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INFORMATION NOTE

from: General Secretariat
to: Permanent Representatives Committee/Council

Subject: 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 and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...] /2013 and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official Controls Regulation)
- Outcome of the European Parliament's first reading
(Strasbourg, 14 to 17 April 2014)

I. INTRODUCTION

The Committee on the Environment, Public Health and Food Safety submitted 313 amendments to the proposal for a Regulation (amendments 1-313). In addition:

- the EPP political group tabled five amendments (amendments 314-318);
- the S&D political group tabled one amendment (amendment 319);
- the Greens/EFA political group tabled eighteen amendments (amendments 320-337);
- the ECR political group tabled nine amendments (amendments 338-346); and
- the EUL/NGL political group tabled three amendments (amendments 347-349).

II. DEBATE

The debate, which took place on 14 April 2014, was a joint debate which covered three Ordinary Legislative Procedure proposals:

- 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 and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...]/2013 and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official Controls Regulation) **[2013/0140 (COD) / Rapporteur: Mr Mario PIRILLO (S&D - IT)] - see section III below for the voting results;**
- the proposal for a Regulation of the European Parliament and of the Council on Animal Health **[2013/0136 (COD) / Rapporteur: Mrs Marit PAULSEN (ALDE - SE)] - see doc. 8306/14 for the voting results;** and
- the proposal for a Regulation of the European Parliament and of the Council on protective measures against pests of plants **[2013/0141 (COD) / Rapporteur: Mr Hynek FAJMON (ECR - CZ)] - see doc. 8307/14 for the voting results.**

Mr Mario PIRILLO (S&D - IT) opened the debate and:

- stressed the economic significance of the food sector, as well as the need to protect health and to ensure the correct implementation of regulations in order to maintain the sector's reputation, which is also a key factor in the EU's ability to export food products to third countries;
- noted that the Commission had submitted a proposal based on the principle that controls should be proportionate to risk and aiming at the creation of a single harmonised control procedure framework;
- welcomed the Committee's work to clarify the Commission's test and to reduce the scope for differing national interpretations, which have in the past resulted in non-homogeneous application of controls by different Member States;
- noted the Committee's introduction of a principle of minimum inspection frequency in all sectors of the food chain. This should put an end to the current divergence in national practices. It should allow the EU to restore consumer confidence, particularly after the various recent food scandals such as the horse-meat affair;

- warned against allowing budgetary pressures to compromise the effectiveness of controls. Tariffs need to remain, but there should be appropriate flexibility for Member States; and
- noted the exemptions proposed by the Commission for SMEs from the payment of compulsory tariffs, but stressed the need to set the exemption criteria at the right level. The Commission's proposed criteria seem too wide and would exempt 90% of enterprises, thus rendering unsustainable the management of controls by the competent authorities. The exemption should, however, be maintained for micro-enterprises, with more reduced parameters.

Mrs Marit PAULSEN (ALDE - SE):

- stated that the Parliament's work on her proposal must take account of the fact that the proposal is not about animals' living conditions, but about protection from infectious disease; and
- argued that the Committee's report represents a sensible and serious compromise.

Mr Hynek FAJMON (ECR - CZ) stressed the importance of Article 40 of his proposal. Article 40 defines the rules on imports of plants and plant-based products into the EU. It is crucial because it defines the overall philosophy of the proposal. The EU has always been an open trading system. In the Committee on Agriculture and Rural Development, most MEPs had voted for a re-evaluation of the current approach and for a closed system. This would breach international trading rules and provoke retaliation from the EU's partners.

Commissioner BORG:

- welcomed the three reports as a solid basis for future negotiation between the co-legislators during the Parliament's next term. The institutions are still in disagreement, but are already aligned on many points;
- stated that the proposed new rules on official controls seek to help Member State authorities to fulfil their control and enforcement duties. There is no point in having a law if they do not have the funds and human resources to enforce it. Since funding is essential, the proposal provides for mandatory fees that would enable the recovery of the costs - but no more - incurred by the competent authorities in charge of controls;
- warned that some public spending reviews being carried out in the Member States could have potentially devastating consequences. The horsemeat scandal - which was never a food safety issue but rather a serious issue of fraudulent labelling - is a reminder of what might happen should controls be reduced to insufficient levels. The sustainability and credibility of the control system as a whole is at stake;

- stated that when, as now, fees are necessary, it is the duty of the regulator to ensure that they are applied fairly, equitably and transparently. This in turn requires clear and uniform methods for the calculation and application of fees, and stringent transparency requirements. All sectors should contribute - unlike in the current system where only some businesses are charged. Micro-enterprises across all areas will nonetheless be exempted. That means that 80% of all operators will not need to pay fees. In addition, the remaining 20% will be inspected on the basis of risk. This will allow for better prioritisation of controls and a more efficient allocation of resources. A law-abiding enterprise would therefore face fewer controls and fewer expenses;
- noted that the proposal also provides for improved tools for cross-border cooperation between competent authorities. This will ensure that cases of non-compliance which have effects in more than one Member State - as usually happens in a single market - are actively and effectively remedied;
- stated that the mechanisms for cooperation in the area of food fraud that the Commission has been piloting in recent months will be strengthened under the new regulation. One of the proposals is that, in the event of a scandal like the fraudulent labelling of horsemeat, the financial penalty for the company breaking the law must be at least equal to the illicit gain from the fraudulent labelling;
- argued that consumers and importers of animals and products would benefit from a modernised border control system. This means documentary and identity checks on all consignments, physical checks based on risk, simpler procedures and full use of electronic documents and certificates;
- stated that the Commission's main objective for animal health is to introduce a single piece of legislation to regulate animal health in the EU. A simple system is needed to improve the detection and control of animal diseases in the framework of the farm-to-fork approach to food chain safety;
- noted the concerns raised by the number of Commission empowerments in the animal health proposal, but reminded the MEPs that the Commission's proposal brings together 37 different directives and regulations which currently contain 600 empowerments. These will be reduced to 163;

- called for flexibility in the EU's animal health legislation. The Commission's proposal is intended to strike the right balance between due deliberation and swift action in response to emergencies. He particularly noted the wish of some MEPs to see the list of diseases relating to animal health and species adopted in an annex to the Regulation. The Commission maintains that the adoption of this list through implementing acts is legally sound and is practically and technically necessary. This is not a new approach, but is rather in line with much of the current animal health legislation, such as the lists of diseases affecting aquatic animals and requiring Union notification. If a new disease were to emerge (for example one similar to Schmallenberg, but with more serious effects), the Commission would have to take swift action to combat it. The Commission therefore needs the flexibility easily to amend or adapt rules in response to the development of the disease;
- welcomed many of the amendments in the Committee's report, which are constructive and within the spirit of the proposal - but nevertheless cautioned against pressing for amendments that could go against the common goals. He cited as an example the amendments to allow Member States to restrict the movement of animals or products within the EU if they themselves judge that there is an animal health risk: This would be a retrograde step because it might undermine existing systems and the internal market;
- noted the amendments on animal welfare and antimicrobial resistance. These are important amendments. Animal welfare and AMR ('anti-microbial resistance') are becoming increasingly prominent in political agendas - an extremely positive development. The Commission therefore believes that they should be considered separately and specifically. The Commission is already taking steps to improve the implementation of the current animal welfare rules and what has already been achieved, particularly for laying hens and pregnant sows. As regards AMR, the Commission would continue to deliver on its action plan during 2014;
- stressed the importance of the import rules set out in the plant health proposal. These would make it possible to prohibit or restrict pests, through appropriate measures, in response to identified and well-assessed risks. They would also allow the provisional suspension of imports of plants posing hitherto unidentified risks. This precautionary approach would strengthen the current import requirements, ensure preventive action wherever necessary and support the EU's importers in satisfying the considerable market demand for plant products from outside the EU under safe conditions;

- emphasised the need to adapt measures to a dynamically changing environment of pests and trade. The EU's import strategy must therefore be easily adaptable to scientific and technical developments. He recalled the examples of western corn rootworm, red palm weevil, the pinewood nematode, longhorn beetles and the Xylella. In many cases, due to insufficient controls and/or untimely reactions, and despite subsequent efforts and budget allocations, all these cited pests have proved impossible to eradicate. A pro-active approach is therefore needed together with a reinforcement of the import regime with swift detection and eradication measures; and
- welcomed the Parliament's agreement to the financial incentives which will be included in the regulation for the management of expenditures. The Union will co-finance costs linked to the early detection of new pests through survey programmes. It will also co-finance costs linked to eradication measures, including compensation to owners for the value of their destroyed plants.

Speaking on behalf of the Committee on the Environment, Public Health and Food Safety, Mr Oreste ROSSI (EFD - IT):

- expressed his conviction that the new framework proposed by the Commission would guarantee greater efficiency and coherence in all the EU's foodchain control mechanisms;
- stressed the need for greater simplification in all sectors;
- stated that his Committee's report represents a balanced compromise; and
- emphasised the need for adequate controls for all seed categories.

Also speaking on behalf of the Committee on the Environment, Public Health and Food Safety, Mrs Kartika LIOTARD (EUL/NGL - NL):

- regretted the fact that the Committee on Agriculture and Rural Development had not adopted many of the animal health points of her Committee's report;
- stated that prevention is better than the cure. Much animal suffering can be prevented by measures to stop epidemics (for example, provisions on the space accorded to animals and on animal transportation);
- warned that excessive medication could lead to anti-microbial resistance; and
- called for traceability of cloned animals and their descendants. 90% of cloned animals give birth to stillborn animals. Traceability would make it possible to kill two birds with one stone (i.e. deal with animal health and also inform consumers of products from cloned animals).

Speaking on behalf of the Committee on Agriculture and Rural Development, Mrs Britta REIMERS (ALDE - DE):

- stressed the need for proper protection, but without distorting competition;
- emphasised the need for a risk-based approach, focusing controls where the risk is greatest is whilst also reducing controls where the risk is low;
- noted that many micro-enterprises can simply not bear extremely high control costs (costs which include not just purely bureaucratic costs, but also the costs of labour); and
- stressed the importance of the proportionality principle.

Speaking on behalf of the Committee on Fisheries, Mrs Isabella LÖVIN (Greens/EFA - SE):

- argued that prevention is better than cure;
- warned against permitting a free trade in animal diseases in the EU. Zones which are currently disease-free should be kept that way. Trade in meat is one thing. Trade in live animals is another. Thousands of EU citizens die every year from this type of disease; and
- called for a level playing-field. The lack of such a level playing-field is bankrupting Swedish pig-farmers.

Speaking on behalf of the EPP political group, Mr Horst SCHNELLHARDT (EPP - DE):

- stressed the need for a clear fee framework, stipulating who can be charged and when - and to what use the fees should be put;
- expressed his scepticism regarding the likely efficacy of delegated acts. A swift response is already possible so there is no need for delegated acts, which take much longer; and
- stated that controls should be applied according to risk (rather than according to size).

Speaking on behalf of the S&D political group, Mr Giovanni BARBAGALLO (S&D - IT):

- stressed the need to avoid excessive red tape and to maintain current derogations which reflect the special circumstances of individual countries;
- stated that the Parliament had at committee level, for reasons of clarity and subsidiarity, distinguished between the rules for obligatory disease eradication programmes and facultative rules. The provisions on animal welfare and AMR had also been reinforced;
- stated the need to guarantee the Parliament's codecision role with regard to a Commission proposal that he described as being excessively self-referential;
- recalled the opposition of many S&D MEPs to cloning;
- noted that different countries have different rules for disease notification; and
- argued against addressing maximum transportation times in the current proposal.

Speaking on behalf of the Greens/EFA political group, Mr Bart STAES (Greens/EFA - BE) argued that controls should remain independent and under the responsibility of national competent authorities.

Speaking on behalf of the ECR political group, Mrs Julie GIRLING (ECR - UK):

- warned that the Parliament was in danger of adopting amendments that would render the three proposals more complicated and even contradictory;
- argued that, whilst the Commission proposal was that fees should be levied, the wording should be changed so that fees may be levied. Member States must ensure adequate resources, but it would be wrong to require the charging of fees in cases where they are not currently charged. This would lead to micro-management and cause problems; and
- called for support for her amendment 343, since each Member State has different economic, practical and delivery conditions and because these should remain.

Speaking on behalf of the EUL/NGL political group, Mrs Martina ANDERSON (EUL/NGL - UK) called for the new EU animal health law to recognise Ireland as one island and to remove barriers to animal movement and trade.

Mrs Elisabeth JEGGLE (EPP - DE):

- stressed the need to keep the animal health proposal clear, slim-line and focused on its objectives;
- opposed the various animal welfare amendments;
- opposed the amendments on labelling of sheeps and goats;
- called for the retention of current legislation regarding the registration of animals (especially bovine), whilst leaving open the possibility of accepting some minor changes during the trilogue phase;
- supported the proposals for regular risk-based animal controls and for responsible use of antibiotics;
- argued that Member States should in certain circumstances be allowed to apply national prevention measures;
- stressed the need for the lists of animal diseases and animal species to be in an annex; and
- called for precautionary measures regarding stray and wild animals, which can pose a risk for animals and humans.

Mr Alyn SMITH (Greens/EFA - UK) called for support for amendment 238 of the animal health proposal, which addresses problems in implementing the rules on the electronic identification of sheep. The amendment would allow Member States to introduce a voluntary derogation. The amendment would not undermine traceability.

Mrs Pilar AYUSO (EPP - ES):

- supported amendments 78 and 85 to the plant protection proposal. These amendments would establish a more effective and global approach to importation controls. The EU should protect itself from plant diseases just as effectively as the USA, Russia and other parts of the world. The EU's bans on many pesticides have rendered the EU's crops more vulnerable to pests than crops elsewhere in the world; and
- argued that the animal health proposal should not address the issues of animal welfare, AMR or animal transportation. It should deal only with animal diseases that might spread within the EU.

Mrs Åsa WESTLUND (S&D - SE):

- called for a maximum limit of eight hours transportation to slaughter; and
- stressed the need for rules to address AMR.

Mr James NICHOLSON (ECR - UK):

- stressed the need for legislation that is simple, flexible and outcomes-based;
- expressed his concern that issues that fall outside the scope of the Regulation, such as cloning and animal transportation times, had been included and that they might distract from the primary animal health concerns;
- stated the need to ensure that the animal health regulation is not so prescriptive as to damage trade between Northern Ireland and the Republic of Ireland. The proposed regulation should not undermine existing animal health and welfare strategies in the United Kingdom and the Republic of Ireland; and
- asked the Commission to confirm that the recently adopted bovine electronic identification regulation would be incorporated without change in the animal health regulations. Mr Nicholson would himself support its inclusion.

Dr Peter LIESE (EPP - DE):

- argued that fines should be at least twice as high as profits made from fraud; and
- opposed the Committee's deletion of the exemption for SMEs. The ten-employee limit is too low.

Mr Justas Vincas PALECKIS (S&D - LT):

- argued that animal welfare is an essential part of the animal health proposal; and
- called for action to combat AMR.

Mr Albert DESS (EPP - DE) called for a negative rather than a positive list for the plant protection proposal, because a positive list would hinder global trade and give rise to retaliatory measures.

Mrs Christa KLAß (EPP - DE) argued that national authorities should be able to set fees.

Commissioner BORG once more took the floor and:

- summarised the debate as being about whether to control more or less. He believed that the Commission's proposal and many of the submitted amendments were a reasonable compromise;
- recalled that the Commission had responded to the horsemeat scandal by introducing a number of measures, including a food fraud network within the Member States, an IT system to report fraud, increased penalties, more sampling plans and a food fraud section within DG SANCO;
- agreed on the need to be more vigilant about imports. The EU maintains the so-called open system, because it has signed the International Plant Protection Convention and because it has obligations under the WTO, which obliges the contracting parties to base their phytosanitary legislation on identified pest risks to plant health;
- noted the debate on whether fees linked to official controls should be mandatory or should be left to Member States. The Commission thinks that this choice should not be offered for two reasons:
 - firstly, to harmonise and thus create a level playing-field across the EU, the competent authorities should be required to take the same costs into account (i.e. the fees should be based on the direct and indirect costs, rather than being a tax). The fees should only be intended to recover the cost of the control and nothing more; and
 - secondly, if Member States were entitled to consider the costs they want, this would allow the perpetration of differing and potentially distortive practices. Operators in the richer Member States could be advantaged as these Member States would either not impose fees or would impose lower fees whilst operators in less rich Member States would pay relatively more;
- noted that micro-enterprises (80% of operators) will be exempt from fees;
- recognised the importance of animal welfare, but argued that it should not be included in the current proposals. The Commission has already shown its commitment in this regard. Not only has the Commission taken the first preparatory steps for a general animal welfare law, but it was the Commission that prohibited the marketing of animal-tested cosmetics in the EU. The Commission has also enforced the legislation on pregnant sows and laying hens' cages, as well as launching its cloning proposal;

- agreed on the need for more action on AMR (25,000 people in the EU die annually from infections that are resistant to antibiotics), but not in the current proposal. The Commission has already launched an action plan in this regard. The current proposal is only one element in the EU's action against AMR. The Commission's forthcoming proposal on veterinary medicines will be crucial. Some of the amendments to the current proposal are outside its scope and stray into the area of veterinary medicine regulation; and
- expressed his hope for a second-reading agreement in the next Parliament at the earliest possible opportunity.

Mr Mario PIRILLO (S&D - IT) once more took the floor and noted the amendments on exemptions for SMEs.

Mrs Marit PAULSEN (ALDE - SE) once more took the floor and stressed the need for:

- clear and comprehensible legislation;
- the Commission to be able to take swift action as and when required; and
- effective controls as the *quid pro quo* of the single market.

Mr Hynek FAJMON (ECR - CZ) once more took the floor and warned against protectionist tendencies.

III. VOTE

When it voted on 15 April 2014, the plenary adopted 319 amendments (amendments 1-14, 16-261, 263-264, 266-307, 309-317, 326-328, 336, 341 and 343).

The text of the amendments adopted and the European Parliament's legislative resolution are set out in the Annex hereto.

Food and feed law, rules on animal health and welfare, plant health, plant reproductive material and plant protection products *I**

European Parliament legislative resolution of 15 April 2014 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 and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...]/2013 and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official Controls Regulation) (COM(2013)0265 – C7-0123/2013 – 2013/0140(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0265),
 - having regard to Article 294(2) and Articles 43(2), 114 and 168(4)(b) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0123/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Luxembourg Chamber of Deputies, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 16 October 2013¹,
 - having regard to the opinion of the Committee of the Regions of 29 November 2013²,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A7-0162/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

¹ Not yet published in the Official Journal

² OJ C 23, 27.1.2014, p. 14.

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Proposal for a regulation

Title

Text proposed by the Commission

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 and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...] /2013 [*Office of Publications, please insert number of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material*], and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation)

Amendment

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 protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...] /2013 [*Office of Publications, please insert number of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material*], and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation)

Amendment 2

Proposal for a regulation

Recital 3

Text proposed by the Commission

(3) Union legislation provides for a set of harmonised rules to ensure that food and feed are safe and wholesome and that activities which might have an impact on the safety of the food chain or on the protection of consumers interests in relation to food and food information are performed in accordance with specific requirements. Union rules exist also to

Amendment

(3) Union legislation provides for a set of harmonised rules to ensure that food and feed are safe and wholesome and that activities which might have an impact on the safety of the food chain or on the protection of consumers interests in relation to food and food information are performed in accordance with specific requirements. Union rules exist also to

ensure a high level of human, animal **and plant** health and animal welfare along the food chain and in all those areas of activity where a key objective is the fight against the possible spread of animal diseases, in some cases transmissible to humans, or of pests injurious to plants or plant products, and to ensure the protection of the environment from risks that might arise from GMOs and plant protection products. ***Union rules also guarantee the identity and quality of plant reproductive material.*** The correct application of those rules, hereinafter collectively referred to as 'Union agri-food chain legislation', contributes to the functioning of the internal market.

ensure a high level of human **and** animal health and animal welfare along the food chain and in all those areas of activity where a key objective is the fight against the possible spread of animal diseases, in some cases transmissible to humans, or of pests injurious to plants or plant products, and to ensure the protection of the environment from risks that might arise from GMOs and plant protection products. The correct application of those rules, hereinafter collectively referred to as 'Union agri-food chain legislation', contributes to the functioning of the internal market.

Amendment 3

Proposal for a regulation Recital 8

Text proposed by the Commission

Amendment

(8) Union legislation on plant reproductive material regulates the production with a view to placing on the market, and the placing on the market, of plant reproductive material of agricultural, vegetable, forest, fruit and ornamental species and vines. The objective of those rules is to ensure the identity, health and quality of plant reproductive material for its users, and the productivity, diversity, health and quality of the agri-food chain as well as contributing to the protection of biodiversity and the environment.

deleted

Amendment 4

Proposal for a regulation Recital 14

Text proposed by the Commission

Amendment

(14) There are a number of provisions in Union agri-food chain legislation, the enforcement of which has not, or has only

deleted

partially, been governed by Regulation (EC) No 882/2004. In particular, specific official control rules were kept in place in Union legislation on plant reproductive material and in Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002¹². Plant health also largely falls outside the scope of Regulation (EC) No 882/2004 with certain rules on official controls being laid down in Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community¹³.

¹² OJ L 300, 14.11.2009, p. 1.

¹³ OJ L 169, 10.7.2000, p. 1.

Amendment 5

Proposal for a regulation Recital 16

Text proposed by the Commission

(16) In order to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of better regulation, the rules applicable to official controls *in specific areas should be integrated into a single legislative framework for official controls*. For that purpose, Regulation (EC) No 882/2004 and other acts currently governing official controls in specific areas should be repealed and replaced by this Regulation.

Amendment

(16) In order to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of better regulation, the rules applicable to official controls *should be more closely integrated, provided that they pursue the same objective with regard to control activities*. For that purpose, Regulation (EC) No 882/2004 and other acts currently governing official controls in specific areas should be repealed and replaced by this Regulation.

Amendment 6

Proposal for a regulation

Recital 18

Text proposed by the Commission

(18) For the verification of compliance with the rules on the common organisation of the markets of agricultural products (arable crops, wine, olive oil, fruit and vegetables, hops, milk and milk products, beef and veal, sheepmeat and goatmeat and honey), a well-established and specific control system is already in place. This Regulation should therefore not apply to the verification of compliance with the provisions of Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation).

Amendment

(18) For the verification of compliance with the rules on the common organisation of the markets of agricultural products (arable crops, wine, olive oil, fruit and vegetables, hops, milk and milk products, beef and veal, sheepmeat and goatmeat and honey), a well-established and specific control system is already in place. This Regulation should therefore not apply to the verification of compliance with the provisions of Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation), *with the exception of Part II, Title II, Chapter I of that Regulation.*

Amendment 7

Proposal for a regulation

Recital 20

Text proposed by the Commission

(20) Union agri-food chain legislation entrusts the competent authorities of the Member States with specialised tasks to be carried out for the protection of animal health, plant health and animal welfare, for the protection of the environment in relation to GMOs and plant protection products, *and in order to ensure the identity and a high quality of plant reproductive material.* Those tasks are the public interest activities which the competent authorities of the Member States must carry out for the purpose of eliminating, containing or reducing risks which may arise for human, animal or plant health, animal welfare, or for the environment. Those activities, which include product approval, surveying,

Amendment

(20) Union agri-food chain legislation entrusts the competent authorities of the Member States with specialised tasks to be carried out, *not least* for the protection of animal health, plant health and animal welfare, for the protection of the environment in relation to GMOs and plant protection products. Those tasks are the public interest activities which the competent authorities of the Member States must carry out for the purpose of eliminating, containing or reducing risks which may arise for human, animal or plant health, animal welfare, or for the environment. Those activities, which include product approval, surveying, surveillance and monitoring including for epidemiologic purposes, and the

surveillance and monitoring including for epidemiologic purposes, and the eradication and containment of diseases, and other disease control tasks, are governed by the same sectoral rules which are enforced through the official controls.

eradication and containment of diseases, and other disease control tasks, are governed by the same sectoral rules which are enforced through the official controls.

Amendment 8

Proposal for a regulation

Recital 23

Text proposed by the Commission

(23) For the performance of official controls aimed at verifying the correct application of Union agri-food chain legislation, and of the other official activities entrusted to Member State authorities by Union agri-food chain legislation, Member States should designate competent authorities which act in the public interest, *are* appropriately resourced and equipped, and *offer guarantees of* impartiality and professionalism. *Competent authorities should ensure the quality, consistency and effectiveness of official controls.*

Amendment

(23) For the performance of official controls aimed at verifying the correct application of Union agri-food chain legislation, and of the other official activities entrusted to Member State authorities by Union agri-food chain legislation, Member States should designate competent *public* authorities which act in the public interest *and ensure the quality, consistency and effectiveness of official controls. The designated competent authority, or authorities, should be* appropriately resourced and equipped, and *Member States should be able to guarantee their* impartiality and professionalism *by ensuring their independence from any operator operating within the agri-food chain.*

Amendment 9

Proposal for a regulation

Recital 24 a (new)

Text proposed by the Commission

Amendment

(24a) The audits undertaken by the competent authorities, or at the request of the competent authorities, to ensure compliance with this Regulation may be based on international standards, where the requirements of those standards correspond to the requirements of this Regulation.

Amendment 10

Proposal for a regulation

Recital 25

Text proposed by the Commission

(25) Operators *should* have *a* right to appeal against the decisions taken by the competent authorities, *and be informed of such a right*.

Amendment

(25) Operators *should* have *the* right to appeal against the decisions taken by the competent authorities. *The competent authorities are to inform operators of this right*.

Amendment 11

Proposal for a regulation

Recital 26

Text proposed by the Commission

(26) The competent authorities should ensure that staff responsible for official controls does not disclose information acquired during the performance of such controls which is covered by professional secrecy. *Unless there is an overriding interest justifying disclosure, professional secrecy should include information which would undermine the purpose of inspections, investigations or audits, the protection of commercial interests and the protection of court proceedings and legal advice. However, professional secrecy should not prevent competent authorities from disclosing* factual information on the outcome of official *controls* regarding individual operators when the operator concerned has been allowed to comment upon it prior to the disclosure and such comments have been taken into account, *or* released alongside the information being divulged by the competent authorities. *The need to respect professional secrecy is also without prejudice to the obligation to inform the general public where there are reasonable grounds to suspect that food or feed may present a risk for health in accordance with Article 10 of Regulation (EC) No 178/2002.* The obligation for competent authorities to inform the general

Amendment

(26) The competent authorities should ensure that, *with the exception of internal reporting obligations*, staff responsible for official controls does not disclose information acquired during the performance of such controls which is covered by professional secrecy. *Where there is 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. The measures taken should be in proportion to the scale of the infringement, in particular when naming specific products or operators concerned.* Factual information on the outcome of *an* official *control* regarding individual operators *may be divulged* when the operator concerned has been allowed to comment upon it prior to the disclosure and such comments have been taken into account *and* released alongside *and at the same time as* the information being divulged by the competent authorities. The obligation for competent authorities to inform the general public in cases where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, in accordance with Article 10 of Regulation (EC)

public in cases where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, in accordance with Article 10 of Regulation (EC) No 178/2002, and the right of individuals to the protection of their personal data as provided for in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data¹⁶ should not be affected by this Regulation.

¹⁶ OJ L 281, 23.11.95, p. 31.

No 178/2002, and the right of individuals to the protection of their personal data as provided for in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data¹⁶ should not be affected by this Regulation.

¹⁶ OJ L 281, 23.11.95, p. 31.

Amendment 12

Proposal for a regulation Recital 29 a (new)

Text proposed by the Commission

Amendment

(29a) Official controls should be performed by staff free from any conflict of interests, and in particular not engaged, directly or through a spouse, in an economic activity subject to the official controls laid down.

Amendment 13

Proposal for a regulation Recital 34

Text proposed by the Commission

Amendment

(34) To facilitate the identification of non-compliances and streamline the taking of corrective action by the operator concerned, the outcome of official controls should be recorded in a report, a copy of **which** should be given to the operator. Where official controls require the continuous or regular presence of the staff of the competent authorities to monitor the operator's activities, a report of each individual inspection or visit to the

(34) To facilitate the identification of non-compliances and streamline the taking of corrective action by the operator concerned, the outcome of official controls **which identify non-compliances with the rules** should be recorded in a report. A copy of **that report** should **also** be given to the operator. Where official controls require the continuous or regular presence of the staff of the competent authorities to monitor the operator's activities, a report of

operator would be disproportionate. In such cases reports should be prepared with a frequency that enables the competent authorities and the operator to be regularly informed of the level of compliance and immediately notified of any identified shortcomings.

each individual inspection or visit to the operator would be disproportionate. In such cases reports should be prepared with a frequency that enables the competent authorities and the operator to be regularly informed of the level of compliance and immediately notified of any identified shortcomings. ***In the interests of reducing the administrative burden, it should also be sufficient to record the outcome of official controls at border control posts in the Common Health Entry Document.***

Amendment 14

Proposal for a regulation Recital 54

Text proposed by the Commission

(54) Member States should be required to ensure that adequate financial resources are always available in order to appropriately staff and equip the competent authorities performing official controls and other official activities. Although operators are primarily responsible for ensuring that their activities are carried out in compliance with Union agri-food chain rules, the system of own controls that they put in place for that purpose needs to be complemented by a dedicated system of official controls maintained by each Member State to ensure effective market surveillance along the agri-food chain. Such a system is, by its very nature, complex and resource demanding and should be provided with a stable influx of resources for official controls, at a level appropriate to the enforcement needs at any given moment. To reduce the dependency of the official control system from public finances, competent authorities should collect fees to cover the costs they incur when performing official controls on certain operators and for certain activities for which Union agri-food chain legislation requires registration or approval in accordance with Union rules on the hygiene of food and feed or rules

Amendment

(54) Member States should be required to ensure that adequate financial resources are always available in order to appropriately staff and equip the competent authorities performing official controls and other official activities. Although operators are primarily responsible for ensuring that their activities are carried out in compliance with Union agri-food chain rules, the system of own controls that they put in place for that purpose needs to be complemented by a dedicated system of official controls maintained by each Member State to ensure effective market surveillance along the agri-food chain. Such a system is, by its very nature, complex and resource demanding and should be provided with a stable influx of resources for official controls, at a level appropriate to the enforcement needs at any given moment. To reduce the dependency of the official control system from public finances, competent authorities should ***be able to collect fees or contributions to costs*** to cover the costs they incur when performing official controls on certain operators and for certain activities for which Union agri-food chain legislation requires registration or approval in accordance with Union rules

governing plant health **and plant reproductive material**. Fees should also be collected from operators to compensate the costs of official controls performed in view of issuing an official certificate or attestation, and costs of official controls performed by the competent authorities at border control posts.

on the hygiene of food and feed or rules governing plant health. Fees **or contributions to costs** should also be collected from operators to compensate the costs of official controls performed in view of issuing an official certificate or attestation, and costs of official controls performed by the competent authorities at border control posts.

Amendment 16

Proposal for a regulation Recital 60 a (new)

Text proposed by the Commission

Amendment

(60a) Article 32(1) of Regulation (EC) No 1829/2003 and Article 21(1) of Regulation (EC) No 1831/2003 confer respectively on the European Union reference laboratory for genetically modified food and feed and on the European Union reference laboratory for feed additives, specific tasks as part of the authorisation procedure for genetically modified food or feed, or feed additives, relating, in particular, to the testing, evaluation and validation of the method of detection or analysis proposed by applicants. Experience shows that knowledge and expertise in the testing, evaluation and validation of methods in the context of the authorisation procedure is crucial in order to provide a high-level, state-of-the-art contribution to the efficiency of official controls. Laboratories designated as such under Article 32(1) of Regulation (EC) No 1829/2003 and Article 21(1) of Regulation (EC) No 1831/2003 should therefore act as European Union reference laboratories for the purposes of this Regulation.

Amendment 17

Proposal for a regulation Recital 61

Text proposed by the Commission

(61) For the performance of official controls and other official activities ***on the production and marketing of plant reproductive material, and*** in the field of animal welfare, the competent authorities should have access to updated, reliable and consistent technical data, to research findings, new techniques and expertise necessary for the correct application of Union legislation applicable in those areas. For that purpose the Commission should be able to designate, and rely on the expert assistance of, European Union reference centres for ***plant reproductive material and for*** animal welfare.

Amendment

(61) For the performance of official controls and other official activities in the field of animal welfare, the competent authorities should have access to updated, reliable and consistent technical data, to research findings, new techniques and expertise necessary for the correct application of Union legislation applicable in those areas. For that purpose the Commission should be able to designate, and rely on the expert assistance of, European Union reference centres for animal welfare.

Amendment 18

Proposal for a regulation

Recital 62

Text proposed by the Commission

(62) In order to pursue the objectives of this Regulation and contribute to the smooth functioning of the internal market, ensuring consumer confidence in it, non-compliances with Union food chain legislation requiring enforcement action in more than one Member State should be pursued efficiently and consistently. The Rapid Alert System for Food and Feed (RASFF) established by Article 50 of Regulation (EC) No 178/2002 already enables competent authorities to rapidly exchange and disseminate information on serious direct or indirect risks to human health in relation to food or feed, or serious risks to human or animal health or to the environment in relation to feed, for the purpose of enabling rapid measures to be taken to counter those risks. However, that instrument, while allowing for timely action across all Member States concerned to counter certain serious risks along the food chain, cannot serve the purpose of enabling effective cross border assistance

Amendment

(62) In order to pursue the objectives of this Regulation and contribute to the smooth functioning of the internal market, ensuring consumer confidence in it, non-compliances with Union food chain legislation requiring enforcement action in more than one Member State should be pursued efficiently and consistently. The Rapid Alert System for Food and Feed (RASFF) established by Article 50 of Regulation (EC) No 178/2002 already enables competent authorities to rapidly exchange and disseminate information on serious direct or indirect risks to human health in relation to food or feed, or serious risks to human or animal health or to the environment in relation to feed, ***or in the case of food fraud,*** for the purpose of enabling rapid measures to be taken to counter those risks. However, that instrument, while allowing for timely action across all Member States concerned to counter certain serious risks along the food chain, cannot serve the purpose of

and cooperation between competent authorities to ensure that non-compliances with Union agri-food chain legislation which have a cross-border dimension are effectively pursued not only in the Member State where the non-compliance is first detected but also in the Member State where the non-compliance originated. In particular, administrative assistance and cooperation should enable competent authorities to share information, detect, investigate and take effective and proportionate action to pursue cross-border violations of agri-food chain rules.

enabling effective cross border assistance and cooperation between competent authorities to ensure that non-compliances with Union agri-food chain legislation which have a cross-border dimension are effectively pursued not only in the Member State where the non-compliance is first detected but also in the Member State where the non-compliance originated. In particular, administrative assistance and cooperation should enable competent authorities to share information, detect, investigate and take effective and proportionate action to pursue cross-border violations of agri-food chain rules.

Amendment 19

Proposal for a regulation

Recital 73

Text proposed by the Commission

(73) It is important for the performance of effective official controls and other official activities that the competent authorities in the Member States, the Commission and, where relevant, operators be able to exchange data and information related to official controls or results therefrom rapidly and efficiently. Several information systems are established by Union legislation and managed by the Commission to allow such data and information to be handled and managed through Union wide computerised and internet-based tools. A system dedicated to recording and tracing official control results is the Trade Control and Expert System (TRACES system), established by Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system and currently used for the management of data and information on animals and products of animal origin and official controls thereon²¹. That system should be upgraded so as to allow its use for all goods for which Union agri-food chain legislation establishes specific

Amendment

(73) It is important for the performance of effective official controls and other official activities that the competent authorities in the Member States, the Commission and, where relevant, operators be able to exchange data and information related to official controls or results therefrom rapidly and efficiently. Several information systems are established by Union legislation and managed by the Commission to allow such data and information to be handled and managed through Union wide computerised and internet-based tools. A system dedicated to recording and tracing official control results is the Trade Control and Expert System (TRACES system), established by Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system and currently used for the management of data and information on animals and products of animal origin and official controls thereon²¹. That system should be upgraded **and adapted** so as to allow its use for all goods for which Union agri-food chain legislation establishes

requirements or official control modalities. Dedicated computerised systems also exist for the rapid exchange of information between Member States and with the Commission on risks which might arise in the food chain or for animal and plant health. Article 50 of Regulation (EC) No 178/2002 establishes the RASFF, Article 20 of Regulation (EU) XXX/XXXX [Office of Publications, please insert number, date, title and, in a footnote, the OJ reference for the Regulation on animal health] a system for the notification and reporting on the measures on listed diseases, and Article 97 of Regulation (EU) XXX/XXXX [Office of Publications, please insert number, date, title and, in a footnote, the OJ reference for the Regulation on protective measures against pests of plants] a system for the notification and reporting of the presence of pests and the notification of non-compliances. All such systems should work in a harmonious, consistent manner that makes use of synergies between the different systems, avoids duplications, simplifies their operation and makes them more efficient.

²¹ OJ L 8, 14.1.2003, p. 44.

specific requirements or official control modalities. Dedicated computerised systems also exist for the rapid exchange of information between Member States and with the Commission on risks which might arise in the food chain or for animal and plant health. Article 50 of Regulation (EC) No 178/2002 establishes the RASFF, Article 20 of Regulation (EU) XXX/XXXX [Office of Publications, please insert number, date, title and, in a footnote, the OJ reference for the Regulation on animal health] a system for the notification and reporting on the measures on listed diseases *and on food fraud*, and Article 97 of Regulation (EU) XXX/XXXX [Office of Publications, please insert number, date, title and, in a footnote, the OJ reference for the Regulation on protective measures against pests of plants] a system for the notification and reporting of the presence of pests and the notification of non-compliances. All such systems should work in a harmonious, consistent manner that makes use of synergies between the different systems, avoids duplications, simplifies their operation and makes them more efficient.

²¹ OJ L 8, 14.1.2003, p. 44.

Amendment 20

Proposal for a regulation Recital 74 a (new)

Text proposed by the Commission

Amendment

(74a) In order to minimise administrative burdens and control costs and in order to allow the EU and its Member States to effectively communicate electronically in trade relations with third countries, it is necessary that when exchanging electronic certificates or other electronic data, the Commission and the competent authorities of the Member States use internationally standardised language,

message structure and exchange protocols based on guidance for electronic certification in standardised World Wide Web Consortium (WC3) Extensible Markup Language (XML schemas) as well as secure exchange mechanisms between competent authorities as is provided by the UN Centre for Trade Facilitation and Electronic Business (UN/CEFACT).

Amendment 21

Proposal for a regulation

Recital 77

Text proposed by the Commission

(77) Infringements of the rules should be subject to effective, dissuasive and proportionate sanctions at national level throughout the Union. For financial penalties applicable to intentional infringements to be sufficiently dissuasive, they should be set at a level ***which is likely to offset*** the economic advantage sought by the perpetrator through the violation. Member States should also be required to apply appropriate criminal and/or administrative penalties in cases where operators fail to cooperate during an official control.

Amendment

(77) Infringements of the rules should be subject to effective, dissuasive and proportionate sanctions at national level throughout the Union. For financial penalties applicable to intentional infringements to be sufficiently dissuasive, they should be set at a level ***of at least double*** the economic advantage sought by the perpetrator through the violation. Member States should also be required to apply appropriate criminal and/or administrative penalties in cases where operators fail to cooperate during an official control.

Amendment 22

Proposal for a regulation

Recital 77 a (new)

Text proposed by the Commission

Amendment

(77a) Account should be taken of the specific needs of the developing countries, in particular the least developed countries, who should be given support in organising their official controls so that they can meet the criteria for the import of animals and goods into the EU.

Amendment 23

Proposal for a regulation

Recital 78

Text proposed by the Commission

(78) This Regulation covers areas that are already covered in certain acts currently in force. To avoid duplications and to establish a coherent legislative framework, the following acts should be repealed and replaced by the rules of this Regulation: Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters²³; Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market²⁴; Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market²⁵; Council Directive 91/496/EEC; Council Decision 92/438/EEC of 13 July 1992 on computerization of veterinary import procedures (Shift project), amending Directives 90/675/EEC, 91/496/EEC, 91/628/EEC **and Decision 90/424/EEC**, and repealing Decision 88/192/EEC²⁶; Council Directive 96/23/EC; Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products²⁷; Council Directive 97/78/EC; Regulation (EC) No 882/2004; **and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption²⁸.**

Amendment

(78) This Regulation covers areas that are already covered in certain acts currently in force. To avoid duplications and to establish a coherent legislative framework, the following acts should be repealed and replaced by the rules of this Regulation: Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters²³; Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market²⁴; Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market²⁵; Council Directive 91/496/EEC; Council Decision 92/438/EEC of 13 July 1992 on computerization of veterinary import procedures (Shift project), amending Directives 90/675/EEC, 91/496/EEC, 91/628/EEC and repealing Decision 88/192/EEC²⁶; Council Directive 96/23/EC; Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products²⁷; Council Directive 97/78/EC; Regulation (EC) No 882/2004.

²³ OJ L 351, 21.12.1989, p. 34.

²⁴ OJ L 395, 30.12.1989, p. 13.

²⁵ OJ L 224, 18.8.1990, p. 29.

²⁶ OJ L 243, 25.8.1992, p. 27.

²⁷ OJ L 13, 16.01.97, p. 28.

²⁸ *OJ L 139, 30.4.2004, p. 206.*

²³ O J L 351, 21.12.89, p. 34.

²⁴ OJ L 395, 30.12.89, p. 13.

²⁵ OJ L 224, 18.08.90, p. 29.

²⁶ O J L 243, 25.08.92, p. 27.

²⁷ OJ L 13, 16.01.97, p. 28.

Amendment 24

Proposal for a regulation

Recital 79

Text proposed by the Commission

(79) In order to ensure consistency, amendments should also be effected to the following acts: Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies²⁹; Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/9730; Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum levels of pesticides in or on food and feed of plant of animal origin and amending Council Directive 91/414/EEC³¹; Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) 2092/91³²; **Regulation (EC) No 1069/2009**; Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing³³; Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC³⁴; Regulation (EU) No 1151/2012 of the European

Amendment

(79) In order to ensure consistency, amendments should also be effected to the following acts: Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies²⁹; Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/9730; Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum levels of pesticides in or on food and feed of plant of animal origin and amending Council Directive 91/414/EEC³¹; Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) 2092/91³²; Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing³³; Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC³⁴; Regulation (EU) No 1151/2012 of the European Parliament and

Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs³⁵; Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes³⁶; Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens³⁷; Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed³⁸; Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition³⁹; Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production⁴⁰; Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves⁴¹; Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs⁴²; Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the Community action to achieve the sustainable use of pesticides⁴³.

²⁹ OJ L 147, 31.5.2001, p. 1.

³⁰ OJ L 3, 5.1.2005, p. 1.

³¹ OJ L 70, 16.3.2005, p. 1.

³² OJ L 189, 20.7.2007, p. 1.

³³ OJ L 303, 18.11.2009, p. 1.

³⁴ OJ L 309, 24.11.2009, p. 1.

³⁵ OJ L 343, 14.12.2012, p. 1.

³⁶ OJ L 221, 8.8.1998, p. 23.

³⁷ OJ L 203, 3.8.1999, p. 53.

³⁸ OJ L 268, 18.10.2003, p. 1.

³⁹ OJ L 268, 18.10.2003, p. 29.

⁴⁰ OJ L 812, 12.7.2007, p. 19.

of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs³⁵; Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes³⁶; Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens³⁷; Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed³⁸; Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition³⁹; Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production⁴⁰; Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves⁴¹; Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs⁴²; Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the Community action to achieve the sustainable use of pesticides⁴³.

²⁹ OJ L 147, 31.5.2001, p. 1.

³⁰ OJ L 3, 5.1.2005, p. 1.

³¹ OJ L 70, 16.3.2005, p. 1.

³² OJ L 189, 20.7.2007, p. 1.

³³ OJ L 303, 18.11.2009, p. 1.

³⁴ OJ L 309, 24.11.2009, p. 1.

³⁵ OJ L 343, 14.12.2012, p. 1.

³⁶ OJ L 221, 8.8.1998, p. 23.

³⁷ OJ L 203, 3.8.1999, p. 53.

³⁸ OJ L 268, 18.10.2003, p. 1.

³⁹ OJ L 268, 18.10.2003, p. 29.

⁴⁰ OJ L 812, 12.7.2007, p. 19.

⁴¹ OJ L 10, 15.1.2009, p. 7.

⁴² OJ L 47, 18.2.2009, p. 5.

⁴³ OJ L 309, 24.11.2009, p. 71.

⁴¹ OJ L 10, 15.1.2009, p. 7.

⁴² OJ L 47, 18.2.2009, p. 5.

⁴³ OJ L 309, 24.11.2009, p. 71.

Amendment 25

Proposal for a regulation Article 1 – paragraph 2

Text proposed by the Commission

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

(a) governing food **and** food safety, at any stage of production, the processing and distribution of food, including rules aimed at guaranteeing fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food;

(b) governing the deliberate release into the environment **and the contained use** of GMOs;

(c) governing feed and feed safety, at all stages of production, processing and distribution of feed and the use of feed, including rules aimed at guaranteeing fair practices in trade and protecting consumer interests and information;

(d) laying down animal health requirements,

(e) aiming at preventing and minimising risks to human and animal health arising from animal by-products and derived products;

(f) laying down welfare requirements for animals;

(g) on protective measures against pests of plants;

Amendment

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

(a) governing food, food safety, **food quality and food wholesomeness**, at any stage of production, the processing and distribution of food, including rules aimed at guaranteeing , fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food;

(b) governing the deliberate release into the environment of GMOs;

(c) governing feed and feed safety, at all stages of production, processing and distribution of feed and the use of feed, including rules aimed at guaranteeing fair practices in trade and protecting consumer **health**, interests and information;

(d) laying down animal health requirements,

(e) aiming at preventing and minimising risks to human and animal health arising from animal by-products and derived products;

(f) laying down welfare requirements for animals;

(g) on protective measures against pests of plants;

(h) on the production, with a view to placing on the market, and placing on the market of plant reproductive material;

(i) laying down requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides;

(j) governing organic production and labelling of organic products;

(k) on the use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed.

(i) laying down requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides;

(j) governing organic production and labelling of organic products;

(k) on the use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed.

Amendment 26

Proposal for a regulation

Article 1 – paragraph 2 – point e a (new)

Text proposed by the Commission

Amendment

(ea) aiming at preventing and minimising antimicrobial resistance in animals and humans, as well as in the environment;

Amendment 27

Proposal for a regulation

Article 1 – paragraph 2 – point k a (new)

Text proposed by the Commission

Amendment

(ka) laying down requirements on monitoring certain substances and residues thereof in live animals and animal products.

Amendment 28

Proposal for a regulation

Article 1 – paragraph 4 – point a

Text proposed by the Commission

Amendment

(a) the rules laid down in Regulation (EC) No 1234/2007;

(a) the rules laid down in Regulation (EC) No 1234/2007 ***in areas other than those under Part II, Title II, Chapter I of that Regulation. However, this Regulation***

shall apply to official controls on protected designations of origin and protected geographical indications for wine;

Amendment 29

Proposal for a regulation

Article 1 – paragraph 4 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the rules laid down in Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for veterinary use.

Amendment 30

Proposal for a regulation

Article 2 – paragraph 1 – point 1 – introductory part

Text proposed by the Commission

Amendment

1) 'official control' means any form of control that the competent authorities perform for the verification of compliance with:

1) 'official control' means any form of control, *also including controls of requirements for animals and goods from third countries intended for export to third countries*, that the competent authorities perform for the verification of compliance with:

Amendment 31

Proposal for a regulation

Article 2 – paragraph 1 – point 2 – point b

Text proposed by the Commission

Amendment

(b) the rules referred to in Article 1(2) to ensure the application of those rules;

(b) the rules referred to in article 1 (2), *except letter g*, to ensure the application of those rules.

Amendment 32

Proposal for a regulation

Article 2 – paragraph 1 – point 5 – point a

Text proposed by the Commission

(a) the central authorities of a Member State responsible for *the organisation of* official controls and *of* other official activities, *in accordance with* this Regulation and the rules referred to in Article 1(2);

Amendment

(a) the central authorities of a Member State responsible for *organising and carrying out* official controls and 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* this Regulation and the rules referred to in Article 1(2)

Amendment 33

Proposal for a regulation

Article 2 – paragraph 1 – point 6

Text proposed by the Commission

6. 'animals' means animals as defined in point (1) of Article 4(1) of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on animal health];

Amendment

6. 'animals' means animals as defined in point (1) of Article 4(1) of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on animal health] *with the exception of 'pets'*;

Amendment 34

Proposal for a regulation

Article 2 – paragraph 1 – point 14

Text proposed by the Commission

14. 'plant reproductive material' means plant reproductive material as defined in point (2) of Article 3 of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number, date, title and, in a footnote, the OJ reference for the Regulation on the production and making available on the market of plant reproductive material];

Amendment

deleted

Amendment 35

Proposal for a regulation

Article 2 – paragraph 1 – point 15

Text proposed by the Commission

15. 'plant protection products' means plant protection products as referred to in Article 2(1) of Regulation (EC) No 1107/2009;

Amendment

15. 'plant protection products' means plant protection products as referred to in Article 2(1) of Regulation (EC) No 1107/2009; **for the purposes of this Regulation, 'plant protection products' also refers to the active substances referred to in Article 2(2) of Regulation (EC) No 1107/2009 and other substances or preparations referred to in Article 2(3) of that Regulation;**

Amendment 36

Proposal for a regulation

Article 2 – point 16

Text proposed by the Commission

16. 'alien species' means a species, subspecies or lower taxon, introduced outside its natural past or present distribution and includes any part, gametes, seeds, eggs, or propagules of such species, as well as any hybrids, varieties or breeds, that might survive and subsequently reproduce;

Amendment

deleted

Amendment 37

Proposal for a regulation

Article 2 – point 25

Text proposed by the Commission

25. 'official attestation' means any label, mark or other form of attestation issued by **the operators under the supervision, through dedicated official controls, of** the competent authorities, or by the competent authorities themselves, and providing assurance concerning compliance with one or more requirements laid down in the

Amendment

25. 'official attestation' means any label, mark or other form of attestation issued by the competent authorities, or by the competent authorities themselves, and providing assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2);

rules referred to in Article 1(2);

Amendment 38

Proposal for a regulation

Article 2 – paragraph 1 – point 28 – point b

Text proposed by the Commission

(b) activities under the control of operators falling within the scope of the rules referred to in Article 1(2) and equipment, means of transport, substances **and** materials used to perform those activities;

Amendment

(b) activities under the control of operators falling within the scope of the rules referred to in Article 1(2) and equipment, means of transport, substances, materials, **plant protection products and precautionary measures** used to perform those activities;

Amendment 39

Proposal for a regulation

Article 2 – paragraph 1 – point 28 – point c a (new)

Text proposed by the Commission

Amendment

(ca) the documentation referred to in points a), b) and c);

Amendment 40

Proposal for a regulation

Article 2 – point 29

Text proposed by the Commission

29. 'border control post' means a **place**, and the facilities belonging to it, designated by a Member State to perform the official controls provided for in Article 45(1);

Amendment

29. 'border control post' means an **inspection centre**, and the facilities belonging to it, designated by a Member State to perform the official controls provided for in Article 45(1);

Amendment 41

Proposal for a regulation

Article 2 – paragraph 1 – point 30

Text proposed by the Commission

30. 'audit' means a systematic and independent examination to determine

Amendment

30. *Does not affect English version. Linguistic amendment to German and*

whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve objectives;

Spanish text.

Amendment 42

Proposal for a regulation

Article 2 – paragraph 1 – subparagraph 32 – introductory part

Text proposed by the Commission

32. 'official veterinarian' means a veterinarian appointed by the competent authorities and appropriately qualified to perform **the** official controls and other official activities in accordance with:

Amendment

32. 'official veterinarian' means a veterinarian appointed by the competent authorities and appropriately qualified to perform official controls and other official activities in accordance with:

Amendment 43

Proposal for a regulation

Article 2 – paragraph 1 – point 38

Text proposed by the Commission

38. 'delegated body' means a third party, to which the competent authorities have delegated specific **official control** tasks;

Amendment

38. 'delegated body' means **an independent** third party, to which the competent authorities have delegated specific tasks **relating to official controls and other official activities**;

Amendment 44

Proposal for a regulation

Article 2 – paragraph 1 – point 39

Text proposed by the Commission

39. 'control authority for organic **products**' means a public administrative organisation of a Member State to which the competent authorities have conferred, in whole or in part, their competences in relation to the **application** of Regulation (EC) No 834/2007, including, where appropriate, the corresponding authority of a third country or operating in a third country;

Amendment

39. 'control authority for organic **production**' means a public administrative organisation of a Member State to which the competent authorities have conferred, in whole or in part, their competences **for inspections and certification in the organic production sector**, in relation to the **provisions** of Regulation (EC) No 834/2007, including, where appropriate, the corresponding authority of

a third country or operating in a third country;

Amendment 45

Proposal for a regulation

Article 2 – paragraph 1 – point 44 – introductory part

Text proposed by the Commission

Amendment

44. 'equivalence' or 'equivalent' means:

44. 'equivalence' or 'equivalent' means ***systems that are broadly the same and meet the same objectives;***

Amendment 46

Proposal for a regulation

Article 2 – paragraph 1 – point 44 – point a

Text proposed by the Commission

Amendment

(a) the capability of different systems or measures to meet the same objectives;

deleted

Amendment 47

Proposal for a regulation

Article 2 – paragraph 1 – point 44 – point b

Text proposed by the Commission

Amendment

(b) different systems or measures capable of meeting the same objectives;

deleted

Amendment 48

Proposal for a regulation

Article 2 – paragraph 1 – point 49

Text proposed by the Commission

Amendment

49) 'transshipment' means the movement of goods subject to the official controls provided for in Article 45(1) which arrive by sea or by air transport from a third country from a vessel or aircraft and are transported under customs supervision to another vessel or aircraft in the same port

49) 'transshipment' means the movement of goods ***or animals*** subject to the official controls provided for in Article 45(1) which arrive by sea or by air transport from a third country from a vessel or aircraft and are transported under customs supervision to another vessel or aircraft in the same port or airport in preparation for onward

or airport in preparation for onward travel;

travel;

Amendment 49

Proposal for a regulation

Article 2 – paragraph 1 – point 53

Text proposed by the Commission

53. 'official detention' means the procedure by which the competent authorities ensure that animals and goods subject to official controls are not moved or tampered with pending a decision on their destination; it includes storage by operators under the control of the competent authorities;

Amendment

53. 'official detention' means the procedure by which the competent authorities ensure that animals and goods subject to official controls are not moved or tampered with pending a decision on their destination; it includes storage by operators ***in accordance with the instructions and*** under the control of the competent authorities;

Amendment 50

Proposal for a regulation

Article 2 – paragraph 1 – point 57 a (new)

Text proposed by the Commission

Amendment

(57a) “Official auxiliary” means a person qualified, in accordance with Annex III a of this Regulation, to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian.

Amendment 51

Proposal for a regulation

Article 3 – paragraph 1

Text proposed by the Commission

1. For each of the areas governed by the rules referred to in Article 1(2), Member States shall ***designate the*** competent ***authority or*** authorities ***on which they confer the responsibility to perform*** official controls ***and other official activities.***

Amendment

1. For each of the areas governed by the rules referred to in Article 1(2), Member States shall ***have one or more*** competent authorities ***responsible for planning, organising and where necessary performing*** official controls.

Amendment 52

Proposal for a regulation

Article 3 – paragraph 2 – introductory part

Text proposed by the Commission

2. Where, for the same area, a Member State ***confers the responsibility to perform official controls or other official activities on*** more than one competent authority, at national, regional or local level, or where the competent authorities designated in accordance with paragraph 1 are allowed ***by that designation*** to transfer specific responsibilities for official controls ***or other official activities*** to other public authorities, ***the Member State*** shall:

Amendment

2. Where, for the same area, a Member State ***has*** more than one competent authority, at national, regional or local level, or where the competent authorities designated in accordance with paragraph 1 are allowed to transfer specific responsibilities for official controls to other public authorities, ***care shall be taken to ensure that:***

Amendment 53

Proposal for a regulation

Article 3 – paragraph 2 – point a

Text proposed by the Commission

a) ***put in place*** procedures to ensure efficient and effective coordination between all authorities involved, and the consistency and effectiveness of official controls or other official activities across its territory;

Amendment

a) procedures ***are put in place*** to ensure efficient and effective coordination between all authorities involved, and the consistency and effectiveness of official controls or other official activities across ***the whole of*** its territory;

Amendment 54

Proposal for a regulation

Article 3 – paragraph 2 – point b

Text proposed by the Commission

b) designate a single authority responsible to coordinate the cooperation and the contacts with the Commission and other Member States in relation to the official controls and other official activities performed in ***that area***.

Amendment

b) designate a single authority responsible to coordinate the cooperation and the contacts with the Commission and other Member States in relation to the official controls and other official activities performed in ***each of the sectors defined by the Member State, in such a way as to cover all the areas referred to in Article 1(2)***.

Amendment 55

Proposal for a regulation

Article 3 – paragraph 3

Text proposed by the Commission

3. Competent authorities responsible for the verification of compliance with the rules referred to in point (j) of Article 1(2) may confer specific official control tasks to one or more control authorities for organic **products**. In such cases, they shall attribute a code number to each of them.

Amendment

3. Competent authorities responsible for the verification of compliance with the rules referred to in point (j) of Article 1(2) may confer specific official control tasks to one or more control authorities for organic **production**. In such cases, they shall attribute a code number to each of them.

Amendment 56

Proposal for a regulation

Article 3 – paragraph 5

Text proposed by the Commission

5. Member States may confer to the competent authorities referred to in paragraph 1 the responsibility to carry out controls for the verification of compliance with, or for the application of, rules, **including those regulating specific risks which may arise from the presence of alien species in the Union**, other than those referred to in Article 1(2).

Amendment

5. Member States may confer to the competent authorities referred to in paragraph 1 the responsibility to carry out controls for the verification of compliance with, or for the application of, rules, other than those referred to in Article 1(2).

Amendment 57

Proposal for a regulation

Article 3 – paragraph 6

Text proposed by the Commission

6. The Commission may, by means of implementing acts, determine the means by which the information referred to in paragraph 4 is to be made available to the public. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Amendment

6. The Commission may, by means of implementing acts, determine the means by which the information referred to in paragraph 4 is to be made available to the public. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2). **The means by which the information referred to in paragraph 4 is to be made available to the public shall in**

any case include publication on the internet.

Amendments 58 and 341

Proposal for a regulation Article 4

Text proposed by the Commission

1. The competent authorities shall:
- (a) have procedures and arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities;
 - (b) have arrangements in place to ensure the impartiality, quality and consistency of official controls and other official activities at all levels;
 - (c) have arrangements in place to ensure that staff performing official controls and other official activities are free from any conflict of interest;
 - (d) have, or have access to, an adequate laboratory capacity for analysis, testing and diagnosis;
 - (e) have, or have access to, a sufficient number of suitably qualified and experienced staff so that official controls and other official activities can be performed efficiently and effectively;
 - (f) have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls and other official activities efficiently and effectively;
 - (g) have the legal powers to perform official controls and other official activities

Amendment

1. The competent authorities shall:
- (a) have procedures and arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities;
 - (b) 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;***
 - (c) have arrangements in place to ensure that staff performing official controls and other official activities are ***independent, impartial, and*** free from any conflict of interest, ***and have no improper connection from which they stand to make economic gain or which might jeopardise their impartiality;***
 - (d) have, or have access to, an adequate laboratory capacity for analysis, testing and diagnosis;
 - (e) have, or have access to, a sufficient number of ***independent, suitably qualified and experienced staff (with regard to the control requirements under Article 1(1) and (2),*** so that official controls and other official activities can be performed ***fully,*** efficiently and effectively;
 - (f) have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls and other official activities efficiently and effectively;
 - (g) have the legal powers to perform official controls and other official activities

and to take the action provided for in this Regulation and in the rules referred to in Article 1(2);

(h) have legal procedures in place in order to ensure that staff have access to the premises of and documents kept by operators so as to be able to accomplish their tasks properly;

(i) have contingency plans in place, and be prepared to operate such plans in the event of an emergency, where appropriate in accordance with the rules referred to in Article 1(2).

2. Staff performing official controls and other official activities shall:

(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to perform official controls and other official activities in a consistent manner;

(b) keep up-to-date in their area of competence and receive regular additional training as necessary;

(c) receive training in the subject matters set out in Chapter I of Annex II and on the obligations of the competent authorities resulting from this Regulation.

Competent authorities shall develop and implement training programmes for the purpose of ensuring that staff performing official controls and official activities receive the training referred to in points (a), (b) and (c).

3. For the purpose of ensuring that the staff of the competent authorities referred to in point (e) of paragraph 1 and in paragraph 2 have the necessary qualifications, skills and knowledge, the Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules for the specific qualification and training requirements of

and to take the action provided for in this Regulation and in the rules referred to in Article 1(2);

(h) have legal procedures in place in order to ensure that staff have access to the premises of and documents kept by operators so as to be able to accomplish their tasks properly;

(i) have contingency plans in place, and be prepared to operate such plans in the event of an emergency, where appropriate in accordance with the rules referred to in Article 1(2).

2. Staff performing official controls and other official activities shall:

(-a) 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;

(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to perform official controls and other official activities in a consistent manner;

(b) keep up-to-date in their area of competence and receive regular additional training as necessary;

(c) receive training in the subject matters set out in Chapter I of Annex II and on the obligations of the competent authorities resulting from this Regulation.

Competent authorities shall develop and implement training programmes for the purpose of ensuring that staff performing official controls and official activities receive the training referred to in points (a), (b) and (c).

such staff, having regard to the scientific and technical knowledge necessary to perform official controls and other official activities in each of the areas referred to in Article 1(2).

4. When, within the *services of* a competent authority, more than one unit is competent to perform official controls or other official activities, efficient and effective coordination and cooperation shall be ensured between the different units.

4. When, within the *activities carried out by* a competent authority, more than one unit is competent to perform official controls or other official activities, efficient and effective coordination and cooperation shall be ensured between the different units.

Amendment 59

Proposal for a regulation Article 5 – paragraph 2

Text proposed by the Commission

2. Competent authorities shall make available the results of the audits referred to in paragraph 1 to the Commission upon request.

Amendment

2. Competent authorities shall make available the results of the audits referred to in paragraph 1 to the Commission upon *justified* request.

Amendment 60

Proposal for a regulation Article 7

Text proposed by the Commission

1. Competent authorities shall require members of their staff not to disclose information acquired when undertaking their duties in the context of official controls and other official activities which by its nature is covered by professional secrecy, *subject to paragraph 2.*

2. Unless there is an overriding public interest in its disclosure, information covered by professional secrecy as referred to in paragraph 1 shall include information whose disclosure would undermine:

(a) the purpose of inspections,

Amendment

1. Competent authorities shall require members of their staff not to disclose, *except within the competent authority,* information acquired when undertaking their duties in the context of official controls and other official activities which by its nature is covered by professional secrecy.

2. Unless there is an overriding public interest in its disclosure, *or disclosure is required by other Union legislation,* information covered by professional secrecy as referred to in paragraph 1 shall include information whose disclosure would undermine:

(a) the purpose of inspections,

- investigations or audits;
- (b) the protection of commercial interests of a natural or legal person;
- (c) *the protection of* court proceedings and legal advice.

3. Paragraphs 1 and 2 *shall not prevent* the competent authorities *from* publishing or making otherwise available to the public information about the outcome of official controls regarding individual operators, provided that the following conditions are met:

- (a) the operator concerned is given the opportunity to comment on the information that the competent authority intends to publish or make otherwise available to the public, prior to the publication or release;
- (b) the information which is published or made otherwise available to the public takes into account the comments expressed by the operator concerned or is published or released together with such comments.

- investigations or audits;
- (b) the protection of commercial interests of a natural or legal person;
- (c) *ongoing* court proceedings and legal advice.

(ca) the decision-making process of competent authorities.

2a. The competent authorities, when determining whether there is an overriding public interest in disclosure, shall take into account inter alia the following elements:

- (a) possible risks to human, animal or plant health, or to the environment;*
- (b) the nature, severity and extent of such risks, so as to ensure that disclosure is proportionate in the circumstances;*

3. *Without prejudice to* Paragraphs 1 and 2, the competent authorities *shall* publish or make otherwise available to the public information about the outcome of official controls regarding individual operators, provided that the following conditions are met:

- (a) the operator concerned is given the opportunity to comment on the information that the competent authority intends to publish or make otherwise available to the public, prior to the publication or release;
- (b) the information which is published or made otherwise available to the public takes into account the comments expressed by the operator concerned or is published or released *simultaneously and* together with such comments.

3a. Competent authorities shall ensure that any information published or made available to the public pursuant to this Article is accurate and that, if any such information eventually proves to be inaccurate, it is appropriately rectified.

Amendment 61

Proposal for a regulation

Article 8 – paragraph 1 – introductory part

Text proposed by the Commission

1. Competent authorities shall perform official controls on all **operators** regularly, on a risk basis and with appropriate frequency, taking account of:

Amendment

1. Competent authorities shall perform official controls on all **undertakings** regularly, on a risk basis and with appropriate frequency, taking account of:

Amendment 62

Proposal for a regulation

Article 8 – paragraph 1 – point a – point ii

Text proposed by the Commission

(ii) the activities under the control of operators;

Amendment

(ii) the activities **and precautionary measures** under the control of operators;

Amendment 63

Proposal for a regulation

Article 8 – paragraph 1 – point a – point iv

Text proposed by the Commission

(iv) the use of products, processes, materials or substances that may influence food **or** feed safety, animal health or animal welfare, plant health or **plant reproductive material identity and quality**, or, in the case of GMOs and plant protection products, may adversely impact on the environment;

Amendment

(iv) the use of products, processes, materials, **feed additives** or substances that may influence food **safety and wholesomeness**, feed safety, animal health or animal welfare, plant health or, in the case of GMOs and plant protection products, may adversely impact on the environment;

Amendment 64

Proposal for a regulation

Article 8 – paragraph 1 – point a – point iv a (new)

Text proposed by the Commission

Amendment

(iva) 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.

Amendment 65

Proposal for a regulation

Article 8 – paragraph 1 – point a – point iv a (new)

Text proposed by the Commission

Amendment

(iva) the process requirements according to article 1(2)(j);

Amendment 66

Proposal for a regulation

Article 8 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) *operators'* past record as regards the results of official controls performed on them and their compliance with the rules referred to in Article 1(2);

(b) *undertakings'* past record as regards the results of official controls performed on them and their compliance with the rules referred to in Article 1(2);

Amendment 67

Proposal for a regulation

Article 8 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) the reliability and results of own controls that have been performed by the operators, or by a third party at their request, for the purpose of ascertaining compliance with the rules referred to in Article 1(2);

(c) the reliability and results of own controls that have been performed by the operators, or by a third party at their request, for the purpose of ascertaining compliance with the rules referred to in Article 1(2). *Transfer of information on these own controls shall be utilised as much as possible, in a manner that minimizes the burden on operators;*

Amendment 68

Proposal for a regulation

Article 8 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) consumer expectations regarding nature, quality and composition of foods

and goods;

Amendment 69

Proposal for a regulation

Article 8 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) private quality assurance schemes put in place by operators, which are certified and audited by independent and recognised certification bodies.

Amendment 70

Proposal for a regulation

Article 8 – paragraph 2

Text proposed by the Commission

Amendment

2. Competent authorities shall perform official controls on a regular basis and with appropriate frequency to identify possible intentional violations of the rules referred to in Article 1(2), taking into account, in addition to the criteria referred to in paragraph 1, information regarding such possible intentional violations shared through the mechanisms of administrative assistance provided for in Title IV and any other information pointing to the possibility of such violations.

2. Competent authorities shall perform official controls on a regular basis and with appropriate frequency to identify possible intentional violations of the rules referred to in Article 1(2), ***to verify compliance with the requirements and process criteria according to Article 1(2)(j)***, taking into account, in addition to the criteria referred to in paragraph 1, information regarding such possible intentional violations shared through the mechanisms of administrative assistance provided for in Title IV and any other information pointing to the possibility of such violations.

Amendment 71

Proposal for a regulation

Article 8 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 in order to establish a uniform minimum frequency for carrying out the controls referred to in paragraphs 1 and 2. Where necessary, such minimum

frequency, based on risk, shall be established differently for each product, process or activity that is subject to official controls pursuant to this Regulation.

Amendment 72

Proposal for a regulation Article 8 – paragraph 4 – point a

Text proposed by the Commission

Amendment

(a) prior notification of the operator is necessary;

deleted

Amendment 73

Proposal for a regulation Article 8 – paragraph 4 – point b

Text proposed by the Commission

Amendment

(b) the operator has requested such official controls.

(b) the operator has requested such official controls. *Such announced controls cannot replace standard controls without prior warning.*

Amendment 74

Proposal for a regulation Article 8 – paragraph 4 – point b a (new)

Text proposed by the Commission

Amendment

ba. audits for verification of requirements in accordance with Article 1(2)(j) are performed.

Amendment 75

Proposal for a regulation Article 8 – paragraph 5

Text proposed by the Commission

Amendment

5. Official controls shall be performed as much as possible in a manner that

5. Official controls shall be performed as much as possible in a manner that the *administrative burden and operational*

minimises the burden *on the* operators.

disruption for operators is kept to the necessary minimum, but without this affecting the quality of the control negatively; to that end, where the same operator is subject to various official controls over the same period, the competent authority shall aggregate them. Where various official controls are applied to operators, Member States shall ensure a coordinated approach with the aim of combining existing control measures.

Amendment 76

Proposal for a regulation Article 8 – paragraph 7

Text proposed by the Commission

7. To the extent *strictly* necessary for the organisation of the official controls, Member States of destination *may* require operators who have animals or goods delivered to them from another Member State to report the arrival of such animals or goods.

Amendment

7. To the extent necessary for the organisation of the official controls, Member States of destination *shall* require operators who have animals or goods delivered to them from another Member State to report the arrival of such animals or goods.

Amendment 77

Proposal for a regulation Article 9 – title

Text proposed by the Commission

Persons, processes *and* activities subject to official controls

Amendment

Persons, processes, activities, *methods and techniques* subject to official controls

Amendment 78

Proposal for a regulation Article 9 – paragraph 1 – point a

Text proposed by the Commission

(a) on animals and goods at all stages of production, processing and distribution;

Amendment

(a) on animals and goods at all stages of production, processing, *marketing*, and distribution;

Amendment 79

Proposal for a regulation

Article 9 – paragraph 1 – point b

Text proposed by the Commission

(b) on substances, materials or objects which may influence the characteristics of animals and goods, at all stages of production, processing and distribution;

Amendment

(b) on substances, materials or **other** objects which may influence the characteristics **or health** of animals and goods, at all stages of production, processing and distribution;

Amendment 80

Proposal for a regulation

Article 9 – paragraph 1 – point c

Text proposed by the Commission

(c) on operators and the activities and operations under their control, on their premises and processes, on the storage, transport, and the use of goods and the keeping of animals.

Amendment

(c) on operators and the activities and operations under their control, on their premises, **land, crops** and processes, on the storage, transport, and the use of goods and **on** the keeping of animals.

Amendment 81

Proposal for a regulation

Article 9 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) on all documentation, including documentation kept in electronic form, linked to the activity being performed, or to operations including transport.

Amendment 82

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

1. Competent authorities shall perform official controls with a high level of transparency and make available to the public relevant information concerning the

Amendment

1. Competent authorities shall perform official controls with a high level of transparency and make available to the public relevant information concerning the

organisation and the performance of official controls.

They shall also ensure the regular and timely publication of information on the following:

- (a) the type, number and outcome of official controls;
- (b) the type and the number of non-compliances detected;
- (c) the cases where measures were taken by the competent authorities in accordance with Article 135;
- (d) the cases where the penalties referred to in Article 136 were imposed.

organisation and the performance of official controls.

They shall also ensure the regular publication of information, *at least once a year*, on the following:

- (a) the type, number and *final* outcome of official controls;
- (b) the type and the number of non-compliances detected;
- (c) the *type and number of* cases where measures were taken by the competent authorities in accordance with Article 135;
- (d) the *type and number of* cases where the penalties referred to in Article 136 were imposed.

Amendment 83

Proposal for a regulation Article 10 – paragraph 2

Text proposed by the Commission

2. To ensure the uniform implementation of the rules provided for in paragraph 1 of this Article, the Commission shall, *by means of implementing acts, lay down and update as necessary the format in which the information referred to in that paragraph shall be published. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).*

Amendment

2. To ensure the uniform implementation of the rules provided for in paragraph 1 of this Article, the Commission shall *provide Member States with appropriate guidance documents, including a proposal for a standardised reporting format, which shall in any case include the publication on the internet.*

Amendment 84

Proposal for a regulation Article 10 – paragraph 3

Text proposed by the Commission

3. Competent authorities shall be entitled to publish or make otherwise available to the public information about the rating of individual operators based on the outcome of official controls, provided that the following conditions are met:

Amendment

3. Competent authorities shall be entitled to publish or make otherwise available to the public information about the rating of individual operators based on the outcome of *the last four* official controls, provided that the following conditions are met:

- (a) the rating criteria are objective, transparent and publicly available;
- (b) appropriate arrangements are in place to ensure the consistency and transparency of the rating process.

- (a) the rating criteria are objective, transparent and publicly available;
- (b) appropriate arrangements are in place to ensure the consistency and transparency of the rating process.

(ba) subsequent inspections are carried out without delay if the findings are unfavourable;

Amendment 85

Proposal for a regulation Article 10 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. To enable rating systems to be compared from one Member State to another, the Commission shall, by means of delegated acts and in consultation with the stakeholders, lay down guidelines to establish objective criteria which shall be made available to the Member States and which they may use on a voluntary basis.

Amendment 86

Proposal for a regulation Article 12 – title

Text proposed by the Commission

Amendment

Reports on official controls

Recording of, and reports on, official controls

Amendment 87

Proposal for a regulation Article 12 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

Competent authorities shall ***draw up reports on*** every official control that they ***perform***.

Competent authorities shall ***keep documentary records of*** every official control that they ***have performed***. ***They shall draw up reports on controls in which this Regulation or the provisions of Article 1(2) were found to have been***

infringed.

Amendment 88

Proposal for a regulation

Article 12 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The outcome of official controls performed at a border control post shall be recorded in the Common Health Entry Document in accordance with Article 54(2)(b).

Amendment 89

Proposal for a regulation

Article 13 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

2. Official controls shall include the following, ***as appropriate***:

2. Official controls shall include the following:

Amendment 90

Proposal for a regulation

Article 13 – paragraph 2 – point b – point ii a (new)

Text proposed by the Commission

Amendment

(iia) materials intended to come into contact with food;

Amendment 91

Proposal for a regulation

Article 13 – paragraph 2 – point e

Text proposed by the Commission

Amendment

(e) an examination of documents and other records which may be relevant to the assessment of compliance with the rules referred to in Article 1(2);

(e) an examination of documents, ***traceability records*** and other records which may be relevant to the assessment of compliance with the rules referred to in Article 1(2);

Amendment 326

Proposal for a regulation

Article 13 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Specific rules for the performance of official controls shall always take into account not only potential health risks, but also consumer expectations with regard to food composition and the likelihood of fraudulent practices.

Amendment 92

Proposal for a regulation

Article 14 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. To the extent that this is necessary for the performance of official controls or of other official activities, operators shall, where required by the competent authorities, give staff of the competent authorities access to:

1. To the extent that this is necessary for the performance of official controls or of other official activities, operators shall, where required by the competent authorities, give staff of the competent authorities ***and staff of the delegated bodies, where specific official control tasks have been delegated in accordance with the provisions of Article 25,*** access to:

Amendment 93

Proposal for a regulation

Article 14 – paragraph 1 – point d

Text proposed by the Commission

Amendment

(d) their documents and any other ***relevant*** information.

(d) their ***relevant*** documents and any other information, ***including the results of potential own tests, that is relevant for the purpose of performing such controls or activities and the control subjects listed in Article 13(2). Every operator shall be able to indicate at least each operator he is***

supplied by and each operator he is supplying.

Amendment 94

Proposal for a regulation Article 14 – paragraph 2

Text proposed by the Commission

2. During official controls and other official activities, operators shall assist the staff of the competent authorities in the accomplishment of their tasks.

Amendment

2. During official controls and other official activities, operators shall assist the staff of the competent authorities ***and the delegated bodies, pursuant to Article 25,*** in the accomplishment of their ***control*** tasks. ***Operators shall supply the competent authorities with sufficient quantities of samples free of charge.***

Amendment 95

Proposal for a regulation Article 14 – paragraph 3 – point b

Text proposed by the Commission

(b) make available all information concerning the consignment on paper or electronically.

Amendment

(b) make available ***without delay*** all ***requested*** information concerning the consignment on paper or electronically.

Amendment 96

Proposal for a regulation Article 14 – paragraph 4 – point a

Text proposed by the Commission

(a) establishing the modalities for access by the competent authorities to the computerised information management systems referred to in paragraph 1(b);

Amendment

(a) establishing the modalities for access by the competent authorities ***and the delegated bodies, pursuant to Article 25,*** to the computerised information management systems referred to in paragraph 1(b);

Amendment 97

Proposal for a regulation Article 15

Text proposed by the Commission

Amendment

-1. Official controls performed to verify compliance with the rules referred to in Article 1(2) in relation to products of animal origin intended for human consumption shall always include the verification of compliance with the requirements laid down in Regulation (EC) No 852/2004 in Regulation (EC) No 853/2004 and in Regulation (EC) No 1069/2009 as applicable, and at least of the following, as appropriate:

(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.

1. ***Official*** controls on the production of meat shall include:

(a) the verification, by ***or under the*** responsibility ***of*** an official ***veterinarian, of the health and welfare of the animals prior to the slaughter;***

(b) official controls, by or ***under*** the responsibility of an official veterinarian, in slaughterhouses, cutting plants and game handling establishments, to verify compliance with the requirements applicable to:

1. ***The official*** controls referred to in ***paragraph 1*** performed in relation to the production of meat shall include:

(a) the verification, by ***an official veterinarian or by*** an official ***auxiliary working under an official veterinarian's*** responsibility,

(b) official controls, by an official veterinarian or by ***an official auxiliary working under an official veterinarian's*** responsibility, in slaughterhouses, cutting and ***processing*** plants and game handling establishments, to verify compliance with the requirements applicable to:

- (i) the hygiene of meat production;
- (ii) the presence of residues of veterinary medicinal products in products of animal origin intended for human consumption;
- (iii) the handling and disposal of animal by-products and of specified risk material;
- (iv) the health and welfare of the animals.

- (i) the hygiene of meat production;
- (ii) the presence of residues of veterinary medicinal products in products of animal origin intended for human consumption;
- (iii) the handling and disposal of animal by-products and of specified risk material;
- (iv) the health and welfare of the animals.

1a. For the purposes of the official controls referred to in paragraph 2:

(a) at least one official veterinarian shall be present during both the ante-mortem and post-mortem inspection or, in the case of game-handling establishments, during the post-mortem inspection;

(b) 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.

1b. Following the official controls referred to in paragraph 2, actions and measures in accordance with Article 135 in relation to the animals, their welfare and the destination of meat shall be taken by or under the responsibility of the official veterinarian.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning specific rules for the performance of official controls on products of animal origin intended for human consumption and on animals intended for the production of such products to verify compliance with the rules referred to in points (a), (c), (d) and (e) of Article 1(2) applicable to those products and animals, and on action to be taken by the competent authorities following official controls. Those delegated acts shall lay down rules on:

- (a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in paragraph 1 and in Articles 4, 8, 9, 10(1), 11, 12, 13, 34(1) and (2), and 36;
- (b) uniform specific requirements for the

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning specific rules for the performance of official controls on products of animal origin intended for human consumption and on animals intended for the production of such products to verify compliance with the rules referred to in points (a), (c), (d) and (e) of Article 1(2) applicable to those products and animals, and on action to be taken by the competent authorities following official controls. Those delegated acts shall lay down rules on:

- (a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in paragraph 1 and in Articles 4, 8, 9, 10(1), 11, 12, 13, 34(1) and (2), and 36;
- (b) uniform specific requirements for the

performance of official controls and uniform minimum frequency of such official controls, having regard, in addition to the criteria referred to in Article 8(1), to the specific hazards and risks which exist in relation to each product of animal origin and the different processes it undergoes;

(c) the cases where and the conditions under which slaughterhouse staff **may be involved in official controls**, and the design and application of tests to assess their performance;

(d) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph;

(e) criteria to determine **when**, on the basis of a risk analysis, the official veterinarian **is not required to be present** in slaughterhouses and game handling establishments **during the official controls referred** to in paragraph 1.

Where, in cases of risks which cannot be effectively addressed in the absence of common specifications for the official controls or for the action to be taken by the competent authorities following such official controls, imperative grounds of urgency so require, the procedure provided for in Article 140 shall apply to delegated acts adopted pursuant to this paragraph.

3. The Commission shall take into account the following when adopting delegated acts as provided for in paragraph 2:

(a) the experience gained by food business operators on the application of the

performance of official controls and uniform minimum frequency of such official controls, having regard, in addition to the criteria referred to in Article 8(1), to the specific hazards and risks which exist in relation to each product of animal origin and the different processes it undergoes;

(c) the cases where and the conditions under which slaughterhouse staff **appropriately qualified and trained, and employed under the control of the official veterinarian in a unit which is segregated and independent from the production units of the establishment, may assist the official veterinarian when performing the official controls referred to in paragraph 2 in relation to the production of meat from poultry and largomorphs**, and the design and application of tests to assess their performance;

(d) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph;

(e) criteria to determine, on the basis of a risk analysis, the **conditions and the frequency of the official control tasks to be carried out by the** official veterinarian in **low throughput** slaughterhouses and **in** game handling establishments, respecting the minimum requirement laid down in paragraph 1a (a).

Where, in cases of risks which cannot be effectively addressed in the absence of common specifications for the official controls or for the action to be taken by the competent authorities following such official controls, imperative grounds of urgency so require, the procedure provided for in Article 140 shall apply to delegated acts adopted pursuant to this paragraph.

3. The Commission shall take into account the following when adopting delegated acts as provided for in paragraph 2:

(a) the experience gained by **competent authorities and** food business operators on

procedures referred to in Article 5 of Regulation (EC) 852/2004 of the European Parliament and of the Council⁴⁸;

(b) scientific and technological developments;

(c) consumer expectations with regard to food composition and changes in patterns of consumption of food;

(d) risks to human health and animal health associated with meat and other products of animal origin intended for human consumption.

4. Insofar as this does not prevent the achievement of the objectives of human health and animal health pursued by the rules referred to in points (a), (c), (d) and (e) of Article 1(2), applicable to products of animal origin intended for human consumption and to animals intended for the production of such products, the Commission shall also take into account the following elements, when adopting delegated acts as provided for in paragraph 2:

(a) the need ***to facilitate the application of*** the delegated acts in small businesses;

(b) the need to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food;

(c) the needs of food businesses situated in regions that are subject to special geographic constraints.

⁴⁸ OJ L 139, 30.4.2004, p. 1.

the application of the procedures referred to in Article 5 of Regulation (EC) 852/2004 of the European Parliament and of the Council⁴⁸;

(b) scientific and technological developments;

(da) consideration of any evidence of the presence of fraudulent practices.

4. Insofar as this does not prevent the achievement of the objectives of human health and animal health pursued by the rules referred to in points (a), (c), (d) and (e) of Article 1(2), applicable to products of animal origin intended for human consumption and to animals intended for the production of such products, the Commission shall also take into account the following elements, when adopting delegated acts as provided for in paragraph 2:

(a) the need for the delegated acts ***to commensurate with the nature and the size of*** small businesses ***to demonstrate an effective application;***

(b) the need to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food;

(c) the needs of food businesses situated in regions that are subject to special geographic constraints.

⁴⁸ OJ L 139, 30.4.2004, p. 1.

Amendment 327

Proposal for a regulation

Article 16 – paragraph 1 – introductory part

Text proposed by the Commission

The Commission shall be empowered to adopt ***delegated acts in accordance with Article 139*** concerning rules on official controls performed to verify compliance with the rules referred to in point (a) of Article 1(2) applicable to certain substances whose use on crops or animals or to produce or process food or feed may result in residues of those substances in food or feed, and on action to be taken by the competent authorities following official controls. Those ***delegated acts*** shall take account of the need to ensure a minimum level of official controls to prevent the use of those substances in violation of the rules referred to in point (a) of Article 1(2), and lay down rules on:

Amendment 98

Proposal for a regulation
Article 17 – title

Text proposed by the Commission

Specific rules on official controls and on action to be taken by the competent authorities in relation to animals, products of animal origin, germinal products, ***animal by-products and derived products***

Amendment 99

Proposal for a regulation
Article 17 – paragraph -1 (new)

Text proposed by the Commission

Amendment

The Commission shall be empowered to adopt ***legislative proposals*** concerning rules on official controls performed to verify compliance with the rules referred to in point (a) of Article 1(2) applicable to certain substances whose use on crops or animals or to produce or process food or feed may result in residues of those substances in food or feed, and on action to be taken by the competent authorities following official controls. Those ***legislative proposals*** shall take account of the need to ensure a minimum level of official controls to prevent the use of those substances in violation of the rules referred to in point (a) of Article 1(2), and lay down rules on:

Amendment

Specific rules on official controls and on action to be taken by the competent authorities in relation to animals, products of animal origin, ***and*** germinal products

Official controls in relation to animals shall include:

- the verification of measures for protection against biological and chemical hazards to human and animal health;

- the verification of animal welfare

measures, without prejudice to the provisions of Article 18;

- the verification of disease control or eradication measures.

Amendment 100

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

The Commission shall be empowered to adopt *delegated acts in accordance with Article 139* concerning rules for the performance of official controls on animals, on products of animal origin, on germinal products, on animal by-products and on derived products to verify compliance with the Union rules referred to in points (d) and (e) of Article 1(2) and on action to be taken by the competent authorities following official controls. Those *delegated acts* shall take account of animal health risks related to animals, products of animal origin and germinal products, *and of human and animal health risks related to animal by-products and derived products*, and lay down rules on:

Amendment

The Commission shall be empowered to adopt *legislative proposals* concerning rules for the performance of official controls on animals, on products of animal origin, on germinal products, on animal by-products and on derived products to verify compliance with the Union rules referred to in points (d) and (e) of Article 1(2) and on action to be taken by the competent authorities following official controls. Those *legislative proposal* shall take account of animal health risks related to animals, products of animal origin and germinal products, and lay down rules on:

Amendment 101

Proposal for a regulation

Article 17 – paragraph 1 – point a

Text proposed by the Commission

(a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Articles **4, 8, 9**, 10(1), 11, 12, **13**, 34(1) and (2) *and 36*;

Amendment

(a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Articles 10(1), 11, 12, *and* 34(1) and (2);

Amendment 102

Proposal for a regulation

Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

1. Official controls to verify compliance with the rules laying down welfare requirements for animals in case of their transport shall include:

Amendment

1. ***In addition to the general rules on official controls provided for in Article 8,*** official controls to verify compliance with the rules laying down welfare requirements for animals in case of their transport shall include:

Amendment 103

Proposal for a regulation

Article 18 – paragraph 1 – point c – point i

Text proposed by the Commission

(i) official controls on the fitness of the animals being transported and on the means of transport;

Amendment

(i) official controls on the fitness of the animals being transported and on the means of transport ***to verify compliance with Chapter II and where applicable Chapter VI of Annex I to Regulation (EC) No 1/1005;***

Amendment 104

Proposal for a regulation

Article 18 – paragraph 1 – point c – point ii

Text proposed by the Commission

(ii) official controls to verify that transporters comply with applicable international agreements and have valid transporter authorisations and certificates of competence for drivers and attendants;

Amendment

(ii) official controls to verify that transporters comply with applicable international agreements, ***including the European Convention for the protection of animals during international transport*** and have valid transporter authorisations and certificates of competence for drivers and attendants;

Amendment 105

Proposal for a regulation

Article 18 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) following official controls under point (c) (i) of this paragraph, where the view of the competent authority is that animals are unfit for transport, they shall be unloaded, watered, fed and rested and veterinary assistance must be sought if necessary, until fit to continue their journey.

Amendment 106

Proposal for a regulation

Article 18 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) in case of long journeys between Member States and with third countries, official controls performed at any stage of the long journey on a random or targeted basis to verify that declared journey times are realistic and that the journey complies with Regulation (EC) No 1/2005 and in particular that travel times and rest periods have complied with the limits set out in Chapter V of Annex I to Regulation (EC) No 1/2005;

Amendment 107

Proposal for a regulation

Article 18 – paragraph 3 – introductory part

Text proposed by the Commission

Amendment

3. The Commission shall be empowered to adopt ***delegated acts in accordance with Article 139*** concerning rules for the performance of official controls to verify compliance with Union rules referred to in point (f) of Article 1(2). Those ***delegated acts*** shall take into account the animal welfare risk related to the farming activities and to the transport, slaughter and killing of animals, and shall lay down rules on:

3. The Commission shall be empowered to adopt ***legislative proposals*** concerning rules for the performance of official controls to verify compliance with Union rules referred to in point (f) of Article 1(2). Those ***legislative proposals*** shall take into account the animal welfare risk related to the farming activities and to the transport, slaughter and killing of animals, and shall lay down rules on:

Amendment 108

Proposal for a regulation

Article 18 – paragraph 3 – point a

Text proposed by the Commission

(a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in paragraph 1 and Articles 4, 8, 9, 10(1), 11, 12, 13, **34(1) and (2), and 36**;

Amendment

(a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in paragraph 1 and Articles 4, 8, 9, 10(1), 11, 12 **and** 13;

Amendment 109

Proposal for a regulation

Article 18 – paragraph 3 – point f

Text proposed by the Commission

(f) the cases and conditions where official controls to verify compliance with animal welfare requirements **may** include the use of specific animal welfare indicators based on measurable performance criteria, and the design of such indicators on the basis of scientific and technical evidence.

Amendment

(f) the cases and conditions where official controls to verify compliance with animal welfare requirements **shall** include the use of specific animal welfare indicators based on measurable performance criteria, and the design of such indicators on the basis of scientific and technical evidence.

Amendment 328

Proposal for a regulation

Article 19 – paragraph 1 – introductory part

Text proposed by the Commission

The Commission shall be empowered to adopt ***delegated acts in accordance with Article 139*** concerning rules for the performance of official controls on plants, plant products and other objects in order to verify compliance with Union rules referred to in point (g) of Article 1(2) applicable to such goods and on action to be taken by the competent authorities following such official controls. Those ***delegated acts*** shall take account of plant health risks associated with plants, plant products and other objects in relation to

Amendment

The Commission shall be empowered to adopt ***legislative proposals*** concerning rules for the performance of official controls on plants, plant products and other objects in order to verify compliance with Union rules referred to in point (g) of Article 1(2) applicable to such goods and on action to be taken by the competent authorities following such official controls. Those ***legislative proposals*** shall take account of plant health risks associated with plants, plant products and other objects in relation to specific pests of

specific pests of plants or operators and lay down rules on:

plants or operators and lay down rules on:

Amendment 110

Proposal for a regulation Article 20

Text proposed by the Commission

Amendment

Article 20

deleted

Specific rules on official controls and action to be taken by the competent authorities in relation to plant reproductive material

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules for the performance of official controls on plant reproductive material in order to verify compliance with the rules referred to in point (h) of Article 1(2) applicable to such goods and on action to be taken by the competent authorities following such official controls. Those delegated acts shall lay down rules on:

(a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Articles 4, 8, 9, 10(1), 11, 12, 13, 34(1) and (2) and 36;

(b) uniform specific requirements for the performance of official controls having regard, in addition to the criteria referred to in Article 8(1), to the risks to the health, identity, quality and traceability of certain categories of plant reproductive material or of specific genera or species;

(c) specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Title IV;

(d) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph.

Amendment 111

Proposal for a regulation

Article 21 – paragraph 1 – introductory part

Text proposed by the Commission

The Commission shall be empowered to adopt ***delegated acts in accordance with Article 139*** concerning rules for the performance of official controls on GMOs and genetically modified food and feed performed to verify compliance with the rules referred to in points (a), (b) and (c) of Article 1(2) and on action to be taken by the competent authorities following such official controls. Those ***delegated acts*** shall take into account the need to ensure a minimum level of official controls to prevent practices in violation with those rules, and lay down rules on:

Amendment

The Commission shall be empowered to adopt ***legislative proposals*** concerning rules for the performance of official controls on GMOs and genetically modified food and feed performed to verify compliance with the rules referred to in points (a), (b) and (c) of Article 1(2) and on action to be taken by the competent authorities following such official controls. Those ***legislative proposals*** shall take into account the need to ensure a minimum level of official controls to prevent practices in violation with those rules, and lay down rules on:

Amendment 112

Proposal for a regulation

Article 21 – paragraph 1 – point b – point ii

Text proposed by the Commission

(ii) the cultivation of GMOs and the correct application of the monitoring plan referred to in point (e) of Article 13(2) of Directive 2001/18/EC and in Articles 5(5) and 17(5) of Regulation (EC) 1829/2003;

Amendment

(ii) the cultivation of GMOs and the correct application of the monitoring plan referred to in point (e) of Article 13(2) of Directive 2001/18/EC and in Articles 5(5) and 17(5) of Regulation (EC) 1829/2003, ***including minimum measures for monitoring and surveillance of potential effects on health, animal health and the environment;***

Amendment 113

Proposal for a regulation

Article 21 – paragraph 1 – point b – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) minimum measures as regards controls and reporting which aim at avoiding the unintended presence of GMOs, in accordance with Article 26a of

Amendment 114

Proposal for a regulation Article 22 – paragraph 1

Text proposed by the Commission

The Commission shall be empowered to adopt ***delegated acts in accordance with Article 139*** concerning rules for the performance of official controls to verify compliance with the rules referred to in Article 1(2)(i).

Amendment

The Commission shall be empowered to adopt ***legislative proposals*** concerning rules for the performance of official controls to verify compliance with the rules referred to in Article 1(2)(i).

Amendment 115

Proposal for a regulation Article 22 – paragraph 2 – introductory part

Text proposed by the Commission

Those ***delegated acts*** shall take into account the risks that plant protection products may represent for human health, animal health or the environment, and shall lay down rules on:

Amendment

Those ***legislative proposals*** shall take into account the risks that plant protection products may represent for human health, animal health or the environment, and shall lay down rules on:

Amendment 116

Proposal for a regulation Article 22 – paragraph 2 – point b

Text proposed by the Commission

(b) uniform specific requirements for the performance of official controls and uniform minimum frequency of such official controls, concerning the manufacture, placing on the market, entry into the Union, labelling, packaging, transport, storage and use of plant protection products, having regard, in addition to the criteria referred to in Article 8(1), to the need to ensure the safe and sustainable use of plant protection products and to combat illegal trade of such products;

Amendment

(b) uniform specific requirements for the performance of official controls and uniform minimum frequency of such official controls, concerning the manufacture, placing on the market, entry into the Union, labelling, packaging, transport, storage, ***parallel trade*** and use of plant protection products, having regard, in addition to the criteria referred to in Article 8(1), to the need to ensure the safe and sustainable use of plant protection products and to combat illegal trade of such products;

Amendment 117

Proposal for a regulation

Article 22 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) uniform specific requirements for the establishment of a register or database concerning production, packaging and storage facilities;

Amendment 118

Proposal for a regulation

Article 23 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

2. ***In relation to*** the rules referred to in point (j) of Article 1(2), ***the delegated acts referred to in paragraph 1*** shall lay down rules on:

2. ***The Commission shall be empowered to adopt delegated acts, in accordance with Article 27 (2) of Regulation (EC) No 834/2007, to verify compliance with the rules referred to in point (j) of Article 1(2) and on action to be taken by the competent authorities following such official controls. Those delegated acts shall lay down rules on:***

Amendment 119

Proposal for a regulation

Article 23 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Articles 4, 8, 9, 10(1), 11 to 13, 34(1) and (2), and Article 36, and in addition to Articles 25, 29, 30 and 32 for the approval and supervision of delegated bodies;

(a) the specific responsibilities and tasks of the ***operators, the*** competent authorities, ***the delegated bodies to ensure compliance with the provisions of Regulation (EC) No 834/2007,*** in addition to those provided for in Articles 4, 8, 9, 10(1), 11 to 13, 34(1) and (2), and Article 36, and in addition to Articles 25, 29, 30 and 32 for the approval and supervision of delegated bodies;

Amendment 120

Proposal for a regulation

Article 23 – paragraph 4

Text proposed by the Commission

4. Where appropriate, the delegated acts referred to in paragraphs 2 and 3 shall derogate from the provisions of this Regulation referred to in those paragraphs.

Amendment

deleted

Amendment 121

Proposal for a regulation

Article 24 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission shall be empowered to adopt **delegated acts in accordance with Article 139** concerning specific rules on official controls performed on certain categories of food or feed to verify compliance with the rules referred to in points (a) to (e) of Article 1(2) and on action to be taken by the competent authorities following such official controls. Those **delegated acts** shall address newly identified risks which may be posed through food or feed to human or animal health or, in relation to GMOs and plant protection products to the environment, or any such risks emerging from new patterns of production or consumption of food or feed, or which cannot be effectively addressed in the absence of common specifications for the official controls and for the action to be taken by the competent authorities following such official controls, and shall lay down rules on:

Amendment

1. The Commission shall be empowered to adopt **legislative proposals** concerning specific rules on official controls performed on certain categories of food or feed to verify compliance with the rules referred to in points (a) to (e) of Article 1(2) and on action to be taken by the competent authorities following such official controls. Those **legislative proposals** shall address newly identified risks which may be posed through food or feed to human or animal health or, in relation to GMOs and plant protection products to the environment, or any such risks emerging from new patterns of production or consumption of food or feed, or which cannot be effectively addressed in the absence of common specifications for the official controls and for the action to be taken by the competent authorities following such official controls, and shall lay down rules on:

Amendment 122

Proposal for a regulation

Article 24 a (new)

Text proposed by the Commission

Amendment

Article 24a

Specific rules on official controls and on action to be taken by the competent authorities in relation to materials and articles intended to come into contact with food.

The Commission may be empowered to adopt delegated acts in accordance with Article 139 concerning rules on the application of the official controls and on action to be taken by the competent authorities in relation to materials and articles intended to come into contact with food.

Amendment 123

Proposal for a regulation Article 25 – paragraph 1

Text proposed by the Commission

1. Competent authorities may delegate specific official control tasks to one or more delegated bodies or natural persons in accordance with the conditions provided for in Articles 26 and 27 respectively.

Amendment

1. Competent authorities may delegate specific official control tasks to one or more delegated bodies or natural persons in accordance with the conditions provided for in Articles 26 and 27 respectively.
Competent authorities shall not delegate specific official control tasks to natural persons concerning official controls performed to verify compliance with the rules referred to in point (j) of Article 1(2).

Amendment 124

Proposal for a regulation Article 25 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The first subparagraph shall not apply to the measures to be taken in accordance with Article 135 or with the rules provided for in point (e) of Article 23(2) following official controls performed to verify compliance with the rules referred to in point (j) of Article 1(2).

Amendment

deleted

Amendment 125

Proposal for a regulation

Article 26 – paragraph 1 – point b – point iii

Text proposed by the Commission

(iii) is impartial and free from any conflict of interest as regards the exercise of the specific official control tasks delegated to it;

Amendment

(iii) is impartial, ***independent, not directly nor indirectly employed by the operator on which it is performing control activities***, and ***otherwise*** free from any conflict of interest as regards the exercise of the specific official control tasks delegated to it;

Amendment 126

Proposal for a regulation

Article 26 – paragraph 1 – letter b – point iv a (new)

Text proposed by the Commission

Amendment

(iva) has sufficient powers to perform the official controls delegated to it;

Amendment 127

Proposal for a regulation

Article 29 – paragraph 1 – point a

Text proposed by the Commission

(a) organise audits or inspections of such bodies or persons ***as necessary***;

Amendment

(a) organise ***periodical and unannounced*** audits or inspections of such bodies or persons;

Amendment 128

Proposal for a regulation

Article 29 – paragraph 1 – point b – point iia (new)

Text proposed by the Commission

Amendment

iia) the independence or impartiality of the delegated body or natural person have been shown to be compromised

Amendment 129

Proposal for a regulation

Article 32 – paragraph 1 – point a

Text proposed by the Commission

(a) organise audits or inspections of such bodies or persons *as necessary*;

Amendment

(a) organise audits or inspections of such bodies or persons;

Amendment 130

Proposal for a regulation

Article 33 – paragraph 2 – introductory part

Text proposed by the Commission

2. In the absence of the Union rules referred to in paragraph 1, official laboratories shall use state-of-the-art methods for their specific analytical, testing and diagnostic needs, taking into account:

Amendment

2. In the absence of the Union rules referred to in paragraph 1, *in the context of official controls*, official laboratories shall use state-of-the-art methods for their specific analytical, testing and diagnostic needs, taking into account, *in the following order*:

Amendment 131

Proposal for a regulation

Article 33 – paragraph 3

Text proposed by the Commission

3. In the context of screening, targeted screening and of other official activities, any of the methods referred to in paragraph 2 may be used in the absence of Union rules referred to in paragraph 1.

Amendment

3. *By way of derogation from paragraph 2*, in the context of screening, targeted screening and of other official activities, any of the methods referred to in paragraph 2 may be used in the absence of Union rules referred to in paragraph 1. *The same rule shall apply to the other official activities.*

Amendment 132

Proposal for a regulation

Article 33 – paragraph 4

Text proposed by the Commission

4. Where laboratory analyses, tests or

Amendment

4. Where laboratory analyses, tests or

diagnoses are urgently needed and none of the methods referred to in paragraphs 1 and 2 exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated in accordance with Article 36(1) may use methods other than those referred to in paragraphs 1 and 2 of this Article until the validation of an appropriate method in accordance with internationally accepted scientific protocols.

diagnoses are urgently needed, *in exceptional cases due to a developing emergency situation*, and none of the methods referred to in paragraphs 1 and 2 exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated in accordance with Article 36(1) may use methods other than those referred to in paragraphs 1 and 2 of this Article until the validation of an appropriate method in accordance with internationally accepted scientific protocols.

Amendment 133

Proposal for a regulation Article 33 – paragraph 6

Text proposed by the Commission

6. Samples shall be taken, handled and labelled in such a way as to guarantee their legal, scientific and technical validity.

Amendment

6. Samples shall be taken, handled and labelled in such a way as to guarantee their legal, scientific and technical validity. ***The size of the sample taken must be such as to enable a second expert opinion to be given, where necessary, should an operator so request under Article 34.***

Amendment 134

Proposal for a regulation Article 33 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. As regards products of animal origin, 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.

Amendment 135

Proposal for a regulation Article 33 – paragraph 7 – subparagraph 1 – introductory wording

Text proposed by the Commission

The Commission may, by means of implementing acts, lay down rules for:

Amendment

The Commission may, by means of implementing acts, ***insofar as these matters are not otherwise regulated***, lay down rules for:

Amendment 136

Proposal for a regulation

Article 34 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The competent authorities shall ensure that operators, whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls, have the right to apply for a second expert opinion.

Amendment

The competent authorities shall ensure that operators, whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls, have the right to apply for a second expert opinion, ***where this is relevant and technically feasible. The operator shall bear the costs of this expert opinion.***

Amendment 137

Proposal for a regulation

Article 34 – paragraph 1 – subparagraph 2 – point a

Text proposed by the Commission

a) shall always entitle the operator to request a documentary review of the sampling, analysis, test or diagnosis by another expert;

Amendment

a) shall always entitle the operator to request a documentary review of the sampling, analysis, test or diagnosis by another expert ***designated by the reference laboratory or, failing that, by another official laboratory which is at least equivalent;***

Amendment 138

Proposal for a regulation

Article 34 – paragraph 1 – subparagraph 2 – point b – introductory part

Text proposed by the Commission

(b) where relevant and technically feasible, having regard in particular to the prevalence and distribution of the hazard in

Amendment

(b) where relevant and technically feasible, having regard in particular to the prevalence and distribution of the hazard in

the animals or goods, to the perishability of the samples or the goods and to the amount of available substrate, shall entitle the operator to request:

the animals or goods, to the perishability of the samples or the goods and to the amount of available substrate, shall entitle the operator to request ***and oblige the competent authorities to ensure:***

Amendment 139

Proposal for a regulation

Article 34 – paragraph 1 – subparagraph 2 – point b – point i

Text proposed by the Commission

(i) that a sufficient number of ***other*** samples be taken ***for*** a second expert opinion; ***or,***

Amendment

(i) that a sufficient number of samples be taken ***and divided into three parts for the purpose of an initial analysis and, if appropriate,*** a second expert opinion ***at the request of the operator, then another final analysis, if there is a discrepancy between the two previous ones;***

Amendment 140

Proposal for a regulation

Article 34 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Samples shall be handled and labelled in such a way as to guarantee their legal and technical validity.

Amendment 141

Proposal for a regulation

Article 35 – paragraph 2 – introductory part

Text proposed by the Commission

2. Competent authorities shall take all steps to ensure that the operators from whom ***the*** samples are ordered in accordance with paragraph 1:

Amendment

2. Competent authorities, ***once they are in possession of the samples,*** shall take all steps to ensure that the operators from whom ***these*** samples are ordered in accordance with paragraph 1:

Amendment 142

Proposal for a regulation

Article 36 – paragraph 4 – point c

Text proposed by the Commission

(c) is impartial and free from any conflict of interest as regards the exercise of its tasks as official laboratory;

Amendment

(c) is **independent**, impartial and free from any conflict of interest as regards the exercise of its tasks as official laboratory;

Amendment 143

Proposal for a regulation

Article 36 – paragraph 4 – point e

Text proposed by the Commission

(e) operates in accordance with the standard EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' and is **assessed and** accredited in accordance with that standard by a national accreditation body operating in accordance with Regulation (EC) No 765/2008.

Amendment

(e) operates in accordance with the standard EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' and is accredited in accordance with that standard by a national accreditation body operating in accordance with Regulation (EC) No 765/2008.

Amendment 144

Proposal for a regulation

Article 36 – paragraph 5 – subparagraph 1 – introductory part

Text proposed by the Commission

The scope of the **assessment and** accreditation of an official laboratory referred to in point (e) of paragraph 4:

Amendment

The scope of the accreditation of an official laboratory referred to in point (e) of paragraph 4:

Amendment 145

Proposal for a regulation

Article 39 – title

Text proposed by the Commission

Derogations from the condition for the mandatory **assessment and** accreditation for certain official laboratories

Amendment

Derogations from the condition for the mandatory accreditation for certain official laboratories

Amendment 146

Proposal for a regulation

Article 39 – paragraph 1 – point a – point iii

Text proposed by the Commission

Amendment

(iii) that carry out the detection of Trichinella under the supervision of the competent authorities or of an official laboratory designated in accordance with Article 36(1), and **assessed and** accredited in accordance with the standard EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’ for the use of the methods referred to in point (a)(ii) of this paragraph;

(iii) that carry out the detection of Trichinella under the supervision of the competent authorities or of an official laboratory designated in accordance with Article 36(1), and accredited in accordance with the standard EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’ for the use of the methods referred to in point (a)(ii) of this paragraph;

Amendment 147

Proposal for a regulation

Article 39 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) laboratories carrying out analyses or tests to verify compliance with the rules on plant reproductive material referred to in point (h) of Article 1(2);

deleted

Amendment 148

Proposal for a regulation

Article 40 – title

Text proposed by the Commission

Amendment

Powers to adopt derogations from the condition for the mandatory **assessment and** accreditation of all the methods of laboratory analysis, test and diagnosis used by official laboratories

Powers to adopt derogations from the condition for the mandatory accreditation of all the methods of laboratory analysis, test and diagnosis used by official laboratories

Amendment 149

Proposal for a regulation

Article 41 – title

Text proposed by the Commission

Amendment

Temporary derogations from the condition for the mandatory **assessment and**

Temporary derogations from the condition for the mandatory accreditation of official

accreditation of official laboratories

laboratories

Amendment 150

Proposal for a regulation

Article 41 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) pending the assessment by, and decision of, the accreditation body.

Amendment 151

Proposal for a regulation

Article 41 a (new)

Text proposed by the Commission

Amendment

Article 41a

Official controls on animals and goods entering the Union shall be organised according to risk, and may take place at border control posts in accordance with Section II of this chapter, with a view to checking compliance with the regulatory provisions specific to certain animals or goods, or at an appropriate place in accordance with Section I of this chapter.

Amendment 152

Proposal for a regulation

Article 42 – paragraph 1 – subparagraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) the likelihood of fraudulent practices which might deceive consumer expectation regarding nature, quality and composition of foods and goods;

Amendment 153

Proposal for a regulation

Article 45 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) products of animal origin, germinal products and animal by-products;

(b) ***products of animal origin, foods that contain*** products of animal origin, germinal products and animal by-products;

Amendment 154

Proposal for a regulation Article 46 – point a

Text proposed by the Commission

Amendment

(a) goods sent as commercial or trade samples or as display items for exhibitions, which are not intended to be placed on the market;

deleted

Amendment 155

Proposal for a regulation Article 46 – point b

Text proposed by the Commission

Amendment

(b) animals and goods intended for scientific purposes;

deleted

Amendment 156

Proposal for a regulation Article 46 – point f

Text proposed by the Commission

Amendment

(f) pet animals as defined in point (10) of Article 4(1) of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on animal health];

deleted

Amendment 157

Proposal for a regulation Article 47 – paragraph 4 – subparagraph 2

Text proposed by the Commission

Where such checks are performed on animals they shall be carried out by an official veterinarian **or under his supervision.**

Amendment

Where such checks are performed on animals **or on products of animal origin**, they shall be carried out by an official veterinarian, **who may be assisted by specially trained support staff whilst retaining responsibility for the checks carried out.**

Amendment 158

Proposal for a regulation

Article 51 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing the cases where and the conditions under which:

Amendment

1. Competent authorities may perform the identity and physical checks of the animals and goods entering the Union from third countries referred to in Article 45(1) at control points other than border control posts, provided that those control points comply with the requirements provided for in article 62(3) and in the implementing acts adopted in accordance with article 62(4).

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing the cases where and the conditions under which:

Amendment 159

Proposal for a regulation

Article 51 – paragraph 1 – point a

Text proposed by the Commission

(a) identity and physical checks on consignments of the categories of animals and goods referred to in Article 45(1) may be performed by competent authorities at control points other than border control posts provided that those control points comply with the requirements provided for in Article 62(3) and in the implementing

Amendment

deleted

acts adopted in accordance with Article 62(4);

Amendment 160

Proposal for a regulation

Article 51 – paragraph 1 – point c – point iii

Text proposed by the Commission

iii) *goods ordered by distance selling.*

Amendment

iii) *small consignments sent to private individuals or acquired at a distance (by telephone, post or internet).*

Amendment 161

Proposal for a regulation

Article 51 – paragraph 1 – letter c – point iii a (new)

Text proposed by the Commission

Amendment

(iiia) pet animals which meet the conditions laid down in Article 5 of Implementing Regulation (EU) No 576/2013 of the European Parliament and of the Council^{1a}.

^{1a} *Regulation (EU) No 576/2013 of the European Parliament and of the Council on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003.*

Amendment 162

Proposal for a regulation

Article 52 – paragraph 2 – point a – introductory part

Text proposed by the Commission

(a) the criteria and the procedures for determining and modifying the frequency rates of physical checks to be performed on consignments of the categories of animals and goods referred to in points (a), (b) and (c) of Article 45(1) and to adjust them to the level of risk associated with those categories, having regard to:

Amendment

(a) the criteria and the procedures for determining and modifying the *minimum* frequency rates of physical checks to be performed on consignments of the categories of animals and goods referred to in points (a), (b) and (c) of Article 45(1) and to adjust them to the level of risk associated with those categories, having

regard to:

Amendment 163

Proposal for a regulation

Article 52 – paragraph 2 – point c

Text proposed by the Commission

(c) the procedures for ensuring that the frequency rates of physical checks established in accordance with point (a) are applied in a timely and uniform manner.

Amendment

(c) the procedures for ensuring that the **minimum** frequency rates of physical checks established in accordance with point (a) are applied in a timely and uniform manner.

Amendment 164

Proposal for a regulation

Article 52 – paragraph 3 – subparagraph 1 – point a

Text proposed by the Commission

(a) the frequency of physical checks for the categories of goods referred to in point (d) of Article 45(1);

Amendment

(a) the **minimum** frequency of physical checks for the categories of goods referred to in point (d) of Article 45(1);

Amendment 165

Proposal for a regulation

Article 52 – paragraph 3 – subparagraph 1 – point b

Text proposed by the Commission

(b) the frequency of physical checks for the categories of animals and goods referred to in points (e) and (f) of Article 45(1) as long as this is not already provided for in the acts referred to therein.

Amendment

(b) the **minimum** frequency of physical checks for the categories of animals and goods referred to in points (e) and (f) of Article 45(1) as long as this is not already provided for in the acts referred to therein.

Amendment 166

Proposal for a regulation

Article 53 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Decisions on consignments of animals shall be taken by an official veterinarian *or*

Amendment

Decisions on consignments of animals *and products of animal origin* shall be taken by an official veterinarian *who may be*

under his supervision.

assisted by specially trained support staff whilst retaining responsibility for the checks carried out.

Amendment 167

Proposal for a regulation Article 53 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. These decisions shall be recorded in the CHED referred to in the following articles.

Amendment 168

Proposal for a regulation Article 54 – paragraph 2 – point b – point ii

Text proposed by the Commission

Amendment

(ii) communicate the information referred to in point (i) through the TRACES system.

(ii) communicate the information referred to in point (i) through ***or in electronic exchange with*** the TRACES system.

Amendment 169

Proposal for a regulation Article 54 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The operators and competent authorities referred to in this paragraph may also use a national information system to feed data into the TRACES system.

Amendment 170

Proposal for a regulation Article 54 – paragraph 4

Text proposed by the Commission

Amendment

4. The competent authorities of the border control post shall ***finalise the CHED*** as

4. The competent authorities of the border control post shall ***record the decision on the consignment in the Common Health***

soon as:

Entry Document as soon as ***all official controls required by Article 47(1) have been performed.***

- a) all official controls required by Article 47(1) have been performed;***
- b) the results from physical checks, where such checks are required, are available;***
- c) a decision on the consignment has been taken in accordance with Article 53 and recorded on the CHED.***

Amendment 171

Proposal for a regulation Article 56 – paragraph 2

Text proposed by the Commission

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing the cases where and the conditions under which the CHED must accompany consignments of the categories of animals and goods referred to in Article 45(1) to the place of destination.

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing the cases where and the conditions under which the CHED must accompany consignments of the categories of animals and goods referred to in Article 45(1) to the place of destination. ***A copy of the CHED shall in any case accompany consignments of the categories of animals and goods referred to in Article 45(1) to the place of destination.***

Amendment 172

Proposal for a regulation Article 61 – paragraph 1

Text proposed by the Commission

1. A Member State shall immediately suspend the designation of a border control post and order its activities to be stopped, for all or for certain categories of animals and goods for which the designation was made, in cases where such activities may result in a risk to human, animal or plant health, animal welfare ***or, as regards GMOs and plant protection products,*** to the environment.

Amendment

1. A Member State shall immediately suspend the designation of a border control post and order its activities to be stopped, for all or for certain categories of animals and goods for which the designation was made, in cases where such activities may result in a risk to human, animal or plant health ***or*** animal welfare, to the environment.

Amendment 173

Proposal for a regulation Article 62 – paragraph 1

Text proposed by the Commission

1. Border control posts shall be located in the immediate vicinity of the point of entry into the Union and in a place suitably equipped **to be designated by the customs authorities** in accordance with Article 38(1) of Regulation (EEC) No 2913/92.

Amendment

1. Border control posts shall be located in the immediate vicinity of the point of entry into the Union and in a place **that is** suitably equipped, in accordance with Article 38(1) of Regulation (EEC) No 2913/92.

Amendment 174

Proposal for a regulation Article 63 – paragraph 1

Text proposed by the Commission

1. In case of suspicion of non-compliance of consignments of the categories of animals and goods referred to in Article 45(1) with the rules referred to in Article 1(2), the competent authorities shall perform official controls in order to confirm or to eliminate that suspicion.

Amendment

1. In case of suspicion of non-compliance of consignments of the categories of animals and goods referred to in Article 45(1) with the rules referred to in Article 1(2), the competent authorities shall perform official controls **or delegate the responsibility to other competent authorities** in order to confirm or to eliminate that suspicion.

Amendment 175

Proposal for a regulation Article 63 – paragraph 4

Text proposed by the Commission

4. Where the competent authorities have reasons to suspect fraudulent behaviour by an operator or official controls give grounds to believe that the rules referred to in Article 1(2) have been seriously or repeatedly infringed, they shall, **where appropriate, and** in addition to the measures provided for in Article 64(3), intensify official controls on consignments with the same origin or use **as appropriate**.

Amendment

4. Where the competent authorities have reasons to suspect fraudulent behaviour by an operator or official controls give grounds to believe that the rules referred to in Article 1(2) have been seriously or repeatedly infringed, they shall, in addition to the measures provided for in Article 64(3), intensify official controls on consignments with the same origin or use.

Amendment 176

Proposal for a regulation

Article 64 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The competent authorities shall place under official detention any consignment of animals or goods entering the Union from third countries which does not comply with the rules referred to in Article 1(2) and refuse entry into the Union to it.

Amendment

When the competent authority ascertains as a result of the official controls performed at the border control posts in accordance with Article 45, that consignments of animals and goods do not comply with the requirements under Article 1(2), it shall issue a report or a decision: ‘Non-compliant consignment’ or ‘Negative control’ which shall be recorded in the CHED. Furthermore the competent authorities shall officially detain said consignment of animals or goods and refuse entry into the Union to it.

Amendment 177

Proposal for a regulation

Article 64 – paragraph 1 – subparagraph 2

Text proposed by the Commission

As appropriate, any such consignment shall be isolated or quarantined and animals belonging to it shall be kept and treated under appropriate conditions pending any further decision.

Amendment

As appropriate, any such consignment ***or part thereof*** shall be isolated or quarantined and animals belonging to it shall be kept and treated under appropriate conditions pending any further decision. ***The special needs of other goods shall also be borne in mind.***

Amendment 178

Proposal for a regulation

Article 64 – paragraph 3 – introductory wording

Text proposed by the Commission

3. ***Having, where possible, heard*** the operator responsible for the consignment, ***the competent authorities*** shall, without delay, order that the operator:

Amendment

3. ***The competent authorities shall hear*** the operator responsible for the consignment. ***The competent authority may omit this if an immediate decision is necessary either because a delay would be dangerous or in the public interest. It***

shall, without delay, order that the operator:

Amendment 179

Proposal for a regulation

Article 64 – paragraph 3 – point a

Text proposed by the Commission

a) destroy the consignment in compliance, where appropriate, with the rules referred to in Article 1(2); or

Amendment

a) destroy the consignment ***or part thereof, humanely in the case of live animals,*** in compliance, where appropriate, with the rules referred to in Article 1(2); or

Amendment 180

Proposal for a regulation

Article 64 – paragraph 3 – point b

Text proposed by the Commission

b) re-dispatch the consignment outside the Union in accordance with Article 70(1) and (2); or

Amendment

b) re-dispatch the consignment ***or part thereof*** outside the Union in accordance with Article 70(1) and (2); or

Amendment 181

Proposal for a regulation

Article 64 – paragraph 3 – point c

Text proposed by the Commission

c) subject the consignment to special treatment in accordance with Article 69(1) and (2) or to any other measure necessary to ensure compliance with the rules referred to in Article 1(2), and, where appropriate, destines the consignment for purposes other than those for which it was originally intended.

Amendment

c) subject the consignment ***or part thereof*** to special treatment in accordance with Article 69(1) and (2) or to any other measure necessary to ensure compliance with the rules referred to in Article 1(2), and, where appropriate, destines the consignment for purposes other than those for which it was originally intended.

Amendment 182

Proposal for a regulation

Article 65 – title

Text proposed by the Commission

Measures to be taken **on animals or goods entering the Union** from third countries presenting a risk

Amendment

Measures to be taken **in cases of an attempt to bring non-compliant consignments into the EU** from third countries presenting a risk

Amendment 183

**Proposal for a regulation
Article 65 – paragraph 1**

Text proposed by the Commission

Where official controls indicate that a consignment of animals or goods presents a risk to human, animal **or plant** health, animal welfare or, **as regards GMOs and plant protection products**, to the environment, such consignment shall be isolated or quarantined and animals belonging to it shall be kept and treated under appropriate conditions pending any further decision.

Amendment

Where official controls indicate that a consignment of animals or goods presents a risk to human **or** animal health, animal welfare or to the environment, such consignment shall be isolated or quarantined and animals belonging to it shall be kept and treated under appropriate conditions pending any further decision.

Amendment 184

**Proposal for a regulation
Article 65 – paragraph 2 – point a**

Text proposed by the Commission

(a) order that the operator destroy the consignment in compliance, where appropriate, with the rules referred to in Article 1(2), taking all the measures necessary to protect human, animal or plant health, animal welfare or the environment;
or

Amendment

(a) order that the operator destroy the consignment, **humanely in the case of live animals**, in compliance, where appropriate, with the rules referred to in Article 1(2), taking all the measures necessary to protect human, animal or plant health, animal welfare or the environment; or

Amendment 185

**Proposal for a regulation
Article 66 – paragraph 2 – subparagraph 1**

Text proposed by the Commission

The competent authorities in the Member

Amendment

The competent authorities in the Member

State where the official controls were performed shall supervise the application of the measures ordered pursuant to Article 64(3) and (5) and Article 65 to ensure that the consignment does not give rise to adverse effects on human, animal *or plant* health, animal welfare, or the environment, during or pending the application of those measures.

State where the official controls were performed shall supervise the application of the measures ordered pursuant to Article 64(3) and (5) and Article 65 to ensure that the consignment does not give rise to adverse effects on human *or* animal health, animal welfare, or the environment, during or pending the application of those measures.

Amendment 186

Proposal for a regulation

Article 67 – paragraph 1

Text proposed by the Commission

1. The operator shall carry out all the measures ordered by the competent authorities in accordance with Article 64 (3) and (5) and 65 without delay and, at the latest, within 60 days from the day on which the competent authorities notified the operator of their decision in accordance with Article 64(4).

Amendment

1. The operator shall carry out all the measures ordered by the competent authorities in accordance with Article 64 (3) and (5) and 65 without delay and, at the latest, *in the case of products*, within 60 days from the day on which the competent authorities notified the operator of their decision in accordance with Article 64(4).

Amendment 187

Proposal for a regulation

Article 70 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Member States receiving imports which have been authorised by pre-export-controls shall regularly check if the imports actually comply with EU requirements.

Amendment 188

Proposal for a regulation

Article 72 – paragraph 1 – point a

Text proposed by the Commission

a) notify the Commission and the other Member States and operators concerned via the TRACES system in addition to

Amendment

a) notify the Commission and the other Member States and operators concerned via the TRACES system, *including the*

seeking administrative assistance in accordance with the procedures established in Title IV;

measures to be applied, in addition to seeking administrative assistance in accordance with the procedures established in Title IV;

Amendment 189

Proposal for a regulation Article 73 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The customs authorities shall only release those consignments of animals and goods under Article 45 in respect of which the competent authority at the border control post has carried out the official controls provided for in Article 47 and issued a decision recorded in the CHED.

Amendment 190

Proposal for a regulation Article 75 – paragraph 1 – point d

Text proposed by the Commission

Amendment

(d) wood packaging material;

deleted

Amendment 191

Proposal for a regulation Article 76

Text proposed by the Commission

Amendment

General rules

General rules

1. Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to perform official controls and other official activities.

1. Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to perform official controls and other official activities. **With that aim in view they shall collect fees or contributions to the costs or make resources available from general tax revenue.**

2. In addition to the fees collected in

accordance with Article 77, Member States may collect fees to cover costs occasioned by official controls other than those referred to in Article 77(1) and (2).

3. This Chapter also applies in the case of delegation of specific official control tasks in accordance with Article 25.

4. Member States shall consult the operators concerned on the methods used to calculate the fees provided for in Article 77.

3. This Chapter also applies in the case of delegation of specific official control tasks in accordance with Article 25.

4. Member States shall consult the operators concerned on the methods used to calculate the fees *or contributions to the costs*.

Amendments 192, 343, 314 and 316

Proposal for a regulation Article 77

Text proposed by the Commission

Mandatory fees

1. For the purpose of ensuring that competent authorities are provided with adequate resources for the performance of official controls, the competent authorities **shall** collect fees to recover the costs they incur in relation to:

(a) official controls performed to verify that the following operators comply with the rules referred to in Article 1(2):

(i) food business operators as defined in Article 3(3) of Regulation (EC) No 178/2002 that are either registered or approved, or registered and approved, in accordance with Article 6 of Regulation (EC) No 852/2004;

(ii) feed business operators as defined in Article 3(6) of Regulation (EC) No 178/2002 registered or approved in accordance with Articles 9 and 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene⁵²;

(iii) professional operators as defined in point (7) of Article 2 of Regulation (EU)

Amendment

Mandatory fees *or contributions to the costs*

1. For the purpose of ensuring that competent authorities are provided with adequate resources for the performance of official controls, the competent authorities **may** collect fees *or contribution to the costs* to recover, **some or all of** the costs they incur in relation to:

(a) official controls performed to verify that the following operators comply with the rules referred to in Article 1(2):

(i) food business operators as defined in Article 3(3) of Regulation (EC) No 178/2002 that are either registered or approved, or registered and approved, in accordance with Article 6 of Regulation (EC) No 852/2004;

(ii) feed business operators as defined in Article 3(6) of Regulation (EC) No 178/2002 registered or approved in accordance with Articles 9 and 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene⁵²;

(iii) professional operators as defined in point (7) of Article 2 of Regulation (EU)

No XXX/XXXX [Office of Publications, please insert number of the Regulation on protective measures against pests of plants];

(iv) professional operators as defined in point (6) of Article 3 of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on the production and making available on the market of plant reproductive material];

(b) the official controls performed in view of the issuance of official certificates or to supervise the issuance of official attestations;

(c) official controls performed to verify that the conditions are met:

(i) to obtain and maintain the approval provided for in Article 6 of Regulation (EC) No 852/2004 or in Articles 9 and 10 of Regulation (EC) No 183/2005;

(ii) to obtain and maintain the authorisation referred to in Articles 84, 92 and 93 of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on protective measures against pests of plants];

(iii) to obtain and maintain the authorisation referred to in Article 25 of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on the production and making available on the market of plant reproductive material];

(d) official controls performed by the competent authorities at the border control posts or at the control points referred to in point (a) of Article 51(1).

2. For the purposes of paragraph 1, the official controls referred to in point (a) of that paragraph shall include official controls performed to verify compliance with measures adopted by the Commission in accordance with Article 137 of this Regulation, Article 53 of Regulation (EC) No 178/2002, Articles 27(1), 29(1), 40(2),

No XXX/XXXX [Office of Publications, please insert number of the Regulation on protective measures against pests of plants];

(b) the official controls performed in view of the issuance of official certificates or to supervise the issuance of official attestations;

(c) official controls performed to verify that the conditions are met:

(i) to obtain and maintain the approval provided for in Article 6 of Regulation (EC) No 852/2004 or in Articles 9 and 10 of Regulation (EC) No 183/2005;

(ii) to obtain and maintain the authorisation referred to in Articles 84, 92 and 93 of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on protective measures against pests of plants];

(d) official controls performed by the competent authorities at the border control posts or at the control points referred to in point (a) of Article 51(1).

2. For the purposes of paragraph 1, the official controls referred to in point (a) of that paragraph shall include official controls performed to verify compliance with measures adopted by the Commission in accordance with Article 137 of this Regulation, Article 53 of Regulation (EC) No 178/2002, Articles 27(1), 29(1), 40(2),

41(2), 47(1), 49(2) and 50(2) of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on protective measures against pests of plants], **Articles 41 and 144 of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on the production and making available on the market of plant reproductive material]** and Part VI of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on animal health], unless the decision establishing the measures requires otherwise.

3. For the purposes of paragraph 1:

(a) the official controls referred to in point (a) of that paragraph shall not include official controls performed to verify compliance with temporary restrictions, requirements or other disease control measures adopted by the competent authorities in accordance with Articles 55(1), 56, 61, 62, 64, 65, 68(1) and 69, and rules adopted pursuant to Articles 55(2), 63, 67 and 68(2) of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on animal health] and Article 16 of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on protective measures against pests of plants];

(b) the official controls referred to in point (a) and (b) of that paragraph shall not include official controls performed to verify compliance with the rules referred to

41(2), 47(1), 49(2) and 50(2) of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on protective measures against pests of plants], and Part VI of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on animal health], unless the decision establishing the measures requires otherwise.

3. For the purposes of paragraph 1:

(a) the official controls referred to in point (a) of that paragraph shall not include official controls performed to verify compliance with temporary restrictions, requirements or other disease control measures adopted by the competent authorities in accordance with Articles 55(1), 56, 61, 62, 64, 65, 68(1) and 69, and rules adopted pursuant to Articles 55(2), 63, 67 and 68(2) of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on animal health] and Article 16 of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on protective measures against pests of plants];

aa) the official controls referred to in point (a) of that paragraph shall not include controls performed at the level of primary production as defined in Article 3(17) of Regulation (EC) No 178/2002, including on farm processing. This includes controls to verify compliance with statutory management requirements in the area of public health, animal health, plant health, and animal welfare in accordance with Article 93 of Regulation (EU) No 1306/2013.

(b) the official controls referred to in point (a) and (b) of that paragraph shall not include official controls performed to verify compliance with the rules referred to

in Article 1(2)(j) and (k).

⁵² OJ L 35, 8.2.2005, p. 1.

in Article 1(2)(j) and (k).

⁵² OJ L 35, 8.2.2005, p. 1.

Amendment 193

Proposal for a regulation Article 78

Text proposed by the Commission

Costs

1. The competent authorities shall **collect fees** in accordance with Article 77 to **recover** the following **costs**:

(a) the salaries of the staff, including support staff, **involved in the performance** of official controls, their social security, pension and insurance costs;

(b) the cost of facilities and equipment, including maintenance and insurance costs;

(c) the cost of consumables, services and tools;

(d) the cost of training of staff referred to in point (a), with the exclusion of the training necessary to obtain the qualification necessary to be employed by the competent authorities;

(e) the cost of travel of the staff referred to in point (a), and associated subsistence costs;

(f) the cost of sampling and of laboratory analysis, testing and diagnosis.

2. If the competent authorities collecting fees in accordance with Article 77 also perform other activities, only the fraction of the cost elements referred to in paragraph 1 of this Article which results from the official controls referred to in

Amendment

Costs

1. The competent authorities shall **be entitled, when calculating the fees or contributions to the cost** in accordance with Article 77, to **take** the following **criteria into account** :

(a) the salaries of the staff, including support staff, **insofar as they correspond to the actual costs** of official controls **in accordance with point(b) of article 79(1), excluding** their social security, pension and insurance costs;

(c) the cost of consumables, services and tools;

(e) the cost of travel of the staff **for the performance of the official controls** referred to in point (a), and associated subsistence costs, **calculated in accordance with Article 79 (2);**

(f) the cost of sampling and of laboratory analysis, testing and diagnosis.

2. If the competent authorities collecting **mandatory fees or contributions to the costs** in accordance with Article 77 also perform other activities, only the fraction of the cost elements referred to in paragraph 1 of this Article which results

Article 77(1) shall be considered for the calculation of the fees.

from the official controls referred to in Article 77(1) shall be considered for the calculation of the *mandatory* fees *or contribution to the costs*.

Amendment 194

Proposal for a regulation Article 79

Text proposed by the Commission

Calculation of fees

1. Fees collected in accordance with Article 77 shall be:

(a) established at a flat-rate on the basis of the overall costs of official controls borne by the competent authorities over a given period of time, and applied to all operators irrespective of whether any official control is performed during the reference period in relation to each operator charged; in establishing the level of the fees to be charged on each sector, activity and category of operators, the competent authorities shall take into consideration the impact that the type and the size of the activity concerned and the relevant risk factors have on the distribution of the overall costs of those official controls; or,

(b) calculated on the basis of the actual costs of each individual official control, and applied to the operators subject to such official control; such fee shall not exceed the actual costs of the official control performed and may be partly or entirely expressed as a function of the time employed by the staff of the competent authorities to perform the official controls.

2. Travel costs as referred to in point (e) of Article 78(1) shall be considered for the calculation of the fees referred to in Article 77(1) in a manner that does not discriminate between operators on the basis of the distance of their premises from the

Amendment

Calculation of *mandatory* fees or *contributions to the costs*

1. The fees *or contribution to the costs* collected in accordance with Article 77 shall be:

(b) calculated on the basis of the actual costs of each individual official control, and applied to the operators subject to such official control; such fee shall not exceed the actual costs of the official control performed and may be partly or entirely expressed as a function of the time employed by the staff of the competent authorities to perform the official controls.

2. Travel costs as referred to in point (e) of Article 78(1) shall be considered for the calculation of the fees *or contributions to the costs* referred to in Article 77(1) in a manner that does not discriminate between operators on the basis of the distance of

location of the competent authorities.

3. Where fees are calculated in accordance with point (a) of paragraph 1, the fees collected by competent authorities in accordance with Article 77 shall not exceed the overall costs incurred for the official controls performed over the period of time referred to in point (a) of paragraph 1.

their premises from the location of the competent authorities.

3. Where ***the fees or contributions to the costs*** are calculated in accordance with point (a) of paragraph 1, the fees ***or contribution to the costs*** collected by competent authorities in accordance with Article 77 shall not exceed the overall costs incurred for the official controls performed over the period of time referred to in point (a) of paragraph 1.

Amendment 195

Proposal for a regulation Article 80

Text proposed by the Commission

Reduction of fees for consistently compliant operators

Where fees are established in accordance with ***point (a) of*** Article 79(1), the rate of the fee to be applied to each operator shall be determined taking into account the operators' record of compliance with the rules referred to in Article 1(2) as ascertained through official controls, so that fees applied to consistently compliant operators are lower than those applied to other operators.

Amendment

Reduction of fees ***or contributions to the costs*** for consistently compliant operators

Where fees ***or contributions to the costs*** are established in accordance with Article 79(1), the rate of the fee to be applied to each operator shall be determined taking into account the operators' record of compliance with the rules referred to in Article 1(2) as ascertained through official controls, so that fees or contribution to the costs applied to consistently compliant operators are lower than those applied to other operators.

Amendment 196

Proposal for a regulation Article 81

Text proposed by the Commission

Application of fees

1. Operators shall receive proof of the payment of fees provided for in Article 77(1).
2. Fees collected in accordance with point (d) of Article 77(1) shall be paid by the operator responsible for the consignment or

Amendment

Application of fees ***or contributions to the costs***

1. Operators shall receive proof of the payment of fees ***or contributions to the costs*** provided for in Article 77(1).
2. Fees ***or contributions to the costs*** collected in accordance with point (d) of Article 77(1) shall be paid by the operator

its representative.

responsible for the consignment or its representative.

Amendments 197, 315 and 348

Proposal for a regulation Article 82

Text proposed by the Commission

Fees refunds and exemption for microenterprises

1. Fees provided for in Article 77 shall not directly or indirectly be refunded, unless unduly collected.

2. Enterprises employing fewer than 10 persons and whose annual turnover or annual balance sheet total does not exceed EUR 2 million shall be exempted from the payment of the fees provided for in Article 77.

3. The costs referred to in Articles 77, 78 and 79 shall not include those incurred for the performance of official controls on the enterprises referred to in paragraph 2.

Amendment

Fees refunds and exemption for microenterprises

Member States can exempt small and medium enterprises that fulfil certain objective and non-discriminatory criteria from the payment of fees or cost contributions provided for in Article 77.

Amendment 198

Proposal for a regulation Article 83

Text proposed by the Commission

Transparency

1. The competent authorities shall ensure the highest level of transparency of:

(a) the method and data used to establish the fees provided for in Article 77(1);

(b) the use of resources collected through such fees;

(c) the arrangements in place to ensure an efficient and thrifty use of the resources

Amendment

Transparency

1. The competent authorities shall ensure the highest level of transparency of:

(a) the method and data used to establish the fees *or contributions to the costs* provided for in Article 77(1);

(b) the use of resources collected through such fees *or contributions to the costs, including the number of controls performed;*

(c) the arrangements in place to ensure an efficient and thrifty use of the resources

collected through such fees.

2. Each competent authority shall make available to the public the following information for each reference period:

(a) the costs to the competent authority for which a fee is due in accordance with Article 77(1), indicating the breakdown of such costs per activity referred to in Article 77(1) and per cost element referred to in Article 78(1);

(b) the amount of the fees provided for in Article 77(1) applied to each category of operators, and for each category of official controls;

(c) the method used to establish the fees provided for in Article 77(1), including the data and estimates used for the establishment of the flat rate fees referred to in point (a) of Article 79(1);

(d) where point (a) of Article 79(1) applies, the method used to adjust the level of the fees in accordance with Article 80;

(e) the overall amount of fees corresponding to the exemption referred to in Article 82(2).

collected through such fees **or contributions to the costs**.

2. Each competent authority shall make available to the public the following information for each reference period:

(a) the costs to the competent authority for which a fee is due in accordance with Article 77(1), indicating the breakdown of such costs per activity referred to in Article 77(1) and per cost element referred to in Article 78(1);

(b) the amount of the fees **or contributions to the costs** provided for in Article 77(1) applied to each category of operators, and for each category of official controls;

(c) the method used to establish the fees **or contributions to the costs** provided for in Article 77(1), including the data and estimates used for the establishment of the flat rate fees **or contribution to the costs** referred to in point (a) of Article 79(1);

(d) where point (a) of Article 79(1) applies, the method used to adjust the level of the fees **or contributions to the costs** in accordance with Article 80;

(e) the overall amount of fees **or contributions to the costs** corresponding to the exemption referred to in Article 82(2).

Amendment 199

Proposal for a regulation Article 84

Text proposed by the Commission

Expenses arising from additional official controls and from enforcement measures

Competent authorities shall charge fees to cover the additional costs they have incurred as a result of:

(a) additional official controls:

(i) which have become necessary following the detection of a non-compliance during an official control performed in accordance

Amendment

Expenses arising from additional official controls and from enforcement measures

Competent authorities shall charge fees **or contributions to the costs** to cover the additional costs they have incurred as a result of:

(a) additional official controls:

(i) which have become necessary following the detection of a non-compliance during an official control performed in accordance

with this Regulation;

(ii) performed to assess the extent and the impact of the non-compliance or to verify that the non-compliance has been remedied;

(b) official controls performed at the request of the operator;

(c) corrective action taken by the competent authorities, or by a third party upon request by the competent authorities, where an operator has failed to carry out corrective action ordered by the competent authorities in accordance with Article 135 to remedy the non-compliance;

(d) official controls performed and action taken by the competent authorities in accordance with Articles 64 to 67, 69 and 70, and corrective action taken by a third party upon request by the competent authorities, in cases where the operator has failed to carry out corrective action ordered by the competent authorities in accordance with Articles 64(3) and (5), 65 and 67.

with this Regulation;

(ii) performed to assess the extent and the impact of the non-compliance or to verify that the non-compliance has been remedied;

(b) official controls performed at the request of the operator;

(c) corrective action taken by the competent authorities, or by a third party upon request by the competent authorities, where an operator has failed to carry out corrective action ordered by the competent authorities in accordance with Article 135 to remedy the non-compliance;

(d) official controls performed and action taken by the competent authorities in accordance with Articles 64 to 67, 69 and 70, and corrective action taken by a third party upon request by the competent authorities, in cases where the operator has failed to carry out corrective action ordered by the competent authorities in accordance with Articles 64(3) and (5), 65 and 67.

Amendment 200

Proposal for a regulation

Article 85 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) official health attestations.

Amendment 201

Proposal for a regulation

Article 86 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Regarding the issuance of an official certificate for products referred to in Article 1(2) point (j), in addition to the provisions mentioned in article 85(2), the delegated body works and is accredited in accordance with standard EN ISO/IEC 17065: 2012.

Amendment 202

Proposal for a regulation

Article 87 – paragraph 1

Text proposed by the Commission

1. Official certificates shall be issued by the competent authorities.

Amendment

1. Official certificates shall be issued by the competent authorities **or delegated bodies pursuant to Articles 25 to 32.**

Amendment 203

Proposal for a regulation

Article 87 – paragraph 2 – point a

Text proposed by the Commission

(a) be free from conflict of interest in relation to what is being certified and act impartially;

Amendment

(a) be free from conflict of interest in relation to what is being certified and act **independently and** impartially;

Amendment 204

Proposal for a regulation

Article 88 – paragraph 1 – point d

Text proposed by the Commission

(d) enable the identification of the person who signed them;

Amendment

(d) enable the identification of the person who signed them **and the date of issue;**

Amendment 205

Proposal for a regulation

Article 88 – paragraph 1 – point e

Text proposed by the Commission

(e) allow the verification of the link between the certificate and the consignment, lot or individual animal or good covered by the certificate.

Amendment

(e) allow the **easy** verification of the link between the certificate, **the issuing authority** and the consignment, lot or individual animal or good covered by the certificate.

Amendment 206

Proposal for a regulation

Article 90 – paragraph 2 – point b

Text proposed by the Commission

(b) be drawn up in one of the official languages of the institutions of the Union;

Amendment

(b) be drawn up in one of the official languages of the institutions of the Union;
or in any of the official languages of a Member State;

Amendment 207

Proposal for a regulation

Article 90 – paragraph 3 – point a

Text proposed by the Commission

(a) are impartial and free from any conflict of interest in relation to what is being certified by the official attestations;

Amendment

(a) are ***independent***, impartial and free from any conflict of interest in relation to what is being certified by the official attestations;

Amendment 208

Proposal for a regulation

Article 91 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission ***may***, by means of implementing acts, designate European Union reference laboratories in the areas governed by the rules referred to in Article 1(2) where the effectiveness of official controls also depends on the quality, uniformity and reliability of:

Amendment

1. The Commission ***shall***, by means of implementing acts, designate European Union reference laboratories in the areas governed by the rules referred to in Article 1(2) where the effectiveness of official controls also depends on the quality, uniformity and reliability of:

Amendment 209

Proposal for a regulation

Article 91 – paragraph 2 – point b

Text proposed by the Commission

b) be reviewed regularly.

Amendment

b) be reviewed regularly ***every five years***.

Amendment 317

Proposal for a regulation

Article 91 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(ba) be made only to laboratories that hold a supporting letter from the authority competent in the field in question.

Amendment 210

Proposal for a regulation

Article 91 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The Commission may, where it considers appropriate, designate more than one reference laboratory for the same disease and thus promote the rotation of national laboratories meeting the requirements of paragraph 3 of this Article.

Amendment 211

Proposal for a regulation

Article 91 – paragraph 3 – point b

Text proposed by the Commission

Amendment

(b) be impartial and free of conflict of interests as regards the exercise of its tasks as European Union reference laboratories;

(b) be ***independent***, impartial and free of conflict of interests as regards the exercise of its tasks as European Union reference laboratories;

Amendment 212

Proposal for a regulation

Article 91 – paragraph 3 – point g a (new)

Text proposed by the Commission

Amendment

(ga) where relevant, cooperate with European Union research centres and Commission services to develop high standards in methods of laboratory analysis, testing and diagnosis.

Amendment 213

Proposal for a regulation
Article 91 – paragraph 3 – point g b (new)

Text proposed by the Commission

Amendment

(gb) be able to receive a financial contribution from the Union in accordance with Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field.

Amendment 214

Proposal for a regulation
Article 91 – paragraph 3 – point g c (new)

Text proposed by the Commission

Amendment

gc) ensure that their staff respect the confidential nature of certain subjects, results or communications.

Amendment 215

Proposal for a regulation
Article 91 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. By way of derogation from paragraphs 1 and 2 of this Article, the reference laboratories referred to in Article 32(1) of Regulation (EC) No 1829/2003 and Article 21(1) of Regulation (EC) No 1831/2003 shall be European Union reference laboratories having the tasks and responsibilities set out in Article 92 of this Regulation, as regards, respectively:

(a) GMOs and genetically modified food and feed;

(b) feed additives.

Amendment 216

Proposal for a regulation
Article 92 – paragraph 2 – point a a (new)

aa) providing reference material free of charge and for unrestricted use (in respect of animal health, strains and serums) to the national reference laboratories to facilitate the adjustment and harmonisation of methods of analysis, testing and diagnosis;

Amendment 217

Proposal for a regulation

Article 92 – paragraph 2 – point b

Text proposed by the Commission

Amendment

b) coordinating the application by the national reference laboratories ***and, if necessary, by other official laboratories*** of the methods referred to in point (a), in particular, by organising regular inter-laboratory comparative testing and by ensuring appropriate follow-up of such comparative testing in accordance, where available, with internationally accepted protocols;

b) coordinating the application by the national reference laboratories of the methods referred to in point (a), in particular, by organising regular inter-laboratory comparative testing and by ensuring appropriate follow-up of such comparative testing in accordance, where available, with internationally accepted protocols; ***they shall inform the competent authorities of the follow-up and results of such inter-laboratory comparative testing;***

Amendment 218

Proposal for a regulation

Article 92 – paragraph 2 – point d

Text proposed by the Commission

Amendment

d) conducting training courses for the benefit of staff from national reference laboratories and, if needed, from other official laboratories, as well as of experts from third countries;

d) conducting training courses ***free of charge*** for the benefit of staff from national reference laboratories and, if needed, ***conducting training courses for the benefit of staff*** from other official laboratories, as well as of experts from third countries;

Amendment 219

Proposal for a regulation

Article 92 – paragraph 2 – point h

Text proposed by the Commission

(h) assisting actively in the diagnosis of outbreaks in Member States of foodborne, zoonotic or animal diseases, ***or of pests of plants***, by carrying out confirmatory diagnosis, characterisation and taxonomic or epizootic studies on pathogen isolates or pest specimens;

Amendment

(h) assisting actively in the diagnosis of outbreaks in Member States of foodborne, zoonotic or animal diseases, by carrying out confirmatory diagnosis, characterisation and taxonomic or epizootic studies on pathogen isolates or pest specimens;

Amendment 220

Proposal for a regulation

Article 92 – paragraph 2 – point j – point i

Text proposed by the Commission

(i) ***reference collections of pests of plants*** or reference strains of pathogenic agents;

Amendment

(i) reference strains of pathogenic agents;

Amendment 221

Proposal for a regulation

Article 92 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Paragraphs 1 and 2 of this Article shall apply without prejudice to Article 32, first paragraph, of Regulation (EC) No 1829/2003 and the rules adopted under the fourth and fifth paragraphs of Article 32 of that Regulation, in addition to Article 21, first paragraph, of Regulation (EC) No 1831/2003 and the rules adopted under the third and fourth paragraphs of Article 21 of that Regulation.

Amendment 222

Proposal for a regulation

Article 92 a (new)

Text proposed by the Commission

Amendment

Article 92a

1. The Commission shall, by means of

delegated acts, designate an EU reference laboratory for food authenticity;

2. Member States may designate national reference laboratories as part of a network of laboratories working within the EU.

Amendment 223

Proposal for a regulation Article 93

Text proposed by the Commission

Amendment

Article 93

deleted

Designation of European Union reference centres for plant reproductive material

1. The Commission may, by means of implementing acts, designate European Union reference centres that shall support the activities of the Commission, the Member States and the European Plant Variety Agency (EPVA) in relation to the application of the rules referred to in point (h) of Article 1(2).

2. The designations provided for in paragraph 1 shall:

- (a) follow a public selection process;*
- (b) be reviewed regularly.*

3. European Union reference centres for plant reproductive material shall:

- (a) possess a high level of scientific and technical expertise in inspection, sampling and testing of plant reproductive material;*
- (b) have suitably qualified staff with adequate training in the areas referred to in point (a) and support staff as appropriate;*
- (c) possess or have access to the infrastructure equipment and products needed to carry out the tasks assigned to them;*
- (d) ensure that their staff have good knowledge of international standards and*

practices in the areas referred to in point (a) and that the latest developments in research at national, Union and international level in those areas are taken into account in their work.

Amendment 224

Proposal for a regulation Article 94

Text proposed by the Commission

Amendment

Article 94

deleted

Responsibilities and tasks European Union reference centres for plant reproductive material

The European Union reference centres designated in accordance with Article 93(1) shall be responsible, in accordance with annual or multiannual work programmes approved by the Commission for the following tasks:

(a) providing scientific and technical expertise, within the scope of their mission, on:

(i) field inspection, sampling and testing performed for the certification of plant reproductive material;

(ii) post-certification tests of plant reproductive material;

(iii) tests on standard material categories of plant reproductive material;

(b) organising comparative tests and field trials on plant reproductive material;

(c) conducting training courses for the benefit of staff of the competent authorities and of experts from third countries;

(d) contributing to the development of certification and post-certification test protocols for plant reproductive material, and of performance indicators for the certification of plant reproductive material;

(e) disseminating research findings and technical innovations in the fields within the scope of their mission.

Amendment 225

Proposal for a regulation

Article 95 – paragraph 1

Text proposed by the Commission

1. The Commission *may*, by means of implementing acts, designate European Union reference centres that shall support the activities of the Commission and of the Member States in relation to the application of the rules referred to in point (f) of Article 1(2).

Amendment

1. The Commission *shall*, by means of implementing acts, designate European Union reference centres that shall support the activities of the Commission and of the Member States in relation to the application of the rules referred to in point (f) of Article 1(2).

Amendment 226

Proposal for a regulation

Article 95 – paragraph 3 – point a

Text proposed by the Commission

(a) possess a high level of scientific and technical expertise in human-animal relationship, animal behaviour, animal physiology, animal health and nutrition related to animal welfare, and animal welfare aspects related to the commercial and scientific use of animals;

Amendment

(a) possess *suitably qualified staff with* a high level of scientific and technical expertise in human-animal relationship, animal behaviour, animal physiology, animal health and nutrition related to animal welfare, and animal welfare aspects related to the commercial and scientific use of animals, *taking ethical aspects into consideration*;

Amendment 227

Proposal for a regulation

Article 95 – paragraph 3 – point b

Text proposed by the Commission

(b) have suitably qualified staff with adequate training in the areas referred to in point (a) and in ethical issues related to animals and support staff as appropriate;

Amendment

deleted

Amendment 228

Proposal for a regulation

Article 96 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) coordinating a network of institutions with recognised knowledge on animal welfare that could assist the competent authorities and stakeholders in implementing relevant EU legislation.

Amendment 229

Proposal for a regulation

Article 96 – point c

Text proposed by the Commission

Amendment

(c) developing or coordinating the development of methods for the assessment of the level of welfare of animals ***and of*** methods for the improvement of the welfare of animals;

(c) helping to develop and coordinate methods for the assessment of the level of welfare of animals and methods for the improvement of the welfare of animals;

Amendment 230

Proposal for a regulation

Article 96 – paragraph 1 – point d

Text proposed by the Commission

Amendment

(d) carrying out scientific and technical studies on the welfare of animals used for commercial or scientific purposes;

(d) coordinating the carrying out ***of*** scientific and technical studies on the welfare of animals used for commercial or scientific purposes;

Amendment 231

Proposal for a regulation

Article 96 a (new)

Text proposed by the Commission

Amendment

Article 96a

Designation of European Union reference centres for the authenticity and integrity

of the agri-food chain

1. The Commission may, by means of implementing acts, designate European Union reference centres that shall support the activities of the Commission and of the Member States to prevent, detect and combat any intentional violations of the rules referred to in Article 1(2).

2. The designations provided for in paragraph 1(a) shall follow a public selection process and be reviewed regularly.

3. European Union reference centres for the authenticity and integrity of the agri-food chain shall:

(a) possess a high level of scientific and technical expertise in the sectors governed by the rules referred to in Article 1(2) and in applied forensic science in those sectors, thus having the ability to carry out or coordinate research at the highest levels on the authenticity and integrity of goods and to develop, apply and validate the methods to be used for the detection of intentional violations of the rules referred to in Article 1(2);

(b) have suitably qualified staff with adequate training in the areas referred to in point (a) and the necessary support staff;

(c) possess or have access to the infrastructure, the equipment and the products necessary to carry out the tasks assigned to them;

(d) ensure that their staff have good knowledge of international standards and practices in the subjects referred to in point (a) and that the latest research developments at national, Union and international level in those areas are taken into account in their work.

Amendment 232

Proposal for a regulation Article 96 b (new)

Text proposed by the Commission

Amendment

Article 96b

Responsibilities and tasks of European Union reference centres for the authenticity and integrity of the agri-food chain

1. The European Union reference centres designated under Article 96a(1) shall be responsible, in accordance with the annual or multiannual work programmes approved by the Commission, for the following activities:

(a) providing specific knowledge of the authenticity and integrity of goods and methods for detecting intentional violations of the rules referred to in Article 1(1), in relation to the forensic science applied to the areas governed by these rules;

(b) providing specific analyses designed to identify the segments of the agri-food chain that are potentially subject to intentional violations, for economic reasons, of the rules referred to in Article 1(2) and helping to develop specific official control techniques and protocols;

(c) where necessary, performing the tasks referred to in Article 92(2), points (a) to (g);

(d) where necessary, establishing and storing collections or databases of authenticated reference materials, to be used to verify the authenticity or integrity of goods;

(e) disseminating research findings and technical innovations in the fields within the scope of their missions.

Amendment 233

Proposal for a regulation

Article 97 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) European Union reference centres for plant reproductive material provided for in Article 93;

deleted

Amendment 234

Proposal for a regulation

Article 97 – paragraph 2

Text proposed by the Commission

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the establishment of requirements, responsibilities and tasks for the European Union reference laboratories, **the European Union reference centres for plant reproductive material** and the European Union reference centres for animal welfare in addition to those laid down in Articles 91(3), 92, **93(3)**, 95(3) and 96.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the establishment of requirements, responsibilities and tasks for the European Union reference laboratories, and the European Union reference centres for animal welfare in addition to those laid down in Articles 91(3), 92, 95(3) and 96.

Amendment 235

Proposal for a regulation

Article 97 – paragraph 3

Text proposed by the Commission

Amendment

3. European Union reference laboratories and European Union reference centres shall be subject to Commission controls to verify compliance with the requirements of Articles 91(3), 92, **93(3)**, 95(3) and 96.

3. European Union reference laboratories and European Union reference centres shall be subject to Commission controls to verify compliance with the requirements of Articles 91(3), 92, 95(3) and 96.

Amendment 236

Proposal for a regulation

Article 98 – paragraph 3 – point a

Text proposed by the Commission

Amendment

(a) be impartial and free of conflict of interests as regards the exercise of its tasks

(a) be **independent**, impartial and free of conflict of interests as regards the exercise

as national reference laboratories;

of its tasks as national reference laboratories;

Amendment 237

Proposal for a regulation

Article 98 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. This Article shall apply without prejudice to Article 32, second paragraph, of Regulation (EC) No 1829/2003 and the rules adopted under the fourth and fifth paragraphs of Article 32 of that Regulation, in addition to Annex II to Regulation (EC) No 1831/2003 and the rules adopted under the third and fourth paragraphs of Article 21 of that Regulation.

Amendment 238

Proposal for a regulation

Article 99 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

fa) assist actively in the diagnosis of outbreaks on national territory of animal, foodborne or zoonotic diseases by carrying out confirmatory diagnosis, characterisation and epizootic or taxonomic studies on pathogen isolates or pest specimens, as specified for the national reference laboratories of the Union in Article 92(2)(h).

Amendment 239

Proposal for a regulation

Article 99 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

This Article shall apply without prejudice to Article 32, second paragraph, of Regulation (EC) No 1829/2003 and the rules adopted under the fourth and fifth

paragraphs of Article 32 of that Regulation, in addition to Annex II to Regulation (EC) No 1831/2003 and the rules adopted under the third and fourth paragraphs of Article 21 of that Regulation.

Amendment 240

Proposal for a regulation Article 100 – paragraph 2

Text proposed by the Commission

Amendment

2. Administrative assistance shall include, where appropriate, participation by the competent authorities of a Member State in on-the-spot official controls that the competent authorities of another Member State perform.

deleted

Amendment 241

Proposal for a regulation Article 100 – paragraph 5

Text proposed by the Commission

Amendment

5. In order to streamline and simplify communication exchanges, the Commission shall, by means of implementing acts, establish a standard format for:

deleted

a) the requests for assistance provided for in Article 102(1);

b) the communication of common and recurrent notifications and responses.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141 (2).

Amendment 242

Proposal for a regulation Article 100 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. Communications between competent authorities conducted in accordance with the provisions of this title shall be without prejudice to the provisions of Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid Alert System for Food and Feed (RASFF) regarding communications through the RASFF system.

Amendment 243

Proposal for a regulation Article 101 – paragraph 7

Text proposed by the Commission

Amendment

7. The Commission shall, by means of implementing acts, establish the specifications of the technical tools and the procedures for communication between liaison bodies designated in accordance with paragraph 1.

deleted

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141 (2).

Amendment 244

Proposal for a regulation Article 102 – paragraph 1 – point b

Text proposed by the Commission

Amendment

b) indicate within **ten** days from the date of receipt of the request, the time necessary to provide an informed response to the request;

b) indicate within **15** days from the date of receipt of the request, the time necessary to provide an informed response to the request;

Amendment 245

Proposal for a regulation Article 103 – paragraph 2 – point b – introductory part

Text proposed by the Commission

b) shall indicate within **ten** days from the date of receipt of the notification:

Amendment

b) shall indicate within **15 working** days from the date of receipt of the notification:

Amendment 246

Proposal for a regulation

Article 104 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The other concerned Member States referred to in paragraph 1 shall, in the case of infringements of Regulation (EC) No 1/2005 on the protection of animals during transport include:

(a) the one that granted the authorisation to the transporter:

(b) where a deficiency in the means of transport is involved in the failure to observe the requirements of the Regulation, the one that granted the certificate of approval of the means of transport:

(c) where the driver is involved in the failure to observe the requirements of the Regulation, the one that issued the driver's certificate of competence;

Amendment 247

Proposal for a regulation

Article 104 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) inform all relevant, concerned stakeholders, as specified in national food safety contingency plans.

Amendment 248

Proposal for a regulation

Article 107 – paragraph 2 – introductory part

Text proposed by the Commission

2. Member States shall designate **a single** authority responsible for:

Amendment

2. Member States shall designate **the** authority **or authorities** responsible for:

Amendment 249

Proposal for a regulation

Article 108 – paragraph 2 – introductory part

Text proposed by the Commission

2. Multi-annual national control plans shall contain general information on the structure and organisation of the systems of official control in the Member State concerned, and shall contain at least information on the following:

Amendment

2. Multi-annual national control plans shall contain general information on the structure and organisation of the systems of official control in the Member State concerned **for each of the sectors concerned** and shall contain at least information on the following:

Amendment 250

Proposal for a regulation

Article 109 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. such plans may be prepared in consultation with relevant operators, with a view to ensuring a risk-based approach to official controls.

Amendment 251

Proposal for a regulation

Article 109 – paragraph 2 – point a

Text proposed by the Commission

(a) the emergence of new diseases, pests of plants or other risks to human, animal or plant health, animal welfare or, **in the case of GMOs and plant protection products**, to the environment;

Amendment

(a) the emergence of new diseases, pests of plants or other risks to human or plant animal health, animal welfare or to the environment;

Amendment 252

Proposal for a regulation

Article 110

Text proposed by the Commission

Amendment

Article 110

deleted

Delegated powers for multi-annual national control plans

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the multi-annual national control plans provided for in Article 107(1).

Those delegated acts shall lay down rules on:

- a) criteria for the risk categorisation of the operators' activities;*
- b) priorities for official controls based on the criteria laid down in Article 8 and in the rules provided for in Articles 15 to 24;*
- c) procedures to maximise the effectiveness of official controls;*
- d) the main performance indicators to be applied by the competent authorities in assessing the multi-annual national control plan and its implementation.*

Amendment 253

Proposal for a regulation

Article 111 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) the organisation and the implementation of coordinated control plans of limited duration in one of the areas governed by the rules referred to in Article 1(2);

(a) the **preparation**, organisation and the implementation of coordinated control plans of limited duration in one of the areas governed by the rules referred to in Article 1(2);

Amendment 254

Proposal for a regulation

Article 111 – paragraph 1 – point b

Text proposed by the Commission

b) the organisation, on an ad hoc basis, of the collection of data and information in relation to the ***application of a specific set of the rules referred to in Article 1(2) or regarding the*** prevalence of certain hazards.

Amendment

b) the organisation, on an ad hoc basis, of the collection of data and information in relation to the prevalence of certain hazards.

Amendment 255

Proposal for a regulation

Article 111 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the role of stakeholders in the development and implementation of the coordinated control plans.

Amendment 256

Proposal for a regulation

Article 112 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) the type and number of cases of non-compliance with the rules referred to in Article 1(2) detected in the previous year by the competent authorities;

(c) the type and number of cases of non-compliance with the rules referred to in Article 1(2) detected in the previous year by the competent authorities, ***specified per sector, and in an adequate level of detailedness;***

Amendment 257

Proposal for a regulation

Article 112 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) the information on fees referred to in paragraph 2 of Article 83 on transparency.

Amendment 258

Proposal for a regulation

Article 113 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission shall make available to the public an annual report on the operation of official controls in the Member States, taking into account:

Amendment

1. The Commission shall, **by 31st December every second year after the entry into force of this Regulation**, make available to the public an annual report on the operation of official controls in the Member States, taking into account:

Amendment 259

Proposal for a regulation

Article 113 – paragraph 1 – point a

Text proposed by the Commission

(a) the annual reports submitted by the Member States in accordance with Article 112;

Amendment

(a) the annual reports submitted by the Member States in accordance with Article 112, **which shall include the information on fees referred to in paragraph 2 of Article 83 on transparency**;

Amendment 260

Proposal for a regulation

Article 113 – paragraph 2

Text proposed by the Commission

2. The annual report provided for in paragraph 1 **may, where appropriate**, include recommendations on possible improvements to official control systems in Member States and specific official controls in certain areas.

Amendment

2. The annual report provided for in paragraph 1 **shall** include recommendations on possible improvements to official control systems in Member States and specific official controls in certain areas.

Amendment 261

Proposal for a regulation

Article 117 – paragraph 2

Text proposed by the Commission

2. The Commission may, by means of implementing acts, amend its control programme to take account of

Amendment

2. The Commission may, by means of implementing acts, amend its control programme to take account of

developments in the areas governed by the rules referred to in Article 1(2). Any such amendment shall be communicated to the Member States.

developments in the areas governed by the rules referred to in Article 1(2). Any such amendment shall be communicated to the Member States *sufficiently well in advance*.

Amendment 263

Proposal for a regulation Article 119 – paragraph 2 – point f

Text proposed by the Commission

(f) where applicable, the situation regarding animal health, zoonoses *and plant health*, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases *and pests of plants*;

Amendment

(f) where applicable, the situation regarding animal health, zoonoses, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases;

Amendment 264

Proposal for a regulation Article 120 – paragraph 1 – point h a (new)

Text proposed by the Commission

Amendment

(ha) the likelihood of fraudulent practices which might deceive consumer expectations regarding nature, quality and composition of foods and goods;

Amendment 266

Proposal for a regulation Article 125 – paragraph 2 – point e

Text proposed by the Commission

(e) any other requirement necessary to ensure that certain animals and goods *offer a level of protection of health and, as regards GMOs and plant protection products, of the environment, equivalent to that ensured by* the requirements referred to in paragraph 1.

Amendment

(e) any other requirement necessary to ensure that certain animals and goods *comply with* the requirements referred to in paragraph 1.

Amendment 267

Proposal for a regulation Article 127 – paragraph 1

Text proposed by the Commission

1. Where, in cases other than those referred to in Article 53 of Regulation (EC) No 178/2002, Article 249 of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on animal health] and in Articles 27(1), 29(1), 40(2), 41(2), 47(1), 49(2) and 50(2) of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on protective measures against pests of plants], there is evidence that the entry into the Union of certain animals or goods originating from a third country, a region thereof or a group of third countries, may pose a risk to human, animal *or plant* health or, *as regards GMOs and plant protection products*, to the environment, or where there is evidence that widespread serious non-compliance with the rules referred to in Article 1(2) might be taking place, the Commission shall adopt, by means of *implementing* acts, the measures necessary to contain such risk or put an end to the identified non-compliance. *Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).*

Amendment 268

Proposal for a regulation Article 128 a (new)

Text proposed by the Commission

Amendment

1. Where, in cases other than those referred to in Article 53 of Regulation (EC) No 178/2002, Article 249 of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on animal health], and in Articles 27(1), 29(1), 40(2), 41(2), 47(1), 49(2) and 50(2) of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of the Regulation on protective measures against pests of plants], there is evidence that the entry into the Union of certain animals or goods originating from a third country, a region thereof or a group of third countries, may pose a risk to human *or* animal health or to the environment, or where there is evidence that widespread serious non-compliance with the rules referred to in Article 1(2) might be taking place, the Commission shall adopt, by means of *delegated acts in accordance with Article 139*, the measures necessary to contain such risk or put an end to the identified non-compliance.

Amendment

Article 128a

Supporting developing countries

1. With a view to ensuring that developing countries can comply with the provisions of this Regulation, measures may be taken, and may be implemented for as long as they continue to have a

demonstrable impact, to support the following activities:

- compliance with the conditions governing the entry into the Union of animals and goods;*
- drafting of guidelines on the organisation of official controls on products to be exported to the Union;*
- sending of European Union or Member State experts to developing countries to assist with the organisation of official controls;*
- involvement of control staff from developing countries in training programmes or courses.*

2. The Commission shall be empowered, pursuant to Article 139, to adopt delegated acts setting out provisions covering the forms of support for developing countries referred to in paragraph 1.

Amendment 269

Proposal for a regulation

Article 129 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The Commission *may* organise training activities for the staff of the competent authorities and, where appropriate, for staff of other authorities of the Member States involved in investigations of possible violations of the provisions of this Regulation and of the rules referred to in Article 1(2).

Amendment

The Commission *shall* organise training activities for the staff of the competent authorities and, where appropriate, for staff of other authorities of the Member States involved in investigations of possible violations of the provisions of this Regulation and of the rules referred to in Article 1(2).

Amendment 270

Proposal for a regulation

Article 129 – paragraph 1 – subparagraph 2

Text proposed by the Commission

The Commission *may* organise those activities in cooperation with Member States.

Amendment

The Commission *shall* organise those activities in cooperation with Member States.

Amendment 271

Proposal for a regulation Article 130 – paragraph 1

Text proposed by the Commission

1. The Commission shall set up and manage a computerised information management system for the integrated operation of the mechanisms and tools through which data, information and documents concerning official controls are managed and handled ('the IMSOC').

Amendment

1. The Commission shall set up and manage a computerised information management system for the integrated operation of the mechanisms and tools through which data, information and documents concerning official controls are ***automatically forwarded from databases in the Member States and*** managed and handled ***and automatically exchanged*** ('the IMSOC'), ***taking into account existing national systems.***

Amendment 272

Proposal for a regulation Article 130 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. When forwarding electronic certificates or other electronic documents, the Commission and Member States shall use standard international programming languages, message structures and transmission protocols and safe transmission procedures.

Amendment 273

Proposal for a regulation Article 130 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. When exchanging electronic data, such as electronic certificates, the Commission and the competent authorities of the Member States shall use internationally standardised language, message structure and exchange protocols.

Amendment 336

Proposal for a regulation Article 134 – paragraph 1

Text proposed by the Commission

1. When acting in accordance with this Chapter, the competent authorities shall give priority to action to be taken to eliminate or contain risks to human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, to the environment.

Amendment

1. When acting in accordance with this Chapter, the competent authorities shall give priority to action to be taken to eliminate or contain risks to human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, to the environment. ***Given the increasing frequency of fraud in the food area, more emphasis shall be put on tackling practices which mislead consumers as to the nature or the quality of the food they purchase and consume.***

Amendment 274

Proposal for a regulation Article 134 – paragraph 3 – point a

Text proposed by the Commission

a) the performance of intensified official controls on animals, goods and operators for an appropriate period;

Amendment

a) the performance of intensified official controls on animals, goods and operators for an appropriate period, ***in keeping with the nature of the risk;***

Amendment 275

Proposal for a regulation Article 135 – paragraph 1 – subparagraph 1 – point b

Text proposed by the Commission

(b) take appropriate measures to ensure that the operator remedies the non-compliance and ***prevents*** further occurrences of it.

Amendment

(b) take appropriate measures to ensure that the operator remedies the non-compliance and ***establishes systems to prevent*** further occurrences of it.

Amendment 276

Proposal for a regulation Article 135 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) where the outcome of the official controls on journey logs provided for in point (i) of paragraph (b) of Article 18 (1) is not satisfactory, require the organiser to change the arrangements for the intended long journey so that it complies with Regulation (EC) No 1/2005;

Amendment 277

Proposal for a regulation

Article 135 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) order the unloading, transfer to another means of transport, holding **and** care of animals, quarantine periods, the postponement of the slaughter of animals;

(b) order the unloading, transfer to another means of transport, holding **in suitable accommodation with appropriate** care of animals, quarantine periods, the postponement of the slaughter of animals, **that veterinary assistance must be sought if necessary;**

Amendment 278

Proposal for a regulation

Article 135 – paragraph 2 – point e a (new)

Text proposed by the Commission

Amendment

(ea) require business operators carrying out the killing of animals or any related operations falling within the scope of Regulation (EC) No 1099/2009 to amend their standard operating procedures and, in particular, slow down or stop production;

Amendment 279

Proposal for a regulation

Article 135 – paragraph 2 – point j

Text proposed by the Commission

Amendment

(j) order the suspension or withdrawal of

(j) order the suspension or withdrawal of

the approval of the establishment, plant, holding or means of transport concerned, or of the authorisation of a transporter;

the approval of the establishment, plant, holding or means of transport concerned, or of the authorisation of a transporter *or of the certificate of competence of the driver*;

Amendment 280

Proposal for a regulation

Article 136 – paragraph 1 – subparagraph 1 (new)

Text proposed by the Commission

Amendment

Irrespective of the financial advantage sought, the severity of the penalties should also reflect the degree of risk of damage to consumers' health.

Amendment 281

Proposal for a regulation

Article 136 – paragraph 2

Text proposed by the Commission

Amendment

2. Member States shall ensure that financial penalties applicable to intentional violations of the provisions of this Regulation and of the rules referred to in Article 1(2) at least *offset* the economic advantage sought through the violation.

2. Member States shall ensure that financial penalties applicable to intentional violations of the provisions of this Regulation and of the rules referred to in Article 1(2) *are set at* at least *double* the economic advantage sought through the violation.

Amendment 282

Proposal for a regulation

Article 136 – paragraph 3 – point b

Text proposed by the Commission

Amendment

(b) false or misleading official certification;

(b) false or misleading official certification *and declarations*;

Amendment 283

Proposal for a regulation

Article 136 – paragraph 3 – point c a (new)

Text proposed by the Commission

Amendment

(ca) where consumers' health is damaged.

Amendment 284

Proposal for a regulation

Article 136 a (new)

Text proposed by the Commission

Amendment

Article 136a

Reporting of breaches

1. Member States shall ensure that competent authorities establish effective and reliable mechanisms to encourage reporting of potential or actual breaches of this Regulation and of national provisions related to this Regulation to competent authorities.

2. The mechanisms referred to in paragraph 1 shall include at least:

(a) specific procedures for the receipt of reports on breaches and their follow-up;

(b) appropriate protection for employees of institutions who report breaches committed within the institution against retaliation, discrimination or other types of unfair treatment at a minimum;

(c) protection of personal data concerning both the person who reports the breaches and the natural person who is allegedly responsible for a breach, in accordance with Directive 95/46/EC;

(d) clear rules that ensure that confidentiality is guaranteed in all cases in relation to the person who reports the breaches committed within the institution, unless disclosure is required by national law in the context of further investigations or subsequent judicial proceedings.

3. Member States shall require institutions to have in place appropriate procedures for their employees to report

breaches internally through a specific, independent and autonomous channel. Such a channel may also be provided through arrangements provided for by social partners. The same protection as referred to in points (b), (c) and (d) of paragraph 2 shall apply.

Amendment 285

Proposal for a regulation Article 139 – paragraph 2

Text proposed by the Commission

2. The delegation of power referred to in Articles 4(3), 15(2), 16, 17, 18(3), 19, 20, 21, 22, 23(1), 24(1), 25(3), 26(2), 40, 43(4), 45(3), 46, 49, 51(1), 52(1) and (2), 56(2), 60(3), 62(2), 69(3), 75(1) and (2), 97(2), 98(6), 99(2), 101(3), 106(3), 110, 111, 114(4) and 125(1), the third subparagraph of Article 132(1), Articles 133, 138(1) and (2), 143(2), 144(3), 151(3), 153(3) and 159(3) shall be conferred for *an indeterminate* period of *time* from the date of entry into force of this *Regulation*.

Amendment

2. The delegation of power referred to in Articles 4(3), 15(2), 16, 17, 18(3), 19, 20, 21, 22, 23(1), 24(1), 25(3), 26(2), 40, 43(4), 45(3), 46, 49, 51(1), 52(1) and (2), 56(2), 60(3), 62(2), 69(3), 75(1) and (2), 97(2), 98(6), 99(2), 101(3), 106(3), 110, 111, 114(4) and 125(1), the third subparagraph of Article 132(1), Articles 133, 138(1) and (2), 143(2), 144(3), 151(3), 153(3) and 159(3) shall be conferred *on the Commission* for a period of *5 years* from (*Publications Office is to fill in* the date of entry into force of this *amending Act*).

The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of identical duration unless the European Parliament or Council opposes such an extension not later than 3 months before the end of each period.

Amendment 286

Proposal for a regulation Article 139 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. For the period during which these delegated powers are exercised, it is of particular importance that the

Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Amendment 287

Proposal for a regulation Article 141 – paragraph 1

Text proposed by the Commission

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That Committee is a Committee in the meaning of Regulation (EU) No 182/2011.

Amendment

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That Committee is a Committee in the meaning of Regulation (EU) No 182/2011. ***This shall apply with the exception of cases covered by Article 23, which requires the Commission to be assisted by committees set up under Regulation (EC) No 834/2007 on organic production, Regulation (EU) No 1151/2012 regarding DOP, PGI and TSG food product designations, Regulation (EC) No 1234/2007 regarding DOP and PGI wine designations and Regulation (EC) No 110/2008 regarding the geographical indications of spirit drinks.***

Amendment 288

Proposal for a regulation Article 142 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

The designation of each of the European Union reference laboratories referred to in Annex VII to Regulation (EC) No 882/2004 shall continue to apply until the designation, in each of the areas concerned, of a European Union reference laboratory pursuant to Article

91(2) of this Regulation.

Amendment 289

Proposal for a regulation Article 142 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The designation of each of the European Union reference laboratories referred to in Annex VII to Regulation (EC) No 882/2004 shall continue to apply until such time as, in each of the areas concerned, a European Union reference laboratory is designated in accordance with Article 91(2) of this Regulation, without prejudice to Article 91(3a) thereof.

Amendment 290

Proposal for a regulation Article 142 – paragraph 2

Text proposed by the Commission

Amendment

2. Regulation (EC) No 854/2004 and Directives 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC and 97/78/EC are repealed as from [Office of Publications, please insert date of entry into force of this Regulation + 3 years].

2. Directives 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC and 97/78/EC are repealed as from [Office of Publications, please insert date of entry into force of this Regulation + 3 years].

Amendment 291

Proposal for a regulation Article 148 Regulation (EC) 1829/2003 Article 32

Text proposed by the Commission

Amendment

Regulation (EC) No 1829/2003 is amended as follows:

deleted

(a) Article 32 is amended as follows:

(i) the first and second subparagraphs are deleted

(ii) the third subparagraph is replaced by the following:

'Applicants for authorisation of genetically modified food and feed shall contribute to supporting the costs of the tasks of the European Union reference laboratory and the national reference laboratories designated in accordance with Articles 91(1) and 98(1) of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of this Regulation] for that area.'

(iii) in the fifth subparagraph the words 'and the annex' shall be deleted.

(iv) in the sixth subparagraph the words 'and adapting the Annex' shall be deleted.

(b) the Annex is deleted.

Amendment 292

Proposal for a regulation

Article 149

Regulation (EC) 1831/2003

Article 7, 21 and Annex II

Text proposed by the Commission

Amendment

Regulation (EC) No 1831/2003 is amended as follows:

deleted

(a) in Article 7, paragraph 3(f) is replaced by the following

'a written statement that three samples of the feed additive have been sent by the applicant directly to the European Union reference laboratory referred to in Article 21.'

(b) Article 21 is amended as follows:

(i) the first, third and fourth paragraphs are deleted;

(ii) paragraph 2 is replaced by the following:

'Applicants for the authorisation of additives shall contribute to supporting the cost of the tasks of the European Union reference laboratory and the national reference laboratories designated in accordance with Articles 91(1) and 98(1) of Regulation (EU) No XXX/XXXX [Office of Publications, please insert number of this Regulation] for that area.'

(c) Annex II is deleted.

Amendment 293

Proposal for a regulation

Article 150 – paragraph 1 – point b

Regulation (EC) No 1/2005

Article 14, 15, 16, 21, 22, 23, 24, 26

Text proposed by the Commission

(b) Articles 14, 15, 16, 21, 22(2), 23, 24 and 26 *are deleted*;

Amendment

(b) Articles 14, 15, 16, 21, 22(2), 23, 24 and 26 *shall continue to apply until the legislative proposals referred to in Article 18 are established*;

Amendment 294

Proposal for a regulation

Article 151 – paragraph 2

Regulation (EC) No 396/2005

Article 26, 27, 30

Text proposed by the Commission

2. Articles 26, 27(1) and 30 of Regulation (EC) No 396/2005 shall continue to apply until the date to be *determined in the delegated act adopted in accordance with paragraph 3*.

Amendment

2. Articles 26, 27(1) and 30 of Regulation (EC) No 396/2005 shall continue to apply until the date *of the application of the corresponding rules to be established pursuant to the legislative proposals referred to in Article 16 of this Regulation*.

Amendment 295

Proposal for a regulation

Article 151 – paragraph 3

Regulation (EC) No 396/2005

Article 26, 27, 30

Text proposed by the Commission

Amendment

3. The Commission shall be empowered to adopt delegated acts in accordance to Article 139 concerning the date on which Articles 26, 27(1) and 30 referred to in paragraph 2 shall no longer apply. That date shall be the date of the application of the corresponding rules to be established pursuant to the delegated acts provided for in Article 16 of this Regulation.

deleted

Amendment 296

Proposal for a regulation

Article 153 – paragraph 1 – point c – point ii

Regulation (EC) No 834/2007

Article 27 – paragraphs 3 to 6 and 8 to 14

Text proposed by the Commission

Amendment

(ii) paragraphs 2 to 14 are deleted;

(ii) paragraphs **3 to 6 and 8** to 14 are deleted;

Amendment 297

Proposal for a regulation

Article 153 – paragraph 2

Regulation (EC) No 834/2007

Article 27, 30

Text proposed by the Commission

Amendment

2. Articles 27 and 30(2) of Regulation (EC) No 834/2007 shall continue to apply until the date to be determined in the delegated act to be adopted in accordance with paragraph 3.

2. Paragraphs 3 to 14 of Article 27 and paragraph 2 of Article 30 of Regulation (EC) No 834/2007 shall continue to apply until the date to be determined in the delegated act to be adopted in accordance with paragraph 3.

Amendment 298

Proposal for a regulation

Article 153 – paragraph 2
Regulation (EC) No 834/2007
Article 27, 30

Text proposed by the Commission

5. Articles 27 and 30(2) of Regulation (EC) No 834/2007 shall continue to apply until the date to be determined in the delegated act to be adopted in accordance with paragraph 3.

Amendment

5. Articles 27(3 to 6) **and (8 to 14)** and 30(2) of Regulation (EC) No 834/2007 shall continue to apply until the date to be determined in the delegated act to be adopted in accordance with paragraph 3.

Amendment 299

Proposal for a regulation
Article 159 – paragraph 2
Directive 2009/128/EC
Article 8 and Annex II

Text proposed by the Commission

2. Paragraph 1, the second subparagraph of paragraph 2 and paragraphs 3, 4 and 6 of Article 8 and Annex II of Directive 2009/128/EC shall continue to apply until the date *to be determined in the delegated act* to be *adopted in accordance with paragraph 3*.

Amendment

2. Paragraph 1, the second subparagraph of paragraph 2 and paragraphs 3, 4 and 6 of Article 8 and Annex II of Directive 2009/128/EC shall continue to apply until the date *of the application of the corresponding rules* to be *established pursuant to the legislative proposals referred to in Article 22 of this Regulation*.

Amendment 300

Proposal for a regulation
Article 159 – paragraph 3

Text proposed by the Commission

3. The Commission shall be empowered to adopt delegated acts in accordance to Article 139 concerning the date on which the provisions referred to in paragraph 2 shall no longer apply. That date shall be the date of the application of the corresponding rules to be established pursuant to the delegated acts provided for in Article 22 of this Regulation.

Amendment

deleted

Amendment 301

Proposal for a regulation

Article 161 – paragraph 1 – point a – point ii

Regulation (EU) No [...] /2013

Article 29 – paragraph 1

Text proposed by the Commission

Amendment

(b) the European Union reference centres for plant reproductive material referred to in Article 93 of that Regulation;

deleted

Amendment 302

Proposal for a regulation

Article 161 – paragraph 1 – point a – point ii

Regulation (EU) n. [...] /2013

Article 29 – paragraph 1 – letter c a (new)

Text proposed by the Commission

Amendment

(ca) the European Union reference centres for the authenticity and integrity of the agri-food chain.

Amendment 303

Proposal for a regulation

Article 161 – paragraph 1 – point b

Regulation (EU) n. [...] /2013

Article 29 a – paragraph 2

Text proposed by the Commission

Amendment

2. *Grants* may be awarded to a single national reference laboratory in each Member State for each European Union reference laboratory for plant health, up to three years after the designation of that European Union reference laboratory.'

2. *The grants referred to in paragraph 1* may be awarded to a single national reference laboratory in each Member State for each European Union reference laboratory for plant health, up to three years after the designation of that European Union reference laboratory.'

Amendment 304

Proposal for a regulation

Article 162 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

Maximum one year after entry into force of this regulation, the Commission shall provide a comprehensive guidance document, to assist operators and national authorities to effectively implement this regulation.

Amendment 305

Proposal for a regulation

Article 162 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Ia. Maximum five years after the entry into force of this Regulation, the Commission shall submit a report to the European Parliament and the Council to present the experience gained from the application of this Regulation and consider in particular the reduction of administrative burden on private sector and the efficiency and effectiveness of controls carried out by competent authorities.

Amendment 306

Proposal for a regulation

Article 162 – paragraph 3

Text proposed by the Commission

Amendment

3. In the area covered by the rules referred to in point (h) of Article 1(2), this Regulation, shall apply from [Office of Publications, please insert date of application of the Regulation on the production and making available on the market of plant reproductive material], with the following exceptions:

(a) Articles 93, 94 and 97 shall apply in accordance with paragraph 1;

(b) Article 33(1), (2) (3) and (4) shall

deleted

apply from [Office of Publications, please insert date of entry into force of this Regulation + 5 years].

Amendment 307

Proposal for a regulation Article 162 – paragraph 4

Text proposed by the Commission

4. Articles 15(1), 18(1), 45 to 62 and 76 to 84, **point (b) of Article 150, point (b)(i) of Article 152, point (b)(i) of Article 154, point (b)(i) of Article 155 and point (b) of Article 156** shall apply from [Office of Publications, please insert date of entry into force this Regulation + 3 years].

Amendment

4. Articles 15(1), 18(1), 45 to 62 and 76 to 84, points (b) **and (c)(i)** of Article 152, point (b)(i) of Article 154 **and** point (b)(i) of Article 155 shall apply from [Office of Publications, please insert date of entry into force this Regulation + 3 years]. **Point (b) of Article 150 and point (b) of Article 156 shall not apply until the delegated acts that replace them are in force.**

Amendment 309

Proposal for a regulation Annex II – chapter 1 – point 5 a (new)

Text proposed by the Commission

Amendment

5a. The risks posed by antimicrobial resistance to human and animal health;

Amendment 310

Proposal for a regulation Annex II – chapter 1 – point 6

Text proposed by the Commission

6. The different stages of production, processing and distribution, and the possible risks to human health, and where appropriate to the health of animals and plants, to the welfare of animals, to the environment, **and to the identity and quality of plant reproductive material.**

Amendment

6. The different stages of production, processing and distribution, and the possible risks to human health, and where appropriate to the health of animals and plants, to the welfare of animals, **and** to the environment.

Amendment 311

Annex III a

OFFICIAL AUXILIARIES

1. The competent authority may appoint as official auxiliaries only persons who have undergone training and passed a test in accordance with the following requirements.

2. The competent authority must make arrangements for such tests. To be eligible for these tests, candidates must prove that they have received:

(a) at least 500 hours of theoretical training and at least 400 hours of practical training, covering the areas specified in paragraph 5; and

(b) such additional training as is required to enable official auxiliaries to undertake their duties competently.

3. The practical training referred to in paragraph 2(a) is to take place in slaughterhouses and cutting plants, under the supervision of an official veterinarian, and on holdings and in other relevant establishments.

4. Training and tests are to concern principally red meat or poultry meat. However, persons who undergo training for one of the two categories and passed the test, need only undergo abridged training to pass the test for the other category. Training and test should cover wild game, farmed game and lagomorphs, where appropriate.

5. Training for official auxiliaries is to cover, and tests are to confirm knowledge of, the following subjects:

(a) in relation to holdings:

(i) theoretical part:

– familiarity with the farming industry organisation, production methods,

international trade etc. ,

- good livestock husbandry practices,*
- basic knowledge of diseases, in particular zoonoses-viruses, bacteria, parasites etc.,*
- monitoring for disease, use of medicines and vaccines, residue testing,*
- hygiene and health inspection,*
- animal welfare on the farm and during transport,*
- environmental requirements - in buildings, on farms and in general,*
- relevant laws, regulations and administrative provisions,*
- consumer concerns and quality control;*

(ii) practical part:

- visits to holdings of different types and using different rearing methods,*
- visits to production establishments,*
- observation of the loading and unloading of animals,*
- laboratory demonstrations,*
- veterinary checks,*
- documentation;*

(b) in relation to slaughterhouses and cutting plants:

(i) theoretical part:

- familiarity with the meat industry organisation, production methods, international trade and slaughter and cutting technology,*
- basic knowledge of hygiene and good hygienic practices, and in particular industrial hygiene, slaughter, cutting and storage hygiene, hygiene of work,*
- HACCP and the audit of HACCP-based procedures,*
- animal welfare on unloading after transport and at the slaughterhouse,*
- basic knowledge of the anatomy and physiology of slaughtered animals,*

- *basic knowledge of the pathology of slaughtered animals,*
- *basic knowledge of the pathological anatomy of slaughtered animals,*
- *relevant knowledge concerning TSEs and other important zoonoses and zoonotic agents,*
- *knowledge of methods and procedures for the slaughter, inspection, preparation, wrapping, packaging and transport of fresh meat,*
- *basic knowledge of microbiology,*
- *ante-mortem inspection,*
- *examination for trichinosis,*
- *post-mortem inspection,*
- *administrative tasks,*
- *knowledge of the relevant laws, regulations and administrative provisions,*
- *sampling procedure,*
- *fraud aspects;*
- (ii) practical part:*
 - *animal identification,*
 - *age checks,*
 - *inspection and assessment of slaughtered animals,*
 - *post-mortem inspection in a slaughterhouse,*
 - *examination for trichinosis,*
 - *identification of animal species by examination of typical parts of the animal,*
 - *identifying and commenting on parts of slaughtered animals in which changes have occurred,*
 - *hygiene control, including the audit of the good hygiene practices and the HACCP-based procedures,*
 - *recording the results of ante-mortem inspection,*
 - *sampling,*

- *traceability of meat,*
- *documentation.*

6. Official auxiliaries are to maintain up-to-date knowledge and to keep abreast of new developments through regular continuing education activities and professional literature. The official auxiliary is, wherever possible, to undertake annual continuing education activities.

7. Persons already appointed as official auxiliaries must have adequate knowledge of the subjects mentioned in paragraph 5. Where necessary, they are to acquire this knowledge through continuing education activities. The competent authority is to make adequate provision in this regard.

8. However, when official auxiliaries carry out only sampling and analysis in connection with examinations for trichinosis, the competent authority need only ensure that they receive training appropriate to these tasks.

Amendment 312

Proposal for a regulation Annex III – title

Text proposed by the Commission

Annex III

Characterisation of methods of analysis

Amendment

Annex IV

Characterisation of methods of analysis

Amendment 313

Proposal for a regulation Annex IV – title

Text proposed by the Commission

Annex IV

Correlation table referred to in Article 142(3)

Amendment

Annex V

Correlation table referred to in Article 142(3)