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

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1. EXECUTIVE SUMMARY

This report describes the overall outcome of control activities of national authorities¹ and of the Commission which aim to ensure a high level of health protection and trust in the areas of food safety, animal and plant health, animal welfare, organic farming and quality schemes. These areas are of critical importance in the daily lives of European Union (EU) citizens and key to enabling the smooth operation of trade in food, animals and plants, both within the EU itself and with non-EU countries. The report covers the years 2014 to 2016 and concludes that Member States national authorities demonstrated in their annual reports on official controls that they continue to fulfil their important role under the food and feed law. Initiatives aimed at improving effectiveness of official controls and enforcement, ranging from service reorganisation to improved use of IT tools, are particularly encouraging and are proving essential in meeting the challenge of finding efficiencies in public spending.

Nonetheless, the Commission also takes note of the clear signals from Member States that staff resources for controls are increasingly limited and that a potential further reduction risks negatively affecting the levels and/ quality of controls and the capacity to respond to emergencies. This is likely to be an important issue in the future development of official controls which the Commission will carefully consider when developing legislation in the context of its Better Regulation initiative and which Member States will likely aim to address with *inter alia* new IT systems, re-organisation and optimised procedures.

On the basis of an analysis of Commission controls, which are exemplified in the staff working document² accompanying this report, it can be established 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 also deficiencies in official controls and 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, for example, further strengthen their risk-based and targeted controls and to support those with effective IT systems.

The Commission's systematic follow-up of its control findings, complemented where appropriate with other enforcement tools including the judicious use of the infringement procedure, continues to prove an effective means of addressing failures in compliance with EU requirements and is important in conjunction with the Commission's strengthened drive for a deeper and fairer internal market and better law-making, both high political priorities for the current Commission³. The Commission also supports Member States and non-EU countries in their implementation of EU rules through a variety of means, such as the provision of technical assistance and training through the Better Training for Safer Food (BTSF) tool and actively promoting such compliance.

¹ Article 44(4) and (6) of Regulation (EC) No 882/2004 requires the Commission to submit to the European Parliament and Council, and make available to the public, an annual report on the overall operation of controls in Member States

² 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.

³ [Political guidelines for the next European Commission of 15 July 2014](#) and [mission letters of 1 November 2014 from the president to the Vice-Presidents](#) and Commissioners.

Commission controls and their follow-up activities provide the Member States, the Commission and stakeholders with a clear picture of the level of implementation of the feed and food law as well as the animal health and welfare rules. In addition, they contribute significantly to the legislative review process aimed at ensuring that Union legislation is “fit for purpose”. With Regulation (EU) 2017/625 becoming applicable in December 2019⁴, the adoption of the implementing and delegated acts foreseen by this Regulation will provide opportunities to use the knowledge gained from the Commission control and follow-up activities to reinforce and support official controls in the coming years. The aim is that through the new rules businesses and authorities will benefit from reduced administrative burdens, more efficient processes and strengthened controls. Consumers will benefit from more transparency on how controls are carried out to ensure food safety and high standards for plant health, animal health and welfare, and to prevent fraud.

2. INTRODUCTION

There is a comprehensive EU legal framework aimed at ensuring high levels of health protection and trust in the areas of food safety, animal and plant health, animal welfare, organic farming and quality schemes. These areas impact heavily on the daily lives of EU citizens who rightly expect high standards. High standards are also essential to enable smooth operation of trade in food, animals and plants, both within the EU itself and with non-EU countries. Effective implementation of official controls⁵ which underpin these standards is essential to maintain the credibility of this framework.

The Commission plays an important role in the overall control framework at EU level, which is set out in Regulation (EC) No 882/2004⁶ and includes ensuring a high level of transparency. Article 44(4) and (6) of that Regulation requires the Commission to submit to the European Parliament and Council, and make available to the public, an annual report 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; and
- any other relevant information.

This report covers the period from 2014 to 2016.

⁴ Regulation (EU) No 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) No 2016/429 and (EU) No 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), [OJ L 95, 7.4.2017, p. 1–142](#).

⁵ 'official control' means any form of control that the competent authority or the Union performs for the verification of compliance with feed and food law, animal health and animal welfare rules.

⁶ 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](#).

3. LEGAL FRAMEWORK

Regulation (EC) No 178/2002⁷, the "general food law" attributes primary responsibility for ensuring that food is safe to the food/feed businesses all along the food/feed chain. Regulation (EC) No 834/2007⁸ contains requirements for organic production and the labelling of organic products. Regulation (EU) No 1151/2012⁹ contains requirements for quality schemes for agricultural products and foodstuffs.

Member States are required to verify that business operators fulfil the requirements of EU law on food and feed safety, animal and plant health, animal welfare, organic production and quality schemes. They are required to operate systems of official controls for this purpose. Regulation (EC) No 882/2004, in turn, lays down requirements for these control systems, and for the performance of official controls.

Member States are required to draw up Multi-Annual National Control Plans (MANCP) and annual reports on the performance of such controls. They must submit their MANCP and annual reports to the Commission¹⁰.

Regulation (EC) No 882/2004 also sets out rules on controls by the Commission to verify that Member States comply with the obligations laid down in the relevant EU legislation.

4. REVIEW OF MEMBER STATES' ANNUAL REPORTS

4.1. RECEIPT AND REVIEW OF MEMBER STATES' ANNUAL REPORTS

During the period from 2014 to 2016 only a few Member States submitted their annual report to the Commission services within the deadline prescribed in Article 44(3) of Regulation (EC) No 882/2004 ("within 6 months of the end of the year to which the reports relate"). This failure to comply with the prescribed deadline reflects, *inter alia*, difficulties that Member States experience in collating at central level all data necessary for the annual report. To illustrate: as of 10 July 2017, the 2016 annual report had been submitted by three Member States (out of 28), the 2015 annual report by 25 Member States and the 2014 annual report by all 28 Member States. Member States annual reports also vary significantly in the presentation of data and in the nature of the data presented.

These two facts pose a significant challenge for the Commission services charged with producing the report required by Article 44(4) of Regulation (EC) No 882/2004 to review all annual reports received for the period in question with a view to identifying significant trends in the performance of official controls and non-compliances identified by those controls. The current work on the development of the implementing act provided for by Article 113(2) of Regulation (EU) No 2017/625 is expected to help address this problem in the future by introducing standard models for the submission of Member States annual

⁷ 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, 01.2.2002, p.1](#).

⁸ Council Regulation (EC) No 834/2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 - [OJ L 189, 20.07.2007, p.1](#).

⁹ 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](#).

¹⁰ Art. 41 to 44 of Regulation (EC) No 882/2004

reports. These will also allow Member States to more easily and quickly collate annual report information at central level and to submit those to the Commission services.

4.2 ORGANISATION AND PERFORMANCE OF OFFICIAL CONTROLS

The Member States reports presented evidence that overall, the established trend in the Member States towards increasingly risk-based controls continues. This ensures that best use is made of resources by focusing on areas which present the greatest risks. However, and as confirmed by audits by the Commission services, risk based controls are not applied in all areas where such controls are warranted.

There is a particular difficulty when interpreting or comparing data on non-compliances detected during official controls carried out under Regulation (EC) No 882/2004. Article 3 of this Regulation requires that controls be carried out at a frequency that takes risk into account. As a result, an apparently high rate of detection of non-compliance does not necessarily indicate a generally poor level of compliance but may actually indicate good risk-based targeting of controls. Determining whether a high rate of non-compliance detected reflects effective, well-targeted official controls or a poor level of compliance, is not possible solely through examination of annual reports. Such determinations must be made through on-the-spot assessments, such as those carried out during audits by the Commission services (see chapter 5).

One further effect of increasingly risk-based controls is that data on non-compliance are not directly comparable from one year to the next as more targeted controls may well lead to finding (relatively) more cases of non-compliance. A number of Member States annual reports highlight this point.

A clear benefit of more targeted controls is that more resources are potentially available for follow-up and enforcement, and a number of reports provided evidence of progress in this area. Thus Member States can firstly focus more on systematic follow-up of official controls and enforcement posed problems and secondly on control and enforcement activity on operators with poor compliance records, which improves the overall safety of products, and contributes to creating a level playing field for all operators, thus also benefiting the functioning of the Internal Market.

Some reports provide information on other activities undertaken to make controls and enforcement more effective and efficient overall. These activities include reorganisation and consolidation of control services, improved co-operation between services and coordination of controls, and re-attribution of controls. Particular mention should be made of the enhanced use of IT systems, supporting the collection, dissemination and analysis of control and enforcement data. This, in turn, assists better coordination and targeting/planning of controls. The squeeze on resources and public spending in all Member States is driving these efforts to improve efficiencies.

Finally, most reports mention improvements realised in the performance of controls through review of procedures, the organisation of training, and increased availability of relevant documentation (including on-line). Reports also identified the outcome of national audits (see under *National audit systems, Chapter 4.4*) as a relevant source for improvements and efficiencies. The Commission services carried out audits in Member States to obtain information on measures in place to verify the effectiveness of their controls, as required by Regulation (EC) No 882/2004. This has been important in

highlighting the need to focus more on the quality rather than the number of controls as a measure of overall effectiveness.

4.3 IDENTIFIED NON-COMPLIANCE

The main areas of non-compliance identified by Member States include: operational, structural or equipment-based hygiene requirements; Hazard Analysis and Critical Control Points (HACCP); labelling of food and feed; additives in food and feed; poor or absent record keeping and microbiological contamination. While the identification of underlying causes for these problems is limited, some point to high staff turnover in food feed business operators, often linked to low wages and which affects the continuous use of good hygiene practices, lack of training at food business operators, and/or lack of knowledge of the requirements. The latter gives some cause for concern considering that, within the food/feed law framework, operators are primarily responsible for the proper application of the rules.

Given the contribution that HACCP makes to ensure the production of safe food, and in order to a) obtain a good overall picture of the situation, and b) identify opportunities for improvements, the Commission services undertook a series of audits on HACCP in 2014. The results of this series have been brought together in an overview report published in June 2015¹¹. This has in turn led to initiatives on training, information exchange on good practice and a review of current HACCP requirements, as well as guidance on these requirements. Similarly, and as regards hygiene, the Commission services started a review of operational hygiene and official controls in slaughterhouses, in close co-operation with the Member States, to see how slaughter hygiene can be better ensured. This work aims at identifying common problems, dissemination of good practice, and includes training elements.

4.4 ENFORCEMENT: ACTION TAKEN IN CASE OF NON-COMPLIANCE

Member States are required to indicate in their reports what enforcement actions have been taken. While data on enforcement was provided, irrespective of the quality or detail of the information, it is very difficult to make meaningful comparisons between Member States reports. Nonetheless, the reports do suggest an overall greater emphasis on follow-up and enforcement. Some Member States reported the introduction of administrative fines (as opposed to enforcement through the national courts), or the increase of such fines to act as a better deterrent. Interesting examples of alternative and reportedly effective means to improve compliance are the withdrawal of fines if the offender follows training, more official inspections and higher charges for offenders, and the provision of training followed by inspections to measure effectiveness.

4.5 NATIONAL AUDIT SYSTEMS

Audits by Member States of their official control systems, as required by Regulation (EC) No 882/2004, are important in the overall management of these controls as they provide assurance that controls are carried out as required, with information on their effectiveness and, as appropriate, with suggestions for improvements. All Member States confirm that audits are in place, but a number of Member States reported that resource constraints

¹¹ [Report reference DG Health and Food safety \(SANTE\) 2015-7752: HACCP.](#)

limited the implementation of planned audit programmes. There is considerable variation between Member States, but this is plausible given that they all operate their own audit cycles and tend to focus on differing priority areas. For their part, the Commission services continue to organise regular meetings of Member States national audit experts (the National Audit Systems Network - NAS Network), to share and discuss experiences, common problems, and identify good/best practice in addressing the audit requirement. In addition, the Commission services have implemented a series of audits of NAS, in order to obtain a comprehensive picture of their operation (see Chapter 5 for further details).

4.6 RESOURCES

Given the pressures on public expenditure, the Commission services took a particular interest in what the Member States reports said about available control resources, even though Member States are currently not yet required to report specifically on this aspect. Nonetheless, a host of reports addressed the issue. Some stated unequivocally that their staffing falls short of what is required to ensure all controls as required. Others indicate that - either in specific areas, or at certain control levels – a limit had been reached where further reductions risk the levels and/or quality of controls and the capacity to respond to emergencies. Maximising efficiency is also identified as a clear objective of the control strategy in a number of Member States. Resource shortage did not only concern staffing, but also equipment in some Member States (e.g. for laboratories, or means of transport for control staff, affecting performance of controls).

5. 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 published¹², providing stakeholders and citizens with a factual and transparent account of how Member States deliver on correct implementation of EU law.

Commission control activities in Member States, which are in more detail exemplified in the staff working document¹³ accompanying this report, focused on key priorities of the Commission, like for example on the official control systems for Plant Protection Products (PPPs), animal welfare and antimicrobial resistance but also on many other areas crucial for food safety, animal or plant health.

Several Commission audit series in Member States covered controls on the marketing and use, the authorisation and sustainable use of PPPs^{14,15,16}. They identified weaknesses on

¹² https://ec.europa.eu/food/audits_analysis_en

¹³ 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.

¹⁴ [Report reference DG \(SANTE\) 2016-6004: Plant Protection Products - Marketing and Use](#)

¹⁵ [Report reference: DG \(SANTE\) 2016-6250: Plant Protection Products - Authorisation](#)

¹⁶ [Report reference DG \(SANTE\) 2014-7567: Pesticides.](#)

the authorisation and marketing of PPPs in several areas, but also found increasingly well-developed official controls systems on users. Progress has been made in the implementation of the Directive on Sustainable Use of Pesticides¹⁷ with the set-up of training and certification systems for professionals and the testing of sprayers. However, Integrated Pest Management – a cornerstone of the Directive - remains underused. This needs to be addressed by Member States in their revised National Action Plans, which will be audited by the Commission. All the above activities aim to improve current Member State control systems and to provide assurances to consumers on increasingly responsible and sustainable use of PPPs.

In the area of animal welfare the Commission started a three year project to facilitate and ensure better animal welfare during transport. This included the creation of guides to good practice for five main animal species (cattle, horses, pigs, poultry and sheep) and the assessment of their use to better comply with EU welfare rules. Visits to Member States with good practice on checks on livestock vehicles in conjunction with Commission facilitated exchange between Member States national contact points, helped to further the protection of animals during transport. Similarly useful was a desk-study and audit series on the protection of animals at the time of killing, which allowed to share best practices and to organise special training events.

In the context of the European Commission's 2011 Action Plan against the rising threats from antimicrobial resistance (AMR), the Commission carried out audits on the implementation of the mandatory monitoring and reporting of AMR in animals and food, as well as information gathering activities on the policies to encourage the prudent use of antibiotics in animals. Improvement opportunities and good practices identified during these activities were also used when developing the comprehensive "EU One Health Action Plan against Antimicrobial Resistance"¹⁸.

Two other Commission activities 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

¹⁷ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for a Community action to achieve the sustainable use of pesticides – OJ L 309, 24.11.2009, p.71-86

¹⁸ https://ec.europa.eu/health/amr/antimicrobial-resistance_en

the Better Regulation Agenda¹⁹. 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 programme²⁰.

6. COMMISSION FOLLOW-UP AND ENFORCEMENT

Taking effective, on-going action to ensure that EU law is correctly implemented and applied throughout the Union remains a Commission priority in the areas covered by this report. The previous report²¹ described how the Commission systematically follows up its audit findings and related recommendations. These processes continued to be effective in dealing with the vast majority of identified shortcomings. At the end of December 2016 Member States took corrective action, or provided satisfactory commitments to address them within acceptable timelines:

- for 97% of recommendations resulting from audits in the reporting cycle 2012-2014; and
- for 94% of recommendations resulting from audits in the reporting cycle 2013-2015.

The Commission's enforcement policy involves monitoring how EU law is applied and implemented, solving problems with Member States to remedy any possible breaches of the law, and taking infringement action under Article 258 of the Treaty on the Functioning of the European Union²², when appropriate. The initiation of such proceedings against Member States who failed to ensure implementation of the requirements concerning the *welfare of laying hens* and the ban on unenriched cages in 2012, led to several Member States taking accelerated corrective action, averting the need for court action to proceed in most cases. This illustrates that a judicious use of the infringement procedure in areas of overriding importance where the legislation sets out clear legal requirements, can prove very effective in achieving the required corrective actions. The Commission adopted a similar approach in respect of the on-farm welfare of pigs and the group housing of sows.

Notwithstanding these efforts, applying and enforcing EU law remains a challenge and calls for a stronger focus on enforcement in order to serve the general interest. Enforcement supports and complements the delivery of policy priorities. The work done to ensure the effective enforcement of existing EU law needs to be recognised by all involved in the enforcement of EU law, as being key in ensuring that the work devoted to developing new legislation delivers its objective.

¹⁹ https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en

²⁰ 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

²¹ Report from the Commission to the European Parliament and the Council on the overall operation of official controls in the Member States on food safety, animal health and animal welfare, and plant health <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013DC0681>

²² Consolidated version of the Treaty on the Functioning of the European Union <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT>

The partnership between the Commission and the Member States, who play a crucial role in implementation, needs to be strengthened to deliver the benefits of EU law to the public. Enforcement must be dealt with promptly. The Commission and the Member States need to continue their efforts in enforcing EU law and pursuing breaches of the law.

The Commission will encourage and help Member States to improve their capacity to enforce EU law and provide remedies in order to ensure that the end-users of EU law — whether private individuals or businesses — can fully enjoy their rights. Networks and the exchange of best practice are key aspects of this effort.

Independent administrative authorities or inspectorates required by EU legislation play an essential role in implementation and enforcement. The Commission will therefore pay particular attention to their being sufficiently and adequately equipped to perform their tasks.

Finally in line with the principles of its "Better Regulation" agenda, the Commission will focus on the better application and implementation of EU laws which ultimately will also support better enforcement, benefitting citizens and businesses alike.

7. CONCLUSIONS

Member State national authorities demonstrated in their annual reports on official controls that they continue to fulfil their important role under the food and feed law. Initiatives aimed at improving effectiveness of official controls and enforcement, ranging from service reorganisation to improved use of IT tools, are particularly encouraging and are proving essential in meeting the challenge of finding efficiencies in public spending.

Nonetheless, the Commission also takes note of the clear signals from Member States that staff resources for controls are increasingly limited and that a potential further reduction risks negatively affecting the levels and/ quality of controls and the capacity to respond to emergencies. This is likely to be an increasingly important issue in the future development of official controls, which the Commission will carefully consider when developing legislation in the context of its Better Regulation initiative and which Member States will likely aim to address with *inter alia* new IT systems, re-organisation and optimised procedures.

On the basis of an analysis of Commission controls, which are exemplified in the staff working document accompanying this report, it can be established 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, and that complacency should be avoided. In this context the Commission welcomes the huge efforts made by Member States to, for example, further strengthen their risk-based and targeted controls and to support those with effective IT systems.

The Commission's systematic follow-up of its control findings, complemented where appropriate with other enforcement tools including the judicious use of the infringement procedure, continues to prove an effective means of addressing failures in compliance with EU requirements and is important in conjunction with the Commission's

strengthened drive for a deeper and fairer internal market and better law-making, both high political priorities for the current Commission. The Commission also supports Member States and non-EU countries in their implementation of EU rules through a variety of means, such as the provision of technical assistance and training through the Better Training for Safer Food (BTSF) tool and actively promoting such compliance.

Commission controls and their follow-up activities provide the Member States, the Commission and stakeholders with a clear picture of the level of implementation of the feed and food law as well as the animal health and welfare rules. In addition, they contribute significantly to the legislative review process aimed at ensuring that Union legislation is “fit for purpose”. With the coming into force of the provisions of Regulation (EU) 2017/625 in December 2019, the adoption of the implementing and delegated acts foreseen by this Regulation will provide opportunities to use the knowledge gained from the Commission control and follow-up activities to reinforce and support official controls in the coming years. The aim is that through the new rules businesses and authorities will benefit from reduced administrative burdens, more efficient processes and strengthened controls. Consumers will benefit from more transparency on how controls are carried out to ensure food safety and high standards for plant health, animal health and welfare and to prevent fraud.