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From: Presidency

To: Delegations

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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 [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)

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Delegations will find in Annex consolidated Presidency suggestions for rewording of **Articles 1 to 63** of the above proposal, to be examined by the Joint Working Party of Veterinary Experts (Public Health) and Phytosanitary experts at its meeting of 15-16 January 2015.

The suggested changes figure in **bold and underlined** and in ~~strikethrough~~;

NB: Presidency suggestions for rewording of Articles 15 to 24 are **not included** in this document but in doc. 11312/14 and related revisions.

NB: Presidency suggestions for rewording of Articles 1 to 41 as set out in document 8221/3/14-REV 3 have not been revised.

NB: Presidency suggestions for rewording of Articles 42 to 63 , including Articles 47 and 53 , have been revised as compared to document 8221/2/14- REV2 and document 8221/1/14-REV1

NB: The text in Annex has not yet been reviewed by the CLS

# Title I<sup>1</sup>

## Subject matter, scope and definitions

### *Article 1* *Subject matter and scope*

1. This Regulation lays down rules for:
  - (a) the performance of official controls and other official activities performed by the competent authorities of the Member States;
  - (b) the financing of official controls;
  - (c) the administrative assistance and cooperation between Member States in view of the correct application of the rules referred to in paragraph 2;
  - (d) the performance of Commission controls in Member States and in third countries;
  - (e) the adoption of conditions to be met by animals and goods entering the Union from a third country;
  - (f) the establishment of a computerised information system to manage information and data in relation to official controls.
  
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 ~~any~~ **any** 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;

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<sup>1</sup> **The Presidency underlines that a general article on data protection issues will be introduced in the final/common provisions**

- (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]<sup>2</sup>
  - (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.
3. This Regulation shall also apply to official controls performed for the verification of compliance with requirements laid down in the rules referred to in paragraph 2 applicable to animals and goods
- ~~(a) [entering **or leaving** the Union] or to be exported from the Union from third countries;~~
  - ~~(b) to be exported to third countries.~~
4. This Regulation shall not apply to official controls for the verification of compliance with:
- (a) the rules laid down in Regulation (EC) No 1308/2013~~[1234/2007]~~ **except regarding marketing standards laid down in Section I of Chapter I of Title II of part II of this Regulation applied to products referred to in Annex I thereof;**
  - (b) the rules laid down in Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes<sup>3</sup>.
5. Articles 3, 4, 5, 7, 11(2) and (3), 14, 30 to 33, 36 to 41, 76, Titles III and IV, and Articles 129 and 136 of this Regulation shall also apply to other official activities performed by the competent authorities in accordance with this Regulation or with the rules referred to in paragraph 2 of this Article.

<sup>2</sup> To be decided depending on the future of the concerned Commission proposal on PRM

<sup>3</sup> OJ L 276, 20.10.2010, p. 33.

*Article 1a*  
*Official controls and other official activities*

1. For the purposes of this Regulation, "official controls" shall mean activities performed by the competent authorities, or by the delegated bodies or the natural persons to which certain specific official control tasks have been delegated in accordance with this Regulation in order to verify:
  - a) compliance by the operators with the rules of this Regulation and with the rules referred to in Article 1(2) ~~and ensure the enforcement of those rules~~;
  - b) that animals or goods meet the requirements laid down in the rules referred to in Article 1(2), ~~in view of including~~ for the issuance of an official certificate or official attestation by the competent authority.
  
2. For the purposes of this Regulation, "other official activities" shall mean activities, other than official controls, which ~~is~~ are performed by the competent authorities, or by the delegated bodies or the natural persons to which certain other official activities have been delegated in accordance with this Regulation and with the rules referred to in Article 1(2), including activities aimed at verifying the presence of animal diseases or ~~plant~~ pests of plants or at preventing or containing the spread of such diseases or pests, or eradicating those diseases or pests, the granting of authorisations, or approvals and the issuance of official certificates or official attestations by the competent authorities

*Article 2*  
*Definitions*

For the purposes of this Regulation, the following definitions shall apply:

- ~~1. "official control" means any form of control that the competent authorities or a body or a natural person to which official control tasks have been delegated in accordance with this Regulation perform for the verification of compliance with:~~
  - ~~(a) this Regulation;~~
  - ~~the rules referred to in Article 1(2);~~
  - ~~(b) "official control" does not include controls performed to verify compliance by competent authorities with the rules laid down in this Regulation;~~
  
- ~~2. "other official activities" means any activity, other than an official control, which is performed by competent authorities or a body or a natural person to which tasks related to other official activities have been delegated in accordance with this Regulation in accordance with:~~

- (a) ~~this Regulation;~~
- (b) ~~the rules referred to in Article 1(2) to ensure the application of those rules;~~
3. 'food law' means food law as defined in point (1) of Article 3 of Regulation (EC) No 178/2002;
4. 'feed law' means the laws, regulations and administrative provisions governing feed in general and feed safety in particular, whether at Union or national level; ~~it covers~~ all stages of production, processing and distribution of feed and the use of feed;
5. 'competent authorities' means:
- (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);
  - (b) any other authority to which that responsibility has been conferred;
  - (c) where appropriate, the corresponding authorities of a third country;
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*];
7. 'goods' means ~~any good~~ **all that is** subject to one or more of the rules referred to in Article 1(2), excluding animals;
8. 'food' means food as defined in Article 2 of Regulation (EC) No 178/2002;
9. 'feed' means feed as defined in point (4) of Article 3 of Regulation (EC) No 178/2002;
10. 'animal by-products' means animal by-products as defined in point (1) of Article 3 of Regulation (EC) No 1069/2009;
11. 'derived products' means derived products as defined in point (2) of Article 3 of Regulation (EC) No 1069/2009;
12. 'pests' means pests as defined in Article 1(1) of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*];
13. 'plants' means plants as defined in point (1) 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*];

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*];
15. 'plant protection products' means:
- (a) ~~plant protection products as referred to in Article 2(1) and substances as referred to in Articles 3 and 4 of Regulation (EC) No 1107/2009;~~
  - (b) **active substances as referred to in Article 2(2) of Regulation (EC) No 1107/2009;**
  - (c) **safeners, synergists, co-formulants and adjuvants as referred to in Article 2(3) of Regulation (EC) No 1107/2009;**
- ~~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;~~
17. 'products of animal origin' means products of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin<sup>4</sup>;
18. 'germinal products' means germinal products as defined in point (25) of Article 4(1) of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on animal health*];
19. 'plant products' means plant products as defined in point (24) 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*];
20. 'other objects' means other objects as defined in point (4) 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*];
21. 'risk assessment' means **a scientifically based process for evaluating risk,<sup>5</sup> consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation** ~~risk assessment as defined in point (11) of Article 3 of Regulation (EC) No 178/2002;~~
- 21a **'hazard' means any agent or condition with the potential to have an adverse effect on human, animal or plant health, animal welfare or the environment;**

<sup>4</sup> OJ L 139, 30.4.2004, p. 55.

<sup>5</sup> **Delegations shall indicate if they can support this definition or alternatively deletion of point 21.**

- 21b 'risk' means a function of the probability of an adverse effect on human, animal or plant health, animal welfare or the environment and of the severity of that effect, consequential to a hazard;
22. 'certifying officer' means:
- (a) any official of the competent authorities authorised to sign official certificates by such authorities;
  - (b) ~~where provided for by the rules referred to in Article 1(2)~~ any other **natural** person, who is authorised to sign official certificates by the competent authorities **in accordance with the rules referred to in Article 1(2)**;
23. 'official certificate' means ~~any~~ **a** paper or electronic document signed by the certifying officer and providing assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2);
- ~~24. 'non-compliance' means non-compliance with:~~
- ~~(a) this Regulation;~~
  - ~~(b) rules referred to in Article 1(2);~~<sup>6</sup>
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 **this Regulation or in** the rules referred to in Article 1(2);<sup>7</sup>
26. 'operator' means any natural or legal person subject to one or more obligations provided for in the rules referred to in Article 1(2), ~~except the competent authorities and the other bodies in charge of official controls and other official activities;~~
- ~~26a 'primary production' means primary production as defined in point 17 of Article 3 of Regulation (EC) No 178/2002;~~
27. 'consignment' means a number of animals or quantity of goods of the same type, class, or description, covered by the same official certificate, official attestation or any other document, conveyed by the same means of transport and ~~having~~ **originating coming from** the same ~~{territory or}~~ **third country according to the rules laid down in Article 1(2)** ~~origin~~; it may consist of one or more lots;

<sup>6</sup> ~~This definition has to be reviewed in the light of the content of the substantive Articles. If this definition is to be retained, it would mean that wherever there is a reference in the text to non-compliance, this would be considered to include a reference to "(a) this regulation and (b) rules referred to in Article 1(2)." However this is not currently the case and a major rewording of the text would need to be undertaken, should this definition be kept.~~

<sup>7</sup> This definition has to be reviewed in the light of the relevant Article.



- ~~28.~~ 'inspection' means a form of official control involving the examination of:
- ~~(a)~~ animals or goods;
  - ~~(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;
  - ~~(c)~~ places where operators perform their activities;
29. 'border control post' means a place, and the facilities belonging to it, designated by a Member State ~~to~~**for the performance of** the official controls provided for in Article 45(1);
30. 'audit' means a systematic and independent examination to determine 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;
- ~~31.~~ 'rating' means a classification of operators based on an assessment of their conformity with rating criteria;
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:
- (a) this Regulation;
  - (b) **including relevant** the rules referred to in Article 1(2);

**32a. 'Official plant health officer'**<sup>8</sup>

- ~~33.~~ 'hazard' means any agent or condition with the potential to have an adverse effect on human, animal or plant health, animal welfare or the environment;<sup>9</sup>
34. 'specified risk material' means tissues as defined in point (g) of Article 3(1) of Regulation (EC) No 999/2001;
35. 'long journey' means a journey as defined in point (m) of Article 2 of Regulation (EC) No 1/2005;
36. 'exit point' means a border control post or any other place designated by a Member State where animals, falling within the scope of Regulation (EC) No 1/2005, leave the customs territory of the Union;
37. 'pesticide application equipment' means any apparatus as defined in point (4) of Article 3 of Directive 2009/128/EC;

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<sup>8</sup> Definition to be drafted

<sup>9</sup> Move as point 21a

38. 'delegated body' means a **separate legal person**~~third party~~, to which the competent authorities have delegated **certain**~~specific~~ official control tasks **or certain tasks related to other official activities**;
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;
40. 'control verification procedures' means the arrangements put in place and actions performed by the competent authorities for the purpose of ensuring that official controls and other official activities are consistent and effective;
- ~~41. 'screening' means a form of official control performed by conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with this Regulation and the rules referred to in Article 1(2);~~
- ~~42. 'targeted screening' means a form of official control involving observation of one or more operators or their activities;~~
43. 'control system' means a system comprising the competent authorities and the resources, structures, arrangements and procedures set up in a Member State to ensure that official controls are performed in accordance with this Regulation and with the rules provided for in Articles 15 to 24;
- ~~44. 'equivalence' or 'equivalent' means:~~
- ~~(a) the capability of different systems or measures to meet the same objectives;~~
  - ~~(b) different systems or measures capable of meeting the same objectives;~~
45. '**entering the Union**' or 'entry into the Union' means the action of bringing animals and goods into one of the territories listed in Annex I **from outside of these territories**;
46. 'documentary check' means the examination of the official certificates, official attestations and other document(s) including documents of a commercial nature, which are required to accompany the consignment as provided for by the rules referred to in Article 1(2), Article 54(1), or by implementing acts adopted in accordance with Articles 75(3), 125(4), 127(1) and 128(1);
47. 'identity check' means a visual inspection to verify that the content and the labelling of a consignment, including the ~~identification~~ marks on animals, seals and means of transport, correspond with the information provided in the official certificates, official attestations and other documents accompanying it;

48. 'physical check' means a check on animals or goods and, as appropriate, checks on packaging, the means of transport, labelling and temperature, the sampling for analysis, testing or diagnosis and any other check necessary to verify compliance with the rules referred to in Article 1(2);
- ~~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 or airport in preparation for onward travel;~~
50. 'transit' means movement from one third country to another third country passing under customs supervision through one of the territories listed in Annex I or from one of the territories listed in Annex I to another territory listed in Annex I passing through the territory of a third country;
51. 'supervision by the customs authorities' means action as defined in Article 4(13) of Regulation (EEC) No 2913/92<sup>10</sup>;
52. 'control by the customs authorities' means customs controls as defined in Article 4(14) of Regulation (EEC) No 2913/92;
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;
- ~~54. 'additional official controls' means those controls which were not originally planned and which were decided on the basis of the findings of previous official controls, or other official activities;~~
55. 'official certification' means the procedure by which assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2) is provided by the competent authorities;
56. 'control plan' means a description established by the competent authorities containing information on the structure and organisation of the official control system, and of its operation and the detailed planning of official controls to be performed in each of the areas referred to in Article 1(2) over a period of time;
57. 'journey log' means the document set out in points 1 to 5 of Annex II to Council Regulation (EC) No 1/2005;
- 58. 'food contact materials' means materials and articles intended to come into contact with food as defined in Article 1 of Regulation (EC) No 1935/2004.**

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<sup>10</sup> OJ L 302, 19.10.1992, p. 1.

# Title II

## Official controls and other official activities in Member States

### Chapter I

#### Competent authorities

*Article 3*  
*Designation of competent authorities*

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.
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, ~~according to~~ **in accordance with national law**:
  - (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;
  - (b) designate a single authority, **subject to Member States' constitutional requirements**, 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.
3. Competent authorities responsible for the verification of compliance with the rules referred to in point (j) of Article 1(2) may confer **certain responsibilities related to official controls** ~~specific official control tasks or tasks related to~~ **or other official activities** to one or more control authorities for organic productions and labelling of organic products. In such cases, they shall attribute a code number to each of them.
4. Member States shall **ensure that inform** the Commission **is informed** ~~and other Member States of, and shall make publicly available of any changes to,~~ the contact details **and any changes thereto**.

- (a) the competent authorities designated in accordance with paragraph 1;
- (b) the single authorities designated in accordance with point (b) of paragraph 2;
- (c) the control authorities for organic production and labelling of organic products referred to in paragraph 3;
- (d) the delegated bodies referred to in Article 25(1).

The information referred to in the first subparagraph shall also be made available to the public.

- ~~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).~~
- ~~6. The Commission may, by means of implementing acts, **provide guidelines regarding** 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).~~

*Article 4*  
*General obligations of the competent authorities<sup>11</sup>*

- 1. The competent authorities shall:
  - (a) have procedures and/or arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities;
  - (b) have **procedures and/or** arrangements in place to ensure the impartiality, quality and consistency of official controls and other official activities at all levels;
  - (c) have **procedures and/or** 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;

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<sup>11</sup> **Recital to be added addressing the "conflict of interest" where official controls are performed on public goods/places etc.**

- (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, **as appropriate**.

Competent authorities **and where applicable, delegated bodies**, shall develop and implement training programmes for the purpose of ensuring that **those** staff performing official controls and **other** 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 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.

## Article 5

### *Internal Audits of the competent authorities*

1. **In order to ensure their compliance with this Regulation, the competent authorities shall carry out internal audits or have their internal audits carried out on their behalf by a third party, and shall take appropriate measures in the light of their results of such internal audits, to ensure that they are complying with this Regulation.**

Those audits shall be:

- (a) subject to independent scrutiny;
  - (b) carried out in a transparent manner.
2. ~~Competent authorities shall make available the results of the audits referred to in paragraph 1 to the Commission upon request.<sup>12</sup>~~
  3. ~~The Commission may, by means of implementing acts, lay down rules **guidelines** for the conduct of the audits provided for in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).~~

## Article 6

### *Decisions of the competent authorities concerning **operators** natural and legal persons*

The decisions taken by the competent authorities in accordance with Article 53, Article 64(3) and (5), Articles 65, ~~Article 134(2) and~~ **point b of paragraph (3) of Article 134, and Article 135(1) and (2) concerning operators** natural or legal persons shall be subject to the right of **administrative** appeal of such ~~operators~~ persons against those decisions in accordance with national law, **including as regards possible *de minimis* rules** provided for under national law.

**The right of appeal shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human, animal and plant health, or for animal welfare or, as regards GMOs and plant protection products, also for the environment, in accordance with the rules referred to in Article 1(2) and with this Regulation.**

## Article 7

### *Confidentiality obligations of ~~the staff~~ of the competent authorities*

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.

**1a. The provisions of paragraph 1 shall apply to delegated bodies.**

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<sup>12</sup> The content has been moved to Article 112EV

2. Unless there is an overriding public interest in its disclosure, **and without prejudice to situations where disclosure is required by Union or national 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 **an operator or any other** 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 **taking into account the urgency of the situation**;
  - (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.

## **Chapter II**

### **Official Controls**

#### **SECTION I**

#### **General requirements**<sup>13</sup>

##### *Article 8*

##### *General rules on official controls*

1. Competent authorities shall perform official controls on all operators regularly; **on a risk basis** and with appropriate frequency, taking account of:
  - (a) identified risks associated with:
    - (i) animals and goods;
    - (ii) the activities under the control of operators;
    - (iii) the location of the activities or operations of operators;

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<sup>13</sup> **On the basis of Doc. 11312/3/14 - REV3, it has be decided to introduced two sections in Chapter II.**



- (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 **also** adversely impact on the environment;
  - (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);
  - (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);
  - (d) any information that might indicate non-compliance with the rules referred to in Article 1(2).2.
2. ~~When e~~Competent authorities **shall** perform official controls **regularly, on a risk basis referred to in paragraph 1, on a regular basis** and with appropriate frequency ~~they shall also aim~~ to identify possible ~~economically motivated non-compliance~~ **intentional violations of regarding** the rules referred to in Article 1(2), **perpetrated through fraudulent deceptive practices**, taking into account, ~~in addition to the criteria referred to in paragraph 1,~~ information regarding such ~~non-compliance~~ 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 ~~non-compliance~~**violations**.
  3. Official controls performed prior to the placing on the market or the movement of certain animals and goods in view of the issuance of the official certificates or official attestations required by the rules referred to in Article 1(2) as a condition for the placing on the market or the movement of the animals or goods shall be performed in accordance with:
    - (a) the rules referred to in Article 1(2);
    - (b) [the delegated acts adopted by the Commission in accordance with Articles 15 to 24]<sup>14</sup>.
  4. (a) Official controls shall be performed without prior ~~notice warning~~, except where **the competent authority considers such notice warning to be necessary for the official control to be carried outpossible;**
    - (b) **As regards official controls upon request from the operator, the competent authority may decide whether the official control shall be performed with or without prior noticewarning.**
  5. ~~Official controls shall be performed in a manner that minimises the burden on the operators as far as possible, without affecting the effectiveness of official controls.~~
  6. Competent authorities shall perform official controls **in the same manner, while taking account of the need to adapt the controls to the specific situations**, irrespective of whether the animals and goods concerned are:

<sup>14</sup> This point 3.b) will need to be amended depending on the changes made to Articles 15 to 24

- (a) ~~is~~ available on the Union market, whether originating in the Member State where the official controls are performed or in another Member State; **or**
  - (b) ~~is~~ to be exported from the Union; **or**
  - (c) ~~is~~ entering the Union [...]
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.

#### *Article 9*

##### *Persons, processes and activities subject to official controls*

- 1.** To the extent necessary to ascertain compliance with the rules referred to in Article 1(2), competent authorities shall perform official controls:
- (a) on animals and goods at ~~all~~ **any** stages of production, processing and distribution;
  - (b) on substances, materials or ~~other~~ objects which may influence the characteristics of animals and goods, **and their compliance with applicable requirements, at any** ~~all~~ stages of production, processing and distribution;
  - (c) on operators **as regards** activities, ~~processes, storage, equipment, means of transport and other operations under their control, on their premises and other places under their control as well as their use of goods and the keeping of animals.~~
- 2. The competent authorities shall draw up and keep up-to-date a list of operators. Where such a list already exists for other purposes, it may also be used for the purposes of this Regulation**

#### *Article 10*

##### *Transparency of official controls*

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 type and number of** ~~the~~ cases where measures were taken by the competent authorities in accordance with Article 135;

- (d) **the type and number of** the cases where the penalties referred to in Article 136 were imposed.

**This information can be provided, where appropriate, through the publication of the annual report referred to in Article 112 (1).**

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

#### *Article 11*

##### *Documented control ~~and control verification~~ procedures*

1. Competent authorities shall perform official controls in accordance with **documented**~~applicable~~ procedures ~~which shall be documented~~.
- Those procedures shall cover the subject areas for control procedures set out in Chapter II of Annex II and contain ~~detailed~~ instructions for staff performing official controls.
2. Competent authorities shall have **control verification** procedures in place ~~to verify the consistency and effectiveness of official controls and other official activities that they perform~~.
3. Competent authorities shall:
- (a) take corrective actions in all cases where the procedures provided for in paragraph 2 identify shortcomings in the consistency and effectiveness of official controls and other official activities;
  - (b) update the documented procedures provided for in paragraph 1 as appropriate.
- 4. The provisions of paragraphs 1 to 3 shall apply to delegated bodies.**

*Article 12*  
~~Reports~~ **Written records of** ~~official controls~~

1. Competent authorities shall draw up **written records** ~~reports~~ of every official control that they perform.

Those **written records** ~~reports~~ shall contain:

- (a) a description of the purpose of the official controls;
- (b) the control methods applied;
- (c) the results of the official controls;
- (d) where appropriate, action that the competent authorities require the operator concerned to take as a result of their official controls.

- 1a. **References in this Regulation to 'written records' shall be considered to include a reference to the electronic equivalent.**

2. **Unless the purposes of judicial investigations or the protection of court proceedings require otherwise, Competent authorities shall provide the operators subject to an official control shall be provided with a copy of the written records report referred to provided for in paragraph 1, if they so request, and be promptly informed of any shortcoming or non-compliance identified through the official controls.**

**This paragraph shall not apply if the purpose of the official control is to issue an official certificate or official attestation.**

3. Where official controls require the continuous or regular presence of staff or representatives of the competent authorities in the operator's premises, the ~~reports~~ **written records** provided for in paragraph 1 shall be produced with a frequency that enables the competent authorities and the operator to be:
- (a) regularly informed of the level of compliance;
  - (b) **promptly** ~~immediately~~ informed of any shortcoming or non-compliance identified through the official controls.

*Article 13*  
*Official controls, methods and techniques*

1. ~~Competent authorities shall perform Official controls using control methods and techniques~~ **shall include the following** ~~that shall, as appropriate, include in particular screening, targeted screening, (verification), inspections, audits, sampling, analysis, diagnosis and tests.~~

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

- (a) an examination of the **own** controls systems that operators have put in place and of the results obtained;
- (b) an inspection of:
  - (i) **equipment, means of transport, premises and other places under their control**  
~~operators, primary producers' premises, installations, and other businesses places under the control, , including their surroundings, premises, offices, equipment, installations and machinery, means of transport and their animals, and goods and other objects under their control;~~
  - (ii) **animals and goods, including semi-finished goods**, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals;
  - ~~(iii) semi-finished goods;~~
  - (iv) cleaning and maintenance products and processes, ~~plant protection products;~~
  - (v) **traceability, labelling, presentation, advertising and relevant packaging materials**~~advertising;~~
- (c) controls on the hygiene conditions in the operators' premises;
- (d) an assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices, and **of procedures based on the principles of hazard analysis critical control points (HACCP) and hazard analysis critical control points in organic production (OCCP)**];
- (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);
- (f) interviews with operators and with their staff;
- ~~(g) a reading of values recorded, by operators and measuring instruments ;~~
- (g) **the verification of controls performed with the competent authorities' own instruments to verify measurements taken by the operators and other test results;**
- (h) **sampling, analysis, diagnosis and tests;**
- ~~(h)~~(i) **audits of operators;**
- ~~(i)~~(j) any other activity required to identify non-compliances.

*Article 14*  
*Obligations of operators*

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 **and control authorities**, give staff of the competent authorities **and control authorities** access to:
  - (a) ~~their activities~~ **equipment, means of transport, premises, operations, means of transport, premises and other places under their control**;
  - (b) their computerised information management systems;
  - (c) ~~their~~ animals and goods **under their control**;
  - (d) their documents and any other relevant information.
2. During official controls and other official activities, operators shall assist **and cooperate with** the staff of the competent authorities **and control authorities** in the accomplishment of their tasks.
3. The operator responsible for ~~a~~ **the consignment entering the Union** shall, **in addition to the obligations under paragraphs 1 and 2**:
  - (a) ~~(cooperate fully with the competent authorities to ensure the efficient performance of official controls or other official activities;)~~
  - (b) make available all information concerning the consignment on paper or electronically.
- 4. The Commission may, by means of implementing acts, lay down rules:**
  - (a) establishing the modalities for access by the competent authorities to the computerised information management systems referred to in paragraph 1(b);**
  - (b) on the cooperation and exchange of information between operators and competent authorities related to the arrival and unloading of the animals and goods referred to in Article 45 (1) where it is necessary to ensure their complete identification and the efficient performance of official controls on such animals and goods as referred to in paragraph 3.**

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).<sup>15</sup>

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<sup>15</sup> Presidency suggests deletion pending possible alternative wording from the COM.

**5. For the purpose of Article 9(2), operators shall at least provide the competent authorities with the following details:**

**(a) their name and legal form;**

**(b) the specific activities they carried out, including activities undertaken by means of distant communication, and the places under their control.**

**6. The obligations of operators set out in this Article shall also apply in case where official controls and other official activities are performed by delegated bodies and natural persons to which certain control tasks or certain tasks related to other official activities have been delegated.**<sup>16</sup>

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<sup>16</sup> **Moved from Article 32a.**

*Article 15<sup>17</sup>*

*Specific rules on official controls and on action to be taken by the competent authorities in relation to the production of products of animal origin intended for human consumption*

*Article 16*

*Specific rules on official controls and on action to be taken by the competent authorities in relation to the residues of certain substances in food and feed*

*Article 17*

*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*

*Article 18*

*Specific rules on official controls and action to be taken by the competent authorities in relation to the welfare requirements for animals*

*Article 19*

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

*Article 20*

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

*Article 21*

*Specific rules on official controls and action to be taken by the competent authorities in relation to GMOs and genetically modified food and feed*

*Article 22*

*Specific rules on official controls and on action to be taken by the competent authorities in relation to plant protection products*

*Article 23*

*Specific rules on official controls and on action to be taken by the competent authorities in relation to organic products and to protected designations of origin, protected geographical indications and traditional specialties guaranteed*

*Article 24*

*Specific rules on official controls and on action to be taken by the competent authorities in cases of newly identified risks in relation to food and feed*

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<sup>17</sup> **Presidency's suggestions for rewording of Articles 15 to 24 are not dealt with in this document but in Doc.11312/14 and its revisions.**



## Chapter III

### Delegation of certain ~~specific~~ tasks of the competent authorities

#### *Article 25*

##### *Delegation by the competent authorities of **certain** ~~specific~~ official control tasks*

1. Competent authorities may delegate **certain** ~~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. **The competent authority shall ensure that the delegated body or the natural person, to which such tasks have been delegated, have the powers needed to effectively perform these tasks.**
- ~~2. Competent authorities shall not delegate the decision concerning the measures provided for in point (b) of Article 135(1) and in Article 135 (2) and (3).~~  
~~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 points (j) **and (k)** of Article 1(2).~~
- ~~3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 establishing specific **those** official control tasks that may not be delegated in order to preserve the independence or the core functions of the competent authorities, **without prejudice to paragraph 2.**~~
4. Where competent authorities delegate **certain** ~~specific~~ official control tasks for the verification of compliance with the rules referred to in point (j) of Article 1(2) to one or more delegated bodies, they shall attribute a code number to each delegated body and designate **relevant** authorities responsible for their approval and supervision.

#### *Article 26*

##### *Conditions for delegating **certain** ~~specific~~ official control tasks to delegated bodies*

1. The delegation of **certain** ~~specific~~ **official** control tasks to a delegated body referred to in Article 25(1) shall be in writing and shall comply with the following conditions:
  - (a) the delegation contains a precise description of:
    - (i) the **certain** ~~specific~~ official control tasks that the delegated body may perform;
    - (ii) the conditions under which it may perform them;

- (b) the delegated body:
  - (i) has the expertise, equipment and infrastructure required to perform the **certain**~~specific~~ official control tasks delegated to it;
  - (ii) has a sufficient number of suitably qualified and experienced staff;
  - (iii) is impartial and free from any conflict of interest as regards the exercise of the **certain**~~specific~~ official control tasks delegated to it;
  - (iv) works and is ~~assessed and~~ accredited in accordance with **any standard relevant to the delegated tasks in question, including** standard EN ISO/IEC 17020 'Requirements for the operation of various types of bodies performing inspection' or another standard if more relevant to the delegated tasks in question;
- (c) there are arrangements in place ensuring efficient and effective coordination between the delegating competent authorities and the delegated body.

**2. Competent authorities may delegate certain official control tasks in relation to the inspection of pesticide application equipment irrespective of whether the delegated body fulfils the condition referred to in point (b)(iv) of paragraph 1.**

*Article 27*

*Conditions for delegating ~~specific~~ **certain** official control tasks to natural persons*

Competent authorities may delegate ~~certain~~~~specific~~ official control tasks to one or more natural persons where the rules provided for in Articles 15 to 24 so allow. Such delegation shall be in writing **and shall comply with the following conditions:**

- (a) **the delegation contains a precise description of:**
  - (i) ~~certain~~ **official control tasks that the natural persons may perform;**
  - (ii) **the conditions under which the natural persons may perform them;**
- (b) **the natural persons:**
  - (i) **have the expertise, equipment and infrastructure required to perform the ~~specific~~ official control tasks delegated to ~~it~~ them;**
  - (ii) **are suitably qualified and experienced;**

- ~~(iii) have the powers needed to effectively perform the delegated control tasks;~~
- ~~(iv) are impartial and free from any conflict of interest as regards the exercise of certain the official control tasks delegated to them;~~
- (c) there are arrangements in place ensuring efficient and effective coordination between the delegating competent authorities and the natural persons.**

Article 26(1) shall apply to the delegation of specific official control tasks to natural persons, with the exception of points (b)(ii) and (b)(iv).

*Article 28*  
*Obligations of the delegated body and natural person*  
*to which specific official control tasks are delegated*

Delegated bodies or natural persons to whom specific official control tasks have been delegated in accordance with Article 25(1) shall:

- ~~(a) communicate the results of the official controls performed by them to the competent authorities which have delegated the specific official control tasks on a regular basis and whenever those competent authorities so request;~~
- ~~(b) immediately inform the competent authorities which have delegated the specific official control tasks whenever the results of the official controls indicate [serious non-compliance or an intentional violation] or point to the likelihood of non-compliance.~~

*Article 29*  
*Obligations of the competent authorities delegating specific official control tasks*

Competent authorities that have delegated specific official control tasks to delegated bodies or natural persons in accordance with Article 25(1) shall:

- ~~(a) organise audits or inspections of such bodies or persons as necessary taking into account the results of the assessment referred to in point (iv) (b) of Article 26(1);~~
- ~~(b) fully or partly withdraw the delegation without delay where:
  - ~~(i) following an audit or an inspection as provided in point (a), there is evidence that such delegated bodies or natural persons are failing to properly perform the official control tasks delegated to them;~~
  - ~~(ii) the delegated body or the natural person fails to take appropriate and timely action to remedy the shortcomings identified during the audits and inspections provided for in point (a).~~~~

*Article 30*

*Conditions for delegating **certain specific** tasks related to other official activities*

1. The competent authorities may delegate **certain specific** tasks related to other official activities to one or more delegated bodies subject to compliance with the following conditions:
  - (a) **this Regulation and** the rules referred to in Article 1(2) do not prohibit such delegation;
  - (b) the conditions laid down in Article 26(1) are fulfilled with the exception of point (b)(iv).
  
2. The competent authorities may delegate specific tasks related to other official activities to one or more natural persons subject to compliance with the following conditions:
  - (a) **this Regulation and** the rules referred to in Article 1(2) allow such delegation;
  - (b) the conditions laid down in Article 27(1), **applied mutatis mutandis**, are fulfilled with the exception of points (b)(ii) and (b)(iv);
  - ~~(b)(c) the natural persons are suitably qualified and experienced.~~
  
3. **Competent authorities shall not delegate the decision concerning their tasks provided for in point (b) of Article 135(1) and in Article 135 (2) and (3).**  
  
**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) and (3) following official controls performed to verify compliance with the rules referred to in points (j) and (k) of Article 1(2).**  
  
**The first subparagraph shall not apply to the measures to be taken in accordance with Article 135 and Article 15, by official veterinarians.**
  
4. **Competent authorities shall not delegate the supervision of the delegated bodies or of the natural persons to whom certain control tasks have been delegated, or the powers to suspend or withdraw the delegation.**

*Article 31*

*Obligations of the delegated body and natural person to which specific tasks related to other official activities are delegated*

The delegated body or the natural person to whom specific tasks related to other official activities have been delegated in accordance with Article 30 shall:

- (a) ~~communicate the results of the other official activities performed by it to the competent authorities which have delegated the specific tasks related to other official activities on a regular basis and whenever the competent authorities so request;~~
- (b) ~~immediately inform the competent authorities which have delegated the specific tasks related to other official activities whenever the results of the other official activities indicate non-compliance or point to the likelihood of non-compliance.~~

*Article 31*

***Obligations of the delegated bodies and natural persons  
to whom certain official control tasks or certain tasks related to other official activities are  
delegated***

**Delegated bodies or natural persons to whom certain official control tasks have been delegated in accordance with Article 25(1) or certain tasks related to other official activities have been delegated in accordance with Article 30, shall:**

- (a) **communicate the results of the official controls and other official activities performed by them to the competent authorities which have delegated ~~certain official control~~ tasks on a regular basis and whenever those competent authorities so request;**
- (b) **immediately inform the competent authorities which have delegated ~~certain official control~~ tasks whenever the results of the official controls indicate non-compliance or point to the likelihood of non-compliance, unless specific arrangements established between the competent authority and the delegated body or the natural person concerned provides otherwise.**
- (c) **give competent authorities access to their premises and facilities and cooperate and provide assistance in the framework of the supervision of the tasks delegated to them.**

*Article 32*

***Obligations of the competent authorities delegating specific tasks related to other official activities***

~~Competent authorities that have delegated specific tasks related to other official activities to delegated bodies or natural persons in accordance with Article 30 shall:~~

- (a) ~~organise audits or inspections of such bodies or persons as necessary;~~
- (b) ~~fully or partly withdraw the delegation without delay where:~~
  - (i) ~~following an audit or an inspection as provided for in point (a), there is evidence that such delegated bodies or natural persons are failing to properly perform the tasks related to other official activities delegated to them;~~
  - (ii) ~~the delegated bodies or natural persons fail to take appropriate and timely action to remedy the shortcomings identified during the audits and inspections provided for in point (a).~~

### Article 32

#### *Obligations of the competent authorities delegating certain official control tasks or certain tasks related to other official activities*

Competent authorities that have delegated certain official control tasks to delegated bodies or natural persons in accordance with Article 25(1) or certain tasks related to other official activities to delegated bodies or natural persons in accordance with Article 30, shall:

- (a) **organise audits or inspections of such bodies or persons, as necessary and avoiding duplication, taking into account the ~~any accreditation results of the assessment~~ referred to in point (b)(iv) of Article 26(1), ~~as appropriate~~;**
- (b) **fully or partly withdraw the delegation without delay where:**
  - (i) **there is evidence that such a delegated bodyies or natural persons is ~~are~~ failing to properly perform the ~~official control tasks~~ delegated to it ~~them~~; and/or**
  - (ii) **the delegated body or the natural person fails to take appropriate and timely action to remedy the shortcomings identified.**

### ~~Article 32a~~

#### ~~*Obligations of operators*~~

~~The obligations of operators set out in Article 14 shall apply to ~~delegated bodies and natural persons to which certain control tasks or certain tasks related to other official activities have been delegated.~~~~

## Chapter IV Sampling, analyses, tests and diagnoses

### Article 33

#### *Methods used for sampling, analyses, tests and diagnoses*

1. Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods.
2. In the absence of the Union rules referred to in paragraph 1, **in the context of official controls and other official activities**, official laboratories shall use **one of the following** state-of-the-art methods **according to the suitability** for their specific analytical, testing and diagnostic needs, ~~taking into account:~~
  - (a) ~~the most recent~~ available methods complying with relevant internationally recognised rules or protocols; ~~including those that the European Committee for Standardisation (CEN) has accepted; or,~~

- (b) ~~in the absence of the rules or protocols~~**methods** referred to in point (a), the relevant methods developed or recommended by the European Union reference laboratories and validated in accordance with internationally accepted scientific protocols; ~~or,~~
- (c) ~~in the absence of the~~**methods**~~rules or protocols referred to in point (a) and the~~ methods referred to in point (b), the methods which comply with relevant rules established at national level; ~~or,~~
- (d) ~~in the absence of the~~**methods**~~rules or protocols referred to in point (a), the methods~~ referred to in point (b) and the national rules referred to in point (c), the relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; ~~or,~~
- (e) ~~in the absence of the~~**methods**~~rules or protocols referred to in point (a), the methods~~ referred to in point (b), the national rules referred to in point (c) and the methods referred to in point (d), the relevant methods **developed and validated with inter- or intra-laboratory methods validation studies** in accordance with internationally accepted scientific protocols; ~~or,~~
- (f) ~~in absence of the methods referred to in point (a), (b), (c), (d) and (e),~~ relevant **methods developed in accordance with internationally accepted scientific protocols and validated internally by a single official laboratory.**

~~3. [By derogation to of paragraph 2, in the absence of Union rules referred to in paragraph 1, competent authorities may use in the context of screening, targeted screening and of other official activities, any of the methods referred to in that paragraph~~

~~(a) for the implementation of specific official control plans intended to obtain an overview of the state of compliance with this Regulation or with the rules referred to in Article 1(2) in a group of operators or in a specific sector;~~

~~(b) in the context of may be used in the absence of Union rules referred to in paragraph 1. The same rule applies to other official activities.]~~

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.
5. Wherever possible, methods used for laboratory analyses shall be characterised by the appropriate criteria set out in Annex III.
6. Samples shall be taken, handled and labelled in such a way as to guarantee their legal, scientific and technical validity.

7. The Commission may, by means of implementing acts, lay down rules for:
- (a) the methods to be used for sampling and for laboratory analyses, tests and diagnoses;
  - (b) performance criteria, analysis, test or diagnosis parameters, measurement uncertainty and procedures for the validation of those methods;
  - (c) the interpretation of analytical, testing and diagnostic results.

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

*Article 34*  
*Second expert opinion*

1. 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, **at the operator's own expense**.

Such right:

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

- (b)

2. ~~Where~~ **where** relevant, appropriate<sup>18</sup> 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, **the competent authorities** shall ~~entitle the operator to request~~:

- (a) **when taking the sample, divide it in** ~~that a sufficient number of other samples or sub-samples~~ **to allow for** ~~be taken for~~ a second expert opinion **and for the review referred to in paragraph 3, should this prove necessary**; or,

- (b) where it is not possible to take a sufficient number of samples ~~or sub-samples~~ as referred to in ~~point (i)~~ **paragraph 2, inform the operator thereof and of the right of the operator to request**;

- [(i) to be present during the analysis, test or diagnosis and be assisted by another expert;]**

- [(ii) that the documentary review of the sampling, analysis, test or diagnosis be carried out by another expert.** ~~that an independent second analysis, test or diagnosis on the sample be carried out.~~

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<sup>18</sup> **The term 'appropriate' has been introduced to take into account of the concerns related to the respect of IPPC rules**



**3. Where there is a dispute between the competent authorities and the operators based on the second expert opinion referred to in paragraph 2, operators may request, at their own expenses, the documentary review of the initial analysis, test or diagnosis and, where appropriate, another analysis, test or diagnosis by another official laboratory [identified by the competent authorities for that purpose].**

~~42.~~ The application by the operator for a second expert opinion in accordance with paragraph 1 shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human, animal and plant health, or for animal welfare or, as regards GMOs and plant protection products, **also** for the environment, in accordance with the rules referred to in Article 1(2) and with this Regulation.

~~3.~~ ~~The Commission shall~~may, by means of implementing acts, lay down procedures for the uniform application of the rules provided for in paragraph 1 and for the presentation and handling of applications for a second expert opinion. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

#### *Article 35*

##### *Sampling of animals and goods offered for sale by means of distance communication*

1. In the case of animals and goods offered for sale by means of distance communication, samples ordered from operators by the competent authorities without identifying themselves may be used for the purposes of an official control.

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

(a) are informed that such samples **have been**~~are being~~ taken in the context of an official control and, where appropriate, **are** analysed or tested for the purposes of such official control; and,

(b) where the samples referred to in paragraph 1 are analysed or tested, are entitled to exercise the right to ~~apply for~~ a second expert opinion provided for in Article 34(1).

**3. The Commission shall by means of implementing acts, lay down the rules necessary for the uniform application of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).**

#### *Article 36*

##### *Designation of official laboratories*

1. The competent authorities shall designate official laboratories to carry out the laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities, in the Member State in whose territory those competent authorities operate or in another Member State **or in a third country that is a Contracting Party to the Agreement on the European Economic Area.**

2. Competent authorities may designate as official laboratory a laboratory located in another Member State **or in a third country that is a Contracting Party to the Agreement on the European Economic Area** subject to compliance with the following conditions:
  - (a) appropriate arrangements are in place under which they are enabled to perform the audits and inspections referred to in Article 38(1) or delegate the performance of such audits and inspections to the competent authorities of the Member State **or third country** where the laboratory is located;
  - (b) that laboratory is already designated as an official laboratory by the competent authorities of the Member State on whose territory it is located.
3. The designation shall be in writing and shall include a detailed description of:
  - (a) the tasks that the laboratory shall carry out as official laboratory;
  - (b) the conditions under which it shall carry out those tasks;
  - (c) the arrangements necessary to ensure efficient and effective coordination and collaboration between the laboratory and the competent authorities.
4. The competent authorities may only designate as official laboratory a laboratory which:
  - (a) has the expertise, equipment and infrastructure required to carry out analyses or tests or diagnoses on samples;
  - (b) has a sufficient number of suitably qualified, trained and experienced staff;
  - (c) **guarantees that the tasks conferred upon it as set out in paragraph 1 are performed**is impartially and free from any conflict of interest as regards the exercise of its tasks as official laboratory;
  - (d) can deliver timely the results of the analysis, test or diagnosis carried out on the samples taken during official controls and other official activities;
  - (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.
5. The scope of the ~~assessment and~~ accreditation of an official laboratory referred to in point (e) of paragraph 4:
  - (a) shall include ~~all~~<sup>19</sup> the methods of laboratory analysis, test or diagnosis required to be used by the laboratory for analyses, tests or diagnoses, when it operates as an official laboratory;
  - (b) may comprise one or more methods of laboratory analysis, test or diagnosis or groups of methods;

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<sup>19</sup> **This has been deleted to clarify that only the methods within the scope of the accreditation - point (e) of paragraph 4 are concerned.**

(c) may be defined in a flexible manner, so as to allow the accreditation scope to include modified versions of the methods used by the official laboratory when the accreditation was granted or new methods in addition to those methods, on the basis of the laboratory's own validations without a specific assessment by the national accreditation body prior to the use of those modified or new methods.

6. Where no official laboratory designated in the Union **or in a third country that is a Contracting Party to the Agreement on the European Economic Area** in accordance with paragraph 1 has the expertise, equipment, infrastructure and staff necessary to perform new or particularly uncommon laboratory analyses, tests or diagnoses, the competent authorities may request a laboratory or diagnostic centre which does not comply with one or more of the requirements of paragraphs 3 and 4 of this Article to carry out those analyses, tests and diagnoses.

#### *Article 37*

##### *Obligations of official laboratories*

1. ~~Official laboratories shall immediately inform the competent authorities~~ **Where the results of an analysis, test or diagnosis carried out on samples taken during official controls or other official activities indicate a risk to human, animal and plant health, or, as regards GMOs and plant protection products, also for the environment, non-compliance or point to the likelihood of a non-compliance by an operator, official laboratories shall immediately inform the competent authorities which designated them for that analysis, test or diagnosis and, where relevant, delegated bodies or natural persons to whom tasks have been delegated. This information shall be provided immediately, unless specific arrangements provide otherwise.**
2. Upon request by the European Union reference laboratory or national reference laboratory, official laboratories shall take part in inter-laboratory comparative tests organised for the analyses, tests or diagnoses they perform as official laboratories.
3. Official laboratories shall, **upon request of the competent authorities**, make available to the public the list of methods used for analyses, tests or diagnoses performed in the context of official controls and other official activities.
4. **Official laboratories shall indicate in their reports the method used for each analysis, testing or diagnosis, performed in the context of official controls and other official activities.**

#### *Article 38*

##### *Audits and inspections of official laboratories*

1. The competent authorities shall organise audits or inspections of the official laboratories they have designated in accordance with Article 36(1) **taking into account the results of the assessments referred to in point (e) of Article 36(4):**
  - (a) on a regular basis;
  - (b) any time they consider that an audit or inspection is necessary.

2. The competent authorities shall immediately withdraw the designation of an official laboratory, either completely or for certain tasks, where it fails to take appropriate and timely remedial action following the results of an audit or an inspection provided for in paragraph 1 which disclose any of the following:
  - (a) it no longer complies with the conditions provided for in Article 36(4) and (5);
  - (b) it does not comply with the obligations provided for in Article 37;
  - (c) it is underperforming at inter-laboratory comparative tests referred to in Article 37(2).

*Article 39*

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

1. By derogation from point (e) of Article 36(4), competent authorities may designate the following as official laboratories irrespective of whether they fulfil the condition provided for in that point:
  - (a) laboratories:
    - (i) whose sole activity is the detection of *Trichinella* in meat;
    - (ii) that only use for the detection of *Trichinella* the methods referred to in Article 6 of Commission Regulation (EC) No 2075/2005 laying down specific rules on official controls for *Trichinella* in meat<sup>20</sup>;
    - (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;
    - [(iv) that participate regularly and have satisfactory performance in the inter-laboratory comparative tests organised by the national reference laboratories for the methods they use.]**
  - (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);
  - (c) laboratories which only carry out analyses, tests or diagnoses in the context of other official activities, provided that they:
    - (i) only use the methods of laboratory analysis, test and diagnosis referred to in Article 33(1) and points (a), (b) and (c) of Article 33(2);

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<sup>20</sup> OJ L 338, 22.12.2005, p. 60.

- (ii) carry out the analyses, tests or diagnoses under the supervision of the competent authorities or of the national reference laboratories for the methods they use;
  - (iii) participate regularly **and have satisfactory performance** in the inter-laboratory comparative tests organised by the national reference laboratories for the methods they use;
  - (iv) have a quality assurance system in place to ensure sound and reliable results from the methods for laboratory analysis, test and diagnosis used.
2. Where the methods used by the laboratories referred to in point (c) of paragraph 1 require confirmation of the result of the laboratory analysis, test or diagnosis, the confirmatory laboratory analysis, test or diagnosis shall be carried out by an official laboratory which complies with the requirements of point (e) of Article 36(4).
  3. The official laboratories designated in accordance with points (a) and (c) of paragraph 1 shall be located in the Member States in whose territory the competent authorities which have designated them are located.

#### *Article 40*

*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<sup>21</sup>*

The Commission shall ~~be empowered to~~ adopt delegated acts in accordance with Article 139 concerning the cases where, and the conditions under which, competent authorities may designate as official laboratories in accordance with Article 36(1) laboratories which do not fulfil the conditions referred to in point (e) of Article 36(4) in relation to all the methods they use **for official controls or other official activities**, provided that such laboratories comply with the following conditions:

- (a) they operate, are ~~assessed and~~ accredited in accordance with the standard EN ISO/IEC 17025 for the use of one or more methods which are similar to and representative of the other methods they use;
- (b) they make regular and significant use of the methods for which they have obtained the accreditation referred to in point (a).

#### *Article 41*

*Temporary derogations from the condition for the mandatory ~~assessment and~~ accreditation of official laboratories*

1. By derogation from point (a) of Article 36(5), the competent authorities may temporarily designate an existing official laboratory as official laboratory in accordance with Article 36(1) for the use of a method of laboratory analysis, test or diagnosis for which it has not obtained the accreditation referred to in point (e) of Article 36(4):

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<sup>21</sup> **Delegations are invited to indicate whether further specifications of the COM powers should be introduced (e.g. case of plant health, clearly setting out that the methods for plant pests should benefit from derogation).**

- (a) when the use of that method is newly required by Union rules; or,
  - (b) when changes to a method in use require a new accreditation or an extension of the scope of the accreditation obtained by the official laboratory; or,
  - (c) in cases where the need for the use of the method results from an emergency situation or an emerging risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment.
2. The temporary designation referred to in paragraph 1 shall be subject to the following conditions:
    - (a) the official laboratory is already accredited in accordance with the standard EN ISO/IEC 17025 for the use of a method which is similar to the one not included within the scope of its accreditation;
    - (b) a quality assurance system is in place in the official laboratory to ensure sound and reliable results from the use of the method which is not included within the scope of the existing accreditation;
    - (c) the analyses, tests or diagnoses are carried out under the supervision of the competent authorities or the national reference laboratory for that method.
  3. The temporary designation provided for in paragraph 1 shall not exceed a period of one year, and may be renewed once for a further period of one year.
  4. The official laboratories designated in accordance with paragraph 1 of this Article shall be located in the Member States in whose territory the competent authorities which have designated them are located.

## Chapter V

### Official controls on animals and goods entering the Union

#### SECTION I

#### ANIMALS AND GOODS OTHER THAN THOSE NOT SUBJECT TO SPECIFIC OFFICIAL CONTROLS AT BORDERS UNDER SECTION II

##### *Article 42*

*Official controls on animals and goods **other than those not subject to specific official controls at borders control posts under Section II***

1. The competent authorities shall perform official controls regularly, **on a risk basis and with appropriate frequency**, on animals and goods entering the Union to ascertain compliance with the rules referred to in Article 1(2).
- 1a. On animals and goods to which Articles 45 and 46 does not apply, **the appropriate frequency of the official controls shall be determined** ~~those official controls shall be performed with appropriate frequency~~, taking into account:

- (a) the risks to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, **also** to the environment, associated with different types of animals and goods;
  - (b) the history of compliance with the requirements established by the rules referred to in Article 1(2) applicable to the animals or goods concerned:
    - (i) of the third country and establishment of origin;
    - (ii) of the exporter;
    - (iii) of the operator responsible for the consignment;
  - (c) the controls that have already been performed on the animals and goods concerned;
  - (d) the guarantees that the competent authorities of the third country of origin has given with regard to compliance of the animals and goods with the requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto.
2. The official controls provided for in paragraph 1 shall be performed at an appropriate place within the customs territory of the Union, including:
- (a) the point of entry into the Union;
  - (b) a border control post;
  - (c) the point of release for free circulation in the Union;
  - (d) the warehouses and the premises of the operator responsible for the consignment;-
  - (e) the place of destination.**
3. **Notwithstanding paragraphs 1 and 2,** the competent authorities at border control posts and other points of entry into the Union shall perform official controls on the following whenever they have reason to believe that their entry into the Union may pose a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, **also** to the environment:
- (a) means of transport, including where empty;
  - (b) packaging, **including pallets.**
4. The competent authorities may also perform official controls on goods that are placed under one of the customs procedures defined in [points (a) to (g) of Article 4(16) of Council Regulation (EEC) No 2913/92].

*Article 43*

*Types of official controls on animals and goods **other than those not** subject to ~~specific~~ official controls at border control posts under Section II*

1. ~~The~~ **Where** official controls **are performed in accordance** ~~referred to in~~ **with** Article 42(1), **they** shall:
  - (a) always include a documentary check; **and**
  - (b) , include identity and physical checks depending on the risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, **also** to the environment.
2. The competent authorities shall carry out the physical checks referred to in point (b) of paragraph 1 under appropriate conditions allowing investigations to be conducted properly.
3. Where the documentary, identity ~~or~~ **and** physical checks referred to in paragraph 1 show that animals and goods do not comply with the rules referred to in Article 1(2), Articles 64(1), (3) **and**, (4) ~~and (5)~~, 65, 66, 67, 69(1) and (2), ~~and~~ 70(1) and (2), **134 and 135** shall apply.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the cases where and the conditions under which competent authorities may request operators to notify the arrival of certain goods entering the Union.

*Article 44*

*Samples taken on animals and goods **other than those not** subject to ~~specific~~ official controls at borders control posts under Section II*

1. Where samples on animals and goods are taken, the competent authorities shall, **without prejudice to Chapter IV**:
  - (a) inform **the operators concerned and, where appropriate,** the customs authorities ~~and the operators concerned~~;
  - (b) decide whether or not the animals or goods **need to be detained** ~~can be released before~~ **pending** the results of the analysis, test or diagnosis carried out. ~~on the samples are available, provided that the traceability of the animals or goods is ensured.~~



2. The Commission shall, by means of implementing acts:
- (a) establish the **procedures** ~~mechanisms~~ necessary to ensure the traceability of the animals or goods referred to in point (b) of paragraph 1;
  - (b) identify the documents that must accompany the animals or goods referred to in paragraph 1 when samples have been taken by the competent authorities.

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

## SECTION II

### OFFICIAL CONTROLS AT BORDER CONTROL POSTS ON ANIMALS AND GOODS

#### *Article 45*

#### *Animals and goods subject to official controls at border control posts*

1. To ascertain compliance with the rules referred to in Article 1(2),<sup>22</sup> the competent authorities shall perform official controls, at the border control post of first arrival to the Union, on each consignment of the following categories of animals and goods entering the Union ~~from third countries~~:
- (a) animals;
  - (b) products of animal origin, germinal products and animal by-products;
  - (c) plants, plant products, and other objects ~~and materials~~ capable of harbouring or spreading pests of plants as referred to in the lists established pursuant to Articles 68(1) and 69(1) of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*];
  - (d) goods originating from certain third countries for which the Commission has decided, by means of implementing acts provided for in point (b) of paragraph 2, that a measure requiring a temporary increase of official controls at their entry into the Union is necessary due to a known or emerging risk or because there is evidence that widespread serious non-compliance with the rules referred to in Article 1(2) might be taking place;
  - (e) animals and goods which are subject to an emergency measure provided for in acts adopted in accordance with 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*], or 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*] requiring consignments of those animals or goods, identified by means of their codes from the Combined Nomenclature, to be subject to official controls at their entry into the Union;

(f) animals and goods in relation to whose entry into the Union conditions or measures have been established by acts adopted in accordance with Articles 125 or 127 respectively, or with the rules referred to in Article 1(2), which require that compliance with those conditions or measures be ascertained at the entry of the animals or goods into the Union.

2. The Commission shall, by means of implementing acts:

(a) establish lists detailing **all** the animals and goods ~~belonging to the categories~~ referred to in points (a) and (b) of paragraph 1, indicating their codes from the Combined Nomenclature;

(b) establish the list of goods belonging to the category referred to in point (d) of paragraph 1, indicating their codes from the Combined Nomenclature, and update it as necessary in relation to the risks referred to in that point.

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

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning amendments of the categories of consignments referred to in paragraph 1, ~~to include other products which may give rise to~~ **taking into account the** risks to human, animal or plant health or, as regards GMOs and plant protection products, to the environment.

4. Unless otherwise provided by the acts establishing the measures or conditions referred to in points (d), (e) and (f) of paragraph 1, this Article shall also apply to consignments of the categories of animals and goods referred to in points (a), (b) and (c) of paragraph 1 when they are of a non-commercial nature.

5. **Operators responsible for the consignment shall ensure that animals and goods of the categories referred to in paragraph 1 are presented for official controls at the border control post referred to therein.**

#### *Article 46*

#### *Animals and goods exempted from official controls at border control posts*

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 following categories of animals and goods are exempted from the provisions of Article 45, **when such exemption is justified**:

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

(b) animals and goods intended for scientific purposes;

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<sup>22</sup> The initial wording of the Commission proposal has been reinstalled as Article 42a has been deleted.

- (c) goods on board means of transport operating internationally which are not unloaded and are intended for consumption by the crew and passengers;

- (d) goods which form part of passengers personal luggage and are intended for personal consumption **or use**;
- (e) small consignments of goods sent to natural persons which are not intended to be placed on the market;
- (f) ~~pet animals as defined in point (110) of Article 4(1) of Regulation (EU) No XXX /XXXX~~ [Office of Publications, please insert number of the Regulation on animal health] **and in Article 3(b) of Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals;**<sup>23</sup>
- (g) goods which have undergone heat treatment and do not exceed quantities to be defined in those delegated acts;
- (h) ~~any other categories~~ of animals or goods **posing low risks and** for which controls at border control posts are **therefore** not necessary ~~given the risks they pose~~.

*Article 47*

*Official controls at border control posts*

1. The competent authorities shall perform official controls on the consignments of the categories of animals and goods referred to in Article 45(1) upon arrival of the consignment at the border control post. Those official controls shall include documentary, identity and physical checks.
- ~~2. All consignments of the categories of animals and goods referred to in Article 45(1) shall be subject to documentary and identity checks.~~
- ~~3. Physical checks shall be performed on consignments of the categories of animals and goods referred to in Article 45(1) at a frequency dependent on the risk posed by each animal, good or category of animals or goods to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.~~<sup>24</sup>
24. Physical checks to verify compliance with animal health and welfare requirements or with plant health requirements laid down in the rules referred to in Article 1(2) shall be performed by[, or under the supervision of,] staff **trained in accordance with the requirements established pursuant to paragraph 5Article 4(3)** possessing appropriate ~~qualifications~~ in veterinary or phytosanitary matters respectively, designated by the competent authorities for that purpose.

Where ~~physical such~~ checks are performed on animals, they shall be carried out by an official veterinarian or under his supervision **except for live fishes, live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption.**

<sup>23</sup> The references will need to be aligned depending on the outcome of the negotiations on the proposal for Animal Health Law

<sup>24</sup> The content of the paragraphs 2&3 has been moved to new paragraphs 1a & 1b of Article 52

Where physical checks are performed on meat and edible meat offal, they shall be performed by an official veterinarian, under his supervision or under his responsibility<sup>25</sup>.

**Where physical checks are performed to detect the presence of pests of plants, on plants, plants products and other objects they shall be carried out by an official plant health officer.**

35. The competent authorities at border control posts shall systematically perform official controls on consignments of animals being transported and on means of transport to verify compliance with the animal welfare requirements laid down in the rules referred to in Article 1(2). Arrangements shall be put in place by competent authorities to give priority to official controls on animals being transported and to reduce delays on such controls.
46. The Commission may, by means of implementing acts establish the modalities of presentation of consignments of the categories of **animals and** goods referred to in Article 45(1), the **transport units or** sub-entities which can constitute an individual consignment and the maximum number of such **transport units or** sub-entities in each consignment, taking into account the need to guarantee the rapid and efficient handling of the consignments and the official controls to be performed by the competent authorities **and, where relevant, international standards.**

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

- 5. The Commission shall, by means of implementing acts, lay down the specific training requirements necessary to ensure that the staff designated by the competent authorities for performing [or supervising the performance of] the physical checks at the border control posts to verify compliance with the animal health and welfare requirements or with the plant health requirements laid down in the rules referred to Article 1(2) , possess the necessary skills for the performance of those tasks**

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

#### *Article 48*

#### *Certificates and documents accompanying consignments and split consignments*

1. The original official certificates or documents, or electronic equivalents, which are required by the rules referred to in Article 1(2) to accompany consignments of the categories of animals and goods referred in Article 45(1) shall be presented to, and kept by the competent authorities of the border control post **unless otherwise provided for in the rules referred to in Article 1(2).**

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<sup>25</sup> A definition of meat and edible meat referring to the subcategories under the codes from 0201 to 0208 of Combined Nomenclature (CN) provided for in Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature, should be added in Article 2.

2. The competent authorities of the border control post shall issue the operator responsible for the consignment with an authenticated paper or electronic copy of the official certificates or documents referred to in paragraph 1 or, if the consignment is split, with individually authenticated paper or electronic copies of such certificates or documents.
3. Consignments shall not be split until official controls have been performed and the Common Health Entry Document (**referred to as “CHED”**) referred to in Article 54 has been finalised in accordance with Articles 54(4) and 55(1).
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 the CHED must accompany consignments of the categories of animals and goods referred to in Article 45(1) to the place of destination.**

*Article 49*  
*Specific rules for official controls at border control posts*

The Commission shall ~~be empowered to~~ adopt delegated acts in accordance with Article 139 concerning rules to establish:

- (a) the cases where and the conditions under which the competent authorities of a border control post may authorise the onward transportation of consignments of the categories of animals and goods referred to in Article 45(1) to the place of final destination pending the availability of the results of physical checks, where such checks are required;
- (b) the time limits and modalities for carrying out documentary **and, where necessary, identity and physical checks on animals and the goods subject to the official controls provided for in Article 45(1) which enter the Union by sea or by air transport from a third country, are moved 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 travel, referred to as "transhipped" consignments** ~~of the categories of goods referred to in Article 45(1);~~
- (c) the cases where and the conditions under which identity and physical checks of transhipped consignments and of animals arriving by air or sea and staying on the same means of transport for onward travel may be performed at a border control post other than the one of first arrival ~~in~~ to the Union;
- (d) the cases where and the conditions under which the transit of consignments of the categories of animals and goods referred to in Article 45(1) may be authorised and the ~~specific~~ **certain** official controls to be performed at border control posts on such consignments, including the cases and conditions for their storage **of goods** in specially approved free or customs warehouses ~~or in~~ **free zones**.

*Article 50*  
*Details of documentary, identity and physical checks*

For the purposes of ensuring the uniform implementation of the rules laid down in Articles 47, 48 and 49, the Commission shall by means of implementing acts, lay down the details of the operations to be carried out during and after the documentary, identity and physical checks referred to in those rules to ensure the efficient performance of those official controls. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

*Article 51*  
*Official controls not performed at border control posts ~~of first arrival~~*

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:
  - (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 acts adopted in accordance with Article 62(4);
  - (b) physical checks on consignments which have undergone documentary and identity checks at a border control post of first arrival **to the Union** may be performed at another border control post in a different Member State;  
**(bb) identity and physical checks on consignments which have undergone documentary checks at a border control post of first arrival to the Union may be performed at another border control post in a different Member State;**
  - (c) specific control tasks ~~may be performed by relating to the following may be attributed by competent authorities~~ customs authorities or other public authorities, **insofar as those tasks are not already falling under the responsibility of those authorities:**
    - (i) consignments referred to in Article 63(2);
    - (ii) passengers personal luggage;
    - (iii) goods ordered ~~by~~**from distance-selling, including by telephone or via the internet.**
2. Point (b) of Article 54(2), point (a) of Article 55(2) and Articles 57, 58, 60, 61, 62(3) and (4), shall apply to the control points referred to in point (a) of paragraph 1.

*Article 52*  
*Frequency of identity and physical checks*

- 1a. **All consignments of the categories of animals and goods referred to in Article 45(1) shall be subject to documentary checks.**
- 1b. **Identity and physical checks shall be performed on consignments of the categories of animals and goods referred to Article 45(1) at a frequency dependent on the risk posed by each animal, good or category of animals or goods to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.**
- ~~1. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing the categories of animals and goods and the conditions under which, by derogation from Article 47(2) and account taken of the reduced risk, identity checks on consignments of animals and goods referred to in Article 45(1) shall be:~~
- ~~(a) performed at a reduced frequency;~~
- ~~(b) limited to the verification of a consignment's official seal, where any such seal is present.~~
2. **The Commission shall by means of implementing acts, lay down rules for the uniform application of the appropriate frequency rate referred to in paragraph 1b. Such rules shall establish:**~~be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing:~~
- (a) the criteria and the procedures for determining and modifying the frequency rates of **identity and** 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:
- (i) information collected by the Commission in accordance with Article 124(1);
- (ii) the outcome of controls performed by Commission experts in accordance with Article 1195(1);
- (iii) operators' past record as regards compliance with the rules referred to in Article 1(2);
- (iv) data and information collected via the information management system referred to in Article 130;
- (v) available scientific assessments; and,
- (vi) any other information regarding the risk associated to the categories of animals and goods.



- (b) the conditions under which Member States may increase the frequency rates of **identity and** physical checks established in accordance with point (a) so as to take account of local risk factors;
- (c) the procedures for ensuring that the frequency rates of **identity and** physical checks established in accordance with point (a) are applied in a timely and uniform manner.

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

3. The Commission shall, by means of implementing acts, lay down rules establishing:

- (a) the frequency of **identity and** physical checks for the categories of goods referred to in point (d) of Article 45(1);
- (b) the frequency of **identity and** 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.

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

#### *Article 53*

#### *Decisions on consignments*

1. A decision shall be taken by the competent authorities on each consignment of the categories of animals and goods referred to in Article 45(1) following the performance of official controls **including documentary and, where necessary, identity and physical checks**, indicating whether the consignment is in compliance with the rules referred to in Article 1(2) and, where relevant, the applicable customs procedure.
2. Decisions **on the basis of the results of** taken following a physical check **regarding to** ~~verify compliance with~~ animal health and welfare requirements or ~~with~~ plant health requirements **laid down in the rules referred to in Article 1(2)** shall be taken by staff **trained in accordance with the requirements established pursuant to Article 47(5)4(3)** ~~possessing appropriate qualifications in~~ veterinary or phytosanitary matters respectively, and designated by the competent authorities for that purpose.

**Such decisions, as regards ~~on~~ consignments of animals, except live fishes, live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption, shall be taken by an official veterinarian ~~or under his supervision~~. ~~This subparagraph shall not apply to live bivalve molluscs and live fish.~~**

**Such decisions as regards consignments of meat and meat offal shall be taken by the official veterinarian, or under his supervision[, or under his responsibility].**

**Such decisions on the presence of pests of plants, as regards consignments of plants, plants products and other objects ~~living plants and plants for planting~~, shall be taken by an official plant health officer.**

*Article 54*

*Use of the Common Health Entry Document by the operator and by the competent authorities*

1. For each consignment of the categories of animals and goods referred to in Article 45(1) the operator responsible for the consignment shall complete **the relevant part of the** CHED, providing the information necessary for the immediate and complete identification of the consignment and its destination.
- 1a. References in this Regulation to the CHED, shall be considered to include a reference to its electronic equivalent.**
2. The CHED shall be used:
  - (a) by the operators responsible for consignments of the categories of animals and goods referred to in Article 45(1) in order to give prior notification to the competent authorities of the border control post of ~~the~~ **first** arrival of those consignments;
  - (b) by the competent authorities of the border control post, in order to:
    - (i) record the outcome of the official controls performed and any decisions taken on that basis, including the decision to reject a consignment;
    - (ii) communicate the information referred to in point (i) through the ~~TRACES~~ **integrated computerised system referred to in Article 132(4)**<sup>26</sup>.
3. Operators **responsible for the consignment** shall give prior notification in accordance with point (a) of paragraph 2 by completing and submitting the relevant part of the CHED into the ~~TRACES~~-system **referred to in (2)(b)(ii)** for transmission to the competent authorities of the border control post prior to the physical arrival of the consignment into the Union.
4. The competent authorities of the border control post shall finalise the CHED as soon as:
  - (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.

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<sup>26</sup> Reference has been amended following Presidency suggestions in Doc. 13603/14.

*Article 55*  
*Use of the Common Health Entry Document by customs authorities*

1. The placing of consignments of the categories of animals and goods referred to in Article 45(1) under supervision or control by the customs authorities, including the entry or handling in free zones or customs warehouses **or in free zones** shall be subject to the presentation by the operator **responsible for the consignment** to the custom authorities of the CHED, ~~or its electronic equivalent,~~ duly finalised in the **TRACES integrated computerised** system **referred to in Article 132(4)** by the competent authorities of the border control post.
2. Customs authorities shall:
  - (a) not allow the placing of the consignment under a customs procedure different from the one indicated by the competent authorities of the border control post;
  - (b) only allow the release for free circulation of a consignment upon presentation of a duly finalised CHED which confirms that the consignment is in compliance with the rules referred to in Article 1(2).
3. Where a customs declaration is made for a consignment of the categories of animals or goods referred to in Article 45(1) and the CHED is not presented, the customs authorities shall detain the consignment and immediately notify the competent authorities of the border control post. The competent authorities shall take the necessary measures in accordance with Article 64(5).

*Article 56*  
*Format, time requirements and specific rules for the use of the Common Health Entry Document*

1. The Commission shall, by means of implementing acts, lay down rules establishing:
  - (a) the format of the CHED and the instructions for its presentation and use, **taking into account relevant international standards;**
  - (b) the minimum time requirements for prior notification of consignments by operators **responsible for the consignment** as provided for in point (a) of Article 54(2) in order to enable the competent authorities of the border control post to perform official controls in a timely and effective manner.

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

- ~~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.~~

*Article 57*  
*Designation of border control posts*

1. Member States shall designate border control posts for the purpose of performing official controls on one or more of the categories of animals and goods referred to in Article 45(1).
2. Member States shall notify the Commission ~~at least three months~~ before designating a border control post. That notification shall include all the information necessary for the Commission to verify that the proposed border control post complies with the minimum requirements laid down in Article 62.
3. Within three months of receiving the notification referred to in paragraph 2, the Commission shall inform the Member State:
  - (a) whether the designation of the proposed border control post is dependent upon the favourable outcome of a control performed by Commission experts in accordance with Article 115 in order to verify compliance with the minimum requirements laid down in Article 62;
  - (b) of the date of such a control **which should be not later than six months from the notification.**
- 3a. **In cases where the Commission has informed a Member State, in accordance with paragraph 3(a), that a favourable outcome of a control is not necessary, the Member State may proceed with the designation.**
4. The Member State shall delay designating the border control post until the favourable outcome of the control has been communicated to it by the Commission. **The Commission shall communicate the results of its control referred to in paragraph 3 at the latest within three months from the date of that control.**

*Article 58*  
*Listing of border control posts*

1. Each Member State shall make available on the Internet up-to-date lists of border control posts on its territory, providing the following information for each border control post:
  - (a) its contact details and opening hours;
  - (b) its exact location and whether it is a port, airport, rail or road entry point;
  - (c) the categories of animals and goods referred to in Article 45(1) ~~and their codes from the Combined Nomenclature~~, which are included in the scope of its designation;
  - ~~(d) the equipment and premises available for performing official controls on each of the categories of animals and goods for which it is designated;~~
  - ~~(e) the volume of the animals and goods handled per calendar year for each of the categories of animals and goods referred to in Article 45(1) for which it is designated.~~
2. The Commission shall, by means of implementing acts, establish the format, categories, abbreviations for designations and other information to be used by Member States in the lists of border control posts.

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

#### *Article 59*

##### *Withdrawal of approvals for, and re-designation of, existing border control entities*

1. The approval of border inspection posts in accordance with Article 6 of Council Directive 97/78/EC and Article 6 of Council Directive 91/496/EEC ~~and~~ the designation of points of entry in accordance with Article 5 of Regulation (EC) No 669/2009 and with Article 13(c)(4) of Council Directive 2000/29/EC **and the designation of first points of introduction in accordance with Article 5 of Regulation (EU) No 284/2011** shall be withdrawn.
2. Member States may re-designate border inspection posts, designated points of entry and points of entry referred to in paragraph 1 as border control posts in accordance with Article 57(1) provided that the minimum requirements referred to in Article 62 are complied with.
3. Article 57(2), ~~and (3)~~ **and (4)** shall not apply to the re-designation referred to in paragraph 2.

#### *Article 60*

##### *Withdrawal of the designation of border control posts*

1. Where border control posts cease to comply with the requirements referred to in Article 62, the Member States shall:
  - (a) withdraw the designation provided for in Article 57(1) for all or for certain categories of animals and goods for which the designation was made;
  - (b) remove them from the lists referred to in Article 58(1), for the categories of animals and goods for which the designation is withdrawn.
2. Member States shall inform the Commission and the other Member States of the withdrawal of the designation of a border control post as provided for in paragraph 1 and of the reasons for such withdrawal.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the cases where, and the procedures by which, border control posts whose designation has only been partially withdrawn in accordance with point (a) of paragraph 1 may be re-designated by derogation from the provisions of Article 57.
4. **This Article shall be without prejudice to Member States' competence to decide on the withdrawal of designation of border control posts for other reasons than those referred to in this Regulation.**

#### *Article 61<sup>27</sup>*

##### *Suspension of the designation of border control posts*

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

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<sup>27</sup> A Recital should be added to explain what type of risk is referred to in paragraph 1

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. **In case of a serious risk, the suspension shall be immediate.**

2. Member States shall immediately inform the Commission and the other Member States of any suspension of the designation of a border control post and the reasons for such a suspension.
3. Member States shall indicate the suspension of the designation of a border control post in the lists referred to in Article 58(1).
4. Member States shall remove the suspension provided for in paragraph 1 as soon as:
  - (a) the competent authorities are satisfied that the risk referred to in paragraph 1 no longer exists;
  - (b) they have communicated to the Commission and to the other Member States the information on the basis of which the suspension is removed.
5. ~~The Commission may, by means of implementing acts, establish procedures for the exchanges of information and communications referred to in paragraph 2 and in point (b) of paragraph 4.~~

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

*Article 62*  
*Minimum requirements for border control posts*

1. Border control posts shall be located in the immediate vicinity of the point of entry into the Union and in a place **which is suitably equipped to be designated** by the customs authorities in accordance with Article 38(1) of Regulation (EEC) No 2913/92 **or in a free zone**.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the cases where and conditions under which a border control post ~~may~~ be situated at a ~~certain~~ distance **other than in immediate vicinity of** ~~from~~ the point of entry into the Union **in cases of** ~~given~~ specific geographical constraints.
3. Border control posts shall have:
  - (a) a sufficient number of suitably qualified staff;
  - (b) premises **or other facilities** appropriate for the nature and volume of the categories of animals and goods handled;
  - (c) equipment and premises **or other facilities** to allow the performance of official controls for each of the categories of animals and goods for which the border control post has been designated;
  - (d) arrangements in place to guarantee, as appropriate, access to any other equipment, premise and service necessary to apply the measures taken in accordance with Articles 63, 64 and 65 in cases of suspicion, non-compliant consignments or consignments presenting a risk;
  - (e) contingency arrangements to ensure the smooth operation of official controls and the effective application of the measures taken in accordance with Articles 63, 64 and 65 in cases of ~~unforeseeable and~~ unexpected conditions or events;
  - (f) the technology and equipment necessary for the efficient operation of the ~~TRACES~~ **integrated computerised system referred to in Article 132(4)** and, as appropriate, of other computerised information management systems necessary for the handling and exchange of data and information;
  - (g) access to the services of official laboratories capable of providing analytical, testing and diagnostic results within appropriate deadlines ~~and equipped with the information technology tools necessary to ensure the introduction of the results of analyses, tests or diagnoses carried out into the TRACES system as appropriate;~~
  - (h) appropriate arrangements for the proper handling of different categories of animals and goods and to prevent risks which may result from cross-contamination;

(i) arrangements to comply with relevant biosecurity standards in order to prevent the spread of diseases into the Union.

4. The Commission may, by means of implementing acts, detail the requirements laid down in paragraph 3 to take into account specific features and logistic needs related to the performance of official controls and to the application of the measures taken in accordance with Article 64(3) and (5) and Article 65 in relation to the different categories of animals and goods referred to in Article 45(1).

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

5. **The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the cases and conditions under which border control posts designated for the imports of unprocessed logs may be exempted ~~processed~~ from one or more of the obligations referred to in paragraph 3 to take into account the needs of competent authorities in charge of official controls at remote geographical locations, while ensuring the proper performance of the controls.**

**SECTION III**  
**ACTION IN CASE OF SUSPICION OF NON-COMPLIANCE AND OF NON-**  
**COMPLIANCE OF ANIMALS AND GOODS ENTERING THE UNION**  
**~~FROM THIRD COUNTRIES~~**

*Article 63*

*Suspicion of non-compliance and intensified official controls*

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.
2. Consignments of animals and goods which are not declared by operators to consist of the categories of animals and goods referred to in Article 45(1), shall be subject to official controls by the competent authorities where there is reason to believe that such categories of animals or goods are present in the consignment.
3. The competent authorities shall place the consignments referred to in paragraphs 1 and 2 under official detention **pending** ~~until they obtain~~ the results of the official controls provided for in those paragraphs.



Where appropriate, those consignments shall be isolated or quarantined and animals **or living plants** shall be sheltered, fed, watered and **as necessary** treated pending the results of the official controls.

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.
5. The competent authorities shall notify the Commission and the Member States through the ~~TRACES~~ **integrated computerised** system **referred to in Article 132(4)** of their decision to perform intensified official controls, as provided for in paragraph 4, indicating the purported fraudulent behaviour or serious or repeated infringement.
6. The Commission shall, by means of implementing acts, establish procedures for the coordinated performance by competent authorities of the intensified official controls referred to in paragraphs 4 and 5.

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

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