


Procedure file

Basic information	
<p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p> <p>2003/0030(COD)</p>	Procedure completed
<p>Food safety: feed and food law, animal health and animal welfare rules, official controls</p> <p>Repealing Directive 95/53/EC 1993/1039(CNS) Repealing Decision 1999/313/EC 1997/0182(CNS) Repealed by 2013/0140(COD) Amended by 2013/0169(COD)</p> <p>Subject</p> <p>3.10.08 Animal health requirements, veterinary legislation and pharmacy 3.10.08.01 Feedingstuffs, animal nutrition 3.10.10 Foodstuffs, foodstuffs legislation 4.60.02 Consumer information, advertising, labelling 4.60.04.04 Food safety</p>	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy		25/03/2003
		ELDR PAULSEN Marit	
	Committee for opinion	Rapporteur for opinion	Appointed
	AGRI Agriculture and Rural Development		19/03/2003
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2578	26/04/2004
	Agriculture and Fisheries	2486	20/02/2003
European Commission	Commission DG	Commissioner	
	Health and Food Safety		

Key events			
04/02/2003	Legislative proposal published	COM(2003)0052	Summary
20/02/2003	Debate in Council	2486	
10/03/2003	Committee referral announced in Parliament, 1st reading		
27/11/2003	Vote in committee, 1st reading		Summary
26/11/2003	Committee report tabled for plenary, 1st reading	A5-0449/2003	
09/03/2004	Debate in Parliament		
09/03/2004	Decision by Parliament, 1st reading	T5-0146/2004	Summary
26/04/2004	Act adopted by Council after Parliament's 1st reading		

29/04/2004	End of procedure in Parliament		
30/04/2004	Final act signed		
30/04/2004	Final act published in Official Journal		

Technical information

Procedure reference	2003/0030(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealing Directive 95/53/EC 1993/1039(CNS) Repealing Decision 1999/313/EC 1997/0182(CNS) Repealed by 2013/0140(COD) Amended by 2013/0169(COD)
Legal basis	EC Treaty (after Amsterdam) EC 152
Stage reached in procedure	Procedure completed

Documentation gateway

Legislative proposal		COM(2003)0052	05/02/2003	EC	Summary
Economic and Social Committee: opinion, report		CES0925/2003	16/07/2003	ESC	
Economic and Social Committee: opinion, report		CES0949/2003 OJ C 234 30.09.2003, p. 0025-0029	16/07/2003	ESC	
Committee draft report		PE331.675	19/09/2003	EP	
Committee opinion	AGRI	PE329.786/DEF	30/09/2003	EP	
Committee of the Regions: opinion		CDR0267/2003 OJ C 023 27.01.2004, p. 0014-0015	09/10/2003	CofR	
Amendments tabled in committee		PE331.675/AM	28/10/2003	EP	
Amendments tabled in committee		PE331.675/AMC	24/11/2003	EP	
Committee report tabled for plenary, 1st reading/single reading		A5-0449/2003	27/11/2003	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0146/2004 OJ C 102 28.04.2004, p. 0032-0183 E	09/03/2004	EP	Summary
Implementing legislative act		32005R2074 OJ L 338 22.12.2005, p. 0027-0034	05/12/2005	EU	Summary
Implementing legislative act		32005R2075 OJ L 338 22.12.2005, p. 0060-0082	05/12/2005	EU	Summary
Implementing legislative act		32005R2076 OJ L 338 22.12.2005, p. 0083-0088	05/12/2005	EU	Summary

Implementing legislative act		32006R0401 OJ L 070 09.03.2006, p. 0012-0034	23/02/2006	EU	Summary
Follow-up document		COM(2009)0334	08/07/2009	EC	Summary
Follow-up document		COM(2010)0441	25/08/2010	EC	Summary
Follow-up document		COM(2012)0122	23/03/2012	EC	Summary
Follow-up document		COM(2013)0681	04/10/2013	EC	Summary
Follow-up document		SWD(2014)0252	16/07/2014	EC	Summary
Follow-up document		COM(2018)0627	14/09/2018	EC	Summary
Follow-up document		SWD(2018)0402	14/09/2018	EC	

Additional information

European Commission

[EUR-Lex](#)

Final act

[Regulation 2004/882](#)
[OJ L 191 28.05.2004, p. 0001-0052](#) Summary

Final legislative act with provisions for delegated acts

Food safety: feed and food law, animal health and animal welfare rules, official controls

PURPOSE : to propose new controls on official feed and food. **CONTENT** : the proposed Regulation will streamline and reinforce the existing control system with added bite, consisting of stricter enforcement mechanisms. The proposal aims to cure weaknesses in current legislation by improving the efficiency of control services performed by both Member States and the Commission. It defines tougher enforcement measures, including criminal sanctions. The proposal also creates a framework to support developing countries in meeting EU import requirements and provides for a financial framework to organise activities that enhance food and feed safety. More specifically, it lays down the rules to be respected by the competent authorities responsible for carrying out official controls as well as the tasks of the Commission with regard to the organisation of those controls. It is the result of a review of the existing Community rules on the subject, which were adopted separately for the animal feed sector, the food sector and the veterinary sector. It covers the entire range of activities covered by feed and food law, which includes feed and food safety but also other aspects that relate to consumer protection, such as feed and food labelling. The present proposal aims to create such Community framework of national control systems by merging and completing existing rules for national and Community controls within the EU, at the borders and in third countries. Special attention is paid to enforcement measures and in particular the imposition of sanctions at national and Community level. For that purpose, the proposal contains minimum requirements on criminal sanctions to be imposed by the Member States with regard to serious offences that are committed intentionally or through serious negligence. The proposal also contains new tools for the Commission to enforce the implementation of Community feed and food law by the Member States. The proposal takes into account the principles of food safety that are spelled out in the Commission's White Paper on Food Safety, and in particular that: - food safety policy must be based on a comprehensive, integrated approach, - feed and food businesses operators have the prime responsibility for feed and food safety, whilst the competent authorities monitor and enforce this responsibility through the operation of national surveillance and control systems; the Commission's control services concentrate on evaluating the ability of competent authorities to deliver these systems through audits and inspections, - feed and food safety policy must be risk-based, - the farm to table policy, covering all sectors of the food chain, including feed production and animal feeding, primary production, food processing, storage and distribution, animal health and animal welfare, needs to be systematically implemented.?

Food safety: feed and food law, animal health and animal welfare rules, official controls

The committee adopted the report by Marit PAULSEN (ELDR, S) amending the proposal under the 1st reading of the codecision procedure: - it should be clearly stated that feed and food labelling should be included in the scope of this legislation; - every company should be inspected at least once a year. Under the "name and shame" principle, inspection reports and lists of firms that break the rules should be made public. Moreover, in the interests of transparency, business operators should be given access to the documented control procedures. The committee adopted a number of other amendments at various points in the text with the aim of ensuring maximum transparency, arguing that this was necessary to guarantee consumer confidence; - in addition to controls of the final product, systematic process controls - along the lines of those implemented for the organic farming sector - should be carried out through the whole food and feed chain; - it should be possible for official national inspectors and, where necessary, Commission inspectors to carry out spot checks at any stage of production, processing or marketing of food and feed products; - the Commission may prohibit the marketing of products and ingredients from a Member State which has not set up a national control programme, although special exemptions may be granted for specific named feed and food businesses; - as regards the cost of inspections, MEPs argued that the current system of equal fee levels for all business operators placed a greater burden on

small and medium-sized firms than on larger food companies. They therefore proposed a fee system, to apply from 1 January 2007, that takes account of the category of the risk and the turnover of a company as well as the cost for the authorities. The fee would be calculated as a proportion of the turnover of the businesses, grouped according to risk category, and the fees in Member States would not be able to differ by more than 10% from the average within the Community. As an incentive for companies to invest in food safety, risk categorisation could include rules for upgrading and downgrading, so that, for example, a good inspection result could mean that a business would be downgraded to a lower risk category and hence have to pay less for the inspections. One amendment also introduced a new clause providing for the Commission to monitor the imposition of fees and take any necessary steps to ensure that such imposition does not distort trade or hamper the proper functioning of the internal market; - all imports of feed and food should be subject to official controls and a consignment should be destroyed immediately "where there is a well-founded suspicion that direct danger to human or animal health cannot be excluded"; - it should be possible to allow access to the internal market for individual businesses from non-EU countries that do not comply with EU rules, if those businesses have invested in food safety to EU standards. A list of such businesses should be drawn up and subject to regular inspections by the competent authorities.?

Food safety: feed and food law, animal health and animal welfare rules, official controls

The European Parliament adopted a compromise on a regulation on official controls on food and feed, by 287 votes in favour, 194 against and 23 abstentions. By adopting a number of amendments in a report by Marit PAULSEN (ELDR, S), Parliament clarified the scope of the regulation, introduced transparency to the inspections and incorporated animal welfare and health issues into the regulation. The compromise was reached after long political negotiations with the Council. It ensures that the regulation enters into force as soon as possible. Parliament clarified the scope of the official controls: they must prevent, eliminate or reduce to acceptable levels risks to humans and animals. They must also guarantee fair practices in trade and protect consumer interests, including labelling and other forms of consumer information. The Member States must ensure that official controls are carried out regularly and that they identify risks associated with animals, feed or food. The controls must take into account food safety and animal health and welfare. Official controls will be carried out without prior warning, except in cases such as audits. Official controls may also be carried out on an ad hoc basis. A controversial issue was the question on criminal sanctions. Parliament passed an amendment stating that Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and protection of animal health and welfare. The sanctions must be effective, proportionate and dissuasive. The Regulation provides for administrative enforcement measures for member states to address particular problems of non-compliance as well as enforcement measures at EU level. Where the commission has proof that a national control system is inadequate, it is permitted to take interim measures to ensure the protection of human health, animal health and welfare and the environment. These measures would be taken in cooperation with Member States within the Standing Committee, or in serious cases, on the Commission's initiative. The measures include suspending the right to place food and feed in the internal market. Another difficult issue was the question of transparency and confidentiality of the feed and food controls. The original proposal only mentions the need to safeguard confidentiality. Parliament instead adopted an amendment, which puts emphasis on transparency of the controls. Relevant information held by the food and feed authorities should be made available to the public as soon as possible. Confidentiality however is not overruled, as the authority also has to ensure that it does not disclose information, which by its nature is covered by professional secrecy. Parliament also had to decide whether the level of control fees should be dealt within Member States or whether an EU-wide fee should be introduced. Costs currently vary greatly from one country to another - particularly when the comparison is made between current Member States and the ten new countries due to join the Union on May 1. Parliament avoided standardising the costs of inspections across the EU, for fear that this would drive businesses - in particular slaughterhouses - out of the EU altogether. Instead Parliament adopted an amendment that allows the Member States to collect fees to cover the costs occasioned by official controls. The fees shall not be higher than the costs and they may be fixed at flat rates on the basis of the costs borne by the competent authorities over a given period of time. The fees may also be fixed, where applicable, at the minimum amounts fixed in the annexes of the regulation. The regulation also covers issues such as the delegation of control to specific control bodies, imports from third countries, community laboratories, liaison bodies with other Member States and multi-annual control plans. Finally, Parliament adopted an amendment on the entry into force of the regulation. The new rules on feed and food controls will apply from January 2006 instead of 2005 as proposed by the Commission.?

Food safety: feed and food law, animal health and animal welfare rules, official controls

PURPOSE : to adopt new Community legislation on the controls of official feed and food with a view to streamlining and reinforcing the existing control system. **LEGISLATIVE ACT :** Regulation 882/2004/EC of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. **CONTENT :** the Council adopted this Regulation on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. This Regulation completes the first package of the food and feed hygiene review of Community legislation. It lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at preventing, eliminating or reducing to acceptable levels risks to humans and animals and guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information. The Regulation establishes official controls at all stages, underlines the responsibility and training of competent staff in performing official controls, sets the same procedures for controls on food and feed from third countries, and establishes the financing of the official controls by minimum rates of fees and charges collected by the Member States. More specifically, it lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at: - preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment; - guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information. As regards the general obligations with regard to the organisation of official controls, Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this Regulation taking account of: - identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare; - feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules; - the reliability of any own checks that have already been carried out; and - any information that might indicate non-compliance. Official controls shall: - be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an ad hoc basis; - be carried out at any of the stages of production, processing and distribution of feed or food and of animals and animal products. They shall include controls on feed and food businesses, on the use of feed and food, on the storage of feed and food, on any process, material, substance, activity or operation including transport applied to feed or food and on live animals, required to

achieve the objectives of this Regulation; - be applied, with the same care, to exports outside the Community, to the placing on the market within the Community and to introductions from third countries. Member States, on the other hand, shall take all necessary measures to ensure that products intended for dispatch to another Member State are controlled with the same care as those intended to be placed on the market in their own territory. The competent authority of the Member State of destination may check compliance of feed and food with feed and food law by means of non-discriminatory checks. To the extent strictly necessary for the organisation of the official controls, Member States may ask operators who have goods delivered to them from another Member State to report the arrival of such goods. If, during a check carried out at the place of destination or during storage or transport, a Member State establishes non-compliance, it shall take the appropriate measures, which may include re-dispatch to the Member State of origin. Competent authorities shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this Regulation. These audits shall be subject to independent scrutiny and shall be carried out in a transparent manner. On the issue of the staff performing official controls, this Regulation states that the competent authority shall ensure that all of its staff performing official controls: - receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner. Other provisions are set out in this Regulation such as : training of control staff; support for developing countries; The Commission shall, not later than 20 May 2007, submit a report to the European Parliament and the Council reviewing the experience gained from the application of this Regulation. ENTRY INTO FORCE : 20/05/2004. This Regulation shall apply from 1 January 2006. However, Articles 27 (fees or charges) and 28 (Expenses arising from additional official controls) shall apply from 1 January 2007.

Food safety: feed and food law, animal health and animal welfare rules, official controls

ACT : Commission Regulation 2075/2005/EC laying down specific rules on official controls for Trichinella in meat.

CONTENT : Regulations 853/2004/EC, 854/2004/EC and 882/2004/EC of the European Parliament and of the Council lay down the health rules and requirements regarding food of animal origin and the official controls required.

In addition to those rules, more specific requirements should be laid down for Trichinella. Meat of domestic swine, wild boar, horses and other animal species may be infested with nematodes of the genus Trichinella. Consumption of meat infested with Trichinella can cause serious disease in humans.

Consequently, this Regulation lays down measures to prevent human disease caused by the consumption of meat infested with Trichinella.

It defines:

- the obligations of competent authorities and of food business operators; sampling of carcasses; derogations; trichinella examination and application of health mark; staff training; methods of detection; contingency plans; recognition of officially Trichinella-free holdings; obligations on food business operators to inform; monitoring programmes; withdrawal of official recognition of Trichinella-free holdings or regions with negligible risk;

- rules relating to import health requirements.

ENTRY INTO FORCE : 11/01/2006. The Regulation shall apply from 01/01/2006.

Food safety: feed and food law, animal health and animal welfare rules, official controls

ACT : Commission Regulation 2074/2005/EC laying down implementing measures for certain products under Regulation 853/2004/EC of the European Parliament and of the Council and for the organisation of official controls under Regulation 854/2004/EC of the European Parliament and of the Council and Regulation 882/2004/EC of the European Parliament and of the Council, derogating from Regulation 852/2004/EC of the European Parliament and of the Council and amending Regulations 853/2004/EC and 854/2004/EC.

CONTENT :

- Regulation 853/2004/EC lays down specific requirements concerning hygiene rules for food of animal origin. It is necessary to lay down certain implementing measures for meat, live bivalve molluscs, fishery products, milk, eggs, frogs' legs and snails, and processed products thereof;

- Regulation 854/2004/EC lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. It is necessary to develop certain rules and further specify other requirements;

- Regulation 882/2004/EC establishes at Community level a harmonised framework of general rules for the organisation of official controls. It is necessary to develop certain rules and further specify other requirements.

The main elements of this Regulation are as follows :

- requirements concerning food chain information for the purpose of Regulations 853/2004/EC and 854/2004/EC;

- requirements concerning fishery products for the purpose of Regulations 853/2004/EC and 854/2004/EC;

- recognised testing methods for marine biotoxins for the purpose of Regulations 853/2004/EC and 854/2004/EC;

- calcium content of mechanically separated meat for the purpose of Regulation 853/2004/EC;

- lists of establishments for the purpose of Regulation 882/2004/EC;

- model health certificates for frogs' legs, snails, gelatine and collagen for the purpose of Regulation 853/2004/EC;

- derogation from Regulation 852/2004/EC for foods with traditional characteristics.

ENTRY INTO FORCE : 11/01/2006. This Regulation shall apply from 01/01/2006 with the exception of Chapters II and III of Annex V (list of approved food establishments) which shall apply from 01/01/2007.

Food safety: feed and food law, animal health and animal welfare rules, official controls

ACT : Commission Regulation 2076/2005/EC laying down transitional arrangements for the implementation of Regulations 853/2004/EC, 854/2004/EC and 882/2004/EC of the European Parliament and of the Council and amending Regulations 853/2004/EC and 854/2004/EC.

CONTENT : Regulations 853/2004/EC, 854/2004/EC and 882/2004/EC of the European Parliament and of the Council lay down the health rules and requirements regarding food of animal origin and the official controls required.

The entry into application on 1 January 2006 of these Regulations will entail considerable changes to the rules and procedures to be followed by food operators and the competent authorities of the Member States. The application of some of these measures with immediate effect from 1 January 2006 would present practical difficulties in some cases. A period should therefore be envisaged in order to permit a smooth transition to the full implementation of the new rules and procedures.

It is appropriate that the duration of the transitional period of 4 years, ending on 31 December 2009, be fixed taking into account a first review of the new regulatory framework on hygiene scheduled within the first four years. Provision should therefore be made for a transitional period during which certain requirements laid down in those Regulations can be progressively implemented. With a view to a harmonised approach, that transitional period should in principle last four years but could, where justified, be shorter. Provision should also be made for the possibility or reviewing any of those arrangements in the light of experience gained.

ENTRY INTO FORCE : 11/01/2006. The Regulation shall apply from 01/01/2006.

Food safety: feed and food law, animal health and animal welfare rules, official controls

ACT : Commission Regulation 401/2006/EC laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

CONTENT : Commission Regulation 466/2001/EC of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs provides for maximum limits for certain mycotoxins in certain foodstuffs. Sampling plays a crucial part in the precision of the determination of the levels of mycotoxins, which are very heterogeneously distributed in a lot.

Consequently, this Regulation:

- fixes general criteria which the sampling method should comply with (Annex I);
- fixes general criteria which the method of analysis should comply with in order to ensure that control laboratories use methods of analysis with comparable levels of performance (Annex II).

ENTRY INTO FORCE : 29/03/2006.

TRANSPPOSITION : from 01/07/2006.

Food safety: feed and food law, animal health and animal welfare rules, official controls

Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules (Official Controls Regulation or OCR) requires the Commission to submit a report to the European Parliament and Council, in particular to review the experience gained from the application of the Regulation.

This report considers the following issues:

- re-evaluating the scope, in relation to animal health and animal welfare;
- ensuring that other sectors contribute to the financing of official controls by extending the list of activities referred to in Annex IV, section A and in Annex V, section A, and taking into account, in particular, the impact of the Community feed and food hygiene legislation after its adoption;
- setting updated minimum rates for fees, taking into account, in particular, risk factors.

The report notes that experience gained so far does not call for a review of the scope of the Regulation in relation to animal health and welfare. However, ongoing discussions in view of the modernisation and simplification of two significant sectors might help clarify the relationship between the general framework established by the Regulation and existing sectoral legislation. This is particularly the case as regards the ongoing review activities carried out as a follow up to the [Animal Health Strategy](#) (2007-2013) and those activities that will result from the forthcoming review of the existing Plant Health acquis (Plant Health Strategy). In addition, consideration should be given to the need to ensure that existing sectoral Community provisions applicable to control activities in specific fields (on residues of veterinary medicines and of pesticides, for instance) are consistent with the principles and requirements of the Regulation.

This report also gives an account of the main actions and initiatives developed in implementing the Regulation, looking at the experience gained since 1 January 2006. Member States are progressively gaining hands-on experience in the preparation and implementation of their Multi-annual control plans (MANCPs), which are also being used by the Commission Food and Veterinary Office (FVO) in the framework of its regular General Audit missions. National Annual Reports are also an important feature of the new framework for official controls established by the OCR, although the experience with such reports is too limited to allow an in-depth analysis to be carried out at this stage or conclusion to be drawn so far.

Moreover, the OCR Regulation requires that special attention be given to the issue of fees collected for the financing of official controls (inspection fees). This report gives account of the current state of play of discussions and reflections on this rather complex issue, on the basis of the results of a recent study carried out for the Commission by an external evaluator.

The study in question provides the Commission with a valuable insight of the current functioning of the fees system, identifies some shortcomings in the current legislative framework applicable to inspection fees and in its implementation by Member States and discusses the possible need to review some of the features of that framework. According to the study, a number of possible options for change may be considered, to enable Member States to 'ensure that adequate financial resources are available to provide the necessary staff and other resources for official controls'. The study suggests possible future scenarios, ranging from full harmonisation of the features of the fees' system to increased flexibility for Member States in the implementation of the system, whilst ensuring transparency and clarity of the functioning of the system across Member States.

Lastly, further analyses on the issues raised by the study are needed, including a public discussion with stakeholders on the results of the evaluation carried out, and an impact assessment of available options for change. The Commission intends to launch such an impact assessment in the course of 2009.

Food safety: feed and food law, animal health and animal welfare rules, official controls

The Commission presents its report on the overall operation of official controls in the Member States on food safety, animal health and animal welfare, and plant health. Regulation (EC) No 882/2004 ("the Feed and Food Controls Regulation") requires Member States to submit to the Commission each year a report on the implementation of their multi-annual national control plans established in compliance with the Regulation. The Commission's annual report provides an overview of the way competent authorities in the Member States carry out official controls to verify compliance with food law legislation (in the broadest sense, including not only food and feed safety but also animal health and welfare and - to some extent - plant health).

In this first report attention is given to the following objectives:

- to provide a first screening of the data and information on official controls which is currently available to the Commission, including an analysis of such data and information resulting from the first set of annual reports transmitted by Member States to the Commission;
- to present some initial conclusions on how to improve the current system of reporting by Member States.

The report recalls the different sources of information available to the Commission regarding official controls in Member States.

Annual reports of Member States: the reports were received by the Commission in the second half of 2008 and early 2009. Overall, the annual reports gave the information as required by the Regulation. However, the information provided varied greatly in nature, detail and quality. Each report was assessed under six main headings, which broadly follow the recommended structure of reports in the Commission's (non-binding) guidelines set out in Commission Decision 2008/654/EC:

Results of controls: in most reports, data were given for the number and type of inspections, samples and analyses carried out although the level of detail, of aggregation and the overall quality varied greatly. Information on controls according to sector, stage of production or hazard/disease was usually given, but with variable levels of detail and differences in how data were structured and presented.

Analysis of non-compliance: information was generally missing or incomplete on the type and number of non-compliances identified.

Actions taken in cases of non-compliance (warnings/recommendations, fines imposed, closures, movement restrictions, destructions ordered and legal proceedings): on the whole, information under this heading was limited and where it was provided the range and level of detail varied between Member States.

National system of audits: the Commission issued guidelines in September 2006 advising how the national systems of audit should be organised. With a few exceptions the details provided for this purpose were incomplete. It should be acknowledged, however, that many Member States were still only in the early stages of establishing audit systems at the time of preparing their 2007 reports.

Actions to improve performance of control authorities: apart from information on training and on routine procedures, Member States generally reported little of significance under this heading, again with some exceptions.

Actions to improve performance of food business operators (publicity, advice, and training): very little information was provided under this heading, and when it was provided it varied across Member States in its detail and content.

Commission audits and inspections in the Member States and subsequent actions of the Commission: the Food and Veterinary Office (FVO) of the Directorate General for Health and Consumers undertakes audits and inspections to verify compliance with feed and food law, animal health and animal welfare and plant health legislation, and to verify that national official controls in these areas are carried out in line with EU legislation. Each year a programme of FVO inspections is developed, identifying priority areas and countries for inspection.

The findings of each audit and inspection are set out in a report, together with conclusions and recommendations to address identified shortcomings. The competent authorities of the country visited are given the opportunity to comment on the reports at draft stage. The FVO makes recommendations to those authorities to deal with any shortcomings revealed during the inspections. Authorities are then requested to present an 'action plan' describing how they have addressed or intend to address the recommendations. In turn, the Commission evaluates the action plan and systematically monitors the implementation of the actions. Where circumstances require it, legal action may be taken by the Commission. This can take two forms: emergency, or safeguard, measures or infringement proceedings.

In 2007 260 inspections were planned by the FVO. The total number of completed inspections was 252, of which 159 took place in Member States, 12 in candidate countries and 81 in third countries. 70% of the inspection objectives in 2007 concerned food safety. No such audit or inspection in Member States identified any immediate threat to consumer, animal or plant health, such that the Commission had to take emergency, or safeguard, measures.

Other means are also used to provide the Commission with information and data on the functioning of national control systems in Member States. These include: (i) sector-specific reporting; (ii) reporting at the Standing Committee of the food chain and animal health meetings; (iii) rapid alert systems for food safety (RASFF) animal disease outbreak (ADNS) and plant disease outbreak (Europhyt).

Conclusions: the Commission forms its assessment of the effectiveness of control systems in Member States based on information and data it receives from the Member States through all the channels outlined above. The Commission considers that, on the whole, the weaknesses in controls identified, through FVO inspections or individual complaints in particular, are adequately addressed by the Member States. Where this

is not the case, the Commission has taken all the measures at its disposal to enforce the requirements of EU legislation, up to and including the taking of infringement actions when necessary.

However, the review of the various sources of information the Commission receives on the operation of controls in Member States indicates that there are a number of potential areas for improvement in the compilation, transmission and analysis of information on the implementation of food chain law, and on official controls in particular, where data production and handling can be simplified, and data presentation streamlined and made more relevant. The availability of more easily accessible and comparable data will in turn allow both national authorities and the Commission to operate more efficiently while at the same time giving full assurance to EU citizens that control systems are comprehensive, robust and effective.

The Commission therefore intends to examine, in close cooperation with Member States, a number of actions to make more efficient the way in which information on controls is collected, analysed and presented at EU level, and in particular:

- how reporting requirements currently imposed on Member States by existing EU legislation can be simplified and streamlined, including by the elimination of duplications and superfluous information, and by the use of standardised templates for quantitative data which could reduce substantially the requirements for translation from different official languages;
- how the considerable potential for the electronic transmission and analysis of data through the use of the Internet can be fully exploited to achieve simplification and standardisation and to reduce the burden of generating, collecting and transmitting controls related data, with appropriate input and assistance from Eurostat;
- how the simplification and standardisation of reporting requirements can assist Member States to deliver on the obligation laid down in the Food and Feed Controls Regulation, which, requires them to ensure that their activities are carried out with "a high level of transparency", and more specifically that the public is given access to information on the control activities of the competent authorities and their effectiveness.

Food safety: feed and food law, animal health and animal welfare rules, official controls

Regulation (EC) No 882/2004 (Feed and Food Controls Regulation) requires Member States to submit to the Commission each year a report on the implementation of their multi-annual national control plans established in compliance with that Regulation.

The Commission submitted its [first report](#) in August 2010 (please see the summary of the document dated 25/08/2010). The main purpose of that report was to provide a first screening of the data and information on official controls contained in the first annual reports from the Member States. The Committees on the Environment and on Agriculture and Rural Affairs of the European Parliament discussed the report in October 2010. The Commission has begun discussions with Member States on the issues raised in the first report, and specifically on how the collection and handling of data on official controls can be streamlined and standardised.

This second report takes a different approach from the first. It aims to give an overview of EU food safety controls that is not confined to the latest year for which annual reports are available from all Member States but draws on the latest information from all three main sources of information on controls to give as up to date an account as possible of how the EU control system is functioning. The main sources this report draws on are: (a) the annual reports from the Member States for 2008 and 2009, (b) the results of the Commissions control activities over the period 2008-2010, and (c) other relevant information on controls including the results of EU rapid alert systems.

EU food chain: the report gives an idea of the scale and complexity of the EU food chain. According to the latest data available from Eurostat, the value of total output from the EU food chain is around EUR 750 billion. Total employment in the sector, from primary production through to retail and catering, is over 48 million. There are around 14 million primary agricultural producers and 3 million food business operators operating along the EU food chain from food manufacturing to retail and catering. The food industry is huge, but it is also highly varied and complex. The report goes on to give an overview of EU food safety controls, noting that Regulation (EC) No 882/2004 sets out how these controls should be organised and operated.

General findings: on the whole, Member States ensure a good level of implementation of official controls across the food chain, and respect for food safety, plant and animal health, and animal welfare issues. While there is scope for improvement, there has been progress in the efficient use of control instruments and resources, and in planning, implementation, and co-ordination of controls across all sectors.

Official controls, and legislative instruments to optimise their effectiveness, are key features of the EU food chain. They allow competent authorities to perform controls on a risk basis, and to identify shortcomings and address them in a timely manner. They also provide competent authorities with an overview of the food safety and health situations.

Member State reports provide reassurance that national competent authorities take their role seriously and with increasing levels of competence, as confirmed by reports from audits carried out by Commission experts.

- Commission audits: on-the-spot specific audits by the Commission, as well as general follow-up audits covering all sectors, are of particular importance in identifying weaknesses to be addressed, and in ensuring that corrective actions are taken. These Commission audit reports, complementing Member State control activities, provide a robust system for assessing the effectiveness of Member State control systems. In recent years the Food and Veterinary Office (FVO) of the Directorate General for Health and Consumers, through its audits, has been placing increased emphasis on the need for Member States to ensure that official controls in all sectors are carried out regularly on a risk basis and with appropriate frequency. In recent years the FVO has carried out around 250 audits each year, covering the whole food chain as well as animal health and welfare and plant health.

Audits in the food safety area make up the main part of the programme. Over the period under review, at least 70% of all audits were concerned with food safety with some of these also covering related aspects of animal health. Around 12% of audits related specifically to animal health only. Animal welfare and plant health accounted for the balance, with roughly 8% of audits focused on each of these areas each year.

In order to give reasonable assurances of compliance with EU legislation, the Commission, whenever necessary, takes the appropriate measures to achieve improvements in official control and audit systems in the Member States.

- Main areas of non-compliance: in food production, there are two main recurring themes in Member States' reports on non-compliance in food production: hygiene controls in establishments; and labelling. Steady progress in this area is recorded in 2008 and 2009 but most reports point to continuing problems for small operators in the retail and catering end of the food chain. The main weaknesses include: outdated buildings

and equipment; absence or weak systems of own-checks by businesses; poor application of HACCP; and inadequate record keeping. On feed, the main non-compliances relate to: delays in the registration of business operators; inadequate application of HACCP principles; hygiene in feed manufacturers; and contraventions of the rules on additives in feed.

On animal health, the main weaknesses reported relate to animal identification and movement controls.

In relation to animal welfare on farms, many of the weaknesses found were attributed to lack of knowledge of farmers, particularly smaller farmers. Some Member States recorded a reduction in the level of non-compliances on farms following the provision of training and information to farmers.

- Commission follow-up and enforcement: sustained attention to and co-ordination of enforcement action remains a priority in all areas. The recommendations contained in FVO audit reports are systematically followed up, through a range of activities. Another source of information which may point to non-compliance or enforcement problems are complaints from members of the public or NGOs, and the Commission is careful to ensure that these are pursued with the Member States concerned as well, with a view to achieving a positive outcome.

In terms of other tools, and during the course of 2009-2010, the Commission found the EU Pilot Project, which has been operating in 15 volunteer Member States since April

2008 with the aim of providing quicker answers to questions arising from the application of EU laws, to be a useful tool as it has enhanced communication between the Commission and Member States.

However, where competent authorities fail to take satisfactory corrective action to address persistent problems, the Commission may have to launch infringement proceedings, to achieve compliance by the Member State.

This occurred in:

- three cases against Greece because it persistently failed to comply with a range of important components of EU food safety legislation. The Court delivered three judgments condemning Greece for failures in the application of EU law;
- reasoned opinions in 2010 against Italy and Spain.

Food safety: feed and food law, animal health and animal welfare rules, official controls

In accordance with the requirements of Regulation (EC) No. 882/2004, the Commission presents its third report on the overall operation of official controls in the Member States on food safety, animal health and animal welfare, and plant health. The report is based on Member States reports of 2010 and on Commission audits. [Regulation \(EC\) No 882/2004](#) sets out how the controls on EU law on food and feed safety should be organised and operated.

Overall effectiveness of controls: annual reports demonstrate that most Member States have in place strategic, operational or compliance indicators to assess performance, although there is considerable variation in the sectors covered, and the scope of the statement on overall effectiveness. Data are often provided in relation to the inspection process, such as the number of planned inspections carried out, rather than related to the outcome of official controls.

Trends on controls: there is a continuing trend towards more risk-based control systems. Some Member States have highlighted an improved level of overall effectiveness linked to more risk-based controls, and an extension of risk-based controls into new sectors. However, other reports suggest that Member States do not use a risk-assessment model in every sector, as confirmed by Commission audits, and limited information has been provided on trends in controls, priorities and results.

One of the outcomes of more risk-based controls has been that the levels of non-compliance may not be directly comparable from one year to the next. For example, the Czech trend analysis indicates that between 2009 and 2010, for animal health and welfare, there has been an increase in the ratio between the number of identified non-compliances and the total number of controls. This could be indicative of a higher rate of non-compliance and thus in the emergence of problems. However, this initial increase is instead attributed to controls recently becoming more risk-based, thereby contributing to their overall effectiveness. The Danish report identified a similar correlation for animal welfare controls. The German annual report highlights the fact that since controls are more risk-based, and therefore more intensive on entities with a previous history of non-compliance, it is not possible to draw conclusions from the annual report on the overall situation on the market. Resources freed up by more risk-based controls are used to inspect establishments less able or willing to comply with the rules. Evidence that they are instead used to target establishments with poor compliance records is reassuring against suggestions that "risk-based controls" might be a smokescreen for resource reductions.

Trend analysis of non-compliance: the main areas of non-compliance identified across sectors include: (i) operational hygiene requirements; (ii) HACCP; (iii) structural or equipment based hygiene requirements; (iv) labelling of food and feed; (v) additives in feed; (vi) record keeping; and (vii) microbiological contamination.

The identification of underlying causes of non-compliance is generally limited. As was the case last year, HACCP/hygiene deficiencies were often attributed to high staff turnover, a lack of training at food business operators (FBOs) and minimal consequences for non-compliances.

Enforcement: there was a lack of analysis in the reports of the overall trends and conclusions. Some Member States have recorded good experience in the use of administrative sanctions directly applied by competent authorities. In addition, some Member States identified the need to train staff on enforcement.

Sustained attention to and co-ordination of enforcement action remains a priority in all areas. The Commission has been engaging in an intense dialogue with some Member States with a view to addressing persistent non-compliances and outstanding enforcement issues, including through regular bilateral high-level meetings. The Greek authorities, for example, have provided a detailed action plan, including clear milestones, which is currently being used to monitor progress towards improved compliance.

The Commission has also designed specially tailored training actions within the Better Training for Safer Food (BTSF) programme in cases where training could assist compliance. In the case of Bulgaria and Romania, specific training activities have been organised to guide the authorities in addressing shortcomings in the handling and disposal of animal by-products.

When necessary and appropriate, infringement proceedings are initiated.

There are a number of areas for improvement regarding annual reports:

- in relation to the comparability of control data within Member States, improved links between data presentations could better demonstrate the extent to which controls translate into identification of non-compliances, and, in turn, into effective enforcement;
- a greater emphasis in reports on self-assessment, such as the results of national audit findings and the impact of the Annual Report review process on future planning, would enhance the process of continuous improvement.

Commission audits: in recent years, the Commission has carried out around 250 audits each year, covering the whole food chain as well as animal health, animal welfare and plant health, of which around 70% relate to food safety. Around 60% of all audits are typically performed in Member States, with the balance in third countries. Pre-accession audits have taken place to Croatia. The report sets out a range of issues of particular interest covered by the programme in Member States on food safety, animal health, and animal welfare and plant health. It also provides a brief summary of the main findings and conclusions arising from the different series of audits.

Food safety: feed and food law, animal health and animal welfare rules, official controls

This Commission Staff Working Document concerns the enforcement by national customs authorities of Regulation (EC) No 669/2009 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.

This document sets out a comprehensive summary of the procedure that must be applied by customs authorities in order to ensure the enforcement of Regulation (EC) No 669/2009 correctly and consistently throughout the EU.

The Commission states that despite the fact that Commission Regulation (EC) No 669/2009 has been very well implemented in the Member States, a series of audits carried out in 2010 and 2011 identified some heterogeneous practices between Member States as regards the contribution of customs to the control of these commodities.

One of the practices observed was that in the case of customs declarations made using a data-processing technique, the release for free circulation was based on the mere reference to the Common Entry Document (CED) number in box 44 of the customs declaration. Neither the physical existence of the CED nor the presence of a favorable decision for release for free circulation in the CED was checked.

The document concludes that customs authorities can release for free circulation consignments of commodities falling under the scope of Commission Regulation (EC) No 669/2009 only after they have checked that the CED exists, that in Box II.14 it is indicated that the consignment is acceptable for release for free circulation and that Box II.21 has been signed.

Food safety: feed and food law, animal health and animal welfare rules, official controls

In accordance with the requirements of Regulation (EC) No. 882/2004, the Commission presents a report on the overall operation of official controls performed in Member States (to ensure the verification of compliance with food and feed law, animal health and welfare rules. The report covers the years 2014 to 2016 and is based on the annual reports submitted by the national authorities and the outcome of Commission controls carried out in Member States.

Organisation and performance of official controls

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 that present the greatest risks. However, risk based controls are not applied in all areas where such controls are warranted. The report also cautions that 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.

The Commission makes particular mention 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.

Non-compliance

The main areas of non-compliance identified by Member States include: (i) operational, structural or equipment-based hygiene requirements; (ii) Hazard Analysis and Critical Control Points (HACCP); (iii) labelling of food and feed; (iv) additives in food and feed; (v) 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 report notes that 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.

A series of audits on HACCP in 2014 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, the Commission services started a review of operational hygiene and official controls in slaughterhouses to see how slaughter hygiene can be better ensured.

Enforcement

Whilst the report notes the difficulty of making meaningful comparisons between Member States reports, it confirms 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) 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.

National audit systems

All Member States confirm that audits are in place, but a number of Member States reported that resource constraints limited the implementation of planned audit programmes. Some stated unequivocally that their staffing falls short of what is required to ensure all controls as required. Others indicate that a limit had been reached where further reductions risk the levels and/or quality of controls and the capacity to respond to emergencies. The report indicates that 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.

Commission control activities and enforcement

The Commission's key priorities focus the official control systems for Plant Protection Products (PPPs), animal welfare and antimicrobial resistance.

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. 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. The Commission adopted a similar approach in respect of the on-farm welfare of pigs and the group housing of sows.

Lastly, the Commission notes that with the coming into force of the provisions of [Regulation \(EU\) 2017/625](#) in December 2019, the adoption of the implementing and delegated acts provided by this Regulation will provide opportunities to use the knowledge gained from the Commission control and follow-up activities to reinforce official controls in the coming years. The new rules will ensure that businesses and authorities will benefit from reduced administrative burdens, more efficient processes and strengthened controls.