EUROPEAN
COMMISSION

Brussels, 24.11.2020
SWD(2020) 283 final

COMMISSION STAFF WORKING DOCUMENT

...

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the overall operation of official controls performed in Member States (2017-2018) to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products

{COM(2020) 756 final}

Table of contents

1. INTRODUCTION

The Commission is required to publish an annual report on the overall operation of official controls in Member States[1]. The report is to be based on the annual reports submitted by the national authorities on their control activities[2] and on the results of Commission controls carried out in Member States.

This staff working document provides further detail on Commission controls in the areas of food and feed safety, animal and plant health, animal welfare, pesticides, organic farming and quality schemes[3].

The following chapters present issues of particular interest from the above mentioned controls undertaken by Commission services during 2017 and 2018.

The Better Training for Safer Food (BTSF) programme is one of the tools used by the Commission to share information on conclusions, good practices or lessons learned during its control activities.

2. COMMISSION CONTROLS IN MEMBER STATES

Within the framework for European Union (EU) controls, Commission services undertake audits to verify compliance with feed and food law, animal health and welfare, and the requirements for official controls.

The Directorate-General for Health and Food Safety establishes a multi-annual audit and analysis programme in line with the key Commission strategic priorities. The 2017-2018 audit and analysis programmes focused on:

- antimicrobial resistance (AMR) management;
- better preparedness, prevention and response to human, animal and plant health threats;
- safe and sustainable food and food production systems;
- effective implementation of EU food legislation;
- a sustainable food production that improves the welfare of animals;
- effective, efficient and reliable controls.

Audit reports contain recommendations to address identified shortcomings. The audit reports, Member States' action plans to address the recommendations, and country profiles documenting progress with the delivery of these plans are published on the

[1] Article 114 of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.

[2] Article 113(1) of Regulation (EU) 2017/625.

[3] Report from the Commission to the European Parliament and the Council On the overall operation of official controls performed in Member States (2017-2018) to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.

Commission website[4], providing stakeholders and citizens with a factual and transparent account of how Member States deliver on correct implementation of EU law.

In addition, overview reports are produced for most audit series. Their purpose is to provide a comprehensive picture of controls carried out by Member States in a given area, and to identify issues that are relevant to all Member States. Moreover, they highlight good practices as well as difficulties encountered with the implementation of the relevant legislation. These overview reports are published and an overview and links can be found online[5].

In 2017 and 2018, the Commission published 22 overview reports on its audit and non-audit activities in the areas of food safety and quality, animal health and welfare, and plant health:

- Use of slaughterhouse data to monitor welfare of broilers on farm
- Educating professionals on animal welfare
- Study visits on rearing pigs with intact tails
- Hazards and management of risks in the feed sector
- Rabies eradication in the EU
- Pesticide residue control in organic production
- Animal health controls in zoos and laboratories
- Audits of official controls in EU-Member States
- Authorisation of plant protection products
- Antimicrobial resistance monitoring in zoonotic and commensal bacteria
- Marketing and use of plant protection products
- Identification and response to new plant health risks
- Sustainable use of pesticides
- Official control systems in place for food additives and smoke flavourings
- Welfare of dairy cattle
- Private assurance schemes in the feed sector
- Mitigation measures in place for Campylobacter spp. in poultry
- Welfare of commercially farmed rabbits in the EU
- Antimicrobial Resistance - Prudent use of antimicrobials in animals
- Third countries' National Policies and Measures on Antimicrobial Resistance
- Veterinary Preparedness for Natural Disasters

[4] https://ec.europa.eu/food/audits_analysis_en

[5] https://ec.europa.eu/food/audits-analysis/overview_reports/index.cfm

• Animal Health Controls for Bivalve Mollusc Aquaculture

2.1. Horizontal issues

National audit systems: audits of official control systems

Between 2016 and 2018, the Commission Services conducted a series of 25 audits in Member States, to evaluate their systems for auditing[6] their official control programmes.

The vast majority of relevant competent authorities had put audit arrangements in place covering most official control activities concerned, and, in some cases, going beyond this scope.

The overall conclusion of the audit series was that effectively implemented audit arrangements contribute to ensuring the quality, and improving the consistency and effectiveness of official controls, if there is strong management commitment to the follow-up of audit recommendations.

The audit series showed that competent authorities still faced some challenges in optimising audit arrangements to provide credible, reliable results that have a positive impact on the effectiveness and consistency of official controls.

The Commission audits were well accepted and appreciated by the auditees and the outputs were helpful to improve the consistency and effectiveness of official controls.

The identified areas for improvement were ensuring the independent scrutiny of the audit process, auditing effective implementation and suitability of official controls, effectively following-up audit results, planning the audit programmes using a risk-based approach and guaranteeing transparency of the audit process outside the organisation. Improvements in these areas would further contribute to the credibility, reliability, relevance and impact of national audit systems.

In addition, the overview report[7] highlighted useful practices, which may be of interest to the Member States. The outcome of this audit series influenced the forthcoming revision of the guidelines for the conduct of these audits of official control systems[8].

---

[6] Article 4(6) of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 required that competent authorities carry out internal audits or may have external audits carried out, and respond appropriately in the light of their results, to ensure that they are achieving the objectives of Regulation (EC) No 882/2004. This requirement has been taken over by Article 6 of Regulation (EU) 2017/625.

[7] Overview report 2018-6810 Audits of official controls in EU Member States.

[8] Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules.

2.2. Food safety

Fipronil

During 2017, and in the wake of the fipronil contamination incident[9], the Commission services carried out four fact-finding missions.

The main objective was to gather information regarding the incident, the operation of official controls and the actions taken by the Member States during this incident.

The missions also sought to identify the challenges and difficulties encountered by the Member States concerned, including the communication with other relevant Member States and with the Commission. The overall aim was to contribute, with information obtained on-the-ground, to a complete picture of the incident and to identify the lessons to be learned with a view to improving, where necessary, the tools[10] available at EU level for the management and containment of similar incidents.

In the four Member States concerned, the contingency plans in place satisfactorily addressed the incident. Equally, and despite considerable difficulties, traceability of eggs back to the farms of origin was overall successful. Nonetheless, certain factors affected the speed of response to the incident, notably initial delays in communication between Member States and subsequent difficulties, at different stages of the incident, including the need to rapidly respond to and disseminate updated information. These factors may have contributed to the extent of the impact of this incident.

Competent authorities as well as food business operators devoted significant efforts to address the incident. A number of key challenges encountered throughout the management of the incident included the interpretation of laboratory results, the handling of large amounts of information updates, and issues related to the destruction of the contaminated products and materials.

The Commission introduced a number of concrete initiatives aimed at supporting and ensuring a harmonised approach among Member States in the management of the incident. These initiatives, agreed by the Member States at the Ministerial conference that took place in Brussels on 26 September 2017, addressed a number of the challenges as subsequently confirmed by the fact-finding missions. The initiatives included the enhancement and coordination of the risk assessment, risk management and risk communication for such incidents, the development of provisions to strengthen the existing flexibility in residue monitoring, the enhancement of the exchange of information and maximising the potential of the RASFF and AAC systems at EU level.

---

[9] The 2017 Fipronil eggs contamination was a fraud incident leading to the contamination of chicken eggs and egg products by the insecticide fipronil.

[10] Tools such as the Rapid Alert System for Food and Feed (RASFF), the Administrative Assistance and Cooperation System (AAC) and the Food Fraud network.

Slaughter hygiene

The slaughter hygiene project, which concluded in 2017, consisted of study visits in 15 Member States and Norway and a series of associated workshops attended by representatives of Member States, Switzerland, Norway, Iceland and the European Free Trade Association Surveillance Authority. The project identified and shared a number of competent authorities' working practices with a positive impact on slaughter hygiene, and thus on consumer protection.

The study visits and workshops presented working practices in place in the countries visited, aimed at addressing problems encountered by all competent authorities and ensuring optimal slaughter hygiene and minimum levels of carcass contamination. The experts reported that they appreciated the opportunity to see how other competent authorities worked and to share ideas and experiences. The Commission noted that some particularly effective working methods were subsequently taken up by a number of Member States.

The participating Member States shared a number of their working arrangements and practices to support their verification and controls such as: "clean livestock policy"[11], on-line clipping of livestock, carcass contamination recording systems, official verification procedures for carcass contamination, pooling technical and managerial responsibilities, sampling and analysis performed by competent authorities on microbiological criteria, risk profiling of slaughterhouses and publication of official control results.

In addition, this series of study visits highlighted a number of key elements found in environments that are conducive to good slaughter hygiene. These elements include among others the existence of well-organized and committed processors' associations, the availability of strong vocational education in the sector and company policies to retain skilled staff. Also underlined was the importance of slaughterhouse operators having well thought-out and developed slaughtering techniques, and for competent authorities to be aware of these and to have a positive attitude towards new developments in this area.

Labelling

The objective of this audit series, carried out in eight Member States, was to obtain an overview of the performance of Member States' official control systems on the implementation of the relevant national and EU legislation[12] on food information to consumers and nutrition and health claims made on foods at producers, importers and all points of entry in the market.

While the majority of the Member States audited perform official controls in this area, in a number of cases, the coverage of such controls on food information was limited. In

[11] See the COMMISSION STAFF WORKING DOCUMENT Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin (paragraph 5.2) for more background to the cleanliness of the animals going to slaughter.

[12] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers and Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

some cases, there were no controls on nutrition and health claims at all or not to the extent necessary for a satisfactory assessment that the claims used comply with EU rules. This can lead to the non-detection of relevant non-compliances and consequently lack of subsequent enforcement measures. This could in turn lead to insufficient protection of consumers from fraudulent practices. The individual audit reports identify the reasons, ranging from issues related to the designation and organisation of competent authorities to insufficient training and knowledge of officials.

In practice, the authorities perform official controls at all stages of the food chain both on prepacked and non-prepacked foods. The assessment of food information provided and nutrition and health claims made can be very time-consuming. In addition, it requires specific knowledge and experience due to the complexity of these areas. The verification of the correlation between the content and the information provided for foods is only possible if all relevant supporting documentation and records related to the raw materials used as ingredients and semi-finished products are available. In addition, sampling and analysing for different parameters can be of assistance for verification purposes.

National legislation for substances causing allergies and intolerance in non-prepacked foods and on country of origin information for certain foods is in force in several Member States. However, two Member States did not follow the notification procedures of these to the Commission.

Ready-to-eat (RTE)

During 2017 and 2018, the Commission experts undertook a targeted series of five audits in the RTE area, due to the number and significance of foodborne outbreaks linked to such foods.

The findings of these audits point to some common areas among the official controls systems of most of the Member States audited that need to be reinforced in order to achieve effective systems.

The most significant issues fall into two main areas:

a) the under-detection of non-compliances, mainly due to controls not effectively targeting these riskier foods, making limited use of systematic audits and reviews during these controls and particularly the lack of or ineffective training of and understanding by inspectors of the requirements and of the impact of certain detected issues in RTE food production; and
b) ineffective actions taken to ensure the timely correction of non-compliances, mainly due to issues related to the classification and weighting of non-compliances (including those relating to procedures to prevent cross-contamination), not taking the specific risks linked to RTE food products into account and inadequate procedures which either limit or do not support effective follow-up of inspection results.

The audits also identified an array of good practices that could be helpful for competent authorities in the design and implementation of the official control system, including

- guidelines and advice for food business operators and authorities in the implementation of key legal requirements;
- access by officials at local level to experts in complex technical areas such as shelf life studies assessment;
- availability of adequate information to officials supporting the evaluation of product process validation;
- use of guidelines, set by the EU reference laboratories, for sampling of processing areas and equipment and specific support for the evaluation of operators' compliance with the required microbiological analytical methods.

E-Commerce

E-commerce in the EU has grown steadily in recent years. Today the EU is one of the largest e-commerce markets in the world. The online marketplace offers all kinds of food, including fresh meat and fish. Moreover, an ever-increasing variety of food supplements is available online. Among those are products that regularly give rise to serious health concerns. The range of products available and the fast growth of internet sales of food create challenges for the official control of food sold via this medium. Therefore, the Directorate-General for Health and Food Safety undertook a number of actions aimed at assisting Member States in their control tasks and to contribute to enhanced cooperation, effective controls and enforcement.

As part of these actions, a series of fact-finding missions in seven Member States, carried out in 2017, evaluated how the competent authorities had integrated controls on the sales of food via the Internet into their official control systems.

The competent authorities in all Member States visited recognised the necessity to enhance their controls related to the online sales of food, and had taken steps to adapt their traditional inspection activities in order to verify that food supplied online is safe and subject to an appropriate level of official controls. The approach taken varied in the Member States visited due to different set-ups and priorities.

The missions showed that official controls of food sold online are relatively limited, and mainly focused on the registered food business operators. Non-compliances identified during controls mostly related to labelling and health claim requirements. A few cases revealed the online marketing of dangerous substances as food supplements.

The identification of non-registered food business operators with an online presence has proven challenging due to the relatively limited resources assigned to this area, and the fact that a considerable number of these operators can easily and rapidly enter and exit the online marketplace, without being aware of their responsibilities. Moreover, the presence of online sellers who actively try to avoid official controls by changing their digital identity is an additional hurdle for competent authorities.

Cooperation and intelligence sharing between different authorities within and across Member States was shown to be crucial. Finally, enforcement and cooperation with non-

EU countries have proved, so far, to be the main constraints for an effective control of food sold via the Internet.

Nonetheless, the competent authorities in the Member States are making continuous efforts to respond to the challenges brought about in the food sector by the digital economy, and are equally eager to share their experiences and to learn from others. The mission series provided an opportunity to bring together all involved in these types of controls. Some Member States have carried out exchange visits for their staff and are cooperating successfully. The published overview report[13] provides more detail on this matter.

Food contact materials (FCM)

With a series of fact-finding missions and audits in seven Member States in 2017-2018, the Commission evaluated the effectiveness, efficiency, relevance, coherence and added value of EU legislation concerning FCM. The objectives were to establish how Member States have integrated FCM controls into their official control systems and to identify challenges, good practices, as well as any measures needed to improve these official controls where necessary. A Commission workshop complemented the series in 2017.

The series established that, in general, the Member States visited have designated competent authorities and official control laboratories in charge of FCM, and that some competent authorities have set up a registration system to identify the business operators involved in the FCM chain. As with controls over E-commerce, approaches vary, partly depending on the level of priority given to this area.

Furthermore, the series found that in terms of effectiveness, controls in this area face some serious challenges, crucially the lack of laboratory analytical methods and technical knowledge and expertise amongst official control staff, in what is acknowledged as a very technical area. In addition, health risks associated with FCM are perceived as relatively low, with an associated minimal level of priority being attributed to this area. Therefore, controls are generally limited to a verification of the presence of generic declarations of compliance or indication of suitability for use.

This, in combination with an absence of systems for hands-on training for control staff, leads to inspectors not being able to build up technical knowledge. Hence, they are not in a position to evaluate specific and relevant details of the declarations of compliance and supporting documentation, as required by legislation.

As a result, fundamental aspects may be and, indeed, are, overlooked during controls. Together with the already relatively low frequency of controls, this results in limited findings and consequently, in a failure to identify potential risks. This hampers risk-based and targeted controls and reinforces the perception that it concerns a low-risk or in any event low priority area.

[13] Overview report 2018-6537 Overview report on internet sales of food.

Currently, in the majority of the cases, inspectors cannot reliably establish compliance with the general requirements of the relevant EU legislation[14] covering the safety of FCM, or provisions in EU legislation for specific types of FCM and substances used, or in national legislation.

This does not mean or suggest that the products are unsafe, but that the official control systems in place are not or, at least, not sufficiently capable of identifying non-compliances and their associated food safety risks.

2.3. Feed safety

Risk-based official controls in the feed sector

In 2017, the Commission services carried out nine fact-finding missions in Member States on the risk-based approach implemented by competent authorities for the organisation of official feed controls. A 2016 overview report[15] based on a series of audits carried out between 2012 and 2014 had concluded that in a general context of resource constraints, risk prioritisation of official controls in the feed sector was weak or at an early stage of development.

The fact-finding missions sought to establish whether there had been positive developments in the application of risk-based principles and identify any examples of good practice or mechanisms, which, if adopted by more Member States, would improve the risk-basis for official controls on feed. The overall conclusion of these missions was that Member States largely apply a risk-based approach for organising official controls, although with a variation in how the different criteria set out in the legislation form the basis for these assessments. The inspection frequency and feed sampling programmes are mainly based on the risk inherent in the activities of the operator and to a lesser extent on other criteria (such as past record of compliance, reliability of own-checks or participation in private quality assurance schemes). While many Member States established advanced risk-scoring systems for compound feed producers, risk scoring applicable to other operators (primary producers or traders) is less developed. A BTSF workshop in September 2018 enabled a discussion with Member States representatives on the outcomes of this series, including good practices identified.

Evaluation of official controls on feed additives, their ingredients and traceability

In 2018, the Commission audited five Member States' implementation of official controls on feed additives and ingredients for their production in the EU. Feed additives and their mixtures (premixtures) are the essential ingredients in modern compound feed manufacture. A substantial quantity of feed additives and ingredients for their production is sourced from third countries and it is important to be able to demonstrate that such imports do not contain undesirable substances. The main issues detected during these

[14] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

[15] Overview report 2016-8965 Hazards and Management of Risks in the Feed Sector.

audits concerned the competent authorities' assessment of operators' HACCP[16]-plans, actions taken to correct and prevent non-compliances, implementation of appropriate sampling protocols and labelling. Recommendations were made accordingly and corrective actions undertaken to improve the effectiveness of the control systems in place.

Evaluation of the implementation of hygiene, traceability and trade requirements of processed animal proteins, including exports, imports and intra-union trade

In 2018, a series of five audits evaluated the measures put in place by Member States' competent authorities to verify and ensure that relevant business operators implement the legal requirements on the hygiene, traceability and the trade of processed animal protein (PAP)[17]. The audits focused on PAP produced and traded between Member States, imported and exported to and from the EU and on the traceability and trade of organic fertilizers and soil improvers. Attention was paid to the practical implementation of the export procedure of PAP containing ruminant protein following a relaxation of the feed ban rules in July 2017. Common problems identified included poor or limited implementation of official controls on channelling of consignments of ruminant PAP intended for export and as regards intra-union trade of PAP, failure of the competent authority of destination to inform the competent authority of origin on the arrival of PAP consignments, thus undermining traceability of these consignments. The audit series established that corrective actions were taken to improve the effectiveness of the control systems in place in the Member States visited.

2.4. Animal health

African swine fever

This animal disease with important social and economic impact entered the EU in 2014 and spread to several EU countries. The Commission audited affected Member States to verify the effectiveness of the control measures applied by national authorities and to trigger constant improvement. The audits indicated that most Member States were applying appropriate measures to contain the disease. The audits have an important role in reassuring trade partners about the reliability of the EU system for regionalisation[18].

The Commission also started fact-finding visits to Member States at risk but free from the disease (i.e. with common borders with affected countries) to get an overview of their preparedness and response capacity, especially in the areas related to wild boar.

---

16 HACCP – Hazard Analysis Critical Control Points, a management tool used to control food safety hazards, Codex Alimentarius Standard CAC/RCP 1-1969 provides more background.

17 PAP are by-products from parts of slaughtered animals that are in principle fit for human consumption but are not used for production of food (e.g. udder, ovary, bones). If properly sterilised, these products are seen as a valuable protein source in animal nutrition. In the aftermath of the mad cow disease crisis, the feed ban was introduced to limit these Transmissible Spongiform Encephalopathies. It bans the use of PAP in feed for farmed animals.

18 The classification of Member States' territories or parts thereof related to the local epidemiological situation and its evolution of the disease in domestic pigs and wild boars.

Highly pathogenic avian influenza

The Commission carried out two projects in this area. The first (2017) covered surveillance and preparedness for the disease. The results of the fact-finding visits and meetings fed the discussions of experts for the implementing and delegated acts related to the disease, developed under the Animal Health Law (AHL)[19]. The published overview report provides more detail[20].

In the second project (2018), The Commission audited Member States affected by the avian influenza epidemics in 2016-2017 to check the effectiveness of the measures they took to control outbreaks of the disease. The audits also looked at what lessons the authorities learned from that crisis and if they used them to improve their contingency plans.

Bivalve mollusc aquaculture

In 2018, a project based on fact-finding missions to the main EU producing countries assessed the implementation of the EU animal health rules in this € 1 billion EU sector. The project also assessed the legislation and possible improvements for appropriate prevention, surveillance and control measures of diseases in bivalve molluscs facilitating safe movements within EU waters. The analysis of the findings provided a solid basis to identify what was working or not, in relation to the enforcement of controls and the implementation of legislation within this area. This fed the drafting of the new delegated and implementing acts of the AHL.

The main findings are currently being reviewed in the process of drafting the new delegated and implementing acts of the AHL**.** The Commission published an overview report[21].

2.5. Animal welfare

Animal welfare during transport

The Commission carried out a project (2016-2018) focused on the transport of live animals destined for export outside the EU. It covered road and sea transport.

For road transport, the project had a significant impact:

- The export of live animals by road to Turkey decreased significantly (72% decrease in two years).
- Most Member States took actions to limit transport of live animals during hot days[22].

---

19 Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')

20 Overview report 2017-6304 Avian Influenza.

21 Overview report 2018-6568 on bivalve mollusc aquaculture

22 At least 13 Member States took actions and there were another five Member States that did not export animals by road.

- The number of animal welfare incidents at the Bulgarian-Turkish border during the summer months decreased, having zero incidents in 2018.
- The compliance rate (measured at the last EU border) increased, reaching over 97% in 2018.

There are still big challenges regarding monitoring and enforcing EU rules for the non-EU part of the journeys. There are no systems to check the actual route followed by livestock trucks and Member States have no means to check the availability and adequacy of resting points along the route outside the EU. The published report[23] provides an overview of the good practices and problems that the project identified.

Regarding sea transport, the project included audits on the official control systems to ensure welfare of live animals transported in livestock vessels. The results showed a defective system of checks in most Member States, ineffective to minimise animal welfare issues during the trip. The Commission is working to get the European Maritime Safety Agency involved in the checks for livestock vessels, with the aim to improve the quality of the checks, increase compliance of livestock vessels with the relevant EU legislation[24] and improve communication between Member States in this area.

For sea transport of animals, there are currently no mechanisms to gather information about the welfare of the animals during the journey and at arrival. This makes it impossible to establish the welfare quality of the journeys and hinders continuous improvement.

The Commission published an overview report that contains the good practices and main problems identified during the project[25].

Animal welfare on farm

Pigs

The Commission made pig welfare one of its priorities for enforcement and implemented a two-year work programme in this area. There are 26 Member States that routinely tail dock pigs, although the EU legislation prohibits this as a routine[26]. The 26 non-compliant Member States presented and refined action plans to move towards compliance, which constitutes a shift in the correct direction. Even though the quality of the plans is highly variable, there is some progress and some Member States have started to trial rearing batches of pigs with intact tails. Member States are not near full compliance and conditions on farm must improve if the number of tail docked pigs is to start to decrease.

The biggest challenge for stopping routine tail docking of pigs is serious and uniform enforcement. Another challenge is the very active internal market for live pigs. Member

[23] Overview report 2019-6834 Welfare of animals exported by road.
[24] Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations.
[25] Overview report 2019-6835 Welfare of animals exported by sea
[26] Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs.

States' authorities and producers are afraid of losing competitiveness if they enforce before others who are competitors and/or clients.

Rabbits

Following a request from the European Parliament[27], information was gathered during 2017 about the health and welfare of farmed domestic rabbits.

The objective of this work was to further understand the rabbit production sector and identify good practices relating to the health, welfare and housing of rabbits reared for meat production.

It showed that the actual size of rabbit farming in the EU is just over a third of previously available figures and it is highly concentrated in Spain, France and Italy. The overview report[28] outlined the factors that contribute to the animal welfare of rabbits at the time of production and their impact in the different production systems. It included pros and cons for animal health and welfare of the different rearing systems and it concluded that the rabbit farming sector is broadly in line with existing EU legislative requirements regarding protection of rabbits at the time of production.

2.6. Plant health

Plant health is of global importance for sustainable agriculture and horticultural production, food security and protection of the natural environment. These are all at risk from the combined effects of the increasing globalisation of trade in plants and plant products and climate change, which increases the likelihood of introduction and establishment of pests not previously present in the EU. To verify that EU rules are adhered to, the Commission services continued conducting a wide range of audit and analysis activities in the field of plant health.

EUROPHYT-*Interceptions*

Based on data from the EUROPHYT-*Interceptions*[29] system, to which Member States and Switzerland notify the occurrence of pests in imported consignments of plants and other objects, and a monthly alert list[30], audits were focused on those non-EU countries from which a high number of import consignments containing pests were intercepted. The impact of Commission measures and audits based on the EUROPHYT-Interceptions system may be illustrated by the trend in the number of interceptions made due to the presence of pests. Thus, the number of annual pest interceptions indicated by the mentioned trade alert list has been reduced by over 30% over the five years (from 2,310 on the first list in 2014 to 1,597 on the list for 2018).

---

27 Follow up to the European Parliament resolution of 14 March 2017 on minimum standards for the protection of farm rabbits (2016/2077(INI)).

28 Overview report 2017-6303 Commercial farming of Rabbits in the EU.

29 https://ec.europa.eu/food/plant/plant_health_biosecurity/europhyt_en

30 https://ec.europa.eu/food/plant/plant_health_biosecurity/non_eu_trade/alert_list_en

The annual EUROPHYT-*Interceptions* reports present further statistics and analysis of the interceptions of consignments[31].

Europhyt-*Outbreaks*

There is a continuous need for better identification and assessment of the risk factors and for better targeting of the Member States activities, in particular in the light of new outbreaks and spread of pests in the EU. In relation to the identification of pests in Member States, a new module under the EUROPHYT system was developed for Member States to notify outbreaks in the EU. The launch of the web-based notification system EUROPHYT-*Outbreaks* at the beginning of 2017 and the development of a common protocol for notifications facilitated rapid reporting and fostered the harmonisation of practices to control the outbreaks between Member States. This in turn has contributed to timely decision-making at EU level for an increased level of protection of the EU territory against phytosanitary risks. The annual reports on the outbreak notifications are available online[32].

Import Controls on plant health

The EU's import controls on plants and plant products aim to minimise the plant health risks, using a combination of prohibitions on import of pests and the highest-risk commodities, imposition of special requirements for other commodities to be certified by the plant health authorities of the exporting countries and including official checks on their import into the EU. A project was organised to evaluate Member States' capacity and performance of import controls on plant health against the requirements of the relevant EU legislation, and to identify and promote best practices across the EU. The findings of the project were taken into account during the negotiation process of the Plant Health Law and Official Controls Regulation. The project findings also shaped many of the implementing and delegated acts for the application of the import procedures and controls provided for under the new legislation. An overview report on the project is available online[33].

Export controls for plants for planting and seeds from non-EU countries

An overview report describes a further project[34] to evaluate the official plant health controls for the export of plants for planting and seeds from non-EU countries to the EU. Many quarantine pests of concern are widespread in the exporting countries. The production technologies in non-EU countries audited can reduce the plant health risk but cannot ensure that the places of production or the consignments are free from pests. The majority of the exporting countries audited did not adequately observe the EU requirements, and there is a plant health risk that quarantine pests are present in the growing medium of the imported plants. Additional efforts are needed to inform the

[31] EUROPHYT – interceptions annual reports.

[32] https://ec.europa.eu/food/sites/food/files/plant/docs/phb_ho_annual_report_2015-6_en.pdf

[33] Overview report 2019-6876 Plant Health – Import Controls.

[34] http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=133

exporting countries about the EU rules in commonly understandable form and about the practical aspects of achieving conformity. To protect the health of plants in the EU, the Commission services continue to conduct audits in these countries, train staff from exporting countries and regularly update EU legislation to limit the potential risks.

Xylella fastidiosa

Xylella fastidiosa, is a destructive bacterium that has done serious damage to olive and almond trees in Italy and Spain. The pathogen has a wide host range and endangers many agricultural, horticultural and forest species, in particular in the southern and central regions of Europe. The Commission has closely followed this pest's outbreaks in various Member States, not least by frequent audits since the first discovery in Italy at the end of 2013. The audits' results and the Commission services' follow-up have contributed significantly to improving the controls in the countries with outbreaks and also contributed to the improvement of the relevant EU legislation. As the Italian authorities failed to control the spread of the pest, the Commission sent Italy two letters of formal notice in 2015 and 2016 and a reasoned opinion in July 2017, and in May 2018 it referred Italy to the Court of Justice of the EU[35]. In September 2019, the Court declared that Italy had failed to comply with its obligation to implement measures to prevent the spread of the bacterium[36]. The Commission services continued their audit and follow-up activity in Italy and other Member States to address this plant health risk.

2.7. Pesticides

Authorisation of Plant Protection Products (PPPs) and controls on their marketing and use

An overview report[37] on an audit series carried out in 2016 and 2017 showed delayed or reduced access to new pest control tools for growers, due to Member States failing to use the zonal authorisation system envisaged in EU legislation[38], and failing to meet legal deadlines in a majority of cases. In addition, it showed that the re-evaluation of PPPs already on the market, in light of new scientific and technical knowledge, was delayed and finally, that delays in processing requests for authorisation contributed to more emergency authorisations being granted by Member States.

In order to help Member States address the weaknesses in the system, the Commission services created two working groups, on PPP Formulation Analysis and on PPP enforcement. Representatives of over twenty Member States routinely attended the meeting of the Working Group for PPP Formulation Analysis and the three meetings of the PPP Enforcement Working Group organised by the Commission in 2017 and 2018.

---

35 https://ec.europa.eu/commission/presscorner/detail/en/IP_18_3805

36 https://curia.europa.eu/jcms/upload/docs/application/pdf/2019-09/cp190106en.pdf

37 Overview report 2017-6250 Plant Protection Products - Authorisation.

38 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market.

The Sustainable Use of Pesticides

The broad range of measures set out in the Directive on the Sustainable Use of Pesticides (SUD)[39] provides the basis for reducing the risks and impacts of pesticide use on human health and the environment, in particular by promoting the use of Integrated Pest Management (IPM) and alternatives to pesticides.

In 2017, the Commission submitted a report to the European Parliament and the Council on Member States' National Action Plans (NAPs) and on the implementation of the SUD[40], which concluded that despite the substantial progress made by Member States, significant gaps remained. As IPM is a cornerstone of the SUD, it was of particular concern that Member States had not yet set clear targets for its implementation. More generally, the report noted the need for Member States to improve the quality of their NAPs, primarily by establishing specific and measurable targets and indicators for a long-term strategy for the reduction of risks and impacts from pesticide use.

In response to the weaknesses identified, the Commission has taken various actions aimed at improving implementation of the SUD. In 2017, these included the establishment of the SUD web-portal[41] to provide a source of relevant information and to facilitate the exchange of information. Following an assessment of NAPs, letters were sent to all Member States highlighting where improvements should be made. In 2018, further letters were sent to some Member States and four targeted audits on the implementation of SUD were carried out. In addition to the audits, web-based surveys are used to collect data on SUD implementation. In December 2018 a survey was organised to collect additional information on NAP implementation and experience gained by Member States. Two meetings of the SUD Working Group were organised each year to discuss and exchange information on SUD related issues. In late 2018, a BTSF programme was launched on the control of IPM implementation at farm level, with 14 training sessions to take place between December 2018 and June 2020.

Harmonised risk indicators

Following the commitment given in response to the European Citizens Initiative "Ban glyphosate and protect people and the environment from toxic pesticides" and, as required by the EU legislation[42], Harmonised risk indicators have been established. These indicators provide a basis for quantifying trends over time in reducing the risks associated with the use of PPP.

The first Harmonised risk indicator is based on the quantities of PPP placed on the market (sold) in each Member State, while the second is based on the number of

[39] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides.

[40] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_sup_report-overview_en.pdf

[41] https://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides_en

[42] Article 15 of the SUD (Directive 2009/128/EC).

emergency authorisations granted by each Member State[43]. Both indicators include weightings that reflect the intrinsic properties of the different active substances. A three-year baseline is used in calculating these indicators to take account of yearly fluctuations in the quantity and type of PPP used due to variations in the extent and severity of pest outbreaks between years. Member States are obliged to calculate and make available to the public their harmonised risk indicators and links to this information, along with the overall EU harmonised risk indicators, are published on the Commission's SUD web–portal[44]. A number of Member States are not making their information available to the public. The Commission has repeatedly reminded Member States of their obligations in this area.

The Harmonised risk indicator I for the EU28 results show there has been a 20% reduction in risk in the period from 2011 to 2017 even though the quantity of PPP placed on the market during this time remained relatively constant[45]. The Harmonised risk indicator II results show a 50% increase from 2011 to 2017. However, it is problematic to calculate and interpret this indicator, as there is no harmonised way to record information on the quantities of PPP used under each emergency authorisation, so this can vary substantially.

Biocides

Biocidal products are substances or mixtures of substances used to control harmful organisms in areas other than those related to agricultural production. Biocides include a wide range of products commonly used by both professionals and non-professionals, such as disinfectants, wood preservatives and those for pest control such as rodenticides. They comprise products containing both chemicals and microorganisms as active substances.

The Biocidal Products Regulation (BPR)[46] that became applicable from 1 September 2013 regulates the marketing and use of biocidal products. The majority of biocidal products on the market are currently undergoing re-evaluation for approval of all biocidal active substances used in them under the BPR. Transitional arrangements allow the availability of biocidal products containing biocidal active substances that have not yet been re-evaluated on the market in Member States[47].

In 2017 and 2018, fact-finding missions in Hungary, Germany, Spain, Belgium and the Netherlands assessed their implementation and enforcement of the BPR. The main objective was to collect information about why the re-evaluation of biocidal products is

43 Article 53 of Regulation (EC) No 1107/2009.

44 https://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/harmonised-risk-indicators_en

45 https://ec.europa.eu/eurostat/statistics-explained/index.php/Agri-environmental_indicator_-_consumption_of_pesticides#Key_messages

46 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products - OJ L 167, 27.6.2012, p. 1–123.

47 Art. 89 of Regulation (EU) 528/2012.

slow. The main challenges identified were the complexity of the review processes, poor quality of dossiers submitted by applicants, the lack of synchronised procedures and insufficient staff resources including resources wasted on applications withdrawn during the evaluation process.

The use of planning and forecasting tools and improving the quality of dossiers through awareness raising and additional pre-submission meetings with applicants were some of the potential good practices found to have minimised delays. Further enhancing cooperation and coordination within and between the authorities involved with biocides and adopting additional harmonised EU guidance would facilitate the evaluation process and save time and resources in the long run. In the meantime, triggering consultations between Member States would help to establish a harmonised approach and avoid disagreements at a later stage.

The significant amount of biocidal products which are not authorised for the market where they are available shows that further attention should be paid to the enforcement of the BPR, particularly aimed at products containing active substances still under evaluation in the Review Programme. More information can be found in the published overview report[48].

2.8. Antimicrobial resistance (AMR)

The development of AMR poses a rising threat to human and animal health. Each year, drug resistant infections result in a significant number of patient deaths and cause substantial healthcare and productivity losses in the EU. The urgent need for concerted action to limit its development and maintain an arsenal of effective antimicrobials is recognised worldwide.

In 2015, the European Commission published guidelines for the prudent use of antimicrobials in animals[49]. These define the prudent use of antimicrobials as leading to more rational and targeted use of these substances, thereby maximising their therapeutic effect and minimising the development of AMR.

In June 2017, the Commission published a European One Health Action Plan against AMR with an emphasised 'One Health' approach[50], acknowledging the interconnections between animal health, human health and the environment, as well as the common danger posed by the development of AMR.

Two overview reports provide further background and information on the prudent use of antimicrobials in animals and on the systems for the monitoring of AMR in zoonotic and commensal bacteria[51]. The EU AMR One-Health Network, chaired by the European

48 Overview report 2018-6780 Biocides.

49 Guidelines for the prudent use of antimicrobials in veterinary medicine. OJ C 299, 11.9.2015, p. 7.

50 https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf

51 Overview reports 2019-6788 Final Overview Report - Measures to tackle Antimicrobial Resistance through the Prudent Use of Antimicrobials in Animals and 2019-6789 Final Overview Report - Antimicrobial Resistance Monitoring in Zoonotic and Commensal Bacteria

Commission, consists of government experts on human health and animal health, the EU scientific agencies (the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA)) and Commission experts. This network holds bi-annual meetings that provide members with a platform to present national action plans and strategies and keep each other up to date on their progress, to share best practices, and to discuss policy options and how to enhance cooperation and coordination.

The Commission and the ECDC organise One Health AMR joint country visits. The overall objective of these country visits is to assist the Member States in further developing and implementing their national strategies and policies to tackle AMR in a One Health context. The scope of visits encompasses the human health, veterinary and environmental aspects of AMR, as well as inter-sectoral coordination and cooperation aspects.

2.8.1. Monitoring of residues of veterinary medicinal products and environmental contaminants in animals and products of animal origin

Veterinary medicinal products are widely used in animal breeding to either prevent or cure diseases. These substances may leave residues in the food products derived from treated animals. Member States implement annual monitoring programmes to verify that the use of veterinary medicinal products is in accordance with the applicable EU rules and to detect their potential misuse or illegal use. These programmes also include monitoring of environmental contamination, either from the use of pesticides or contaminants, to which animals may be exposed. Competent authorities take official samples from live animals or products of animal origin such as meat, eggs, milk, honey or aquaculture fish. In 2017, as part of these monitoring programmes, the 28 Member States took more than 410,000 samples to analyse for the presence of residues. The proportion of non-compliant results remained low (0.35%), at a level comparable to previous years.

In the area of residue monitoring, the Commission actions are two-fold. Firstly, every year, the Health and Food, Audits and Analysis Directorate, together with the responsible European Union Reference Laboratories, reviews all the Member States' residue monitoring plans, making comments and recommendations to the Member States to ensure continuous improvement of the plans. The plans are then formally approved (by a Member States' vote) by comitology[52]. Secondly, Commission audits in Member States verify the implementation of the plans. Elements such as laboratory performance and effectiveness of follow-up investigations of non-compliant results are examined in detail. In 2017 and 2018, seven audits were carried out in Member States resulting in a relatively small number of recommendations to improve the control systems in place.

[52] https://ec.europa.eu/info/implementing-and-delegated-acts/comitology_en

2.9. Organic production

The area under organic farming in the EU has increased by 70% in the last ten years and currently covers 7,5% of the total Utilised Agricultural Area[53]. Imports of organic agri-food products are also significant, reaching 3.3 million tonnes in 2018[54]. The Commission continues to carry out an annual programme of audits of the control systems for organic products produced and/or marketed in the EU. Imports from most non-EU countries are certified by private control bodies that are directly supervised by the Commission. Since 2017, the majority of the Commission audits in the organics sector have been dedicated to auditing these control bodies. Thus, in the period 2017-2018, 12 audits were carried out of control bodies operating in non-EU countries, while seven audits were of controls in Member States. In 2017 the Commission carried out audits in 3 MS (AT, BE and SI) and the same in 2018 (RO, IT and SK). A main difference between the two cases is that control bodies in non-EU countries may apply group certification if the group has an internal control system. This is mainly intended to facilitate exports from small farmers in developing countries that cannot afford individual certification. Many of the non-compliances found in non-EU countries relate to inadequate implementation of this system. In Member States, the audits found a variation of approaches as regards the organisation and implementation of controls and the national catalogue of measures in cases of non-compliances. The most frequent findings concern the supervision of control bodies, the respect of minimum control requirements from the control bodies, the notification of non-compliances of operators from the control bodies to the competent authorities and the enforcement of measures in cases of non-compliances.

2.10. Quality schemes for agricultural products and foodstuffs and Spirit Drinks

EU geographical indications legally protect more than 3,400 names of products in order to promote their unique characteristics and defend the traditional expertise of their producers. Each geographical indication has specific legal standards on how the product is made, while also serving as a guarantee for the quality and authenticity of the products. The Commission continued to carry out a limited annual programme of audits in Member States of their control systems for geographical indications. Thus in 2017-2018, six Member States were audited. The main issues found were weak market controls of products from other Member States and non-EU countries. For their own products, the Member States often failed to cover all the elements of the product specifications when carrying out controls at the producers.

2.11. Import controls

The EU and its Member States are committed to ensuring that official controls on imports of animals and goods are fit for purpose and provide the necessary assurances to

[53] https://ec.europa.eu/eurostat/statistics-explained/index.php/Organic_farming_statistics

[54] EU Agricultural Markets Briefs No 13, March 2019: "Organic farming in the EU. A fast growing sector".

European citizens that imported animals, food and feed meet the same high standards as for animals and goods produced within the EU.

Commission oversight of Member States' performance of import controls continued in the period 2017-2018, the results confirming Member States' efforts to continuously improve the way in which import controls are carried out. The Commission also continued to carry out inspections of new or modified border inspection posts in the context of their approval and subsequent listing[55].

In 2018, an overview report[56] on how Member States implement official controls on goods subject to special import conditions collated the main findings of audits in 12 Member States in 2015 and 2016. The audits focused on how Member States were implementing two particular types of import controls: "enhanced controls"[57] and "re-enforced checks"[58]. Whilst the overall results of these audits were positive, the overview report highlighted opportunities for improvement in the way in which certain Member States developed and implemented their monitoring plans used to target high-risk commodities for laboratory analyses. It also highlighted that recommendations made to the respective Member States had been acted on, resulting in strengthened import control systems in those Member States. The results were shared with all Member States in a Commission-organised workshop, designed to share experiences and good practices.

2.12. Genetically Modified Organisms

Four audits assessed the official controls of genetically modified organisms (GMO) including their deliberate release into the environment.

The audits looked into the organisation of the controls including staffing, planning, documented procedures, and the implementation of those controls including sampling, testing and enforcement measures.

The audits concluded that the official control systems for GMO, including their deliberate release and cultivation, were well organised. Weaknesses were identified in the areas of sampling and testing.

---

55 2009/821/EC: Commission Decision of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in Traces.

56 Overview report 2018-6525 Overview report on the safety of imported food.

57 Where there is a possibility that imports of certain food or feed, be it of animal or non-animal origin, present a risk to the consumer, special import conditions can be set. These "enhanced controls" often require an increased number of samples of the food or feed in question to be taken at the EU borders for testing in an EU laboratory.

58 Where import controls on food or feed of animal origin from a certain third country or a certain producer in a third country give grounds to believe that EU veterinary legislation has been seriously or repeatedly infringed, "re-enforced checks" must be applied by Member States.

3. BTSF

BTSF is a Commission training initiative covering food and feed law, animal health and welfare and plant health rules and also organic farming and quality schemes. .

BTSF held 275 training courses in the Member States covering a whole spectrum of subjects from food and feed law to animal health and welfare to plant health rules during 2017-2018. A range of courses is also offered in non-EU countries. Ten e-learning modules are available in five languages[59].

In this context, it is worth highlighting the awareness-raising work done on AMR. A series of 15 workshops on the prevention and control of AMR in the context of an overall "One Health" approach[60] started at the end of 2017.

The workshops aimed to spread knowledge to government officials in all EU countries working in the human health and veterinary sectors with the following main objectives:

- spreading knowledge on methods of prevention and control of AMR in the veterinary and human medicine sectors with a "One health" approach;
- further harmonising Member States' approaches and sharing best practices in the field of use of antimicrobials;
- increasing the efficacy of the competent authority in the field of AMR monitoring, reporting and control;
- increasing the compatibility of procedures and practices between public health authorities and veterinary/food safety authorities across the EU.

In December 2018, the Commission organised a workshop on preparedness of veterinary services for natural disasters. Based on the results of a questionnaire sent to all veterinary services in the EU and a fact-finding mission to two Member States[61], representatives from all Member States were invited to discuss good practices, similarities and differences. The objective was to enable them to better prepare for the sometimes-devastating effects of natural disasters such as forest fires, floods and earthquakes.

[59] Reports on the BTSF activities can be found online.

[60] More information on One Health can be found on the WHO website.

[61] Overview report 2018-6518 Veterinary Preparedness for Natural Disasters.

4. FOLLOW UP OF AUDIT RECOMMENDATIONS

The focus of the Commission control activities in the Member States is to check whether their competent authorities have in place the necessary control systems and enforcement measures to ensure the safety of the food placed on the EU market, the respect of animal welfare rules, and to keep important animal and plant diseases under control. Audits are generally accompanied by recommendations for corrective action. Audit reports are published and provide important insight into the effectiveness of controls and whether the relevant Union legislation is fit for purpose.

DG SANTE systematically follows up on actions taken by competent authorities to respond to recommendations made in audit reports. For the Member States, this is done mainly through package meetings known as General Follow-up Audits. The General Follow-up Audits cover all open recommendations across all 'food' sectors and are regularly carried out in all Member States. In order to ensure transparency, the results of these audits are published on the Commission website through updates of Member State country profiles[62].

[62] https://ec.europa.eu/food/audits-analysis/country_profiles/index.cfm