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Delegations will find in annex the above-mentioned report.

European Commission

2025 ANNUAL PROGRESS REPORT

Simplification, Implementation & Enforcement

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for Health and Animal Welfare

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1. Introduction

As Commissioner for Health and Animal Welfare, I was tasked to complete the European Health Union by further diversifying supply chains, improving access to the most advanced treatments, boosting the competitiveness, resilience and security of health systems and working on strategic inventories. 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 in my portfolio areas. In respect of simplification, it sets out an overview of recent, ongoing and upcoming initiatives. This first annual progress report on simplification, implementation and enforcement covers the period from 1 January to 31 July 2025 and will be submitted to the relevant Parliamentary committees and Council configurations by 30 September 2025.

2. Executive Summary

European Union action, in complement to national policies shall ensure a high level of human health protection and improve 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.

I am delivering on the Commission's simplification agenda including by simplifying our regulatory framework that will help better deliver the policy objectives. To do so, I will put forward a Food and Feed Safety Simplification Omnibus package in Q4 2025, with the aim to increase

competitiveness of the food and feed industry and of farmers and reduce administrative burdens related to marketing authorisations of products – while not compromising on safety. I also plan to put forward a proposal to revise the rules on medical devices that will enhance innovation in the sector at the end of 2025 based on the findings in the targeted evaluation.

My services will also conduct evaluations on animal health law and the biocidal products Regulation and, in that context, will identify further opportunities for simplification in these sectors with the help of stakeholder views through dedicated hands-on reality checks. Implementation dialogues, and targeted stakeholder consultations, will provide useful input for the forthcoming evaluation by DG SANTE of the biocidal products Regulation.

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.

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 delivered

A. Simplification and stress tests

In the first half of 2025, the Commission started to implement the simplification agenda in line with the Communication on simplification. In the area of health and food safety, this has involved a reality check for medical devices and in-vitro diagnostic medical devices and an implementation dialogue in biocides.

First, the Commission will put forward a **Food and Feed Safety Simplification Omnibus** package in Q4 2025, with the aim to increase competitiveness of the food and feed industry and of farmers and reduce administrative burdens related to marketing authorisations of products.

This envisaged proposal aims to increase competitiveness of EU farmers and the food and feed industry and to reduce administrative burden to Member States' authorities related to marketing authorisations of products. It intends to accelerate the access to the EU market for biocontrol substances and products for plant protection. The proposal will also include simplification and clarification of regulatory requirements for other plant protection products, biocidal products, feed additives, food hygiene and official controls, as well as other measures to simplify the EU legal framework that applies to food and feed safety.

The envisaged changes will bring significant overall savings, i.e. reduce compliance costs for companies, in particular: the removal of the systematic periodic renewal of approval for all active substances (except candidates for substitution), faster market access for biocontrol products (through provisional authorisation), broader market access for products through simplified and facilitated mutual recognition of authorisations and strengthened minor uses authorisations.

Second, this year, the Commission will propose a targeted revision to streamline the **rules and procedures for medical devices** and *in-vitro* diagnostic medical devices to reduce administrative burden, enhance predictability and cost-efficiency, while preserving a high level of public health and patient safety. This revision is based on the ongoing targeted evaluation of the two Regulations.

Thirdly, in 2025 the Commission will present a **Biotech Act** with a focus on health-related biotech. The Act is expected to include simplification elements including on clinical trials.

My services are committed to gradually stress test legislation particularly through evaluations and the new reality checks. A few examples of on-going targeted evaluations in the food and feed safety area are firstly **the European Food Safety Authority (EFSA) evaluation** which assesses the mandate, performance and organisational framework of the agency. The evaluation will also consider the potential for simplification and burden reduction in respect of the functioning of EFSA itself whilst maintaining a high level of health and environmental protection.

Within the context of the ongoing EFSA evaluation, we are assessing the replies of various stakeholders received in the context of the public consultation and through an ongoing study supporting the evaluation. Issues refer amongst others to the timeliness of the EFSA scientific outputs, e.g. challenges relating to the average length of authorisation processes, number and length of stop-the-clock procedures and existing backlogs relating to pre-marketing authorisation of regulated products in the food and feed area. Other issues refer to the provision of services offered by EFSA to applicants and certain requirements imposed by EFSA including EFSA guidance

documents and IT systems for applicants. The services under my responsibility intend to further assess such aspects to reduce the administrative burden in the applicable procedures to the benefit of applicants, including in particular SMEs under the appropriate legal framework.

The second evaluation that is starting this year relates to the **Biocidal Products Regulation.** This evaluation will assess whether the Regulation has performed in accordance with its objectives as well as existing and emerging needs and will identify issues that need to be improved. It will look at simplification of processes that can reduce delays in active substances and product pre-marketing authorisation.

The two last examples in the food and feed area refer to **animal health law and on-farm welfare.** An evaluation is under way of animal health law rules, which impact on small and medium sized farms rearing animals and businesses involved in the moving of animals. The Commission will assess whether the rules meet the objectives, are proportionate, relate to current and emerging needs, align with other EU interventions, and if there is an EU added value. A new initiative refers to the modernisation of EU legislation for **on-farm animal welfare** for certain farming sector(s) to ensure updated animal welfare requirements, modernise existing rules, e.g. end the "Cage Age" for certain farming sector(s), and to better use animal welfare indicators and modern technologies for monitoring and enforcement purposes. Further harmonised and clearer requirements will simplify compliance rules applying to farmer and food business operators who are currently confronted with different layers of animal welfare requirements (EU, Member States, private standards, etc).

In the health area, in the context of the on-going targeted evaluation of **medical devices** and in-vitro diagnostic medical devices Regulations, two hands-on **reality check** workshops, one for manufacturers, and another one for health care professionals, users and patients were organised by my services in February and March 2025 to understand how stakeholders perceive the benefits and the challenges resulting from the medical devices and invitro diagnostic medical devices Regulations. By way of example, the hands-on exchange with stakeholders identified three main concerns for manufacturers: high compliance costs, lack of legal certainty, and the hampering of competitiveness and innovation. These aspects are considered in the on-going targeted evaluation and targeted revision.

I held an **Implementation dialogue** on **Regulation (EU) No 528/2012 governing the placing on the market of biocidal products** on 15 July 2025 with stakeholders representing businesses, including SMEs, and civil society.

Participants underlined that the implementation of the Regulation has improved public health since its adoption. However, they also stressed that the processes for approving active substances and authorising biocidal products are costly, cumbersome and complex, suffer from delays and create uncertainty for companies, while full implementation is not yet achieved for all existing active substances. The Implementation Dialogue allowed to hear about the main obstacles for companies in the EU when complying with the rules and provided important input for the evaluation of the Regulation that we will start this year.

The empowerments for delegated and implementing acts in my entire portfolio area were screened in

2025 and assessed to determine which are to be prioritised and deprioritised. The screened empowerments were either still to be exercised, were expected to still be used to amend already adopted delegated or implementing acts, or are exercised on a regular basis. My conclusion is that 19 empowerments should be deprioritised, as they are not essential for achieving the set policy objectives, whereas 80 empowerments should be prioritised because they allow simplifying already adopted acts, are legally required and/or essential to achieving health policy objectives to the benefit of citizens and businesses.

B. Implementation

Effective implementation of EU legislation is key to ensure consistent standards across Member States.

In the area of public health, my services have actively supported the implementation of the new Regulation on

Substances of Human Origin (SoHO) by equipping authorities and professionals with the necessary tools and training, including through the SoHO Coordination Board. We are working intensely to ensure a successful implementation of the European Health Data Space Regulation (EHDS) and of the Regulation on Health Technology Assessment (HTA). As regards EHDS, this includes the preparation of an implementation strategy, the adoption of several implementing acts, the development of core services and infrastructure, supporting the Member State coordination group and subgroups and funding training. We are also supporting Member States in the implementation of the Delegated Directive on Heated Tobacco Products and via a Joint Action on health promotion and disease prevention, the Council Recommendation on smoke- and aerosol-free environments.

Through the Accelerating Clinical Trials in the European Union (ACT EU) initiative and the cooperation with Member States and stakeholders we are supporting the implementation of the clinical trial framework to the benefit of European patients. We also launched a study to assess the functioning of the Clinical Trials Regulation and whether it has reached its objectives. To turn the tide against cancer and strengthen the European Health Union, we continued to work under 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 ensure a high uptake of 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 also developed a dedicated IT HTA Platform to facilitate the joint work in a secure setting. The European database on medical devices (Eudamed) is also set to digitalise regulatory processes to improve traceability and enforcement across the EU. We adopted improved and simplified electronic instructions for use of medical devices to further digitalise healthcare systems. The MyHealth@EU infrastructure will be expanded to facilitate exchanges in primary use of data under the European Health Data Space Regulation. The Clinical Trials Information System (CTIS), subject to continuous improvement, is now the single entry point for the authorisation of Clinical Trials in the EU and it contains more than 9000 entries. We are pleased that the Clinical Patient Management System (CPMS) could host high specialist consultations over 4500 rare and complex clinical cases in Europe. A new biotechnology portal finally has streamlined regulatory navigation for companies.

With regard to preparedness, the implementation of the Regulation on Serious Cross-Border Threats to Health is underway with the enhancements to the Early Warning and Response System, aligned with the Preparedness Union Strategy.

To underpin the rapid detection and response to serious cross-border threats to health, we have established the first **EU Reference Laboratories in human health** which are funded from EU4Health Programme. Nine of those laboratories are now in place and more are under preparation.

To enhance citizens and business awareness, we supported workshops on patients' rights and obligations with focus on cross-border healthcare, and training sessions for veterinarians and farmers on reducing antimicrobial use.

Regarding food and feed policy, we have led several initiatives to implement the high EU objectives. In particular, we engaged with stakeholders to minimise food loss and waste through the EU Platform on Food Losses and Food Waste. The results of a consumer segmentation study offered vital insights to Member States for crafting targeted waste reduction strategies. The communication materials in all EU languages ensure the widespread outreach.

The preparation of the implementation strategy for the upcoming Regulation on plants obtained by certain new genomic techniques based on the Commission proposal is ongoing and a fast and smooth implementation of this Regulation will be a priority for the Commission given its potential to support competitiveness and innovation goals. In addition, my services have been regularly cooperating with the Member States in regulatory committees facilitating common approaches to implementation across Member States.

The Better Training for Safer Food (BTSF) initiative has continued to equip national authorities with specialized training on EU regulations, prioritizing capacity building through peer learning and best practice sharing. The EU funded Reference Laboratories (EURLs) under the Single Market Programme have continued to offer technical support to the Commission and Member States, developing analytical methods to ensure compliance across a variety of regulated products.

Regarding more specifically animal welfare, implementation gaps in the EU legislation remain challenging, for example with regard to routine tail docking of pigs and transport of unweaned calves. My services have provided comprehensive technical support to facilitate effective implementation of the animal welfare rules, including through the European Reference Centres for Animal Welfare (EURCAWs). On 1 January 2025, a new Animal Welfare network within the iRASFF platform was launched for non-compliance notifications with over 270 notifications received by June 2025, of which 90% relate to animal transport.

We are pursuing digital transformation in the legislative proposals on animal transport, welfare and traceability of dogs and cats through provisions on digitalisation and data access. We launched a study on digital solutions for the traceability of dogs and cats and a study on modalities for the use of new technologies and digitalisation to facilitate the implementation and enforcement of rules on animal welfare during transport.

The implementation work through the EU regulatory agencies in my portfolio is also instrumental to ensure 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, while the European Chemicals Agency (ECHA) has contributed to ensure the uniform implementation of the Biocidal Products Regulation. My services work also 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, DG SANTE opened 13 infringement cases for failure to transpose directives in the area of food safety and plant health and closed four cases, and 23 active infringement cases were open at the end of the reference period.

Through rigorous audits conducted by its Directorate for Health and Food Audits and Analysis (HFAA), DG SANTE monitors systematically compliance with EU rules in the areas of health and food. We have completed the first series of Union controls on clinical trials on human medicines, and the overall conclusion from these controls is that the systems in place can enable compliance with the corresponding legal requirements. In addition, already this year, we have completed 58 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. The overall conclusion from these audits is 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.

My services continue to receive a significant number of complaints. Along with parliamentary questions and petitions 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. We received numerous correspondence regarding alleged breaches of EU law by a Member State through the revocation of pharmacies licences, which was deemed to be an issue falling under the national competence. A recent complaint on the same issue is being assessed.

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.

We have also closely looked into emergency authorisations granted by some Member States for plant protection products and their compliance with the applicable Regulation.

As regards animal welfare, following the report of the European Parliament's Committee of Inquiry on the Protection of Animals during Transport (ANIT) and the EP recommendation on the protection of animals during transport adopted in 2022, as well as some complaints highlighting possible breaches of the rules on animal transport, my services have undertaken a number of actions to promote compliance, such as regular meetings and follow-up with the national authorities of several Member States, including training. To enforce the ban on routine tail docking of pigs, we are following up on national action plans in the context of the EU Animal Welfare working group. We also launched an external study on animal welfare indicators to monitor animal welfare at farm, transport, and slaughter as well as the contribution of relevant Common Agricultural Policy interventions towards animal welfare improvements and for the performance of official controls.

More work is ongoing and the Europa webpage on infringements, EU Pilot dialogues and transposition provides upto-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.

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 and 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 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.

I will hold my second Implementation dialogue still in 2025, focusing on import controls. 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.

The Commission will reflect on the carrying out of future in-house assessments including the commissioning of a study/studies to help testing the acquis and amend/remove rules that are not necessary in achieving the objectives in the area of food and feed safety. In the health area, further analysis is being conducted in the context of the preparation of the Biotech Act, including regarding clinical trials. Priority will be given to the stress test of the rules on medical devices and in-vitro diagnostic medical devices, through a proposal end 2025 for a targeted revision where the potential for impactful simplification and burden reduction is broadly recognised and currently being analysed.

Annex

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

Public health

1. European Reference Networks (ERN) - Clinical Patient Management System (CPMS)

The ERN Clinical Patient Management System (CPMS) is an IT system developed to support doctors' virtual clinical discussions on diagnosis and treatment of patients with rare and low prevalence diseases. In February 2025, the new CPMS 2.0 was delivered addressing the ERNs needs for a modern, simple and user-friendly system, maintaining the highest standards of security and data privacy. As of June, CPMS 2.0 is also available as full-fledged mobile app allowing clinicians to collaborate on the go.

2. European Health Data Space (EHDS) Regulation

Building on the existing voluntary framework, the Commission is rolling out the main building blocks of the European Health Data Space Regulation. In the first half of 2025, we advanced the development of MyHealth@EU, the infrastructure for the primary use of health data, with new cross-border services, such as patient summaries, ePrescriptions, eDispensations, laboratory results, hospital discharge reports and medical images. A reference software solution is being gradually released, supporting Member States in deploying these services nationally.

The Commission has additionally provided the first release for the European database for electronic health record (EHR) systems and for digital testing environments, whose deployment will be supported with a dedicated taskforce under the eHealth Network.

In parallel, we further developed the central platform of the HealthData@EU infrastructure, which will act as the central hub for the secondary use of electronic health data across the EU. It offers two main services: the EU dataset catalogue, which brings together metadata from national catalogues to help researchers, public bodies and other authorised users find datasets available for reuse across Europe; and shared services that support the coordination of cross-border data access applications involving multiple Member States. Two reference implementations releases of the platform were published since the beginning of 2025.

3. Health Technology Assessment (HTA)

The Health Technology Assessment (HTA) platform is a fundamental component of the new Regulation on Health Technology Assessment that became applicable on 12 January 2025. The Commission delivered a brand-new secure system that supports the collaborative work to produce

Joint Clinical Assessments and Joint Scientific Consultations and assess the Declaration of Interests of all users of the platform, from member state representatives to patients and clinical experts (over 500). The platform also serves as the single communication point with health technology developers (companies) as well as the space to exchange confidential information with the European Medicines Agency. The platform is instrumental in ensuring the efficient execution of the Regulation.

4. Medical devices

a) Simplification of the instructions for use of medical devices to further digitalise healthcare systems

Healthcare professionals within the EU are now able to receive instructions for use of medical devices in electronic format, rather than solely on paper, following a regulation adopted by Commission on 25 June 2025. The measure, part of the Commission's ongoing work to streamline and improve the EU's rules for medical devices and to modernise healthcare systems, was broadly supported in recent consultations of the Commission with professionals and industry representatives.

b) Master UDI-DI

The unique device identification (UDI) is a unique numeric or alphanumeric code related to a medical device, allowing for a clear and unambiguous identification of specific devices on the market and facilitating their traceability. For certain devices presenting a high level of individualisation, such as contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles, the "Master UDI-DI" specific assignment solution has been developed and further extended by legal acts adopted in April and in June 2025, as the identifier of a group of devices with specific similarities with respect to defined design (clinically and non-clinically) relevant parameters. This aims at simplifying assignation and reporting obligations on manufacturers. **Food and feed safety**

1. E-submission food chain platform

The E-Submission Food Chain (ESFC) system supports the process for authorisation of food related products to be placed on the EU market. Beyond managing the process, the system also provides the information on authorisations. During 2025 the system has been extended to accommodate in

addition to notifications of emergency authorisations notifications from Member States related to other authorisation types for Plant Protection Products (PPP):

- "for Article 36(6) to notify a rejection of a zonal system application (Article 33)"
- “for Article 36(6) to notify a rejection of a mutual recognition (Article 40)"

2. TRACES

We have prepared the necessary extensions to TRACES to make sure that as of 3 March 2025, as provided for by legislation, results of border checks especially on animals and goods which are checked for compliance with sanitary and phytosanitary as well as with organic rules are seamlessly integrated into the overall customs clearance of those commodities, under the Customs Single Window-CERTEX. This will provide high value to industry as it streamlines and eases administrative processes associated with customs clearance and high value to Member State administrations as it reduces administrative burden as well as the risk for fraud.

We have also worked to allow for the enhanced use of TRACES in other policy areas, for the new system for Import of Cultural Goods in view of the date of application of 28 June 2025 and for the Deforestation Regulation where TRACES will serve as a solution platform for a new system to be developed for the purpose of implementation of environmental legislation.

3. European Reference Centres for Animal Welfare

The four EU-funded animal welfare reference centres contribute to more effective implementation of EU legislation by providing scientific and technical support to the competent authorities of Member States and by organising training courses for the staff of those competent authorities. In the first half of 2025, the EU animal welfare reference centres have done so by publishing factsheets, reviews, newsletters, podcasts, videos for inspectors, replying to questions from Member States competent authorities. The centre for ruminants and equine has launched a ‘community of practice’ amongst inspectors. The centre for pigs has conducted on-site visits to some Member States to support their needs.