing together Member States, healthcare professionals, patients' representatives, industry stakeholders and notified bodies discussed the future of the EU medical device framework following the Commission's proposal to revise the existing rules. Overall, more efficient and predictable processes will make the relevant EU sectors more attractive to investors, both domestic and foreign, which could lead to increased investment and growth in the sector. At most conservative estimates, the simplification will bring about €3-5 billion in cost-savings per year, of which about €2.4 billion annual administrative costs savings.

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Thirdly, the Commission adopted its proposal for the **Biotech Act,** a landmark initiative with a focus on health-related biotechnology. This ambitious legislative package seeks to enhance the health of EU citizens while ensuring the long-term resilience and global competitiveness of the health sector. A key objective is to reduce costs and administrative burdens by simplifying regulatory frameworks and accelerating procedural timelines. For complex and innovative products, the proposal introduces better coordinated regulatory pathways, ensuring for example clear timelines for the consultation of the concerned regulators. A major simplification concerns clinical trials: it is for example proposed that products combining medical devices and medicines undergo a single and streamlined assessment, reducing duplication. Additionally, the Act proposes targeted amendments to EU health and food legislation, ensuring the regulatory ecosystem keeps pace with modern societal needs and the rapid evolution of the biotech sector. The proposal revises existing EU rules on clinical trials; advanced therapy medicinal products (ATMPs); substances of human origin; veterinary medicinal products; General Food Law as regards the risk assessment process overseen by EFSA; human organs; tailoring of the legal framework applicable to genetically modified organisms GMOs to the specific characteristics of genetically modified microorganisms (GMMs) used as or in products. The Biotech Act will bring EUR 1.2 bn of administrative cost savings per year. Negotiations between the European Parliament and the Council on this forward-looking, simplified framework are ongoing with a view of reaching a general approach under the IE Presidency.

Each Commissioner is responsible for carrying out a comprehensive screening of the legislative portfolio under their responsibility, to assess whether it remains relevant and fit for purpose. We are committed to continuing to gradually **stress-test** legislation, particularly through evaluations and reality checks. To ramp up these efforts and give them greater priority, the Commission has launched an **Action Plan for Regulatory Deep Cleaning**, to remove duplications, contradictions, outdated provisions, overlaps, and redundant procedural requirements. In the areas under my remit, such deep cleaning will include actions on health and food safety regulations where we will continue to assess potential areas for simplification and improvement launching an in-depth s*tudy supporting the gradual stress-testing of the EU acquis on food and feed safety* to gather key data, including for composite products, food donation, and double food authorisation, while maintaining a high level of protection of human health. The Regulatory Deep Cleaning will involve an internal **review of** certain **food safety policies** and **an evaluation of the biocidal products legal framework** as non-legislative initiatives in 2027. Furthermore, the **e-submission food chain** will undergo digital updates to simplify and remove duplication for economic operators, streamlining communication channels and reducing delays during the intake phase. This should enable faster and more efficient interactions between operators, ultimately benefiting consumers and promoting a more competitive food industry.

An example of on-going targeted evaluations in the food and feed safety area is firstly **the evaluation of the performance of the European Food Safety Authority (EFSA).** It assesses the mandate, performance and organisational framework of the Authority, to identify areas where EFSA could become more effective and efficient, deliver actionable scientific advice and, where possible, better support applicants. This evaluation should be completed in the third quarter of 2026. Similarly, the **Animal Health Law evaluation** has advanced well, following a study completed last year, and is continuing as a key stress-testing activity. It was published in July 2026.[2] In its Evaluation report, the Commission identified 11 action areas, including simplification and reducing administrative burdens and costs to enhance implementation. To support this, it will continue using simplification options by amending existing delegated and implementing acts where health risks allow. It may also consider clarifying the use of Member State derogations through amendments to these acts, to promote more harmonised and simpler rules.

The second ongoing evaluation relates to the **Biocidal Products Regulation.** This evaluation assesses whether the Regulation has performed in accordance with its objectives as well as existing and emerging needs. It will identify and assess issues that need to be improved, including how to reduce delays in the evaluation of active substances and product authorisations. The evaluation will include a dedicated reality check in the fourth quarter of 2026 and

[2] Commission report highlights achievements of EU rules on animal health - Food Safety

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it might result in a proposal for revision of the BPR supported by an impact assessment, depending on the findings of the evaluation and decisions on the most appropriate follow-up actions.

The last example in the food and feed area refers to **animal welfare.** A first legislative proposal on **on-farm welfare** is planned for adoption in the last quarter of 2026 to modernise some of the existing Directives and address the fragmentation of the single market in this area. This will simplify rules for farmers and reduce costs associated with diverging national rules. The initiative explores options to address shortcomings identified in the 2022 fitness check and will propose the phasing out of cages for certain sector(s) as a follow-up to the European Citizens' Initiative "End the Cage Age" aiming at addressing ethical concerns of citizens while considering its impact on farmers. We have launched an impact assessment to support this proposal, backed by a public consultation that closed in December 2025 with almost 200,000 contributions. We continue to support the co-legislators' negotiations on the legislative proposal on **animal transport**. Once finalised, this legislative revision will reduce burdens and simplify implementation both for operators and competent authorities, in particular thanks to its important digitalisation objectives. My services have supervised an **external study,** published in June 2026, on the best ways to implement the digitalisation provisions in this new legislation We have also supported the negotiations of co-legislators on the new Regulation on the **welfare of dogs and cats and their traceability**. The Regulation will be published in the *Official Journal* around summer 2026, and once applicable, it will simplify work both for competent authorities and reliable operators breeding and trading dogs and cats in the EU, notably thanks to the EU steered inter-operability of national databases that will allow fighting fraud and reducing costs for legitimate operators. An ongoing external study explores, inter alia, the most efficient and effective ways to deploy the digital provisions of the new Regulation. The study will be published in Q3 2026.

My services and I have also supported the successful negotiations on the **Regulation on plants obtained by certain new genomic techniques**. The new Regulation (EU) 2026/1388 was published on 26 June 2026 and will apply on 17 July 2028. These new rules will improve the ability of Europe's plant breeding, farming and food sectors to compete globally. They will also help in tackling growing challenges for plant health, such as climate change or new pests and diseases. The agreed legislation reflects the latest scientific developments and is aligned to the approach taken by many of the EU's trading partners. It will allow better market access for SMEs and help with the development of new plant varieties tailored to European needs, while upholding the European high safety standards.

We furthermore supported the co-legislators' negotiations on the new Regulation on **plant reproductive material** that led to a political agreement on 15 June 2026. This will include several new derogations from the main rules for producing and marketing seed and other material for conservation purposes and for non-professional users. This will allow the targeted operators to work with significantly lighter requirements than those under the current legislation. We have also supported the follow-up to the co-legislators' negotiations on the new **forest reproductive material** Regulation. The Regulation was published in the official journal on 26 June 2026, and once applied in 2031, will ensure the availability of high-quality forest reproductive materials. This will help create more diverse forests that are better adapted to extreme weather conditions and contribute to the resilience of the EU's nature and ecosystems.

I held an **Implementation Dialogue on Import Controls on 9 December 2025**, where stakeholders stressed the potential of digitalisation to enable faster, more targeted risk-based import controls and a more efficient allocation of resources. This dialogue allowed for the gathering of stakeholder input on challenges and opportunities to reinforce controls on food, animal and plant products entering the Union. To address these challenges and ensure a level playing field, **a dedicated task force on import controls** has been established in early 2026 (see below).

On 2 April 2026, we published a comprehensive **evaluation of the Tobacco Products Directive and the Tobacco Advertising Directive** which highlighted growing challenges linked to the emergence and increasing use of novel products. The Commission is carrying out an impact assessment and a wide-ranging consultation process, in view of the announced revision of the rules.

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The Commission has also started preparing **the evaluation of the Health Technology Assessment (HTA) Regulation,** which entered into force on 11 January 2022 and applies from 12 January 2025. The report on the application of this Regulation needs to be completed by mid-January 2028. The report will look into the added value of the joint clinical assessments and scientific consultations carried out pursuant to the Regulation, as well as the uptake of the joint clinical assessment reports in the Member States' pricing and reimbursement decisions, efforts to streamline the request for information, data, analyses and other evidence for joint clinical assessment in terms of reducing the administrative burden for Member States and health technology developers, and review the overall functioning of the support framework.

Finally, I held an Implementation Dialogue on the **European Health Data Space (EHDS)** on 10 June 2026, gathered industry, healthcare providers, researchers, and patient groups to refine the Regulation's rollout. While stakeholders recognised the EHDS's potential to advance personalised medicines, healthcare resilience and research, they highlighted key challenges, including the risk of fragmented national implementations and resource constraints. Calls were made for clearer guidance and clarification of key concepts, harmonised standards and simplified procedures to avoid duplicative burdens. Industry stressed the need for early involvement in standard-setting, while patient groups pushed for greater representation. Healthcare providers pointed out a lack of awareness and resource constraints. I committed to integrating feedback into implementing acts, emphasising the need for practical usability and citizen trust to ensure the EHDS delivers its benefits with minimal administrative hurdles. This input will guide the next phases of implementation.

The Commission has, in the broader context of the simplification and burden reduction work, embarked on a critical exercise of **screening implementing and delegated acts** expected to be adopted and establishing priority acts for 2025-2026. Following the internal screening exercise of the acquis under my remit, I have shared the lists of acts that we considered to prioritise and deprioritise in 2026. For the prioritisation, we have focused on acts that are legally required and on acts that are necessary for the achievement of EU policy objectives in the policy area under my remit, to protect citizens' health, animal health and welfare, plant health, and food safety. We have included among our priorities, acts needed to implement legislation, simplify it and provide benefits for citizens, businesses and administrations. Prioritisation criteria focused on acts that are: legally mandatory, or essential for achieving EU policy objectives, particularly those needed to implement, simplify, or enhance legislation for the benefit of citizens, businesses, and administrations. Conversely, the deprioritised list includes 13 acts that are neither legally required in 2026 nor critical to EU policy goals. In addition, my services have identified a potential need to act on empowerments linked to measures that are conditional on external factors, such as submissions by Member States or third parties, or which address specific situations that might put human, animal, or plant health at risk, or are crucial to ensure that science-based legislation remains up-to-date. The necessity of these measures might only become apparent during the year.

B. Implementation

Effective implementation of EU legislation is key to ensure that the wide acquis in the areas of health and food is consistently applied across Member States.

In the area of public health, we have started the preparations for the forthcoming implementation of the Critical Medicines Act and of the new pharmaceutical legislation that foresees the preparation of numerous implementing and delegated acts ranging from dossier requirements for marketing authorisation applications to electronic product information and to regulatory sandboxes in the area of medicines. A fast and smooth implementation of the new pharmaceutical legislation will be a priority for the Commission given its potential to support competitiveness**,** innovation and public health objectives. For the new Regulation on Substances of Human Origin (SoHO), work has started on delegated and implementing acts ahead of the full implementation of the Regulation and on an IT platform. We are also working to ensure the effective implementation of the European Health Data Space Regulation (EHDS) and of the Regulation on Health Technology Assessment (HTA), where the first joint clinical assessment was

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published in June[3]. As regards EHDS, this includes the work on implementing acts (e.g. on the EHDS Board, the European Electronic Health record Exchange Format, identification management, MyHealth@EU specifications and on other aspects), supporting the Member States in establishing the necessary digital health infrastructures, building communities of practice[4] and funding trainings.

In the area of medical devices, the Commission adopted an Implementing Regulation[5] to ensure uniform requirements for conformity assessment and notified bodies, to improve the efficiency and predictability of their activities in terms of timelines and costs for manufacturers, especially small and medium-sized enterprises. We also expanded the lists of "well-established technologies" through two Delegated Acts[6], for certain medium and high-risk devices to exempt them from the obligation to perform clinical investigations, and to allow for a more streamlined conformity assessment, therefore reducing administrative burden without compromising health and safety. Work is ongoing to finalise an Implementing Regulation on new common specifications for certain in vitro diagnostics. This will simplify the application of the EU regulatory framework by providing a single and uniform set of operational requirements, to be respected by all relevant actors such as manufacturers, notified bodies and EU Reference Laboratories.

To turn the tide against cancer and strengthen the European Health Union, we continued to work on the Europe's Beating Cancer Plan, for example by supporting cancer screening programmes in Member States. We continued to support Member States in achieving a comprehensive approach to mental health as outlined in the Commission's 2023 Communication.

To enhance digital transformation, we have advanced initiatives such as the EU SoHO Platform to facilitate exchange of information for SoHO activities and the European Shortage Monitoring Platform for managing medicinal shortages. We have developed a dedicated IT HTA Platform to facilitate the joint work in a secure setting. The European database on medical devices (Eudamed) became mandatory to use at the end of May 2026, providing information to consumers, producers and competent authorities on devices with the purpose of enhancing patient safety, traceability and enforcement across the EU. The Clinical Trials Information System (CTIS), subject to continuous improvement, has continued to deliver as the single-entry point for the authorisation of Clinical Trials in the EU and it contains more than 9000 entries. Since its inception, the Clinical Patient Management System (CPMS) has surpassed 5000 hosted medical discussions, marking a significant milestone in the collaborative diagnostic and treatment of ultra-rare and highly complex diseases in Europe. A new biotechnology portal finally has streamlined regulatory navigation for companies.

The implementation of the Regulation on Serious Cross-Border Threats to Health is underway to enhance the EU's capacity in prevention, preparedness, risk assessment, early warning and response, aligned with the EU Preparedness Union Strategy. The Action Plan accompanying this strategy outlines as one of the key actions the Union prevention, preparedness and response plan for health crises. **EU Reference Laboratories in human health** which are funded from EU4Health Programme have continued to support the rapid detection and response to serious cross-border threats to health. Ten of those laboratories are now in place and more are under preparation.

To enhance citizens and business awareness, we supported two workshops and a high-level conference on patients' rights on cross-border healthcare and the European Reference Networks across Europe, and training sessions for veterinarians and farmers on reducing antimicrobial use.

The implementation of the **2023 Council Recommendation on 'Stepping up the EU actions to combat Antimicrobial Resistance in a One Health approach'** is ongoing. An AMR monitoring framework has been developed and will be applied to track the progress and results achieved in implementing the Council

[3] Commission publishes joint clinical assessment reports on two new lung cancer medicines.
[4] https://health.ec.europa.eu/ehealth-digital-health-and-care/ehds-action/projects-supporting-ehds/health-data-access-bodies-community-practice_en; Support Center COPEF: https://acceptance.data.health.europa.eu/ehr-systems/support-center
[5] Implementing regulation - EU - 2026/977 - EN - EUR-Lex
[6] Official Journal L series daily view - EUR-Lex

Recommendation on AMR and the 2017 AMR Action Plan. The findings will feed into the report to the Council on the follow-up given to the Recommendation in 2027.

Recognising the interconnectedness of human, animal and environmental health and setting out measures to reinforce cross-sectoral collaboration, the Commission has taken action to further implement the One Health approach at EU level in order to strengthen prevention, preparedness and the EU's response to cross-border health threats. During the autumn of 2025, the One Health Thematic Network was launched on the EU Health Policy Platform, fostering dialogue among stakeholders at the intersection of human, animal, plant and environmental health.

The Commission adopted on 16 December 2025 the **Safe Hearts Plan.** As the first ever EU Cardiovascular Health Plan, it sets out 10 ambitious flagship initiatives across prevention, early detection and screening as well as management of cardiovascular diseases. The Safe Hearts Plan integrates digitalisation and artificial intelligence, research and innovation and addresses health inequalities within the flagship initiatives. Since the adoption of the Safe Hearts Plan in December 2025, preparatory work is underway for its implementation across the flagship initiatives. This Plan includes the proposal for a Council Recommendation on health checks for cardiovascular diseases, expected in the third quarter of 2026, to support Member States in improving the early detection and diagnosis of cardiovascular diseases, as well as the development of an EU Cardiovascular Health Inequalities Dashboard, with a pilot version expected by early 2027.

The EU4Health Programme continued to support the implementation of Union priorities such as the Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe, the EU Global Health Strategy, the Safe Hearts Plan, the Biotech Act as well as the implementation of Union legislation in the public health domain. The Programme addresses the initiatives included in my mission letter and it reinforces the implementation of existing legislation, notably in relation to serious cross-border threats to health, health technology assessment, medical devices, substances of human origin, pharmaceuticals and the European Health Data Space Regulation.

Regarding food and feed policy, we have led several initiatives to support achievement of relevant EU objectives.

In particular, we engaged with stakeholders to reduce food loss and waste through the **EU Platform on Food Losses and Food Waste**, as well as by providing dedicated grants to support stakeholders and Member States in their implementation of measures to reach the EU binding food waste reduction targets. Moreover, the Commission prepared communication materials to ensure the widespread outreach and hosts the EU Food Loss and Waste Prevention Hub to share knowledge and best practices.

The **Task Force on Import Controls and an Expert Pool** contribute to more harmonised enforcement of EU rules through – among other – more intensified monitoring of non-compliant goods and high-risk third countries, besides an enhanced schedule of Commission audits to exporting countries and to border control posts (BCPs) at the external EU border. In response to demands from farmers, traders, and civil society, these measures strengthen biosecurity, food safety, and fair competition for EU producers by closing gaps in enforcement across Member States.

The implementation strategy for **Regulation (EU) 2026/1388 on plants obtained by certain new genomic techniques** was published on 16 July 2026. The fast and smooth implementation of the Regulation will be a priority for the Commission given its potential to support competitiveness and innovation goals. The implementation strategy outlines implementation actions at Union and Member State level identifying key milestones for their preparation and actors involved. It will support coordinated implementation by the Commission, other Union bodies and agencies, and the Member States, and inform stakeholders and the public of planned actions.

The Better Training for Safer Food (BTSF) initiative has continued to equip national authorities with specialised training on EU regulations, prioritisingcapacity building through peer learning and best practice sharing.

The EU funded Reference Laboratories (EURLs) under the Single Market Programme continued to offer technical support to the Commission and Member States, developing analytical methods to ensure compliance across a variety of regulated products. In addition, the Single Market Programme supported a wide range of activities in the areas of food safety, animal and plant health, antimicrobial resistance, reduction of food waste, official controls, food fraud, animal welfare and sustainability. Main beneficiaries are the competent authorities of Member States,

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stakeholders and international organisations. Through the Programme, grants are provided among others for national veterinary and phytosanitary programmes, emergency measures for animal diseases and outbreaks of plant pests. Those emergency measures required significantly more financial support compared to previous years. Outbreaks of animal diseases and priority plant pests have been continuously on the rise, with diseases such as African Swine Fever (ASF), Highly Pathogenic Avian Influenza (HPAI) and Sheep Pox and Goat Pox (SPGP) spreading out significantly. Foot and Mouth Disease (FMD), absent in the Union for almost 20 years, reappeared. Priority plant pests such as the bacterium *Xylella fastidiosa*, pinewood nematode (*Bursaphelenchus xylophilus*), the fall armyworm (*Spodoptera frugiperda*), the Japanese beetle (*Popillia japonica*) and the Emerald Ash Borer (*Agrilus planipennis*) spread more widely in the reporting period, causing increasing concern.

Procurements help different activities such as vaccine banks for animal diseases and IT platforms.

Regarding more specifically animal welfare, implementation gaps in EU legislation remain challenging, for example regarding routine tail docking of pigs and transport of unweaned calves. We have provided comprehensive technical support to facilitate effective implementation of the animal welfare rules, including through the four EU Reference Centres for animal welfare. The new Animal Welfare network within the iRASFF platform continued to provide evidence for the follow-up to non-compliances with over 270 notifications received by June 2026, of which 90% relate to animal transport. In addition, a new series of BTSF trainings on animal welfare will start, including trainings on the farm welfare Directives, and on the new dogs and cats Regulation.

EU regulatory agencies in my portfolio continued to provide essential support for the consistent application of EU laws. The European Medicines Agency (EMA) and the European Centre for Disease Prevention (ECDC) have been key, in their respective remits, for implementing and applying EU legislation consistently, providing scientific guidance, assessing disease risks, and assessing national health preparedness across the EU. The European Food Safety Authority (EFSA) has provided essential scientific advice and support on food and feed safety, animal and plant health, human nutrition, and GMOs and its scientific assessments form the foundation for EU risk management decisions. The European Chemicals Agency (ECHA) has contributed to ensure the uniform implementation of the Biocidal Products Regulation. My services also work closely with the Community Plant Variety Office (CPVO).

C. Enforcement

Coherent enforcement in the areas of my portfolio benefits citizens by meeting their expectations and supports businesses by ensuring a level playing field and enhancing the functioning of the internal market. During the reference period, my services opened 13 infringement cases for failure to transpose directives in the area of food safety and plant health and closed four cases, totalling 23 active infringement cases open at the end of the reference period.

Through rigorous audits, my services monitor systematically compliance with EU rules in the areas of health and food. We have completed the second series of Union controls on clinical trials on human medicines. The main picture emerging is that there are arrangements in place for undertaking the inspection of clinical trials, thus enabling compliance with the corresponding legal requirements. In addition, during the reporting period, we have completed 69 audits in Member States, evaluating the performance of the national authorities across a wide range of topics, including animal welfare, import controls, the eradication of epizootic diseases and food safety. Those audits continue to provide an overall assurance that the official control systems operating in Member States are working correctly. However, where weaknesses are identified, we make relevant audit recommendations and follow up the corrective and preventive actions taken by national authorities. This approach, which includes systematic follow-up and dialogue, has successfully closed the vast majority of audit recommendations, encouraged Member States to implement corrective actions, and thereby strengthened the enforcement of EU law across all Member States.

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We continue to receive a significant number of complaints. Along with parliamentary questions[7], they provide information regarding alleged or real deficiencies in the implementation and enforcement of EU laws. Each of these is carefully evaluated and addressed, as necessary.

In the area of public health, during the timeframe covered by this Report, close cooperation between my services and the national authorities led to improved application of the Cross-Border Healthcare Directive. **In the area of food safety**, the Court of Justice upheld the infringement proceedings brought by the Commission against Bulgaria that had failed to meet its obligations under Directive 2009/54/EC concerning natural mineral waters. Work is ongoing with the competent authorities in order to address outstanding concerns in national legislation which is aimed at complying with the ruling of the Court. Following a request for a preliminary ruling, the Court of Justice also held that a Czech national measure which imposes an obligation to pre-notify the arrival of food supplements from other Member States to Czechia is not in compliance with Regulation (EU) 2017/625 on official controls on the agri-food chain. The consequences of this ruling for ongoing infringement proceedings which the Commission brought against Czechia in relation to the same Czech national measure are assessed in view of the next steps.

In order to better implement the application of the mutual recognition principle in cases of **food supplements** to be placed on the market in a Member State, where there are nationally set maximum amounts of vitamins and minerals to be added to these foods, my services contributed to resolving cases referred to the Commission by SOLVIT centres, to train staff in SOLVIT centres and to the preparation of the Evaluation Study (Implementation Report) on the implementation of Regulation (EU) 2019/515 on the mutual recognition of goods led by DG GROW mapping these issues in this area. In parallel, to solve these issues long-term, my services are working on the harmonisation of the maximum amounts at EU level, as required by EU law.

With regard to **plant protection products** and their compliance with the applicable Regulation, we continued monitoring emergency authorisations granted by Member States. We have sent a mandate to EFSA to assess the justifications for emergency authorisations for the use of plant protection products containing three active substances, which were granted repeatedly by some Member States. Upon my proposal, the Commission sent a letter of formal notice to Romania for failure to fulfil its obligations under the applicable Regulation regarding the continued granting of emergency authorisations for outdoor use of products containing no longer approved neonicotinoid active substances for which the specific uses had been prohibited previously.

As regards animal welfare, following deficiencies observed during audits conducted by my services, as well as some complaints highlighting possible breaches of the rules on animal transport, we have undertaken a number of actions to promote better compliance with EU animal welfare rules, such as regular meetings and follow-up with the national authorities of several Member States. As regards transport of unweaned calves from Ireland to the European continent, the Irish competent authorities have launched a project for the development and the deployment in practice of automated feeding systems for calves during transport over longer periods. My services are working closely with the Irish authorities to follow up on their commitments. The Commission is also working on supporting candidate countries to prepare for proper enforcement of the EU's animal welfare rules and has prepared training that will take place in Montenegro and in Ukraine in 2026 or 2027. Finally, in order to ensure a proper implementation of the upcoming Regulation on the welfare of dogs and cats and their traceability, the Commission has organised a first exchange with Member States' experts on implementation efforts needed, identifying challenges and how to overcome them. More work is ongoing and the Europa webpage[8] on infringements, pre-infringement dialogues and transposition provides up-to-date statistical information on the Commission's enforcement activities and Member States' compliance with EU law, including trends per policy area, topic and Member State.

[7] During the reporting period, no petitions requiring specific follow up by the Commission in the context of this report were identified. The petitions received mainly concerned individual cases, matters falling primarily within Member State competence, or issues on which no further action by the Commission was warranted (for example, because they did not reveal a possible breach of EU law or had already been adequately addressed through existing procedures).

[8] Application of EU law - European Commission

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4. Way forward

Through collaboration, innovation, and targeted support, the Commission will continue to enhance the implementation of EU laws, benefiting citizens and strengthening public health, food safety as well as animal health and welfare across Europe. For example, the results of the implementation dialogues will be key to help identify issues of poor implementation, gold-plating, or fragmentation, and uncover opportunities for simplification and harmonisation.

Through enhanced dialogue with the Member States and audit activities, and, where necessary, infringement procedures we will continue to promote the enforcement of EU legislation in the interest of European citizens and businesses. The Commission will also continue to prevent non-compliance of national laws with EU legislation in health and food safety areas, from the outset through the assessment of Member States' draft laws notified under the Single Market Transparency Directive.

We look forward to completing the co-legislative negotiations on the various initiatives mentioned in this report with the aim to achieve robust frameworks and simplification.

I will hold my fourth Implementation dialogue still in 2026, focusing on feed. In the coming years, further implementation dialogues will address areas where implementation hurdles are identified by stakeholders or through tools for stress tests, such as evaluations, fitness checks and reality checks.

My services will continue to stress-test the acquis to ensure that rules are fit for purpose to achieve the objectives in the area of food and feed safety. This will involve launching the abovementioned study on food and feed safety.

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Annex: examples

Below are some practical and concrete examples of initiatives undertaken, and which show real benefits for citizens and/or companies.

Public health

1. MyHealth@EU

MyHealth@EU is one of the most tangible examples of the EU's digital transformation delivering direct benefits to citizens, health professionals and healthcare systems.

During the reporting period, implementation of the European Health Data Space (EHDS) advanced following the entry into force of the EHDS Regulation on 26 March 2025. The Regulation establishes the legal and technical framework for the secure cross-border exchange of electronic health data and reinforces MyHealth@EU as the EU-wide infrastructure supporting services such as electronic prescriptions and patient summaries.

A key achievement during the reporting period was the continued expansion of the MyHealth@EU network, with Austria, Cyprus, Norway and Slovenia joining the infrastructure. This increased the availability of cross-border digital health services and enabled more citizens and health professionals to benefit from secure access to health information across borders.

Through MyHealth@EU, citizens can already use cross-border electronic prescriptions and patient summaries, allowing health professionals in another participating country to access essential medical information when treating a patient abroad. These services improve continuity of care, enhance patient safety and facilitate access to healthcare for Europe's increasingly mobile population.

The EHDS Regulation provides a clear implementation pathway: from March 2029, all Member States will be required to support cross-border exchange of patient summaries and electronic prescriptions through MyHealth@EU, while medical test results, medical imaging and discharge reports will follow from March 2031.

Food and feed safety

2. Plant health

The Commission has presented to the Standing Committee for Plants, Animals, Food and Feed, for discussion and later for a vote, an Implementing Regulation on plants, plant products and other objects that may be moved within the Union with a plant passport associated with them in a way other than physical attachment. That Regulation will be based on Article 88 of Regulation (EU) 2016/2031 and is scheduled to be adopted by the end of 2026.

The derogation intends to relieve the business sector from the obligation to physically attach plant passports to certain commodities, when due to their size, shape or way of packaging the physical attachment is impossible or very difficult (such wood or turf), thereby reducing administrative and operational burdens to those operators.

Overall, the measure introduces targeted exceptions for certain bulk/unpackaged items where physical attachment is impractical, while ensuring traceability by moving from one operator to another, without mixing or splitting.

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3. Digitalisation: e-submission food chain platform (ESFC)

In the reported period until 31 December 2025, we made targeted updates facilitating the use for companies of the **ESFC** platform, which focused on three key areas: (i) usability, (ii) transparency, and (iii) interaction efficiency.

First, to improve usability, interface refinements such as enhanced validation rules and checks to prevent duplicate documents were introduced. In parallel, expanded workflow tools such as the "Copy Data Between Applications" function were introduced, which helped applicants prepare more consistent dossiers and streamlined re-submissions.

Second, increasing the transparency of dossier information was achieved by granting EFSA early read-only access to pre-stage dossiers and introducing advanced data handling features, such as the "Download Metadata" function and structured downloads for data-protection requests.

Third, to support more efficient interactions among applicants and regulatory authorities, a new direct communication channel was released enabling more direct information exchanges among actors involved in the handling of a dossier. In parallel, enhancements to the notification system have been introduced including automated reminders for RFI and ADR deadlines to ensure better timeline compliance.

Moreover, in the reported period covering the first half of 2026, we have introduced enhanced validation functionality to automatically identify and reject non-compliant file submissions, ensuring alignment with assessment criteria. This improvement will optimise the ESFC submission process by maintaining data quality and reducing manual intervention. Second, in response to industry feedback, a bulk-upload capability for confidentiality assessment justifications has been implemented, enabling applicants to efficiently link supporting documentation to multiple files. These enhancements will further streamline workflows, minimise administrative burden, and improve the overall user experience in ESFC.

4. Digitalisation: The EU Animal Disease Information System (ADIS)

The EU Animal Disease Information System (ADIS) is a key digital tool supporting animal health surveillance and disease reporting across Europe. During the reporting period, the interconnection between ADIS and the World Organisation for Animal Health (WOAH) became fully operational following the successful onboarding of all 44 participating countries and territories in summer 2025. This redesign enables the automatic transmission of animal disease notifications from ADIS to WOAH's World Animal Health Information System (WAHIS), allowing competent authorities to submit information only once while simultaneously fulfilling both EU and international reporting requirements.

Since October 2025, all EU Member States, EFTA countries and several EU candidate countries have been using ADIS as a single-entry point for animal disease notifications. The system has delivered tangible operational benefits by eliminating duplicate data entry and the need for parallel connections to multiple reporting platforms.

As a result, national veterinary authorities can manage disease notifications more efficiently, reduce the risk of reporting errors, and ensure greater consistency and accuracy of animal health data. The initiative also strengthens cooperation between the EU and international partners by improving the timeliness, quality and comparability of disease information, thereby supporting faster responses to animal health threats and contributing to more effective disease prevention and control measures.

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5. Simplifications for the funding of veterinary and phytosanitary programmes under the SMP Food programme

Since August 2025, the funding mechanisms for veterinary and phytosanitary programmes under the Single Market Programme for Food (SMP Food) that we implemented (via the European Health and Digital Executive Agency - HaDEA) have undergone significant simplification, delivering measurable efficiency gains for Member States and stakeholders involved in food safety, animal health, and plant protection. These changes were introduced following requests from and in agreement with the competent authorities of all 27 Member States, ensuring the reforms directly address administrative burdens while maintaining robust oversight.

The most impactful change has been the shift from annual to multiannual grants, now covering a three-year period. This new approach applies not only to veterinary and phytosanitary programmes but also to other key actions, including grants for EU Reference Laboratories and Antimicrobial Resistance (AMR) control plans. As a result, Member States no longer need to submit yearly funding requests or engage in repeated rounds of fine-tuning during evaluation and grant agreement preparations. This reduction in administrative procedures has cut the workload for national authorities by approximately 66%, as the bulk of the paperwork is now required only once every three years instead of annually. Additionally, the new system allows for multiple pre-financing payments, significantly reducing the frequency of financial reporting and improving cash flow for ongoing programmes.

To further streamline processes, data reporting requirements have been substantially simplified. Reports no longer require information that Member States are already legally obliged to submit through other channels to my services or to the European Food Safety Authority (EFSA). This eliminates redundant reporting, reducing the risk of inconsistencies while freeing up administrative resources. Complementing this, the digitalisation of reporting tools has introduced greater efficiency and accuracy. A standout innovation is the Lump Sum Calculator developed by HaDEA within the e-Grants platform. This tool enables Member States to encode their budgetary needs and intermediate financial reports directly online, leveraging prefilled data from previous periods to minimise manual input and eliminate the errors commonly associated with Excel-based submissions.

The cumulative effect of these simplifications has been a substantial reduction in the administrative burden on Member State authorities since August 2025. By cutting unnecessary bureaucracy, accelerating funding disbursements, and leveraging digital tools to improve accuracy, the reforms ensure that public resources are redirected from paperwork to core activities, such as disease surveillance, food safety controls, and emergency response, ultimately benefiting citizens, businesses, and the broader agri-food sector.

Electronically signed on 24/09/2026 17:36 (UTC+02) in accordance with Article 11 of Commission Decision (EU) 2021/2121

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