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**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 (2014-2016) to  
ensure the verification of compliance with food and feed law, animal health and welfare  
rules**

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## 1. INTRODUCTION

The Commission is required based on Articles 44(4) and (6) of Regulation (EC) No 882/2004<sup>1</sup> to submit to the European Parliament and Council a report on the overall operation of controls in Member States. The report is to be based on the annual reports submitted by the national authorities on their control activities and on the results of Commission controls carried out in Member States.

This staff working document provides further detail of Commission control activities in the areas of food safety, animal and plant health, animal welfare, organic farming and quality schemes. The outcome of these control activities formed the basis for several conclusions included in the 2014-2016 Commission report to the European Parliament and to the Council<sup>2</sup>.

The following chapters present issues of particular interest emanating from the above mentioned controls undertaken by Commission services during 2014–2016.

## 2. COMMISSION SERVICES' CONTROL ACTIVITIES IN MEMBER STATES

Within the framework for EU controls, Commission services undertake audits to verify compliance with feed and food law, animal health and welfare, and the requirements for official controls. Audit reports contain recommendations to address identified shortcomings. The reports, Member States action plans to address the recommendations, and country profiles documenting progress with the delivery of these plans are published<sup>3</sup>, providing stakeholders and citizens with a factual and transparent account of how Member States deliver on correct implementation of EU law.

Two developments are worth highlighting. Firstly, “overview reports” are now 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 which are relevant to all Member States. Moreover, they highlight difficulties encountered with the implementation of the relevant legislation as well as good practices identified. Secondly, greater use is being made of desk analysis and fact-finding missions to complement the audit work, to provide the Commission with a clear insight into the functioning of EU law and of any problems that may arise in its application. Overview reports of these activities are also produced and published.

These two activities are specifically designed to support the Commission’s policy of legislative review aimed at ensuring that EU legislation is up-to-date, practicable and enforceable at reasonable cost, in tune with developments on the ground, and thus “fit-for-purpose”. As such, controls undertaken by the Commission services contribute directly to

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<sup>1</sup> 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 – [OJ L 165, 30.04.2004, p.1](#).

<sup>2</sup> Report from the Commission to the European Parliament and to the Council on the overall operation of official controls performed in Member States (2014-2016) to ensure the verification of compliance with food and feed law, animal health and welfare rules.

<sup>3</sup> [https://ec.europa.eu/food/audits\\_analysis\\_en](https://ec.europa.eu/food/audits_analysis_en)

the Better Regulation Agenda<sup>4</sup>. The overview reports also include an indication of planned actions in response to the reports' findings. To disseminate information on conclusions, good practice or lessons learned outlined in these reports, they are also shared in the context of the BTSF programme<sup>5</sup>.

## **2.1 HORIZONTAL ISSUES**

### *2.1.1 Audits of official controls*

To assess how Member States effectively and efficiently audit their whole control system, a series of audits by the Commission services on the Member States National Audit Systems (NAS) required by Article 4(6) of Regulation (EC) No 882/2004 was launched in 2016 and will continue during 2018 to cover all Member States.

The first findings and conclusions of this important series were published in an interim overview report<sup>6</sup> covering audits to 12 Member States.

It found that, in most cases, competent authorities had appropriate audit arrangements in place to cover most official control activities within the scope of Regulation (EC) No 882/2004. The audits' findings were quickly used by most auditees to improve the consistency and effectiveness of their official controls. Some challenges remained in some countries, in particular the lack of required independent scrutiny of their audit process and the effective follow-up of audit results, which, if in place, would have a positive impact on the effectiveness and consistency of official controls.

The interim overview report also identified that the guidelines on implementing Article 4(6), laid down in Commission Decision 2006/677/EC<sup>7</sup> were appreciated and used by the Member States audit services. It further highlights areas difficult to implement by Member States, with weaker performance or shortcomings. These learnings, following consultation with Member States, will be used by Commission services, when drawing up revised guidelines, on how to implement provisions on NAS included in Regulation (EU) 2017/625, which will replace Regulation (EC) No 882/2004 as from 2019.

These efforts will also be supported by the NAS Network, which intends to use the outcome of the interim and final overview report to review its reference document on auditing effectiveness. It also intends to discuss good principles for reporting audits and to possibly produce a respective document for incorporation into the new guidelines.

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<sup>4</sup> [https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how\\_en](https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en)

<sup>5</sup> BTSF is a Commission training initiative, directed at officials working in competent authorities in Member States and non-EU countries, covering food and feed law, animal health and welfare and plant health rules: [https://ec.europa.eu/food/safety/btsf\\_en](https://ec.europa.eu/food/safety/btsf_en)

<sup>6</sup> Report reference DG (SANTE) 2017-6256: Interim Overview Report-Audits of Official Controls in EU-Member States  
[http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=107](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=107)

<sup>7</sup> 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 - [OJ L 278, 10.10.2006, pp15 to 23](https://eur-lex.europa.eu/eli/dec/2006/677/20061010).

Finally, training on audits has been provided to Member States in the context of Better Training for Food Safety (BTFS) in a programme which ended in June 2017. A new BTFS programme will also foresee training on audits and incorporate the issues identified in the interim overview report.

## **2.2 FOOD SAFETY**

### *2.2.1 Salmonella controls in poultry*

The EU's efforts to combat human salmonellosis have already resulted in a 50% reduction (2004 to 2009) in cases, and this reducing trend continued. A key factor in this achievement was the implementation of *Salmonella* National Control Programmes (SNCPs)<sup>8</sup> for the reduction of *Salmonella* prevalence in specific poultry populations (breeding flocks, laying hens of *Gallus gallus*, broiler flocks and turkeys) in all Member States. These programmes have led to a significant reduction of the prevalence of *Salmonella* target serovar-positive poultry flocks in the EU.

The effectiveness of these programmes was first evaluated by the Commission services during audits from 2006 to 2012. The resulting overview report published in 2013<sup>9</sup> found that the SNCPs were largely fit for purpose. It also shared examples of good practice which helped to improve the SNCPs. The Commission services continued the audit activity on this topic during a second audit series in Member States from 2013 to 2016. The findings and conclusions of this series confirm the positive trend described in the previous audit series as regards the effectiveness of the SNCPs. However, some of the issues noted during the first series remain.

In particular, the common practice in some Member States, that in case of detection of a *Salmonella* infected flock through a sample taken by a food business operator, restrictive measures were only taken after an official sample and analysis confirmed that flocks were infected. This was done also in cases where there was no valid reason to question the analysis of the initial food business operator sample. This practice, delaying the imposition of restrictive measures, allowed potentially infected eggs to enter the market in the period between the first non-compliant and subsequent confirmatory test result. Implicated Member States received audit recommendations to amend this practice.

Ensuring that all Member States report the first non-compliant test results, as legally required, would further strengthen the reliability of Member States prevalence data. Commission services are in consultation with Member States to review the SNCPs' targets and respective reporting of data in order to further improve the effectiveness of the SNCPs.

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<sup>8</sup> Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents - [OJ L 325, 12.12.2003, p. 1–15](#)

<sup>9</sup> [http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=59](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=59)

### 2.2.2 *Campylobacter* in poultry production

Campylobacteriosis is the most frequently reported food-borne illness among EU consumers since 2008<sup>10</sup>. In contrast to the decrease in the incidence of Salmonellosis in humans, the number of reported cases of Campylobacteriosis is increasing.

Evidence suggests that much of the Campylobacteriosis disease burden is associated with the presence of *Campylobacter* in poultry production and its supply chain.

To gain a better understanding of how Member States were tackling *Campylobacter*, the Commission services carried out fact-finding missions in three Member States during 2015 and 2016. The competent authorities of these countries made tackling *Campylobacter* a priority in recent years. The objective of the short fact-finding missions was to identify actions taken, as well as to note good practice implemented by these Member States, to prevent, reduce or eliminate a *Campylobacter* risk in the production and distribution of poultry meat. The main conclusions from these fact-finding missions were that it is not feasible, even with strict biosecurity measures, to eliminate *Campylobacter* from, or to keep it out of poultry fattening farms, especially during the summer months. However, interventions at farm level can lead to lower levels of contamination of carcasses, which, given the variation in prevalence and numbers of *Campylobacter* spp. between different farms, highlights the need for further interventions at slaughterhouse level. Such interventions can be part of existing and future slaughterhouse hygiene procedures.

To achieve the latter, Regulation (EC) No 2073/2005<sup>11</sup> has been amended in 2017<sup>12</sup>, establishing a process hygiene criterion for *Campylobacter* in broiler carcasses and aiming to control contamination of these during the slaughtering process.

The Commission services also organised a workshop about the growing problem of *Campylobacter* contamination of poultry to disseminate the lessons learned and good practice examples from the *Campylobacter* fact-finding missions among the Member States competent authorities.

### 2.2.3 Controls on food additives and smoke flavourings

Additives and smoke flavourings are widely used in a variety of food. Their safety is thoroughly assessed and also underpinned by comprehensive EU legislation specifying how and in which foods additives can be used to improve the quality and safety of food. To ensure that their use is fully in compliance with legal requirements is particularly important as they, if used in excessive quantities (e.g. nitrites/nitrates), could pose risks to human health. For this reason, maximum limits for many additives have been established in the EU and product labelling requirements require to adequately inform consumers.

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<sup>10</sup> The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016: [EFSA Journal 2016;14\(12\):4634](#)

<sup>11</sup> Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs - [OJ L 338, 22.12.2005, p. 1-26](#)

<sup>12</sup> Commission Regulation (EU) 2017/1495 of 23 August 2017 amending Regulation (EC) No 2073/2005 as regards *Campylobacter* in broiler carcasses - [OJ L 218, 24.8.2017, p. 1-6](#)

To establish how Member States implement official controls in this area, the Commission conducted during 2015 a series of fact-finding missions. The main conclusion from these missions was that most of the Member States visited had systems in place to control food additives and smoke flavourings at various levels in the food production chain, but few Member States had assigned a high priority to control them and the scope of official controls did not provide sufficient assurances that food business operators always fully complied with EU requirements. Member States which had prioritised controls in particular on higher risk additives such as nitrites and nitrates, had effective controls in place. It was further concluded that food business operators face a significant challenge to fully understand and implement the sometimes complex legislative requirements and the competent authorities to verify that this is the case. The Commission's overview report<sup>13</sup> concluded also that improvements can be made in prioritising official controls on higher risk additives and in providing training and practical guidance to support both official controls and better compliance by food business operators. To achieve this the Commission established in 2016 an expert group on the application of official controls dedicated to food additives and smoke flavourings, provides BTSF trainings and developed specific guidance documents<sup>14</sup>.

#### 2.2.4 Controls on primary production of food of non- animal origin

Food of plant origin, intended to be eaten raw like sprouts and seeds for sprouting, when contaminated with bacteria or viruses, have been recognised in recent years to pose a serious threat to human health.

The Verocytotoxigenic *Escherichia coli* (VTEC) outbreak in Germany in 2011 (over 4,000 human cases and 55 fatalities) related to consumption of sprouted seeds, and the largest ever recorded food-borne outbreak in Germany in 2012 (Norovirus in frozen strawberries, causing nearly 11,000 cases of gastroenteritis) clearly indicated a weakness in official control systems in the EU.

Commission services carried out an audit series from 2013 to 2016 to evaluate the control systems in place to prevent microbiological contamination at primary production of food of non-animal origin intended to be eaten raw. The audits focused in particular on the system of official controls on the traceability of seeds intended for sprouting and sprouts, the applicable microbiological criteria, the approval of sprout-producing establishments and the controls of imported seeds for sprouting.

The audits identified numerous shortcomings with regard to official controls along the sprout production chain. In several Member States there were none, or very limited systems in place for official controls on primary production of food of non-animal origin intended to be eaten raw. In addition, official controls were not planned based on an effective risk evaluation, as statistically-based procedures for sampling, or proper estimates of hospitalisation and death caused by food-borne illnesses due to the consumption of food of plant origin, are not available.

These shortcomings were discussed with Member States competent authorities to find solutions, which were subsequently used by Member States to adapt and improve their official control systems. The findings and conclusions from the audits were also used to

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<sup>13</sup> [http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=115](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=115)

<sup>14</sup> [Guidance notes on the classification of food extracts with colouring properties and Guidance document describing the food categories in Part E of Annex II to Regulation \(EC\) No 1333/2008 on Food Additives](#)

strengthen new Commission guidelines<sup>15</sup> about the prevention of microbiological risks of soft fruits and vegetables. These guidelines also take into account relevant European Food Safety Authority (EFSA) opinions and support the work of Member States competent authorities and growers to implement effective risk-based control systems to tackle emerging microbiological risks of food of plant origin.

## **2.3 FEED SAFETY**

The feed sector is of significant importance in the production chain of food products of animal origin. In 2015 and 2016 the Commission services submitted a questionnaire to all Member States, followed with fact-finding missions in several Member States, examining the interactions between private certification schemes and official controls in the feed sector. In four Member States the competent authorities had close interaction with the private schemes and had assessed their suitability as a means to replace or reduce official controls. The outcome in these countries was a reduction in official controls for those feed business operators who were members of the schemes, and a consequent more rational use of official resources. The Commission services organised a workshop at the end of the process to facilitate discussions between Member States on the benefits of such interactions and the challenges (e.g. ensuring data protection and verifying the reliability of private controls), with most Member States seeing advantages in leveraging private controls for official purposes. This possibility is envisaged by Article 9(1)(d) of Regulation (EU) No 2017/625.

## **2.4 IMPORT CONTROLS**

A comprehensive import regime, supported by effective and reliable controls, is critical to ensure safe imports of animals, animal products, food of plant origin and feed into the EU. For that reason, audits conducted by Commission services in this area constitute an important assurance that there are high and uniform standards applied in all Member States. Audits routinely focus on controls at Border Inspection Posts and on designated points of entry<sup>16</sup> in the EU as well as the areas which are outlined below.

### *2.4.1 Border controls to prevent the entry into the EU of African swine fever*

Effective official border controls are also vital to prevent the introduction of animal diseases caused by viruses in food of animal origin in travellers' luggage and via livestock vehicles. The African swine fever virus, which can cause catastrophic losses in infected pig herds, has in recent years entered the Union from its eastern borders. In April 2016 the Commission carried out a series of targeted fact-finding missions to the eight Member States bordering Russia, Belarus and the Ukraine to assess how the specific border controls laid down in Commission Implementing Decision 2013/426/EU<sup>17</sup> and the general

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<sup>15</sup> Commission notice on guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene - [OJ C 163, 23.5.2017, p. 1-40](#)

<sup>16</sup> Food products of plant origin products enter into the EU through "Designated Points of Entry" whereas life animals and food of animal origin enter into the EU through "Border Inspection Posts".

<sup>17</sup> Commission Implementing Decision of 5 August 2013 on measures to prevent the introduction into the Union of the African swine fever virus from certain third countries or parts of the territory of third countries in which the presence of that disease is confirmed and repealing Decision 2011/78/EU - [OJ L 211, 7.8.2013, p. 5-9](#)

controls on travellers' luggage described in Regulation (EC) No 206/2009<sup>18</sup> were performed. These missions highlighted the need to improve travellers' awareness of risks that foodstuffs can pose, and the need for better communication between the agencies (sanitary authorities, customs and border guards) operating at all of the potential points of disease introduction. The lessons learned have been taken into account by the Member States to improve in particular citizens' information regarding travellers' luggage requirements and better communication between different actors related to border controls.

#### 2.4.2 Import controls on food of non-animal origin

The previous report<sup>19</sup> described the outcome of audits on the operation of official control systems for imports of food of non-animal origin. A key shortcoming concerned the assurance of full traceability of goods subject to the increased level of official controls under Regulation (EC) No 669/2009<sup>20</sup> after onward transport or transfer to designated points of entry for products under Regulation (EC) No 884/2014 for physical checks. In addition, the obligation on operators for prior notification of the arrival of consignments to the control authorities was often not met.

The Commission services took several actions to help address these shortcomings. Firstly, new procedures on co-operation between Member States in the case of onward transportation were agreed<sup>21</sup>. Secondly, the model of the common entry document (CED)<sup>22</sup> to be completed by operators and by the control authority was improved as regards the provisions on onward transportation. Thirdly, the Commission published in 2014 a Staff Working Document<sup>23</sup> on the enforcement of Regulation (EC) No 669/2009 which recommends that customs authorities can release for free circulation the consignments of relevant commodities only after checks confirm that CEDs have been properly completed. Lastly, the Commission adopted Implementing

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<sup>18</sup> Commission Regulation (EC) No 206/2009 of 5 March 2009 on the introduction into the Community of personal consignments of products of animal origin and amending Regulation (EC) No 136/2004 - [OJ L 77, 24.3.2009, p. 1–19](#)

<sup>19</sup> [http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=9](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=9)

<sup>20</sup> Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC - [OJ L 194, 25.7.2009, p. 11](#).

<sup>21</sup> [Article 8.2 of Commission Regulation \(EC\) No 669/2009 of 24 July 2009](#)

<sup>22</sup> [Annex II to Commission Regulation \(EC\) No 669/2009 of 24 July 2009](#)

<sup>23</sup> Commission staff working document on the enforcement by national customs authorities of Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC.

[https://ec.europa.eu/food/sites/food/files/animals/docs/bips\\_guidance\\_eu-reg-2009-669\\_staff-working-doc\\_en.pdf](https://ec.europa.eu/food/sites/food/files/animals/docs/bips_guidance_eu-reg-2009-669_staff-working-doc_en.pdf).

Regulation (EU) No 884/2014<sup>24</sup>, which imposes special import conditions on certain foodstuffs specifically due to the risk of contamination with aflatoxins.

## **2.5 PLANT HEALTH**

### *2.5.1 Controls on harmful pests and diseases*

EU rules on plant health aim to protect crops, fruits, vegetables, flowers, ornamentals and forests from harmful pests and diseases (harmful organisms) by preventing their introduction into the EU or their spread within the EU. This is in particular important given the global trade of such afore mentioned products. To verify that EU rules are adhered to, the Commission services conducted a wide range of audit and analysis activities in the field of plant health. Based on data from the EUROPHYT<sup>25</sup> interceptions system which notifies the occurrence of harmful organisms in imported plants and other objects, and a new monthly alert list, audits were focused on those non-EU countries from which a high number of import consignments containing harmful organisms were intercepted. These data were also analysed in detail by a Commission/Member States working group, which guided the Commission in undertaking certain actions and activities, such as audits, dialogue with the involved countries or selective import bans.

The result of these activities has been a reduction in the number of annual interceptions from 2,310 on the first Alert List (November 2014) to 1,733 as at 1 December 2016, but more work is needed to further reduce interceptions and thus potential risks to plant health.

In general, 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 and diseases in the EU as well as new information about the host range and vectors.

In relation to the eradication of harmful organisms in Member States, a new module under the EUROPHYT system was developed for Member States to notify outbreaks on the EU territory. This is intended to strengthen the rapid sharing and analysis of key information to facilitate a more timely and efficient handling of outbreaks. For one of the most serious pests, the pinewood nematode (PWN), a “task force” comprising Member States' national experts and staff from the Commission's control services was set up to assist with the establishment of a strategy for the control of the pest in the two affected Member States. Its purpose was to peer review the control strategies in place, and to oversee the effective implementation of action plans aimed at keeping PWN under control. Based on several meetings and visits to the countries concerned, an overview report<sup>26</sup> was published. The report's recommendations have already been largely implemented. Another serious pest is *Xylella fastidiosa*, a destructive bacterium which has done serious damage to olive trees, for which the outbreaks in various Member States have been followed closely, not least by frequent audits since the first discovery in Italy at the end of 2013. The audit results and

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<sup>24</sup> Commission Implementing Regulation (EU) No 884/2014 of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009 - [OJ L 242, 14.08.2014, p. 4](#).

<sup>25</sup> [https://ec.europa.eu/food/plant/plant\\_health\\_biosecurity/europhyt\\_en](https://ec.europa.eu/food/plant/plant_health_biosecurity/europhyt_en)

<sup>26</sup> [https://ec.europa.eu/food/sites/food/files/plant/docs/ph\\_biosec\\_legis\\_em-measures\\_pwn-task-force\\_en.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/ph_biosec_legis_em-measures_pwn-task-force_en.pdf).

the Commission services' follow-up have contributed significantly to improving the controls in the countries with outbreaks. To Italy, where the authorities are failing to stop the progression of the harmful organism, the Commission sent a reasoned opinion<sup>27</sup> in July 2017.

## **2.6 PESTICIDES**

### *2.6.1 Controls on the marketing and use of Plant Protection Products*

Plant protection products (PPPs) are primarily used in the agricultural sector but also in forestry, horticulture, amenity areas and in home gardens. In the EU strict rules regarding the marketing and the use of PPPs apply. To verify whether the control systems in Member States function effectively, two comprehensive audit series were conducted between 2012 and 2016, covering controls on the marketing and use of PPPs<sup>28, 29</sup>.

Regarding the marketing of PPPs, the audits by the Commission services found that the risks associated with importers, manufacturers and re-packers of PPPs, had not been sufficiently considered in the planning of Member State controls. Consequently, the frequency and scope of controls at these operators was generally insufficient. Controls at these specialist operators were further weakened by the lack of specific training for inspectors and insufficient formulation and analysis of control plans. The majority of Member States do not conduct controls on PPPs intended for use in other Member States or in non-EU countries. This significant weakness in control systems can be easily exploited to place non-compliant products on the market. As a consequence of the weaknesses in controlling the marketing of PPPs, the audits found that there was insufficient assurance that counterfeit and illegal pesticides would be detected.

Nonetheless, the increasingly well-developed official control systems on users, coupled with the progress being made in the area of sustainable use of pesticides, aim to provide assurances to consumers on increasingly responsible use of PPPs.

In order to help the Member States address the weaknesses in the system, the Commission services created two working groups. The working group on PPP Formulation Analysis develops reference documents to provide guidance to Member States relating to the analytical methods to be used and the interpretation of analytical results in this complex area. The working group on PPP enforcement developed a template for the harmonised reporting of controls on the marketing and use of PPPs. It also organizes workshops, when the need arises, for other specific issues related to controls in PPPs.

### *2.6.2 Authorisation of PPPs*

Once an active substance has been approved at EU level, authorisation for individual PPPs can be granted by a Member State only following a detailed evaluation covering a range of different areas such as operator exposure, toxicology, environmental fate, eco-

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<sup>27</sup> [Reasoned opinion to Italy where authorities are failing to stop the progression of a harmful organism \*Xylella fastidiosa\* \(point 14\)](#)

<sup>28</sup> [Report reference DG \(SANTE\) 2016-6004: Plant Protection Products - Marketing and Use](#)

<sup>29</sup> [Report reference DG \(SANTE\) 2014 7567: Pesticides.](#)

toxicology and efficacy. To optimise this process, Regulation (EC) No 1107/2009<sup>30</sup> establishes a zonal authorisation system. A Commission audit series in Member States which commenced in 2016 to evaluate these authorisation systems, found that the majority of Member States are failing to comply with almost all deadlines set by the legislation. One of the reasons for this is that Member States do not sufficiently avail of the opportunities to rely on the evaluation work done by other Member States, which is the foundation of the EU zonal authorisation system.

These delays in processing applications could undermine the purpose of the EU legislation to ensure a high level of protection of health and the environment.

The Commission audits also identified good practice which can help Member States to improve their authorisation systems.

### *2.6.3 Controls on the sustainable use of pesticides*

The objective of the "Directive on the sustainable use of pesticide"<sup>31</sup> is to reduce the risks and impacts of pesticide use on human health and the environment and to promote the use of Integrated Pest Management (IPM) and alternative approaches. To verify whether the measures foreseen in this Directive are implemented, the Commission conducted a comprehensive survey of all Member States in 2016 which has been followed by a series of fact-finding missions to six Member States in 2017.

The survey and analysis of the Member States National Action Plans shows patchy implementation of the Directive as some Member States have been more active than others.

On the one hand, training and certification systems for professionals have been set up in all EU countries, and to date almost four million farmers have been trained to use pesticides safely. Furthermore, 900,000 sprayers have been tested for accurate and safe application. Member States had taken significant steps in the establishment of operator training programmes and the total area treated with pesticides by aerial spraying has declined significantly as this is now permitted only in very limited circumstances.

On the other hand, although IPM is a cornerstone of the Directive, it remains underused. This is despite the fact that the number of EU-approved low risk/non-chemical pesticide substances has doubled since 2009. Compliance with the principles of IPM at individual grower level is not being systematically checked by Member States. Furthermore, Member States had not yet set clear criteria in order to ensure that the general principles of IPM are implemented by all professional users.

The ongoing revision by Member States of their National Action Plans provides the opportunity to address the deficiencies identified in the Commission's report, including the

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<sup>30</sup> 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 and repealing Council Directives 79/117/EEC and 91/414/EEC - [OJ L 309, 24.11.2009, p. 1–50](#)

<sup>31</sup> 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 - [OJ L 309, 24.11.2009, p. 71–86](#)

need to establish more precise and measurable targets so that the progress made to reduce risks can be demonstrated to citizens.

Building on the series of six fact-finding visits to Member States in 2017, the Commission has a comprehensive work programme to visit Member States and to assess updated National Action Plans, as well as running training events to improve implementation at Member State level.

## **2.7 ANIMAL HEALTH**

The aim of the EU animal health strategy is to have a strong control framework in place focused on preventive measures, disease surveillance, specific official controls and research, as prevention is better than cure. That way, the incidence of potentially devastating animal diseases can be reduced and the impact of outbreaks minimised. To verify Member States' preparedness to respond to animal diseases the Commission services undertook audits in several areas, two of which are mentioned below.

### *2.7.1 Member States' contingency planning to respond to animal diseases*

The Commission services audited contingency plans for animal diseases between 2014 and 2016. As the audits progressed, and comparing with results from previous audits, there was an improvement in areas such as registration of premises with animals, diagnostic capacity, allocation of resources and clarity in the distribution of responsibilities. Member States showed a positive trend in the quality and completeness of written plans and manuals. Procurement procedures and practical training for staff were also improved. The audits indicated important general weaknesses with regard to emergency vaccination and preparedness for rapid depopulation of farms. They also highlighted significant differences in the capacity to detect diseases early and to respond to large-scale outbreaks. Using the information collected, the Commission services organised during this period various related activities, including expert meetings, visits to national authorities, and series of practical training sessions, gathering together officials of several Member States and neighbouring countries, allowing enhanced communication and experience-sharing between national services.

Animal diseases with important social and economic impact entered into the EU in 2014 (African swine fever) and 2015 (Lumpy skin disease), and spread to several countries. The weaknesses detected during the above-mentioned audits on contingency planning were evident when authorities tried to control these two diseases. From 2014, the Commission services audited affected countries focussing on the control measures applied to contain and eradicate the diseases, and other countries at risk to help them enhance their preparedness. The audits identified specific implementation weaknesses and contributed to the promotion of consistent implementation of control and eradication measures in the Union. The Commission services also responded through direct technical and financial support to Member States, with expert emergency team missions and support measures for better preparedness, surveillance and response, and set up an emergency vaccine bank for Lumpy skin disease, in order to secure an efficient early response to outbreaks. The results of and lessons learned from the audits were shared with officials from neighbouring countries during technical meetings, both to show full transparency and to share knowledge and experience, as it is of interest to the Union to lower the risk of introduction of diseases from adjacent non-EU countries.

### 2.7.2 Official controls on finfish aquaculture

Aquaculture is an area of growth across the globe and also an important economic sector in the EU, employing around 85,000 staff and being globally one of the 10 biggest aquaculture producers<sup>32</sup>. To get an overview over how national official control systems comply with EU legislation on aquaculture, including animal health requirements, a series of fact-finding missions to seven Member States and Norway was carried out between September 2014 and November 2015.

The mission series' overview report<sup>33</sup> concluded that official controls on farms are implemented and support the development of the sector as a whole. A number of problems were found in key areas, in particular concerning poor registration procedures, which affected the ability of competent authorities to have a clear overview of the health status of the sector, and for operators to reliably verify the health status of dispatch and recipient farms. Variations in the degree of expertise of competent authorities affected their capability to detect health problems during official controls. Additionally, the effectiveness of early detection of diseases in fish, using passive surveillance data, is reduced by the fact that no common approach to the concept of 'significant increase of fish mortality', exists.

It was also noted that the limited availability of veterinary medicinal products has led to suboptimal treatment of certain diseases and has the potential to increase antimicrobial resistance. The Commission, to counteract the general increase of antimicrobial resistance and to, among other things, limit the inappropriate use of antimicrobials in animals, started a comprehensive programme under the "EU action on antimicrobial resistances"<sup>34</sup>.

As part of a series of actions to address most of the issues highlighted in this report the Commission services will, after consultation with all concerned (e.g. the Member States competent authorities, stakeholders, non-EU countries etc.), adopt under the new animal health law<sup>35</sup> several delegated and implementing acts by April 2019. The intention with these acts is to simplify and clarify where appropriate, requirements regarding movements and disease control, and to reduce administrative burden concerning, *inter alia*, registration and approval.

## 2.8 ANIMAL WELFARE

In the area of animal welfare, the Commission services undertook a number of audit activities and study visits on two key topics.

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<sup>32</sup> [https://ec.europa.eu/fisheries/cfp/aquaculture/facts\\_en](https://ec.europa.eu/fisheries/cfp/aquaculture/facts_en)

<sup>33</sup> [http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=95](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=95)

<sup>34</sup> [https://ec.europa.eu/health/amr/antimicrobial-resistance\\_en](https://ec.europa.eu/health/amr/antimicrobial-resistance_en)

<sup>35</sup> 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') - [OJ L 84, 31.05. 2016, p.1.](#)

### 2.8.1 Animal welfare during transport

Commission service audits have repeatedly identified problems with the implementation of the requirements of Regulation (EC) No 1/2005<sup>36</sup>. The Commission has focused its attention on developing Guides to Good Practice as well as improving co-operation between Member States, to achieve greater harmonisation of the implementation of the existing rules. With this in mind, the Commission services launched a three-year Pilot Project aiming to improve animal welfare during transport by developing and disseminating Guides to Good Practice for the five main animal species (cattle, horses, pigs, poultry and sheep) transported within the EU and to non-EU countries for slaughter, fattening and breeding. The final version of the Guides to Good Practices is already available and has been shared with European stakeholders through a comprehensive dissemination campaign including elements such as a dedicated website<sup>37</sup>, meetings, roadshows, publications, etc. The campaign will continue until mid-2018.

Member States have to provide information to the Commission services on the inspections they carry out<sup>38</sup> pursuant to Regulation (EC) No 1/2005. The Commission services organised visits of national expert teams to Member States with good practices on checks on livestock vehicles, facilitating the exchange of know-how. As a result, national authorities gave undertakings to develop some similar good practices. These included better prioritisation of checks, categorising breaches to ensure harmonised enforcement actions, and more practical training for animal transporters. In addition, the Commission services continued to facilitate co-operation between the Member States National Contact Points for the protection of animals during transport via meetings. Common issues identified from these meetings and study visits were also brought to groups of these national experts who developed, agreed on and produced "network documents" which provide guidance on practical implementation of the requirements, and identify good practices for controls.

### 2.8.2 Protection of animals at the time of killing

The Commission services carried out a desk analysis, a pilot audit in 2013 and a series of audits to review the efforts made by Member States to implement Regulation (EC) No 1099/2009<sup>39</sup> on the protection of animals at the time of killing. This audit series also covered the prevention of transport of unfit animals to slaughterhouses and the use of indicators of the welfare of broilers on farm. The audit series was followed by three overview reports for each section (animal welfare at the time of slaughter<sup>40</sup>, animal welfare during transport<sup>41</sup> and welfare of chickens kept for meat production<sup>42</sup>), each

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<sup>36</sup> Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 - [\*OJL 3, 5.1.2005, p. 1-44\*](#)

<sup>37</sup> <http://animaltransportguides.eu/>

<sup>38</sup> 2013/188/EU: Commission Implementing Decision of 18 April 2013 on annual reports on non-discriminatory inspections carried out pursuant to Council Regulation (EC) No 1/2005 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (notified under document C(2013) 2098) - [\*OJL III, 23.4.2013, p. 107-114\*](#)

<sup>39</sup> Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing - [\*OJL 303, 18.11.2009, p. 1-30\*](#)

<sup>40</sup> [http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=85](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=85)

<sup>41</sup> [http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=72](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=72)

describing good practices and common non-compliances. The Commission also organised two specialised BTSF events: one on the protection of animals at the time of killing and another on the monitoring of indicators at slaughterhouse to improve on-farm welfare of broilers.

## **2.9 ANTIMICROBIAL RESISTANCE**

In the context of the 2011 European Commission's action plan against the rising threats from antimicrobial resistance (AMR), the Commission carried out audits to verify the implementation of the mandatory monitoring and reporting of AMR in animals and food. It also gathered information on the policies to encourage the prudent use of antibiotics in animals.

EU requirements on the monitoring and reporting of AMR in animals and food are laid down by Commission implementing Decision 2013/652/EU<sup>43</sup>. The audit series found that Member States had significantly improved the design and implementation of most of the applicable sampling and testing requirements. Some areas for improvement in relation to data collection and national laboratory networks as well as to the reporting of data to the European Food Safety Authority, were noted in the corresponding overview report<sup>44</sup>. The report also highlighted good practices which go beyond what is required by the legislation.

The gathering of information on the prudent use of antimicrobials was conducted through a series of fact-finding missions. These found that nearly all countries have a range of policies for prudent use in place. These include targets for the reduction of antimicrobial use as well as bans on the use of critically important antimicrobials in certain animal species. The combined effect of the policies implemented can result in substantial reductions in antimicrobial use. These can amount to more than 50 %, even where the national strategies are at an early stage and the associated policies are of voluntary nature. The corresponding overview report<sup>45</sup> highlights the potential association between reductions in antimicrobial use and reduced levels of AMR.

Improvement opportunities and good practices identified during these audits and fact-finding missions were used when developing the comprehensive "EU One Health Action Plan against Antimicrobial Resistance"<sup>46</sup>.

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<sup>42</sup> [http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=97](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=97)

<sup>43</sup> Commission Implementing Decision of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria. *OJ L 303, 14.11.2013, p. 26–39*

<sup>44</sup> [http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=110](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=110)

<sup>45</sup> [http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=121](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=121)

<sup>46</sup> [https://ec.europa.eu/health/amr/antimicrobial-resistance\\_en](https://ec.europa.eu/health/amr/antimicrobial-resistance_en)

## **2.10 ORGANIC PRODUCTION**

The area used for organic farming in the EU grew rapidly during the last decade, by about 500,000 hectares a year. In 2015 it included around 185,000 farms across Europe and around 306,500 registered organic operators (producers, processors and importers)<sup>47</sup>.

The Commission started audits in relation to control systems for organic production in EU Member States in 2012. The overall outcome of the audits was published in an overview report<sup>48</sup> in early 2016.

The overview report identified deficiencies relating to import controls and supervision of control bodies by competent authorities. The report also outlined that significant differences exist between Member States concerning the quality and frequency of inspections as well as with regard to the enforcement of organic rules.

Following the publication of the overview report, a BTSF workshop was organised with participants from Member States as well as from the Directorate-General for Agriculture and Rural Development and the Directorate-General for Health and Food Safety of the Commission, aiming to address weaknesses identified during audits. The audit results contributed to changes in implementing rules in relation to targeted additional controls and risk-based sampling, applicable from January 2014<sup>49</sup>. In addition, they provided valuable input for the Commission, the Council and the European Parliament for an ongoing revision of the Regulation on the organics sector<sup>50</sup>.

## **2.11 QUALITY SCHEMES FOR AGRICULTURAL PRODUCTS AND FOODSTUFFS**

EU food quality schemes for agricultural products aim to highlight the qualities and tradition associated with products with protected names and to assure consumers that these are the authentic products. There were more than 3,300 registered names in 2016<sup>51</sup>.

The Commission services' audit series (2012-2014) to evaluate the official control systems for the quality schemes for agricultural products and foodstuffs (Protected Designation of Origin (PDO), Protected Geographical Indications (PGI) and Traditional Specialty Guaranteed (TSG)) and the overview report<sup>52</sup> published in 2015 concluded that official control systems for controls at the level of producers and processors were effectively implemented, but that official controls at market level were not based on a systematic risk-based approach. The report also identified that Member States have difficulties to control PDO/PGI/TSG coming from other Member States or non-EU countries.

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<sup>47</sup> [Facts and figures on organic agriculture in the European Union](#)

<sup>48</sup> [Report reference \(DG SANTE\) 2015 8950: Organic production – Member States.](#)

<sup>49</sup> Commission Implementing Regulation (EU) No 392/2013 of 29 April 2013 amending Regulation (EC) No 889/2008 as regards the control system for organic production - [OJ L 118, 30.4.2013, p. 5–14](#)

<sup>50</sup> Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 - [OJ L 189, 20.7.2007, p. 1–23](#)

<sup>51</sup> European Commission agriculture and rural development: [https://ec.europa.eu/agriculture/quality\\_en](https://ec.europa.eu/agriculture/quality_en)

<sup>52</sup> [Report reference DG \(SANTE\) 2015-8439: Geographical indications and traditional specialties.](#)

This, combined with the absence of a dedicated IT system facilitating the exchange of information on non-compliances between Member States in the area of PDO/PGI/TSG, limits the effectiveness of the Member States control systems and increases the risk of consumers to be misled. However, starting from November 2015 an IT application known as the Administrative Assistance and Cooperation System has been made available for Member States, where geographical indications are included within a separate section. This has a potential to improve the exchange of information.

The findings of the audit series were used during a BTSF workshop with Member States in December 2016. It created a forum to exchange experiences about controls at market level and to develop solutions for more effective controls.

### **3. CONCLUSIONS**

Commission controls established that overall Member States have the requisite control systems in place which ensure generally acceptable levels of compliance. Having said that, the deficiencies observed in certain areas, highlight that there is still room for improvement, and that complacency should be avoided. In this context the Commission welcomes the huge efforts made by Member States to further strengthen their controls.