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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

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TABLE OF CONTENTS

1. EXECUTIVE SUMMARY 1
2. INTRODUCTION 2
3. LEGAL FRAMEWORK 3
4. REVIEW OF MEMBER STATES' ANNUAL REPORTS 4
   - 4.1. Receipt and review of Member States' annual reports 4
   - 4.2. Organisation and performance of official controls 5
     - 4.2.1. Operational targets and strategic objectives 5
     - 4.2.2. Planned and ongoing official controls 5
     - 4.2.3. Specific control activities 6
     - 4.2.4. Resources 7
   - 4.3. Overall compliance with feed and food law, animal health and animal welfare rules and organic farming rules 7
     - 4.3.1. Types of non-compliance 7
     - 4.3.2. Analysis of non-compliances 7
   - 4.4. National Audit Systems 8
     - 4.4.1. Internal and/or external audits on official controls 8
     - 4.4.2. Audits and inspections of control bodies 8
   - 4.5. Actions to ensure effectiveness in operating the national control plans 9
     - 4.5.1. Actions to ensure compliance by food and feed business operators and other relevant producers and business owners 9
     - 4.5.2. Enforcement: action taken in case of non-compliance 9
     - 4.5.3. Actions taken to ensure the effective operation of official control services 10
   - 4.6. Overall performance of the control system in operating the national control plans 10
   - 4.7. Amendments to the MANCP 10
5. COMMISSION SERVICES' CONTROL ACTIVITIES IN MEMBER STATES 11
   - 5.1. Audits 11
     - 5.1.1. Overview reports 13
     - 5.1.2. Some points to highlight 13
6. COMMISSION FOLLOW-UP AND ENFORCEMENT 14
   - 6.1. Systematic follow-up of recommendations 14
   - 6.2. Support to Member States 15
     - 6.2.1. Networks 15
     - 6.2.2. Better Training for Safer Food (BTSF) 17
   - 6.3. Enforcement 17
7. CONCLUSIONS 18

List of charts

Chart 1: number of missions carried out in Member States in 2017-2018 12
Chart 2: number and type of missions performed per topic 2017-2018 12

1. EXECUTIVE SUMMARY

This report describes the overall outcome of the national and Commission control activities carried out in 2017 and 2018 to ensure a high level of health protection and trust in the areas of food and feed law, animal health and welfare, plant health and plant protection products, organic farming and quality schemes. These areas are critically important in the daily lives of European Union (EU) citizens. They are also key to enabling the smooth operation of trade in food, animals and plants, both within the EU itself and with non-EU countries.

Member States are responsible for the implementation of risk-based official controls, which are detailed and planned in their multi-annual national control plans (MANCP). Official controls aim to verify that operators along the food and feed chain comply with applicable legislation and, where this is not the case, Member States are expected to enforce the said legislation and take steps to bring those operators back into compliance. Through audits, the Commission services verify Member States' implementation of official controls and associated enforcement activities.

Most Member States reported that staffing levels, financial and/or equipment resources were the key issues having an impact on the implementation of their MANCPs. Whilst improved data analysis, the use of IT tools and desk-based controls helped in overcoming these challenges in some Member States, others reported that they could not fully implement their control plans.

The Commission considers that adequate resources must be made available for on-the-spot inspections. When it comes to issues as diverse as food fraud[1], verifying the correct labelling of food and feed, implementation of good hygiene practices at slaughter and the appropriate use of plant protection products, on-site inspections in the field are vital.

Commission controls on Member States' implementation of official controls along the food and feed chain provide a clear picture of Member States' performance in verifying and enforcing operators' compliance with food and feed law, rules on animal health and welfare, plant health and plant protection products. As such, they contribute significantly to the legislative review process aimed at ensuring that the EU legislation is "fit for purpose".

On the basis of the Commission's controls on Member States, it is concluded that, overall, Member States have the requisite control systems in place to ensure the implementation of EU requirements. In some countries the Commission controls identified deficiencies in the implementation of official controls, indicating that there was still room for improvement. The Commission systematically followed-up its recommendations to the Member States and, where necessary, employed other enforcement tools. In addition, the Commission supported Member States (and non-EU

[1] Fraud is an intentional action taken by businesses or individuals for the purpose of deceiving purchasers and gaining an undue advantage therefrom. Such actions may also constitute a risk to human, animal or plant health, or to animal welfare or the environment. The webpages on the EU Food Fraud Network provide more background information.

countries) via the provision of technical assistance and training through the Better Training for Safer Food (BTSF) initiative and technical meetings of Member States' experts.

This report makes some recommendations to further enhance the official control systems through information networks for officials, the use of information from private assurance schemes and the publication of results of official controls.

2. INTRODUCTION

The EU aims to ensure a high level of health protection and trust in the areas of food and feed safety, animal and plant health, animal welfare, organic farming and quality schemes. EU citizens rightly expect high standards in these fields.

There is a comprehensive EU legal framework in place aimed at ensuring coherent controls throughout the food and feed chain, from farm to fork, and adequate monitoring, while ensuring an effective internal market and trade with non-EU countries.

One of the pillars of the EU's integrated food safety policy from farm to fork is an effective official control[2] system to verify operators' compliance with EU standards throughout the food and feed chain.

The Commission plays an important role in the overall control framework at EU level[3] and performs controls, including audits, in the Member States.

Member States submit an annual report on the implementation of their official controls to the Commission[4], which in turn reports[5] to the public, the European Parliament and the Council, on the overall operation of controls in Member States in light of:

- the annual reports submitted by the national authorities on their control activities;
- the outcome of Commission controls carried out in the Member States.

The current report covers the years 2017 and 2018.

3. LEGAL FRAMEWORK

The "General Food Law"[6] attributes the primary responsibility for ensuring that food is safe to the food/feed business operators. Specific EU regulations deal with the

[2] "official control" means any activity performed by EU Member State competent authority to verify compliance with food and feed law, rules on animal health and welfare, plant health and plant protection products and that animals and goods meet the requirements.

[3] Article 116 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 animal welfare, plant health and plant protection products - OJ L 95, 7.4.2017, p.1.

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

[5] Article 114 of Regulation (EU) 2017/625.

[6] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety - OJ L 31, 1.2.2002, p.1.

requirements for organic production and the labelling of organic products[7] and for quality schemes for agricultural products and foodstuffs (protected designations of origin, protected geographical indications and traditional specialities guaranteed)[8].

Member States are obliged to verify that business operators respect applicable EU law. Their MANCPs describe the systems of official controls for this purpose.

From 14 December 2019, changes to the legislation relating to these requirements under the Official Controls Regulation (OCR), became applicable[9]. The OCR describes the requirements for these control systems, the MANCP and the performance of official controls[10]. The most relevant requirements introduced by the new OCR related to the official control systems and MANCP are that:

- the scope now also includes official controls on animal by-products, plant health, plant protection products, organic production and labelling of protected designations of origin, protected geographical indications and traditional specialities;
- Member States are required to designate a single body to coordinate the preparation, coherence, review, updating of and reporting on the MANCP;
- the MANCP is to describe its strategic objectives and the risk categorisation of the official controls detailed therein;
- the MANCP needs to be made public, with certain limited exceptions;
- relevant information concerning the organisation and the performance of official controls is to be made available to the public, ensuring a high level of transparency; this obligation can be met through the publication of the annual report submitted by each Member State to the Commission[11].

The OCR requires the Commission[12] to perform controls, including audits, in the Member States and the Member States are required to take appropriate follow-up measures to remedy the shortcomings identified in these controls[13].

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7 Council Regulation (EC) No 834/2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 - OJ L 189, 20.7.2007, p.1.

8 Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs - OJ L 343, 14.12.2012, p. 1.

9 Regulation (EU) 2017/625 repealed Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

10 Articles 109, 110 and 111 of Regulation (EU) 2017/625.

11 Article 11 of Regulation (EU) 2017/625.

12 Article 116 of Regulation (EU) 2017/625.

13 Article 119 of Regulation (EU) 2017/625.

4. REVIEW OF MEMBER STATES' ANNUAL REPORTS

4.1. Receipt and review of Member States' annual reports

The Member States submitted their 2017 and 2018 annual reports under the earlier Regulation on official controls, which was repealed and replaced by the OCR[14]. The recommended structure for reports detailed in the Commission's guidelines, applicable to those years[15], formed the basis for this assessment.

Relatively few Member States submitted their annual reports to the Commission services within the deadline prescribed. Only Czech Republic, Estonia, Finland, Latvia, Lithuania and Slovak Republic submitted their 2017 and 2018 reports in time. Some countries were very late in their reporting- e.g. the Commission received the last annual report covering 2017 in April 2019 and in June 2020, it had still not received one annual report covering 2018.

The reports vary significantly in the presentation of data and in the nature of the data presented. This makes their analysis and comparison difficult, and poses a significant challenge to the Commission for the production of this annual report.

In relation to organic production, the Commission addressed the comments from the European Court of Auditors[16] and, in 2018, began to send follow-up letters to Member States requesting clarifications and additional information regarding the annual reports on organic production. For the reporting year 2017, a letter was sent to 14 Member States and one European Free Trade Association (EFTA) Country. For the 2018 reporting year, 24 Member States and one EFTA Country[17].

The OCR has introduced a standard model form for the annual reports and Member States[18] will also have to submit them electronically. The OCR extends the deadline (from 30 June to 31 August) for the submission of such information and data. Reporting the outcome of official controls, the type and number of cases of non-compliance and the measures taken to ensure the effective operation of the Member States' MANCP by electronic means and in a uniform way will facilitate the Commission's analysis and comparison of such data within and between Member States.

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14 Article 44 of Regulation (EC) No 882/2004.

15 Commission Decision 2008/654/EC of 24 July 2008 on guidelines to assist Member States in preparing the annual report on the single integrated multiannual national control plan provided for in Regulation (EC) No 882/2004 - OJ L 214, 9.8.2008, p. 56.

16 See the Special report no 04/2019: The control system for organic products has improved, but some challenges remain

17 2017 : Belgium, Czech Republic, Denmark, Germany, Estonia, Finland, Croatia, Hungary, Italy, Lithuania, Luxembourg, Poland, Portugal, Sweden, Norway ; 2018: Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Germany, Estonia, Ireland, Greece, Spain, Finland, France, Croatia, Hungary, Italy, Lithuania, Luxembourg, Malta, Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Sweden, Norway

18 Commission Implementing Regulation (EU) 2019/723 of 2 May 2019 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and the Council as regards the standard model form to be used in the annual reports submitted by Member States – OJ L 124, 13.5.2019, p. 1; adopted under Article 113(2) of Regulation (EU) 2017/625.

4.2. Organisation and performance of official controls

Member States have established official control systems, which largely enable them to ensure the application of the legal framework by food and feed business operators. Specific aspects of these systems are highlighted below to illustrate some of the challenges and initiatives presented by Member States.

4.2.1. Operational targets and strategic objectives

In their MANCPs, Member States should define the strategic objectives for the organisation of official controls[19]. However, less than a third (Belgium, Cyprus, Denmark, Estonia, Ireland, Finland, France, Germany and Italy) reported on specific key performance indicators (KPIs) used in the assessment of the effectiveness of their official controls. The inclusion of the results of such KPIs would provide a better understanding of how each Member State would use the outcome of the controls to amend the MANCP as necessary.

Other Member States report more generally on how their controls impact on objectives. For instance, the Netherlands stated that it uses animal welfare indicators to define targets for official control programmes. The Dutch competent authorities also measured the effectiveness of controls through specific projects such as the "Meat Supply Chain Improvement Plan", "Copper in Pig Feed" and "Compliance Monitor for Red Meat Slaughterhouses and Poultry Slaughterhouses". The annual report stated that the work carried out in 2017 on target group analyses and the development of monitoring strategies in anticipation of impact assessments provided a greater insight into compliance and, therefore, into the effectiveness of official controls.

4.2.2. Planned and ongoing official controls

According to the EU legislation, national authorities should plan their official controls according to identified risk-based priorities[20]. Although all Member States stressed that they define the frequency of official controls through risk-based assessments, they did not describe the methodology used.

Third party conformity assessment bodies certify European food and feed businesses under a number of private quality assurance schemes. Austria, Belgium, Denmark, the Netherlands and the United Kingdom reported on how they use information from these schemes in their risk assessments. As an example, the Netherlands held meetings with the owners of those schemes.

4.2.3. Specific control activities

Besides the planned control activities, Member States react to arising issues with specific control activities. Denmark and Hungary reported that where the number of regular

[19] Articles 42(2)(a) of Regulation (EC) No 882/2004 and 110(2)(a) of Regulation (EU) 2017/625.

[20] Articles 3(1) and 43(1)(b) of Regulation (EC) No 882/2004 and 9(1) of Regulation (EU) 2017/625.

official controls was lower than previous years, they increased the number of ad-hoc specific control activities.

In the Netherlands, risk-based monitoring showed that targeted monitoring of specific foods, targeted inspections of compliance and control of microbiological hazards can have advantages, and can provide businesses and consumers with a framework to base specific actions on.

In 2017-2018, most Member States had to deal with the effects of the fipronil incident originating in the Netherlands and leading to the withdrawal and recall of eggs and egg products throughout the EU (the issue is specifically mentioned in the reports of Belgium, Czech Republic, Denmark, Finland, France, Hungary, Italy, the Netherlands and Poland).

Several Member States (Belgium, Denmark, Finland, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxemburg, Malta, the Netherlands, Spain, Sweden, Slovenia and the United Kingdom) mentioned food fraud and internet sales as areas posing particular challenges. The new possibility under the OCR for sampling goods offered for sale by distance communication[21] and the rules on the level of financial penalties for food fraud[22] should assist Member States with enforcement in these areas.

The presence of African swine fever required significant official resources in the countries affected – to control the disease - or at risk – to prevent its entrance and ensure its early detection -, as reported by Estonia, Finland, Germany, Poland, Romania and Sweden.

4.2.4. Resources

Member States have to ensure adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to perform official controls and other official activities[23].

Belgium, Bulgaria, Cyprus, Finland, Germany, Greece, the Netherlands, Poland, Portugal, Romania, Slovakia, Spain and Sweden emphasised that budget cuts had resulted in reduced staff levels, sometimes declining further from previous years, and insufficient financial and/or material resources. Finland, Germany, Greece, the Netherlands, Poland, Portugal, Romania and Spain acknowledged that they could not perform all of the tasks planned in their MANCPs.

In the Czech Republic, France and the Netherlands, staff numbers were increased to deal with specific issues such as animal health (African swine fever, highly pathogenic Avian Influenza), plant health (*Xylella fastidiosa*), food fraud and preparation for Brexit.

Malta, Spain and Sweden mentioned difficulties in recruiting suitably qualified staff, a problem that food and feed business operators also faced.

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[21] Article 36 of Regulation (EU) 2017/625.

[22] Article 139(2) of Regulation (EU) 2017/625.

[23] Articles 26 of Regulation (EC) No 882/2004 and 78 of Regulation (EU) 2017/625.

Member States reported that the main strategies helping them to mitigate reductions in staff numbers were data analysis and improved IT-systems.

The Member States' competent authorities see sharing knowledge with national experts (within and between Member States) as a key element for improving audit procedures. All Member States welcomed the BTSF initiative.

4.3. Overall compliance with feed and food law, animal health and animal welfare rules and organic farming rules

The Annual Reports provide information on and an analysis of the non-compliances detected by the Member State competent authorities at food and feed business operators.

4.3.1. Types of non-compliance

Most non-compliances reported by the competent authorities across the Member States concerned failures in good hygiene practices, maintenance of infrastructure and operators either failing to perform or register the results of own checks.

Enforcement in the areas of the distribution, sale, labelling and use of pesticides and the labelling of food products destined for the final consumer also remained significant challenges in the Member States.

4.3.2. Analysis of non-compliances

Occurrence of non-compliance

Some reports mentioned percentages of non-compliance. Using percentages to compare Member States' performance can be misleading. When comparing Member States' data, a high(er) percentage of reported non-compliance in a given Member State does not necessarily mean that the situation is worse in this Member State. On the contrary, it may indicate that there is better risk-based targeting of controls and resources in that Member State. Better-targeted controls can lead to a higher number of inspections (and identified non-compliances).

Nature of the risk arising from non-compliance

Only a minority of annual reports provided information on the risks associated with non-compliances found during official controls.

In general, the risks related to the possible spread of animal or plant diseases and/or difficulty in containing them, loss of traceability and food safety hazards to consumers such as allergens, food poisoning and chemical contamination.

Root cause(s) of non-compliance

Most Member States indicated that food business operators still lack an understanding of the legal requirements. Elements such as a high rotation of workers, difficulties in finding qualified staff and insufficient training contribute to insufficient implementation of some legal requirements by operators.

Lower profit margins were also mentioned as an underlying cause of non-compliances in operators' infrastructure.

4.4. National Audit Systems

4.4.1. Internal and/or external audits on official controls

Member States must carry out audits on their own control systems, or have audits carried out on themselves, to ensure their compliance with the Regulation[24].

The Member States' annual reports included limited information on the internal audits performed on the official control systems. Most reports just mention the number of audits performed and a general statement on the follow-up of these (internal) audits. None of the annual reports provided information on the effectiveness of official control systems.

4.4.2. Audits and inspections of control bodies

Member States may delegate some of their official control activities[25]. In most Member States, private control bodies are active in auditing and certification of food business operators under the rules on organic production and the labelling of products under the quality schemes. The competent authorities are required to audit these bodies[26].

The Member States' reports did not provide information on controls over private control bodies, where integrations with the certification of private assurance schemes with the official control plan exist.

Under the rules on organic production, Member States are required to supervise the control bodies to whom they delegate official control tasks and report the results of these supervision audits to the Commission. The supervision audits include office assessments, witnessed audits, where the competent authority observes the inspection by inspectors of the control body, review audits, where the competent authority directly inspects organic operators to verify compliance with the operating procedures of the control body and to assess its effectiveness, and market controls. The competent authorities impose sanctions where necessary, including the withdrawal of these bodies' delegations.

[24] Articles 4(6) of Regulation (EC) No 882/2004 and 6 of Regulation (EU) 2017/625.

[25] Articles 5 of Regulation (EC) No 882/2004 and 28 of Regulation (EU) 2017/625.

[26] Articles 5(3) of Regulation (EC) No 882/2004 and 33(a) of Regulation (EU) 2017/625.

4.5. Actions to ensure effectiveness in operating the national control plans

4.5.1. Actions to ensure compliance by food and feed business operators and other relevant producers and business owners

Member States have developed tools, such as guidance notes, information campaigns and training, to help food business operators achieve compliance with food safety regulations. For example, Denmark introduced an animal welfare label and a "yellow card scheme" to reduce the use of antibiotics in pig farming.

Enhanced knowledge of official control staff and food business operators leads to higher compliance rates (e.g. on microbiological contamination, how to define the shelf life of food and how to perform and understand Listeria challenge tests in the Netherlands).

Competent authorities achieved more transparency through efforts on communication and awareness campaigns aimed at consumers. The Netherlands reported that publication of the results of official controls led to a higher level of compliance by food business operators.

4.5.2. Enforcement: action taken in case of non-compliance

Member States must have effective, proportionate and dissuasive sanctions/penalties in place[27].

Member States applied a range of enforcement actions, ranging from verbal and written warnings, through to seizure and destruction of goods to the (temporary) removal or restriction of approvals of operators. Some used administrative fines as a dissuasive measure. Referral to Court remained a last resort.

Finland and Luxemburg restricted operators' access to financial support systems whereas Belgium operated a system of announced official controls in consumer-facing food businesses in cities, with publication of the results.

Austria, Croatia, Finland, Germany, Italy, Latvia, Luxembourg, Malta and Portugal noted that cooperation with other authorities (e.g. tax authority, police) on food fraud had improved over the years.

4.5.3. Actions taken to ensure the effective operation of official control services

A number of Member States reported the use of (improved) IT-systems and data analysis techniques as ways of improving the effectiveness and efficiency of official controls. Other examples described in the reports included:

- the use of scientific innovations, e.g. whole genome sequencing for analysis of Listeria outbreaks;

[27] Articles 54 and 55 of Regulation (EC) No 882/2004 and 137, 138 and 139 of Regulation (EU) 2017/625.

- accreditation of competent authorities against international quality standards such as the ISO standards on Quality Management Systems (ISO 9001), the operation of various types of bodies performing inspection (ISO 17020) and the requirements for bodies providing audit and certification of management systems (ISO 17021);
- the creation of control networks in certain specialised sectors (e.g. food improvement agents - such as food additives and food flavorings, food contact materials, export control) to enhance the level of competence of both official control staff within the sector and of operators.

4.6. Overall performance of the control system in operating the national control plans

The Member States state in their annual reports that, overall, their official control systems are in place and sufficient. Most also report on plans to further improve efficiency. The most frequently mentioned means of achieving this were IT systems, data analysis, quality manuals and training.

4.7. Amendments to the MANCP

None of the Member States reported specific changes to their MANCPs. The only reported changes were based on results of official inspections and information obtained from laboratory analyses of food and feed products.

5. COMMISSION SERVICES' CONTROL ACTIVITIES IN MEMBER STATES

5.1. Audits

The Directorate for Health and Food Audits and Analysis of the European Commission's Directorate General for Health and Food Safety (DG SANTE) performs verification activities to check whether the EU legislation on food and feed safety, animal health, animal welfare, plant health, organic farming and quality schemes and some areas of human health[28] is properly implemented and enforced. It publishes an annual work programme, and a mid-year update[29] on the website of DG SANTE.

The Directorate performs these controls on a regular basis and in cooperation with the competent authorities of the Member States.

One element of the audits are on-the-spot verifications, where Commission experts engage with competent authorities performing official controls. Experts from the Member States regularly assist the Commission experts.

The aim of the Commission controls is to[30]:

- verify the application of food and feed law, rules on animal health and welfare, plant health and plant protection products;
- verify the functioning and organisation of national control systems and the competent authorities;
- investigate and collect information
    - on official controls and enforcement practices
    - on important or recurring problems with the application or enforcement of the rules;
    - in relation to emergency situations, emerging problems or new developments.

The reports of the individual audits are publicly available[31] on the DG SANTE website.

During 2017 and 2018, the Directorate Health and Food Audits and Analysis carried out a total of 264 missions (mainly audits and also country visits and fact-finding missions[32]) in the Member States. Chart 1 provides an overview of the number of missions per Member State.

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[28] The control activities in the areas of human health are not performed under Regulation (EC) No 882/2004 or 2017/625, and therefore they are not included in this report.

[29] Available at: https://ec.europa.eu/food/audits_analysis/audit_programmes_en

[30] Art. 116(1) of Regulation (EU) 2017/625.

[31] Available at: http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

[32] Audits verify the implementation of official controls while country visits and fact-finding missions are used to gather information on a country or on a topic across a number of Member States.

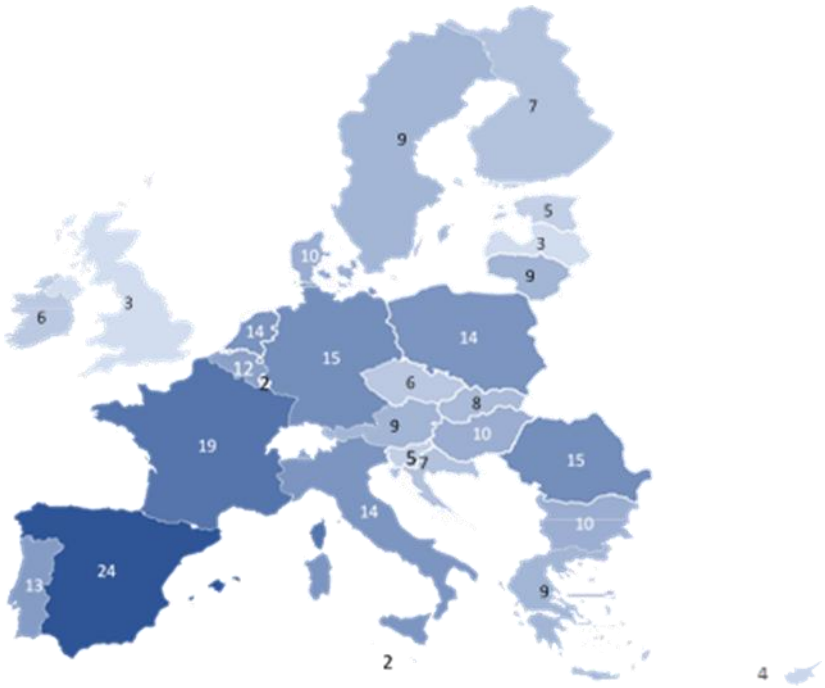


Chart 1: number of missions carried out in Member States in 2017-2018

Chart 2 provides an overview of the type of mission under the different topics of the OCR.

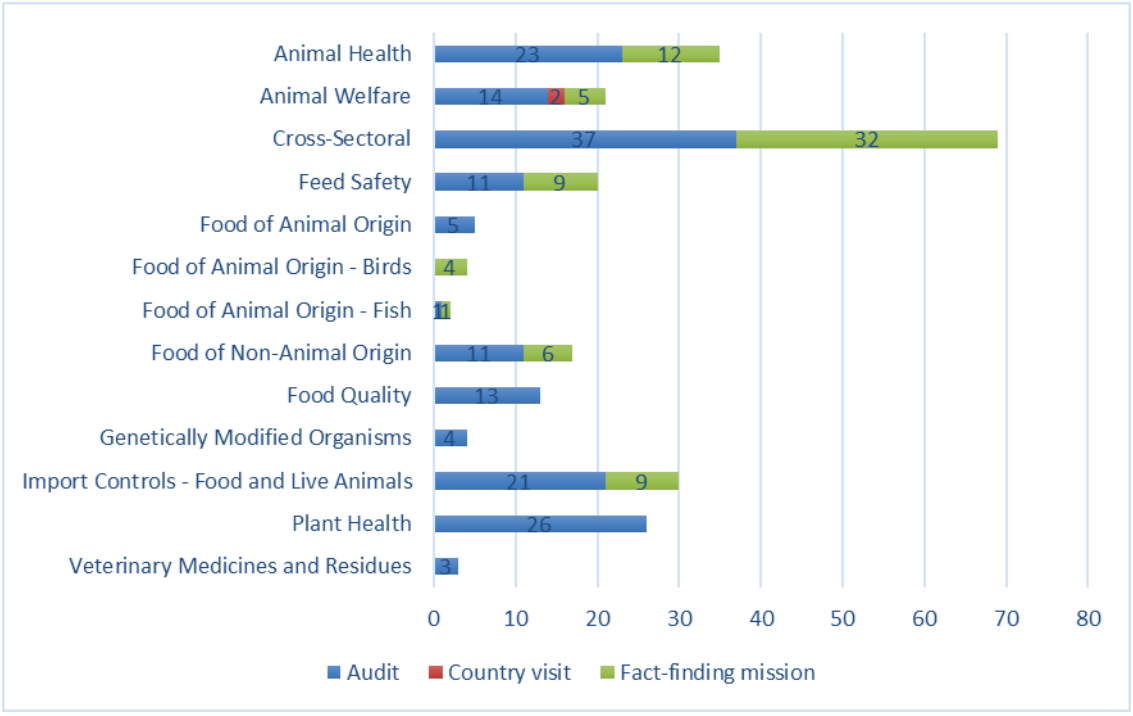


Chart 2: number and type of missions performed per topic 2017-2018

5.1.1. Overview reports

The Commission also publishes[33] overview reports which provide a review of the area covered in an audit series, identifying what is working, or not, in relation to the implementation of controls and the application of legislation and giving examples of good practices in Member States. These reports provide the basis for exchanges with Member State experts in the framework of the BTSF initiative to discuss common problems identified and to share good practices.

In 2017 and 2018, the Commission published 22 overview reports related to its control activities in the Member States in the areas of food safety and quality, animal health and welfare, and plant health.

The Staff Working Document accompanying this report[34] provides a more detailed description of some of the main areas where the Commission performed controls in the Member States in 2017 and 2018.

5.1.2. Some points to highlight

A series of audits on the National Audit Systems found that the outputs of these audit activities contribute to improvements of the consistency and effectiveness of official controls.

In the area of food safety, fact-finding missions in the wake of the fipronil incident, contributed to improving the tools available at EU level for the management and containment of similar incidents.

Audit series on official controls on food labelling (information to consumers and health and nutrition claims), food contact materials, ready-to-eat foods and e-commerce in the food chain showed that these areas needed more attention in the official control plans.

In the field of animal health, African swine fever and avian influenza epidemics were the main areas of concern where the Commission prioritised its controls.

On animal welfare, the Commission concluded its project on the transport of animals by road and by sea. Although there were observable improvements for animal welfare, important problems persist. Regarding sea transport, the Commission is seeking cooperation with the European Maritime Safety Agency to improve compliance of livestock vessels with animal welfare requirements.

A two-year work programme on pig welfare looked into the practices of routine tail docking, where serious and uniform enforcement remains a big challenge.

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[33] Available at: http://ec.europa.eu/food/audits-analysis/overview_reports/index.cfm

[34] Commission staff working document accompanying the document: Report from the Commission to the European Parliament and to the Council on the overall operation of official controls performed in Member States (2017-2018) to ensure the verification of compliance with food and feed law, animal health and welfare rules.

Two audits on the monitoring of antimicrobial resistance in commensal and zoonotic bacteria identified a number of possible improvements to the arrangements in place.

Since 2013, outbreaks of the bacterium *Xylella fastidiosa* has caused severe economic damage in olive and almond plantations in Italy and Spain. The pathogen endangers a wide range of agricultural, horticultural and forest species in Europe. Regular audits in Member States with outbreaks aimed at verifying whether the implemented measures ensure the eradication, or if this is not possible, containment, in order to minimise the risk of further spread in the EU.

The Commission observed certain improvements in the authorisation, marketing and sustainable use of plant protection products (PPP). However, the Member States need to address shortcomings in the authorisation process of PPP, the assessment of integrated pest management systems, the review of national action plans and the testing of application equipment. The Commission started the process of establishing harmonised risk indicators[35], in conjunction with Member States, to estimate the evolution in the risks associated with the use of plant protection products.

Another area where the need for improvement in the Member States' official controls was identified, was in relation to controls on biocidal products, which are frequently not authorised for the market where they are used.

6. COMMISSION FOLLOW-UP AND ENFORCEMENT

6.1. Systematic follow-up of recommendations

The Commission's audits generally lead to recommendations for corrective action. Member States are required to take the necessary actions to address these[36] and describe them in action plans.

Through regular package meetings, known as General Follow-up Audits, DG SANTE's Health and Food Audits and Analysis Directorate systematically follows-up on the actions taken by competent authorities to respond to the recommendations made in audit reports. These General Follow-up Audits cover all of the 'open' recommendations across all sectors and the results are published in country profiles (see below).

This process continued to be effective in dealing with the vast majority of identified shortcomings.

In a small number of cases, when the outcome of the audit is particularly problematic, sector specific follow-up audits are organised to follow up on actions, which are to be urgently implemented by the Member States.

[35] Article 15(1) of Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides - OJ L 309, 24.11.2009, p. 71–86.

[36] Articles 45(3) and 45(5) of Regulation (EC) No 882/2004 and 117(a) and 119(a) of Regulation (EU) 2017/625.

At the end of December 2018, Member States had taken corrective action, or provided satisfactory commitments to address shortcomings within acceptable timelines:

- for 96% of recommendations resulting from audits in the reporting cycle 2014-2016; and

- for 95% of recommendations resulting from audits in the reporting cycle 2015-2017[37].

Specific country knowledge is important for the preparation of audits and for informing policy-making. Therefore, the Health and Food Audits and Analysis Directorate of DG SANTE maintains and publishes country profiles. The updates of these ensure the transparency of this process.

These country profiles are publicly available[38] and give an overview for all Member States of:

- the five most recently published audit reports;
- the Commission's assessment of the actions taken by the Member States in response to its audits and audit recommendations;
- the organisation of controls in the Member States, based on information supplied by them;
- relevant links to Member States' websites, as supplied by them.

6.2. Support to Member States

The Commission supports the Member States to improve their capacity to enforce EU law, through networks and training.

6.2.1. Networks

The Health and Food Audits and Analysis Directorate hosts a number of networks and workings groups comprised of officials from competent authorities of the Member States and member countries of the European Free Trade Association parties to the Agreement on the European Economic Area to discuss and promote the implementation of certain aspects of EU law.

Since 2008, two networks have met regularly to exchange experiences on the preparation, implementation and reporting of MANCPs and on the implementation of national audit systems (NAS) on official controls. During 2017 and 2018, the MANCP Network met nine times. The meetings were mostly dedicated to the development, and finalisation, of the standard model forms for annual reports[39]. One sub-group meeting in

[37] The follow-up indicator is based on a three year rolling cycle, taking account of the time needed by Member States to devise an action plan in response to audit recommendations and the time needed for the implementation of the actions.

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

[39] Regulation (EU) 2019/723 - OJ L 124, 13.5.2019, p. 1–31.

2018 was dedicated to the revision of the guidelines on the preparation of the MANCP[40]. The MANCP network also developed the electronic version of the standard model form for the annual reports, the "Annual Reporting on Official Controls – AROC" tool, to help Member States get ready for the OCR implementation.

The NAS Network met four times during 2017 and 2018. The meetings facilitated the exchange of experiences, common problems, and identified good/best practices between members and the network initiated a review of the guidelines on conduct of audits[41].

The network of Member States' national contact points for the protection of animals during transport (NCPs) meets regularly since 2010 to share knowledge of common issues and find solution to implement and enforce animal welfare requirements during transport. Since 2014, this network has produced consensus Network Documents, which provide guidance on the practical implementation of the animal welfare requirements, and identify good practices for controls. In 2017 and 2018, the NCP network met four times to discuss the changes to annual reports for animal welfare transport controls, the transport of unweaned calves and the transport of animals to non-EU countries and in extreme temperatures. During 2017, the NCP finalised the Network Document on the export of live animal exports by road.

The Working Group, on the sustainable use of pesticides, met four times in 2017-2018. In 2017, the Commission published its first report on the implementation of the legislation on the sustainable use of pesticides (SUD)[42]. The group intensively discussed this report and the SUD implementation in individual Member States, together with the review of their initial National Action Plans[43]. In 2018, the discussions focused on the Harmonised Risk Indicators as prepared by the Commission, environmental aspects of the SUD, and the challenges encountered by Member States regarding the implementation of Integrated Pest Management and its assessment at farm level.

Working Groups on formulation of Plant Protection Products (PPPs) and on enforcement of legislation in this area aim to address the main weaknesses identified in the audit series carried out from 2012 to 2016 regarding official controls on the placing on the market of PPP. During 2017 and 2018, one WG meeting on PPP formulation and analysis was organised, which focused on developing Reference Documents to provide guidance to Member States on analytical strategy and on the interpretation of analytical results. The WG on enforcement of PPP legislation met twice in 2017 and once in 2018. One of these meetings was organised as a workshop, addressing official controls in large-scale warehouses, import controls at ports, and inspections of manufacturers of plant protection

[40] Commission Decision 2007/363/EC - OJ L 138, 30.5.2007, p. 24–49.

[41] Commission Decision 2006/677/EC - OJ L 278, 10.10.2006, p. 15–23.

[42] Report from the Commission to the European Parliament and the Council on Member State National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides.

[43] The Member States were required to adopt National Action Plans to implement the SUD for the first time by November 2012. These plans should contain quantitative objectives, targets, measurements and timetables to reduce the risks and impacts of pesticide use. These plans should be reviewed at least every five years.

products. This provided a useful basis for Member States to improve inspection activities in this area.

6.2.2. Better Training for Safer Food (BTSF)

BTSF is a Commission initiative aimed at organising training for stakeholders in the areas of EU food law, feed law, animal health and animal welfare rules, as well as plant health rules, organic farming and quality schemes. The outcome of the Commission's controls (e.g. audits) helps identify training needs. The 2017 and 2018 BTSF programme[44] contained, workshops on a range of topics such as the prevention and control of antimicrobial resistance, on the preparedness of the veterinary services for natural disasters and training on internal audits.

6.3. Enforcement

When a Member State breaches EU law, the Commission determines appropriate actions on a case-by-case basis in line with its "EU law: Better results through better application" approach[45]. Such actions may range from contacts with the Member States' authorities at appropriate levels aimed at ensuring the correct application of EU law up to the launching of EU Pilot exchanges and/or infringement proceedings in cases where there is a clear and sound legal basis, and where all other avenues to encourage compliance have been exhausted. In the food safety area, enforcement tools other than infringements also include the imposition of protective or safeguard measures. These can range from taking precautionary measures on the trade in and movements of animals, plants or food and feed products to adopting safeguard measures in accordance with the relevant legislation.

A first line of action is a high-level letter to the relevant Member State, where needed, followed by the pre-litigation and litigation phases of the infringement procedure[46].

During 2017-2018 one infringement cases was brought before the Court of Justice of the European Union in the areas covered by the OCR. The Commission decided in May 2018 to refer Italy to the Court of Justice of the EU over its failure to adequately prevent further spread of the quarantine harmful organism *Xylella fastidiosa* in Apulia[47].

7. CONCLUSIONS

The EU has a solid legislative framework to control safety hazards in the supply chain. Member State national authorities demonstrated in their annual reports on official controls that they continue to fulfil their important role to monitor and to verify, through the organisation of official controls, that relevant Union requirements are effectively complied with and enforced.

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44 See https://ec.europa.eu/chafea/food/bookshelf/reports/index_en.htm for annual reports on BTSF.

45 See https://ec.europa.eu/info/publications/communication-commission-eu-law-better-results-through-better-application_en.

46 Article 258 of the Treaty of the Functioning of the EU.

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

The accompanying Staff Working Document provides details of Commission controls carried out in the Member States to verify that Union requirements on food and feed law, animal health and welfare, plant health and plant protection products are properly implemented and enforced by the Member States. The results of these controls show that overall Member States have the requisite control systems in place, which ensure generally acceptable levels of compliance. The Commission controls however, continue to identify deficiencies in official controls and highlight that there is still room for improvement.

Relaxed attitudes to food safety always backfire and when they do, it may not only threaten public health but also affect the trust of our citizens as well as our trading partners in the EU food system as a whole. There cannot be any complacency towards food safety and all planned control activities set out in Member States' MANCPs need to be implemented. Nevertheless, the Annual Reports for 2017 and 2018 again highlight that many Member States are facing challenges to secure adequate financial resources for performing the necessary official controls.

The systematic follow-up of audit recommendations shows that, in general, Member States take the appropriate corrective measures to address identified shortcomings. In addition, the Annual Reports highlight ongoing efforts by the Member States to improve the efficiency and effectiveness of their controls, in particular through better IT systems, data analysis, quality manuals and training.

The adoption of the OCR has introduced significant changes, which will contribute to the improvement of official controls.

In order to ensure coherence of MANCPs, Member States need to designate a single body tasked with coordinating their preparation and collecting information on their implementation, review and update. The MANCPs shall set out strategic objectives and how the prioritisation of official controls and allocation of resources reflect these priorities.

On transparency, the OCR requires that the MANCPs shall be made available to the public. In addition, there is a possibility for Member States to deliver on the requirements of transparency by publishing their annual report.

The introduction of a standard model form for the annual reports to be submitted by Member States will facilitate the collection of comparable information and data on Member States official controls across the EU agri-food chain and will contribute to a smoother drafting and publication of the Commission's Annual Report.

Working in partnership, the Commission remains dedicated to support the Member States to continuously improve their official control systems through the networks and the BTSF initiative.