Basic information

2013/0140(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
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 Repealing Directive 96/23/EC 1993/1037(CNS) Repealing Directive 96/93/EC 1994/0278(CNS) Repealing Directive 97/78/EC 1996/0109(CNS) Repealing Regulation (EC) No 854/2004 2002/0141(COD) Repealing Regulation (EC) No 882/2004 2003/0030(COD) Amending Directive 98/58/EC 1992/1201(CNS) Amending Directive 1999/74/EC 1998/0092(CNS) Amending Regulation (EC) No 999/2001 1998/0323(COD) Amending Regulation (EC) No 396/2005 2003/0052(COD) Amending Regulation (EC) No 1/2005 2003/0171(CNS) Amending Directive 2007/43/EC 2005/0099(CNS) Amending Directive 2008/119/EC 2006/0097(CNS) Amending Regulation (EC) No 1107/2009 2006/0136(COD) Amending Directive 2008/120/EC 2006/0224(CNS) Amending Regulation (EC) No 1069/2009 2008/0110(COD) Amending Regulation (EC) No 1099/2009 2008/0180(CNS) Amending Regulation (EU) No 1151/2012 2010/0353(COD) Amending Regulation (EU) 2016/429 2013/0136(COD) Amending Regulation (EU) 2016/2031 2013/0141(COD) Amending Regulation (EU) No 652/2014 2013/0169(COD) Amended by 2021/0055(COD) Amended by 2023/0226(COD) Amended by 2023/0228(COD) **Subject** 2.80 Cooperation between administrations 3.10.08 Animal health requirements, veterinary legislation and pharmacy 3.10.08.01 Feedingstuffs, animal nutrition 3.10.09.02 Plant health legislation 3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	KADENBACH Karin (S&D)	11/06/2013
	Shadow rapporteur SCHNELLHARDT Horst (PPE) FERREIRA João (GUE/NGL)	

Former committee responsible	Former rapporteur	Appointed

	ENVI Environment, Public Health and Food Safety	PIRILLO Mario (S&D)	11/06/2013

Former committee for opinion	Former rapporteur for opinion	Appointed
AGRI Agriculture and Rural Development (Associated committee)	REIMERS Britta (ALDE)	12/06/2013
PECH Fisheries	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	3446	2016-02-15
Agriculture and Fisheries	3487	2016-10-10
Agriculture and Fisheries	3285	2013-12-16
Environment	3512	2016-12-19

European Commission

Commission DG	Commissioner
Health and Food Safety	BORG Tonio

European Economic and Social Committee

European Committee of the Regions

Key events

Date	Event	Reference	Summary
06/05/2013	Legislative proposal published	COM(2013)0265	Summary
23/05/2013	Committee referral announced in Parliament, 1st reading		
21/11/2013	Referral to associated committees announced in Parliament		
16/12/2013	Debate in Council		
20/02/2014	Vote in committee, 1st reading		
06/03/2014	Committee report tabled for plenary, 1st reading	A7-0162/2014	Summary
14/04/2014	Debate in Parliament		
15/04/2014	Decision by Parliament, 1st reading	T7-0380/2014	Summary
15/04/2014	Results of vote in Parliament		
17/06/2015	Committee decision to open interinstitutional negotiations after 1st reading in Parliament		

15/02/2016	Debate in Council		
12/07/2016	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE601.124 PE609.645	
19/12/2016	Council position published	10755/1/2016	Summary
19/01/2017	Committee referral announced in Parliament, 2nd reading		
31/01/2017	Vote in committee, 2nd reading		
03/02/2017	Committee recommendation tabled for plenary, 2nd reading	A8-0022/2017	Summary
14/03/2017	Debate in Parliament		
15/03/2017	Decision by Parliament, 2nd reading	T8-0081/2017	Summary
15/03/2017	Results of vote in Parliament		
15/03/2017	Final act signed		
15/03/2017	End of procedure in Parliament		
07/04/2017	Final act published in Official Journal		

Technical information

Procedure reference	2013/0140(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Repealing Directive 96/23/EC 1993/1037(CNS) Repealing Directive 96/93/EC 1994/0278(CNS) Repealing Directive 97/78/EC 1996/0109(CNS) Repealing Regulation (EC) No 854/2004 2002/0141(COD) Repealing Regulation (EC) No 882/2004 2003/0030(COD) Amending Directive 98/58/EC 1992/1201(CNS) Amending Directive 1999/74/EC 1998/0092(CNS) Amending Regulation (EC) No 999/2001 1998/0323(COD) Amending Regulation (EC) No 396/2005 2003/0052(COD) Amending Regulation (EC) No 1/2005 2003/0171(CNS) Amending Directive 2007/43/EC 2005/0099(CNS) Amending Directive 2008/119/EC 2006/0097(CNS) Amending Regulation (EC) No 1107/2009 2006/0136(COD) Amending Directive 2008/120/EC 2006/0224(CNS) Amending Regulation (EC) No 1069/2009 2008/0110(COD) Amending Regulation (EC) No 1099/2009 2008/0180(CNS) Amending Regulation (EU) No 1151/2012 2010/0353(COD) Amending Regulation (EU) 2016/429 2013/0136(COD) Amending Regulation (EU) 2016/2031 2013/0141(COD) Amending Regulation (EU) No 652/2014 2013/0169(COD) Amended by 2021/0055(COD) Amended by 2023/0226(COD) Amended by 2023/0228(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 114-p1 Treaty on the Functioning of the European Union TFEU 168-p4 Treaty on the Functioning of the European Union TFEU 043-p2
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions

Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/08230

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE522.944	15/11/2013	
Amendments tabled in committee		PE526.075	18/12/2013	
Amendments tabled in committee		PE526.076	18/12/2013	
Amendments tabled in committee		PE526.078	18/12/2013	
Amendments tabled in committee		PE526.077	19/12/2013	
Amendments tabled in committee		PE526.079	15/01/2014	
Committee opinion	AGRI	PE514.762	23/01/2014	
Amendments tabled in committee		PE529.703	19/02/2014	
Committee report tabled for plenary, 1st reading/single reading		A7-0162/2014	06/03/2014	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0380/2014	15/04/2014	Summary
Committee letter confirming interinstitutional agreement		PE609.645	12/07/2016	
Committee draft report		PE597.501	17/01/2017	
Committee recommendation tabled for plenary, 2nd reading		A8-0022/2017	03/02/2017	Summary
Text agreed during interinstitutional negotiations		PE601.124	10/03/2017	
Text adopted by Parliament, 2nd reading		T8-0081/2017	15/03/2017	Summary

Council of the EU

Document type	Reference	Date	Summary
Council statement on its position	14895/2/2016	16/12/2016	
Council position	10755/1/2016	19/12/2016	Summary
Draft final act	00001/2017/LEX	15/03/2017	

European Commission

Document type	Reference	Date	Summary
Commission document (COM)	COM(2013)0264	06/05/2013	Summary
Legislative proposal	COM(2013)0265	06/05/2013	Summary
Document attached to the procedure	SWD(2013)0166	06/05/2013	
	SWD(2013)0167		

Document attached to the procedure		06/05/2013	
Commission communication on Council's position	COM(2017)0006	06/01/2017	Summary
Follow-up document	COM(2020)0756	24/11/2020	
Follow-up document	SWD(2020)0283	24/11/2020	
Follow-up document	COM(2021)0383	09/07/2021	
Follow-up document	COM(2022)0129	28/03/2022	
Follow-up document	SWD(2022)0073	28/03/2022	
Follow-up document	COM(2023)0235	05/05/2023	
Follow-up document	SWD(2023)0131	05/05/2023	
Follow-up document	COM(2024)0388	04/09/2024	
Follow-up document	SWD(2024)0208	04/09/2024	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	PT_PARLIAMENT	COM(2013)0265	02/07/2013	
Contribution	ES_PARLIAMENT	COM(2013)0265	27/08/2013	
Contribution	CZ_SENATE	COM(2013)0265	17/09/2013	
Contribution	CZ_SENATE	COM(2022)0129	19/10/2022	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES4014/2013	16/10/2013	
CofR	Committee of the Regions: opinion	CDR5295/2013	29/11/2013	

Additional information

Source	Document	Date
National parliaments	IPEX	

European Commission	EUR-Lex	

Final act

Corrigendum to final act 32017R0625R(01)
OJ L 137 24.05.2017, p. 0040

Regulation 2017/0625
OJ L 095 07.04.2017, p. 0001 Summary

Delegated acts

Reference	Subject
2019/2640(DEA)	Examination of delegated act
2019/2836(DEA)	Examination of delegated act
2019/2869(DEA)	Examination of delegated act
2019/2868(DEA)	Examination of delegated act
2019/2867(DEA)	Examination of delegated act
2019/2863(DEA)	Examination of delegated act
2019/2572(DEA)	Examination of delegated act
2019/2766(DEA)	Examination of delegated act
2018/2577(DEA)	Examination of delegated act
2019/2626(DEA)	Examination of delegated act
2019/2865(DEA)	Examination of delegated act
2019/2864(DEA)	Examination of delegated act
2019/2607(DEA)	Examination of delegated act
2019/2762(DEA)	Examination of delegated act
2019/2760(DEA)	Examination of delegated act
2019/2527(DEA)	Examination of delegated act
2020/2855(DEA)	Examination of delegated act
2021/2564(DEA)	Examination of delegated act
2021/2663(DEA)	Examination of delegated act
2021/2889(DEA)	Examination of delegated act
2022/2530(DEA)	Examination of delegated act
2021/2534(DEA)	Examination of delegated act
2021/2927(DEA)	Examination of delegated act
2022/2609(DEA)	Examination of delegated act
2021/2945(DEA)	Examination of delegated act
2022/2612(DEA)	Examination of delegated act
2021/2707(DEA)	Examination of delegated act
2021/2891(DEA)	Examination of delegated act

2023/2858(DEA)	Examination of delegated act
2025/2540(DEA)	Examination of delegated act
2022/2642(DEA)	Examination of delegated act
2022/2818(DEA)	Examination of delegated act
2023/2758(DEA)	Examination of delegated act
2022/2765(DEA)	Examination of delegated act
2022/2807(DEA)	Examination of delegated act
2025/2579(DEA)	Examination of delegated act
2022/2969(DEA)	Examination of delegated act
2023/2575(DEA)	Examination of delegated act
2023/2632(DEA)	Examination of delegated act
2026/2709(DEA)	Examination of delegated act
2026/2844(DEA)	Examination of delegated act
2026/2610(DEA)	Examination of delegated act
2026/2892(DEA)	Examination of delegated act
2026/2776(DEA)	Examination of delegated act

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

2013/0140(COD) - 06/05/2013 - Legislative proposal

PURPOSE: to lay down a harmonised approach governing the performance of official controls to ensure the uniform application of the agri-food chain rules across the EU.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: in order to afford European Union (EU) citizens a high level of human, animal and plant health, and guarantee the functioning of the internal market, Union legislation provides for a set of harmonised rules to prevent, eliminate or reduce the level of health risk to humans, animals and plants, which may arise along the 'agri-food chain'.

To ensure that this extensive set of rules is enforced by the Member States (MS) across the EU in a harmonised manner, a legislative framework for the organisation of official controls has been established through Regulation (EC) No 882/2004.

Based on an extensive review of the provisions of the Regulation, the Commission proposes revising the legislation on official controls to overcome shortcomings identified in its wording and in its application. The aim is to **simplify and clarify the system and to establish a single framework applicable to all official controls along the entire food chain**.

The proposal replaces and repeals Regulation (EC) No 882/2004 and a number of sectoral acts and provisions which will be made redundant by its adoption. It is part of a comprehensive package that also includes three major reviews to modernise the animal health, plant health and plant reproductive material *acquis*.

IMPACT ASSESSMENT: the retained option was that which involves: (i) **streamlining** the legislative framework; (ii) **integrating** within the Regulation's scope plant health, plant reproductive material (PRM) and animal by-products (ABP); and (iii) **extending** mandatory fees to cover all controls performed.

LEGAL BASIS: Articles 43(2), 114 and 168(4)(b) of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the proposal aims to modernise and sharpen enforcement tools, and in particular official controls, as laid down in the existing Regulation, to simplify the legislative framework. It lays down **harmonised rules at EU level** aimed at providing a comprehensive and coherent approach to official controls along the entire agri-food chain.

- **Scope:** it is proposed to integrate the rules currently applicable to official controls in specific areas currently governed by separate sets of rules (e.g. controls on residues of veterinary medicinal products in live animals and animal products, and plant health controls) into the framework of a single Regulation.
- **Lightening administrative burdens:** the proposal makes changes in a number of situations where it is possible to alleviate the burden of organising and implementing official controls by **eliminating redundant requirements** (e.g. separate reporting from official controls on residues of veterinary medicinal products) or allowing a proportionate and flexible approach to some specific situations (e.g. not requiring full accreditation of official laboratories in case of emergencies).
- **Sampling:** requirements on methods of sampling and of laboratory analysis, testing and diagnosis will become applicable to official controls and to other official activities in all the sectors covered by the Regulation (e.g. to surveillance, monitoring and survey activities in the plant health and animal health sectors). A 5 years transitional period will thus be foreseen for the plant health and plant propagating material sectors. The rules for the choice of the method to be used by the official laboratory will be clarified and extended so as to require that methods meet state-of-the-art scientific standards.
- **Official controls on animals and goods entering the Union:** as far as imports are concerned, it is essential that all foodstuffs available on the EU market are safe. The proposal includes therefore **a set of common and comprehensive rules applicable to controls performed on animals and goods from third countries**. Border Control Posts (BCPs) will replace the different entities currently tasked with border control duties. A **Common Health Entry Document** (CHED) will be used (i) by operators for the mandatory prior notification of arrival of consignments of animals and goods and (ii) by competent authorities to record controls on such consignments and any decisions taken.
- **Financing of official controls:** Member States will be required to ensure that adequate financial resources are available to provide the staff and other resources necessary to the competent authorities to perform official controls and the other activities referred to in the Regulation. The proposal **maintains the system of mandatory fees and extends it to most official controls**. **Micro-enterprises will be exempted** from the payment of such fees.
- **Administrative assistance and cooperation:** the administrative assistance and cooperation provisions of the Regulation will be reinforced and clarified so as to increase their usability and effectiveness as a tool for tackling cross-border non-compliances. The proposal envisages the creation of an integrated information management system for official controls, which will allow the integrated operation and updating of all existing and future computerised systems through which information, data and documents regarding official controls are exchanged among competent authorities, and with the Commission.

BUDGETARY IMPLICATIONS: the proposal does not imply incurring any expenditure which is not already foreseen in the financial statement of the common financial framework. No additional human resources are envisaged either.

DELEGATED ACTS: the proposal includes provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union.

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

2013/0140(COD) - 06/05/2013

The objective of ensuring a high level of health for humans, animals, and plants is enshrined in the Treaties underpinning the EU. Over the years, the EU has built up a **comprehensive body of law** designed to prevent and manage risks to animal and plant health and the safety of the food chain at EU and national level. The law in these policy areas is enforced by means of a common set of rules on official controls to be carried out by the competent authorities in the EU Member States.

To date, overall, the legal framework which the EU has developed has proven to be effective in preventing and countering risks. However, the modern global market increasingly exposes the EU to new risks and constantly calls for innovation and competitiveness. This, and the experience gained with EU law in this area, point to the **need to simplify and update available instruments and to further integrate the approach across the different areas**. The Commission has conducted a revision of the current legal framework for animal health, plant health, plant reproductive material and official controls aimed mainly at increasing effectiveness, consistency and legal clarity in those areas.

This Communication presents the resulting four legislative proposals in the four areas of animal health, plant health, plant reproductive material and **official controls** (the 'review package') and explains, for each of them, the current context, the rationale behind the package and the main improvements introduced. The package also includes a fifth proposal establishing a multiannual programme for EU financing of actions aimed at ensuring a high level of health for humans, animals and plants along the agri-food chain and in related areas while allowing businesses to operate in an environment that favours competitiveness and job creation.

A high level of health along the agri-food chain depends on **consistent, effective and timely enforcement of EU standards** by the Member States. The correct application of agri-food chain rules and of the rules on animal health and animal welfare, on plant health, on plant reproductive material and on plant protection products must be ensured across the EU for humans, plants and animals to be healthier and for the internal market to thrive and work smoothly. For this to be possible, the relevant authorities in the Member States must be given a **clear, reliable and consistent legal environment** in which to make effective and efficient use of enforcement tools, and of official controls in particular. They also need appropriate resources to ensure continuity and consistency in their work, on the basis of needs linked to enforcement objectives.

Current EU legislation on official controls: official controls are governed by Regulation (EC) No 882/2004. A series of shortcomings have been identified which call for the following improvements to be made:

- the simplification of the overall legal framework, which currently suffers from the remaining **fragmentation, overlaps and gaps**, and therefore **differences in interpretation and implementation at national level**;
- more consistent use of the **'risk-based controls'** principle;
- more systematic and consistent use of administrative cooperation tools and of computerised information systems;
- the repeal of unnecessary administrative requirements.

As regards the **financing of official controls** and the need to ensure steady and consistent funding of the work of the competent authorities, the evidence also points to current uncertainties about the **long-term sustainability** of official controls.

There is also evidence that the **current rules are failing to ensure a fair and consistent approach** across sectors: only some sectors are charged, and fees are not calculated in a uniform and transparent manner across Member States, or in a manner that rewards operators' compliance.

The Regulation on Official Controls: this proposal to amend the general framework for official controls laid down in Regulation (EC) No 882/2004 incorporates the outcome of a number of evaluations which have dealt with the different aspects of that framework. A major novelty is the broadening of the scope of the rules on official controls, and in particular, their **extension to relevant controls on plant health, plant reproductive materials and animal by-products**. The current detailed set of rules applicable to official controls on **residues of veterinary medicines** will be repealed to allow this area to be regulated in a more **risk-based**, but still health-protective way, under the same legislative framework.

Impact on imports: this revision will have a significant impact on the legal framework governing official controls on products from non-EU countries. It provides a set of common rules for all control activities to be performed at EU borders on animals and goods from non-EU countries which require increased attention for health reasons.

More effective enforcement mechanisms: the toolkit offered to national enforcers is made simpler and more effective:

- each Member State will be asked to designate a **single authority** responsible for coordinating preparation and ensuring the coherence of a **multi-annual control plan** and to act as a contact point for the Commission and other Member States in relation to official controls;
- electronic handling and processing of the **Common Entry Health Document** (CHED) for all animals and goods, subject to controls at the border, will be introduced;
- while the requirement for all official laboratories to be accredited against ISO standard 17025 is reaffirmed, **transitional measures and temporary or permanent derogations** are provided for, as appropriate.

Financing of official controls: the proposal builds on the current system of mandatory fees (at present only charged to certain operators and/or for certain controls). It strengthens the principle according to which **competent authorities should be able to charge businesses in order to recover the costs they incur in carrying out their official control duties** along the agri-food chain and in certain related areas (e.g. veterinary and phytosanitary controls, controls on plant reproductive material).

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

2013/0140(COD) - 06/03/2014 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Mario PIRILLO (EPP, IT) on the proposal for a regulation of the European Parliament and of the Council 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, plant reproductive material, plant protection products.

The Committee on Agriculture and Rural Development, exercising its prerogatives as an associated committee in accordance with Rule 50 of the Rules of Procedure, was also consulted for an opinion on the report.

The committee recommended that Parliament's position in first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

Purpose and scope: it was stipulated that the Regulation should apply to the official controls performed for the verification of compliance with rules governing **food, food safety, food quality and food wholesomeness,** rules governing the **deliberate release into the environment of GMOs**, as well as rules aimed at guaranteeing fair practices in trade and protecting **consumer health, interests and information**.

The text should also apply to rules: (i) aiming at preventing and minimising antimicrobial resistance in animals and humans, as well as in the environment; (ii) laying down requirements on monitoring certain substances and residues thereof in live animals and animal products. However, the Regulation shall apply to official controls on protected designations of origin and protected geographical indications for wine. On the other hand, it should not apply to manufacture of veterinary medicine.

Official controls must verify that the procedures applicable to **organic products** have been respected.

Competent authorities: competent authorities should be responsible not just for organising official controls but **also for carrying them out**, as well as carrying out other official activities, such as issuing certificates and attestations, appointing laboratories, exchanging information in the interest of cooperation between authorities, and taking decisions on measures to remedy breaches of the Regulation.

The official certification or attestation procedure should remain a matter **solely** for the official authority.

Independence: the competent authorities shall have arrangements in place to ensure the impartiality, independence, quality, consistency and unity of purposes of official controls and other official activities at all levels; they should be in no way connected to or dependent of the operators that they control.

Staff performing official controls and other official activities shall be officials employed by the competent authorities or by an independent public body delegated by the competent authority to perform official controls or other official activities who are **free from conflict of interests** and not directly nor indirectly employed by the operator on which it is performing control activities.

The independence of the delegating authority in relation to operators has been strengthened in the text.

Official auxiliaries: this means a person qualified to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian.

The competent authority may appoint as official auxiliaries **only persons** who have undergone training and passed a test in accordance with the requirements set out in a new Annex IIIa of the regulation.

General rules applicable to official controls: competent authorities shall perform official controls on all undertakings regularly, on a risk basis and with appropriate frequency, taking account of:

- the use of products, processes, materials, feed additives or substances that may influence food safety and wholesomeness, feed safety, animal health or animal welfare;

- **the potential for consumers to be misled** as to the nature, quality or substance of a product and/or the potential for consumers to incur financial loss as a result of receiving misleading information from the operator.

The following should also be taken into account: i) consumer expectations regarding nature, quality and composition of foods and goods; ii) private quality assurance schemes put in place by operators, which are certified and audited by independent and recognised certification bodies.

To increase the effectiveness of the controls, **Member States shall require that any animals or goods from other Member States be reported.**

The Commission shall be empowered to adopt delegated acts in order to establish a **uniform minimum frequency** for carrying out the controls

Reducing the administrative burden: Members stated that any additional inconvenience to operators occasioned by controls should be kept to a minimum. In order to reduce the administrative burdens on operators, where possible, the competent authorities should take a coordinated approach to controls. Furthermore, it was enough that the outcome of official controls performed at a border control post be recorded in the Common Health Entry Document.

Products of animal origin intended for human consumption: official controls should relate to the following, (a) the design and maintenance of premises and equipment; (b) personal hygiene; (c) HACCP-based procedures (d) own-controls procedures; (e) verification of compliance by the staff with applicable requirements; (f) verification of the operator's records and of documents accompanying food, feed and any substance or material entering and leaving the establishment; (g) consideration of any evidence of the presence of fraudulent practices.

At least one official veterinarian shall be present during both the ante-mortem and post-mortem inspection. Similarly, an official veterinarian or an official auxiliary shall be present, with a frequency appropriate to achieving the objectives of this Regulation, in cutting plants when meat is being worked on.

Official controls in relation to animals shall include: (i) the verification of measures for protection against biological and chemical hazards to human and animal health; (ii) the verification of animal welfare measures; (iii) the verification of disease control or eradication measures.

Fees: Members considered that the **exemption of micro-enterprises** were too broad and would lead to an average of 80-90% of enterprises working in the agri-food chain being exempted from payment.

The **costs of training control staff should be excluded** from the calculation of fees or contributions to costs, as should the cost of facilities and equipment, including maintenance and insurance costs.Moreover, the fees or contributions to costs collected by the competent authority should fully cover the costs of the controls.

European reference centres: in order, to limit the number of new cases of food fraud as much as possible, the committee proposed that the Commission should, through implementing acts, establish European reference centres **for the authenticity and integrity of the agri-food chain.** These centres should possess a high level of scientific and technical expertise. The tasks and responsibilities of the centres were set out in the report.

Support for developing countries: with a view to ensuring that developing countries can comply with the provisions of the Regulation, measures may be take, to support the following activities: (i) compliance with the conditions governing the entry into the Union of animals and goods; (ii) drafting of guidelines on the organisation of official controls on products to be exported to the Union; (iii) sending of European Union or Member State experts to developing countries to assist with the organisation of official controls;

Reporting of breaches: Members suggested that competent authorities put in place effective and reliable mechanisms to encourage reporting of potential or actual breaches of the Regulation and of national provisions related to the Regulation to competent authorities.

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

2013/0140(COD) - 15/04/2014 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 565 votes to 51 with 29 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council 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, plant reproductive material, plant protection products (Official Controls Regulation).

Parliament's position in first reading following the ordinary legislative procedure amended the Commission proposal as follows:

Purpose and scope: Parliament stated that the Regulation should apply to the official controls performed for the verification of compliance with rules governing **food, food safety, food quality and food wholesomeness,** rules governing the **deliberate release into the environment of GMOs**, as well as rules aimed at guaranteeing fair practices in trade and protecting **consumer health, interests and information**.

'Official control' was defined as means any form of control, including controls of requirements for animals and goods from third countries intended for export to third countries.

The text should also apply to rules: (i) aiming at preventing and minimising antimicrobial resistance in animals and humans, as well as in the environment; (ii) laying down requirements on monitoring certain substances and residues thereof in live animals and animal products; (iii) on protected designations of origin and protected geographical indications for wine. On the other hand, it should not apply to manufacture of veterinary medicine.

Official controls must verify that the procedures applicable to **organic products** have been respected.

Competent authorities: competent authorities should be responsible not just for organising official controls but **also for carrying them out**, as well as carrying out other official activities, such as issuing certificates and attestations, appointing laboratories, exchanging information in the interest of cooperation between authorities, and taking decisions on measures to remedy breaches of the Regulation.

The official certification or attestation procedure should remain a matter **solely** for the official authority.

Where there was a suspicion of risk to human or animal health or of other serious breaches of food law, the competent authorities should take suitable steps to inform the public.

Independence: the competent authorities should have arrangements in place to ensure the impartiality, independence, quality, consistency and unity of purposes of official controls and other official activities at all levels; they should be in no way connected to or dependent of the operators that they control.

Staff performing official controls should be **free from conflict of interests** and not directly nor indirectly employed by the operator on which it is performing control activities.

The independence of the delegating authority in relation to operators has been strengthened in the text.

Official auxiliaries: this meant a person qualified to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian. The competent authority may appoint as official auxiliaries **only persons** who have undergone training and passed a test in accordance with the requirements set out in a new Annex IIIa of the regulation.

General rules applicable to official controls: competent authorities must perform official controls on all undertakings regularly, on a risk basis and with appropriate frequency, taking account of:

- the use of products, processes, materials, feed additives or substances that may influence food safety and wholesomeness, feed safety, animal health or animal welfare;
- **the potential for consumers to be misled** as to the nature, quality or substance of a product and/or the potential for consumers to incur financial loss as a result of receiving misleading information from the operator.

The following should also be taken into account: i) **consumer expectations** regarding nature, quality and composition of foods and goods; ii) **private quality assurance schemes** put in place by operators, which are certified and audited by independent and recognised certification bodies.

To increase the effectiveness of the controls, Member States should require that **any animals or goods from other Member States be reported.**

The Commission will be empowered to adopt delegated acts in order to establish **a uniform minimum frequency for carrying out the controls**

Reducing the administrative burden: Members stated that any additional inconvenience to operators occasioned by controls should be kept to a minimum. In order to reduce the administrative burdens on operators, where possible, the competent authorities should take a coordinated approach to controls. Furthermore, it was enough that the outcome of official controls performed at a border control post be recorded in the Common Health Entry Document.

Products of animal origin intended for human consumption: Parliament wanted official controls should relate to the following, (a) the design and maintenance of premises and equipment; (b) personal hygiene; (c) HACCP-based procedures (d) own-controls procedures; (e) verification of compliance by the staff with applicable requirements; (f) verification of the operator's records and of documents accompanying food, feed and any substance or material entering and leaving the establishment; (g) consideration of any evidence of the presence of fraudulent practices.

At least one official veterinarian should be present during both the ante-mortem and post-mortem inspection. Similarly, an official veterinarian or an official auxiliary should be present, with a frequency appropriate to achieving the objectives of this Regulation, in cutting plants when meat is being worked on.

Official controls in relation to animals should include: (i) the verification of measures for protection against biological and chemical hazards to human and animal health; (ii) the verification of animal welfare measures; (iii) the verification of disease control or eradication measures.

In case of long journeys between Member States and with third countries, official controls should be performed at any stage of the long journey on a random or targeted basis to verify that declared journey times were realistic.

As regards products of animal origin, Parliament stated that methods have to be developed and mandatorily established aimed at identifying and tracing **breeding material from cloned animals** as well as descendants from cloned animals and products derived thereof.

Fees: in order to ensure that adequate financial resources were available to provide the staff and other resources necessary for the competent authorities to perform official controls and other official activities. Member States must **collect fees or contributions to the costs** or make resources available from general tax revenue.

The **costs of training control staff should be excluded** from the calculation of fees or contributions to costs, as should the cost of facilities and equipment, including maintenance and insurance costs. Moreover, the fees or contributions to costs collected by the competent authority should fully cover the costs of the controls.

Parliament proposed that SMEs that fulfil certain objective and non-discriminatory criteria may be exempted from the payment of fees or cost contributions

European reference centres: in order, to limit the number of new cases of food fraud as much as possible, Parliament proposed that the Commission should, through implementing acts, establish European reference centres **for the authenticity and integrity of the agri-food chain.** These centres should possess a high level of scientific and technical expertise. The tasks and responsibilities of the centres were set out in the report.

Support for developing countries: with a view to ensuring that developing countries can comply with the provisions of the Regulation, measures may be take, to support the following activities: (i) compliance with the conditions governing the entry into the Union of animals and goods; (ii) drafting of guidelines on the organisation of official controls on products to be exported to the Union; (iii) sending of European Union or Member State experts to developing countries to assist with the organisation of official controls.

Reporting of breaches: Parliament suggested that competent authorities put in place effective and reliable mechanisms to encourage reporting of potential or actual breaches of the Regulation and of national provisions related to the Regulation to competent authorities.

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

2013/0140(COD) - 03/02/2017 - Committee recommendation tabled for plenary, 2nd reading

The Committee on the Environment, Public Health and Food Safety adopted the recommendation for second reading contained in the report by Karin KADENBACH (S&D, AT) on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council 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.

The committee recommended the European Parliament to **approve the Council position at first reading** without amendment.

The general aim of this proposed Regulation is to modernise and sharpen enforcement tools, and in particular official controls, as laid down in the existing Regulation (EC) No 882/2004, to simplify the legislative framework. It lays down harmonised rules at EU level aimed at providing a comprehensive and coherent approach to official controls along the entire agri-food chain.

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

2013/0140(COD) - 15/03/2017 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council 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.

In line with the recommendation for second reading by the Committee on the Environment, Public Health and Food Safety, Parliament approved the Council position at first reading without amendment.

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

2013/0140(COD) - 06/01/2017 - Commission communication on Council's position

The Commission gave its opinion on the position of the Council at first reading on the adoption of a Regulation 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.

General comments: the Commission considered that the common position adopted by the Council **reflects the original goals of the Commission proposal and takes into account many concerns of the European Parliament**.

Although on certain elements, the common position differs from the Commission's original proposal, the Commission considered that it represents a carefully balanced compromise.

In relation to the **organic sector**, the European Parliament was supportive of the Commission approach to have, in the Official Controls Regulation, Commission empowerments for the adoption of control rules to specifically cater for the organic sector.

This approach was not reflected in the Council general approach, which removed the empowerments and introduced a considerable number of specific rules (and corresponding empowerments) in the organic proposal. To facilitate the co-legislators' agreement, and after careful consideration that the effectiveness of controls would not be compromised, the Commission accepted a fewer number of empowerments in the Official Controls Regulation for the organic sector.

Amendments of the European Parliament: the Commission indicated that it could accept in full, in part, in principle or subject to rewriting 129 of the 319 amendments, as it considered that these amendments could clarify or improve the Commission proposal and were consistent with its general aims.

The European Parliament amendments accepted by the Commission and incorporated in full, in part or in principle in the position of the Council aim to:

- require enforcement authorities to **take account of the likelihood that consumers might be misled** about the nature, identity and properties of food when performing risk-based controls;
- propose the establishment of an **European Reference Centres** for the authenticity and integrity of the agri-food chain;
- oblige Member States to put in place effective mechanisms to **protect whistle-blowers** against retaliation, discrimination or other unfair treatment;
- turn the establishment of European Reference Centres into a legal obligation.

Amendments of the European Parliament accepted by the Commission but not incorporated in the position of the Council concern:

- extending the scope of the proposal to marketing standards and rules for agricultural products as governed by the provisions of Regulation (EU) No 1308/2013. According to the compromise reached, the scope of the official controls Regulation would cover those checks carried out under marketing standards legislation which identify possible fraudulent or deceptive practices;
- establishing financial penalties applicable to fraudulent or deceptive practices to be set at an amount that is at least double to the economic advantage sought by the perpetrator.

Amendments of the European Parliament rejected by the Commission and not incorporated in the position of the Council at first reading concern:

- the deletion of rules on mandatory fees for official controls;
- the permanent presence of an **official veterinarian during ante- and post-mortem inspections** as well as the possibility of involving slaughterhouse staff during official controls, under the supervision of an official veterinarian, should be limited to poultry and lagomorphs;
- the proposal to add "foods containing products of animal origin" to the categories of goods to be subject to mandatory systematic controls at border control posts;

- the obligation for physical checks on animals and on all products of animal origin entering the Union, to be carried out by an official veterinarian.

As regards the **financing of official controls**, the Commission accepted the amendments to the proposal made by the Council which introduce a mandatory fees regime similar to the current one. Furthermore, rules on fees transparency, concerning the calculation of fees, as proposed by the Commission, have been essentially retained.

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

2013/0140(COD) - 15/03/2017 - Final act

PURPOSE: to modernise and improve the performance of official controls to ensure the uniform application of the agri-food chain rules across the EU.

LEGISLATIVE ACT: Regulation (EU) 2017/625 of the European Parliament and of the Council 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 (Official Controls Regulation).

CONTENT: the Regulation replaces Regulation (EC) No 882/2004 on official controls by establishing a single set of rules applicable to official controls for almost all sectors of the agri-food chain.

The new rules aim to improve controls carried out by Member States to ensure compliance with Union legislation on food and feed safety, animal health and welfare, plant health and plant protection products

The Regulation also lays down rules for the deliberate release into the environment of Genetically Modified Organisms (GMOs) for the purpose of food and feed production.

In addition, the Regulation shall apply where **fraudulent or misleading practices** with respect to marketing standards are detected during the controls carried out.

The new Regulation provides in particular for:

- **Improved control system**: official controls regularly, on a **risk-basis** and with appropriate frequency, on all the sectors and in relation to all operators, activities, animals and goods governed by Union agri-food chain legislation. The authorities of the Member States may regularly carry out unannounced official inspections and impose dissuasive financial penalties on operators who commit intentional violations.
- **Role of the official veterinarian**: Member States shall have the discretion to identify the most appropriate staff to perform such controls. In certain cases, where their specific skills are necessary to ensure a sound outcome of the official controls, Member States shall be required to refer to official veterinarians, plant health officers or other specifically designated persons Member States shall also use official veterinarians including for official controls on poultry and lagomorphs.
- **Third countries**: a set of common rules is provided for all control activities to be carried out at Union borders on animals and products from third countries requiring more attention to ensure health protection.
- **Financing**: competent authorities will collect fees or charges to cover the costs they incur when performing official controls. In order to promote compliance with Union legislation by all operators irrespective of the method (based on actual costs or on a flat rate) that each Member States has chosen for the calculation of the fees or charges, when fees or charges are calculated on the basis of overall costs incurred by the competent authorities over a given period of time, and imposed on all operators irrespective of whether they are subject to an official control during the reference period, those fees or charges should be calculated so as to reward operators with a consistent good record of compliance with Union agri-food chain legislation.
- **Whistleblowers**: effective mechanisms shall be put in place to enable the reporting of actual or potential infringements of this Regulation, including appropriate protection for persons reporting an infringement against retaliation, discrimination or other types of unfair treatment.
- **Transparency**: competent authorities shall ensure a high level of transparency on the controls they carry out (type, number and outcome). They shall also be able to publish information on the **rating of individual operators** based on the outcome of the controls they have carried out.

Lastly, transitional measures have been introduced to ensure that a number of delegated acts and implementing acts essential for the proper application of the Regulation shall be adopted before the date of application of the Regulation.

ENTRY INTO FORCE: 27.4.2017.

APPLICATION: from 14.12.2019 (unless otherwise stated).

DELEGATED ACTS: the Commission is empowered to adopt delegated acts to amend this Regulation concerning the references to the European standards, as well as Annexes II and III to the Regulation to take into account of legislative and technical and scientific developments, and to supplement this Regulation with specific rules governing official controls.

The power to adopt such acts shall be conferred on the Commission for a period of five years (renewable) from 28 April 2017. The European Parliament or the Council shall have the right to object to a delegated act within a period of two months (extendable for two months) from the date of the notification of the act.

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

2013/0140(COD) - 19/12/2016 - Council position

The Council adopted its position at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council 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.

The general objective of the proposed Regulation is to simplify and streamline the existing legal framework of Regulation (EC) No 882/2004, encompassing almost all sectors of the agri-food chain in a unique set of rules applicable to official controls.

The Regulation also aims to improve the efficiency of official controls performed by the Member States along the agri-food chain so as to allow for quick responses in crisis situations, while minimising the burden for operators; to that end, it requests that such controls be performed on all operators, on a risk basis and with appropriate frequency.

Scope: this Regulation shall apply to the official controls performed for the verification of compliance with the rules, whether established at Union level or by the Member States, to apply Union legislation, in the areas of:

- food and food safety;
- deliberate release into the environment of Genetically Modified Organisms (GMOs) for the purpose of food and feed production;
- feed and feed safety;
- animal health requirements;
- prevention and minimisation of risks to human and animal health arising from animal by-products and derived products;
- welfare requirements for animals;
- protective measures against pests of plants;
- requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides, with the exception of pesticides application equipment;
- organic production and labelling of organic products;
- use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed.

The Council clarified that although this Regulation should not apply to the verification of compliance with Regulation (EU) No 1308/2013 (Common organisation of the market in agricultural products), it should apply when **fraudulent or deceptive practices** in respect to marketing standards are identified during checks performed pursuant to Article 89 of Regulation (EU) No 1306/2013.

Financing of official controls: Member States should allocate appropriate financial resources to official controls, it proposed expanding the current obligation of collecting fees from only some business operators to all operators in the areas covered by the Regulation.

The Council agreed that Member States willing to charge fees at the level of the costs incurred and not at a fixed level would have to follow harmonised rules on cost coverage and calculation methods. The Council also agreed that Member States should be obliged to enhance the transparency of the calculation, collection and setting of fees or charges, and of the consultation with relevant stakeholders.

Role of the official veterinarian: in order to enable the efficient organisation of the official controls, Member States should have the discretion to **identify the most appropriate staff** to perform such controls provided that a high level of protection of human health, animal health and animal welfare is ensured throughout the agri-food chain and that international standards and obligations are met.

Member States are required to refer to official veterinarians in certain cases where their specific skills are necessary to ensure a sound outcome of the official controls (i.e. for live animals, meat and some other products of animal origin).

Member States should also use official veterinarians including for official controls on poultry and lagomorphs, or other specifically designated persons in cases where this is not required.

Reporting of infringements: the Council position contains provisions obliging Member States to have in place mechanisms to enable the reporting of actual or potential infringements of this Regulation, the follow-up of such a reporting and the protection of the persons reporting against retaliation, discrimination or unfair treatment.

Delegated and implementing powers: the proposed act will constitute a framework Regulation which will empower the Commission to determine a significant amount of its details by delegated and/or implementing acts.

For the provisions concerning specific additional rules for official controls in relation to specific areas - e.g. the production of meat for human consumption, animal welfare, plant protection products or plant health, the Council introduced many essential elements in the basic act and allowed for empowerments for the Commission as appropriate.

Lastly, transitional periods have been introduced to ensure that the existing provisions to be replaced by the above-mentioned acts will continue to apply until the latter have been adopted by the Commission. Such adoption should take place as soon as possible and at the latest 3 years after the date of application of the Regulation.