II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Commission Notice on a guidance document on how to fill in the standard model form in the Annex to Commission Implementing Regulation (EU) 2019/723 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the standard model form to be used in the annual reports submitted by Member States

(2021/C 71/01)

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1. Purpose of the guidance document

The purpose of this guidance document is to assist the Member States in submitting the information and data in their annual report on the implementation of their multi-annual national control plans (MANCP) in a standard model form.

This guidance document is intended to assist national authorities in the application of Article 113(1) of Regulation (EU) 2017/625 of the European Parliament and of the Council (¹) and Commission Implementing Regulation (EU) 2019/723 (²). Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

2. Purpose of the annual report

The purpose of the Member States' annual report is to:

- a) meet the legal obligations for reporting laid down in Article 113(1) of Regulation (EU) 2017/625 of the European Parliament and of the Council;
- b) ensure uniform conditions for the implementation of Regulation (EU) 2017/625 and facilitate the collection and transmission of comparable data and the subsequent compilation of such data into Union-wide statistics;
- c) be used in updating and reviewing the MANCP.

The process of compiling and analysing the data for the purpose of the annual report may facilitate Member States' review of the effectiveness, and contribute towards the development and continual improvement, of their control systems.

Under Article 11(1) of Regulation (EU) 2017/625, Member States' competent authorities are required to ensure the regular and timely publication of information on the following:

- d) the type, number and outcome of official controls;
- e) the type and number of cases of non-compliance detected;
- f) the type and number of cases where measures were taken by the competent authorities in accordance with Article 138 of Regulation (EU) 2017/625; and
- g) the type and number of cases where the penalties referred to in Article 139 of that Regulation were imposed.

This information may be provided, where appropriate, through the publication of the annual reports.

Under Article 114(1)(a) of Regulation (EU) 2017/625, the Commission is required to take the information provided in the annual reports into account in the preparation of the Commission's annual report on the operation of official controls in the Member States.

Legal background

Article 113(1) of Regulation (EU) 2017/625 provides:

- "1. By 31 August every year, each Member State shall submit to the Commission a report setting out:
- (a) any amendments made to its MANCP to take account of the factors referred to in Article 111(2);
- (b) the outcome of official controls performed in the previous year under its MANCP;

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

⁽²⁾ Commission Implementing Regulation (EU) 2019/723 of 2 May 2019 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the standard model form to be used in the annual reports submitted by Member States (OJ L 124, 13.5.2019, p. 1).

- (c) the type and number of cases of non-compliance with the rules referred to in Article 1(2), per area, detected in the previous year by the competent authorities;
- (d) the measures taken to ensure the effective operation of its MANCP, including enforcement action and the results of such measures, and
- (e) a link to the web page of the competent authority containing the public information on fees or charges referred to in Article 85(2)."

4. Definitions

In this guidance document, reference is made to the definitions laid down in the relevant Union legislation and, in particular, the definitions in Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council (³), Article 2 of Regulation (EU) 2016/2031 of the European Parliament and of the Council (⁴), and Articles 2 and 3 of Regulation (EU) 2017/625. In particular, the following definitions set out in Article 2 of Regulation (EU) 2017/625 should be noted:

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

In addition to the definitions referred to above, the following approaches should be taken into account for the purpose of this guidance document:

(a) How to count official controls

The approach to counting official controls is based on Article 13(1) of Regulation (EU) 2017/625, according to which for every official control that the competent authorities perform, they have to draw up written records, which may be on paper or in electronic form. Official controls should, for the purposes of the preparation of annual reports by Member States, be counted on the basis of those records.

During an official control competent authorities may use different methods or techniques and carry out activities in several of the areas mentioned in Article 1(2), including in accordance with different rules (5) within those areas. The written record of the official control should reflect those activities and the competent authorities should report them accordingly (e.g. one official sample leading to several analyses covering five different rules = five analyses results/laboratory reports = official controls in accordance with five different rules; one visit/inspection covering three different rules = official controls in accordance with three different rules).

⁽³⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

⁽⁴⁾ Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

⁽³⁾ Non-exhaustive indicative lists of rules, meant as guidance with regard to the information on official controls to be reported, can be found in Annexes I to X of this guidance document.

If competent authorities carry out an official control on an operator/establishment with several activities (e.g. processing fishery products and cold store for goods) and if the competent authorities cover two or more of those activities, then the competent authorities should report the controls by activity, whenever possible.

(b) How to count operators/establishments

Registered operators and approved establishments may carry out different activities for which requirements are provided in different rules of the EU agri-food chain legislation. Competent authorities keep up-to-date lists of such operators and establishments, including of their activities. Therefore, when counting the number of operators and/or establishments, the competent authorities should count them bearing in mind the activities they carry out and include them in the corresponding categories (e.g. if an establishment has both wholesale and retail activities, such establishment should be counted on both the wholesale and retail categories).

(c) How to count non-compliances

For the purpose of this guidance document a non-compliance corresponds to a breach of the rules in the areas of Article 1(2) of Regulation (EU) 2017/625.

The approach to counting non-compliances is based on Article 13(2) of Regulation (EU) 2017/625, according to which the operator is to be promptly informed in writing by the competent authorities of any case of non-compliance identified through the official controls. Non-compliances should, for the purposes of the preparation of annual reports by Member States, be counted on the basis of an issued written communication from the competent authority to the operator.

During an official control, competent authorities may detect cases of non-compliances in the implementation of:

- different rules within one of the areas mentioned in Article 1(2) (e.g. three legal acts in the area of feed Article 1(2)(c)), or
- the rules within different areas (e.g. one legal act in the area of animal health Article 1(2)(d) and two legal acts in the area of animal welfare Article 1(2)(f)).

The written communication from the competent authority to the operator, identifying the non-compliances, should reflect those cases and the competent authorities should report them accordingly.

(d) Administrative and judicial action/measures

Under Article 138(1) of Regulation (EU) 2017/625, where a non-compliance is established, the competent authorities are required to take appropriate measures to ensure that the operators concerned remedy the non-compliance and prevent further occurrences of such non-compliance. The measures taken by the competent authorities should be reported under two categories: administrative and judicial.

Administrative actions/measures are those that fall under the competence of, and are initiated by, the competent authority.

The judicial actions/measures are those that fall under the competence of the judicial authorities and that are relevant for cases of non-compliances that the competent authority referred to the judicial authority.

The number of actions/measures initiated by the competent authorities, or falling under the competence of the judicial authority, may not correspond automatically to the number of non-compliances detected.

5. Scope of the annual report

The annual report should cover the scope of the MANCP prepared in accordance with Article 110(1) of Regulation (EU) 2017/625, taking into account the requirements of Article 113(1) of that regulation.

Member States already submit information and data on import controls and controls on intra-Union trade to the Commission when using the computerised information management system for official controls (IMSOC). Therefore, this information and data should not be part of the annual report.

Member States are not required to include information in their annual report about other official activities performed by the competent authorities or by the delegated bodies or natural persons to which certain other official activities have been delegated (°).

Likewise, data on control of the cross-compliance requirements in accordance with Article 9 of Commission Implementing Regulation (EU) No 809/2014 (7), are not required to be reported in the Annual Report.

Notwithstanding, Member States should submit information and data on official controls that, in accordance with Article 1(4)(a) of Regulation (EU) 2017/625, Member States are to perform pursuant to Article 89 of Regulation (EU) No 1306/2013 of the European Parliament and of the Council (8), where those controls identify possible fraudulent or deceptive practices in respect of the marketing standards referred to in Articles 73 to 91 of Regulation (EU) No 1308/2013 of the European Parliament and of the Council (9).

Non-exhaustive indicative lists of rules meant as a guidance with regard to the information to be provided in the annual report standard model form can be found in Annexes I to X.

6. Reporting period and submission of annual reports

Pursuant to Article 113(1) and (2) of Regulation (EU) 2017/625 Member States are to submit their annual reports to the Commission by 31 August of the year following the year to which the reports relate, using the standard model form to be adopted by the Commission. That standard model form is laid down in Commission Implementing Regulation (EU) 2019/723, which applies from 14 December 2019. Therefore, the first annual reports, using that standard model form, are to be submitted to the Commission by 31 August 2021.

7. Relationship with other specific reports

Regulation (EU) 2017/625 does not affect specific Union provisions concerning official controls. Therefore, the annual report required by Article 113(1) of Regulation (EU) 2017/625 does not replace the annual or other reports on other official controls provided for under other pieces of Union legislation.

Commission Implementing Regulation (EU) 2019/723 integrates, whenever possible, the standard model forms adopted by the Commission for the submission of other reports on official controls that the competent authorities are required to submit to the Commission in accordance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625. Examples of this integration are the Member States' reports on the information and data on official controls on food contact materials, irradiation of food, registration and identification of animals and organic data.

The scopes of the reporting obligations in Article 68 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (10) as amended by Regulation (EU) 2017/625 and in Article 113(1) of Regulation (EU) 2017/625 are similar. Furthermore, the deadline in Article 68 of Regulation (EC) No 1107/2009 was aligned with that of Article 113(1) of Regulation (EU) 2017/625. Therefore, the Member States should include the issues to be reported under Article 68 of Regulation (EC) No 1107/2009 in their annual report (namely in Section 8 of Part II of the Annex to Implementing Regulation (EU) 2019/723).

⁽⁶⁾ According to Article 1(5) of Regulation (EU) 2017/625, Article 113 of that regulation does not apply to other official activities.

⁽⁷⁾ Commission Implementing Regulation (EU) No 809/2014 of 17 July 2014 laying down rules for the application of Regulation (EU) No 1306/2013 of the European Parliament and of the Council with regard to the integrated administration and control system, rural development measures and cross compliance (OJ L 227, 31.7.2014, p. 69).

⁽⁸⁾ Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

^(°) Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

⁽¹⁰⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

Official controls carried out for the purpose of coordinated control programmes (Article 112 of Regulation (EU) 2017/625) should be reported in the annual report. The controls performed under these programmes are considered official controls and, even if their results have to be reported in a manner defined by the programme, they should also be reported in the annual report. An explanation could be added in the relevant comment box to indicate that such a programme was implemented.

8. General guidance

Regulation (EU) 2017/625 provides for a systems-based approach to Member States' official controls. An essential part of such an approach is the compilation and analysis of the results of official controls and drawing conclusions thereon, with a view to the determination of appropriate system-based corrective actions and adjustment or amendment of the MANCP where necessary. The annual report should therefore be a synthesis of that activity.

A simple statistical account of the number of official controls should not satisfy that requirement. For compiling the annual report, Member States should provide an overview of the overall or aggregate national results on which the analysis of the results of official controls is based.

The issues to be covered in the overview and analysis of the results of official controls are outlined in Section 9 of this guidance document. The analysis of those results might identify trends and comment on their significance and possible future consequences for official controls.

For the purposes of compilation of the raw control data, where Union legislation prescribes the data to be collected for the purpose of specific reports, in relation to the areas of Article 1(2) of Regulation (EU) 2017/625, these data should form the basis of the analysis of the results of official controls for the area in question.

Where there are no such provisions, Member States should follow the standard model form for the annual report for compiling the data.

For the purposes of classifying non-compliances, where Union legislation provides for such classification, this classification should be followed for the purposes of the annual reports. In the absence of any specific provision Member States should follow the classification of non-compliances in the standard model form for the annual report.

The background data supporting the results and analysis of official controls supplied in the annual report may be required by the Commission for the purposes of Commission controls provided for in Article 116 of Regulation (EU) No 2017/625 and should therefore be retained and provided to the Commission on request (Article 119(b) of that Regulation).

9. Guidance on filling in the standard model form of the annual report

The standard model form of the annual report is provided in the Annex to Implementing Regulation (EU) 2019/723. Member States are required to submit the information and data using the electronic version of the standard model form provided in "Annual Reporting on Official Controls" (AROC) in the SANTE Data Collection Platform (under the umbrella of the IMSOC).

The title of the annual report is the following:

"Annual Report submitted by (introduce Member State) for the period 01/01/(introduce reporting year) to 31/12/ (introduce reporting year)".

PART I

The following numbered headings correspond to the headings of the annual report standard model form in the Annex to Regulation (EU) 2019/723.

1. **Introduction**

This section is composed of a text box, numbered 1, for free text.

Member States may present their progress towards achievement of the strategic objectives and the challenges they faced during the reporting year when implementing their MANCP. Where the annual report is related to the first or the last year of the MANCP's implementation this should be taken into account.

A statement on the overall level of compliance with the rules of Regulation (EU) 2017/625 may be included along with an overall assessment of the effectiveness of the official controls carried out under the MANCP and their suitability to achieve the objectives of that Regulation. The statement on the overall performance should be based on an analysis and synthesis of results of the sections in Part II and provide descriptions of:

- a) the performance indicators applied to those objectives, where appropriate; and
- b) results for each objective, where appropriate (11).

In order to achieve a better uniformity when reporting on a) and b) above, Member States may use the following table:

| Article 1(2) area | Strategic objective(s) | Operational objective(s) | Indicator(s) | Target (%) | Result (%) | Assessment |
|-------------------|---------------------------|--------------------------|--------------|------------|------------|------------|
| | | | | | | |
| | | | | | | |

Member States may give a general description of the organisation of their official controls systems for the different areas mentioned in Article 1(2) of Regulation (EU) 2017/625, during the reporting year. A repetition of any detailed description given in the MANCP should be avoided. Instead, Member States should highlight any benefits in terms of effectiveness linked to coordination, cooperation and synergies between the competent authorities in charge of the different official control systems and issues encountered in the reporting year.

2. Measures taken to ensure the effective operation of the MANCP, including enforcement action and the results of such measures

This section is composed of a text box, numbered 2, for free text.

This should be an account of the actions taken to ensure effective operation of the MANCP. The annual report should address actions taken in the following areas:

- a) Actions taken to ensure compliance by operators as provided for in Articles 138(2) and 139(1) of Regulation (EU) 2017/625.
- b) Actions taken to ensure the effective operation of official control services as provided for in Article 5(1) and Article 12(2) and (3) of Regulation (EU) 2017/625. These should include the audits carried out in accordance with Article 6(1) and audits or inspections carried out in accordance with Article 33, and actions taken in response to their findings, where appropriate. In the case of actions taken in response to audit conclusions this may include corrective and preventive actions, or improvement actions based on the identification of good practice.
- c) Substantial actions taken to ensure effective operation of official control services may require amendment of the MANCP and should in such case be included in Section 3 of Part I of the Annex to Implementing Regulation (EU) 2019/723. However, some significant actions might not require an amendment of the MANCP and, in such cases, should be included in this point in the annual report, in order to indicate positive actions taken by the Member State. This information should cover items such as:
 - new, updated or revised control procedures;
 - training initiatives;
 - resource issues;
 - provision of additional resources;
 - reallocation of existing resources following review of priorities;
 - special control initiatives;
 - changes to the organisation or management of competent authorities;

⁽¹¹⁾ The work of the MANCP Network might be a useful source of information.

- provision of guidance or information to feed and food business operators;
- new legislation;
- new delegated bodies or natural persons
- suspension or withdrawal of delegation in the case of delegated bodies or natural persons.

Member States should also indicate relevant issues with negative impact on the operation of the official control systems.

3. Amendments made to the MANCP

This section is composed of a text box, numbered 3, for free text.

In accordance with Article 113(1)(a) of Regulation (EU) 2017/625, Member States shall include in the annual report any amendments to their MANCP during the year to which that report relates, or for the years ahead, to take account at least of the following factors:

- the emergence of new diseases, pests of plants or other risks to human, animal or plant health, animal welfare
 or, in the case of GMOs and plant protection products, also to the environment;
- significant changes to the structure, management or operation of the competent authorities in the Member State;
- the outcome of Member States' official controls;
- the outcome of Commission controls performed in the Member State in accordance with Article 116(1) of Regulation (EU) 2017/625;
- scientific findings; and
- the outcome of official controls performed by the competent authorities of a third country in the Member State.

Other factors that may be taken into account for such amendments are, where applicable:

- new legislation;
- significant changes to the agri-food production sector;
- the outcome of audits carried out in accordance with Article 6(1) of Regulation (EU) 2017/625;
- the outcome of root-cause analysis;
- the conclusions and recommendations contained in the Commission's report in accordance with Article 114(2) of Regulation (EU) 2017/625.

Particular attention should be paid to the need to ensure that amendments made in response to the factors referred to in Article 111(2) of Regulation (EU) 2017/625 are addressed and explained. In particular, relevant changes to the official control systems described in the MANCP and relevant changes to the risk categorisation of activities should be described.

The amendments should be consistent with the analysis and conclusions provided for in Sections 1 to 10 in Part II of the annual report and include cross-references to the relevant section(s), as appropriate.

4. Fees or charges

This section is composed of field, numbered 4, for the inclusion of a hyperlink(s).

Member States are required to include in the annual report the links to the web pages of the competent authorities containing the public information on fees or charges referred to in Article 85(2) of Regulation (EU) 2017/625.

Pursuant to Article 85(2) of Regulation (EU) 2017/625, each competent authority is required to make available to the public the information on the fees or charges provided for in point (a) of Article 79(1), Article 79(2) and Article 80 of Regulation (EU) 2017/625, namely on:

— the method and data used to establish these fees or charges;

- the amount of the fees or charges applied to each category of operators and for each category of official controls or other official activities;
- the breakdown of the costs, as referred to in Article 81;
- the identity of the authorities or bodies responsible for the collection of the fees or charges.

Article 79 of Regulation (EU) 2017/625 does not apply to official controls performed to verify compliance with the rules referred to in points (i) and (j) of Article 1(2). Therefore, in relation to these points, each competent authority is required to make available to the public only the information on the fees or charges provided for in Article 80.

PART II

A. Common information

A.1. Overall conclusion on the level of compliance achieved

This information is presented in a text box, for free text, in each Section of Part II.

Member States should indicate the extent to which annual operational targets (where Member States have established such operational targets), and strategic objectives set out in the MANCP were achieved for each area of Article 1(2) of Regulation (EU) 2017/625.

A brief description of relevant performance indicators and/or operational targets applied may be included here, unless provided in the MANCP, in which case they should be referred to by means of cross-references.

Member States may include an assessment of how official controls (including unplanned) and, where applicable, specific control activities focused on a particular issue, have contributed to the level of compliance achieved.

Member States may mention for planned official controls the extent to which the frequency or intensity and nature of official controls set out in the MANCP were achieved. In the event that operational targets for planned official controls are not achieved, an analysis of relevant mitigating and/or contributing factors may be provided.

Member States may provide a brief explanation of the reasons for the unplanned official controls — particularly when they have diverted resources from planned official controls.

Member States should provide a description on how the overall compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625, per area, was measured during the previous year as well as an overview of the results. A statement or conclusion on the overall level of compliance may provide an overview of results on the basis of competent authorities' performances.

A.2. Outcome of official controls performed in the previous year under the Member State's MANCP

This information is presented in one, or more, tables in each Section of Part II depending on the particularities of each area in Article 1(2) of Regulation (EU) 2017/625.

In the table(s), Member States should indicate at least the number of official controls performed during the previous year. Examples of the methods and techniques used for these controls can be found in Article 14 of Regulation (EU) 2017/625 (e.g. inspection, sampling, analysis, diagnosis and tests).

Annexes I to X provide non-exhaustive indicative lists of rules, per area, meant as a guidance with regard to the information on official controls to be reported in the corresponding Sections of the annual report standard model form.

Optional text boxes, for free text, are provided after the tables for any comments deemed necessary on the performance of official controls, namely any specific context, background or constraints that merit to be highlighted. Member States can add information in these text boxes on the official controls performed for the verification of compliance with requirements laid down in the rules referred to Article 1(2) of Regulation (EU) 2017/625 where those requirements are applicable to products/goods to be exported from the Union (see also Article 9(6)(b) of the same Regulation).

A.3. Type and number of cases of non-compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625, per area, detected in the previous year by the competent authorities

This information is presented in the form of one, or more, tables in each Section of Part II depending on the particularities of each area in Article 1(2) of Regulation (EU) 2017/625.

In the table(s), Member States should indicate at least the type and number of cases of non-compliance detected during the previous year.

In the tables, depending on the particularities of each area in Article 1(2) of Regulation (EU) 2017/625, the non-compliances are divided per type (e.g. linked to an operator (structural or operational) or linked to an animal (by species) or good (e.g. by food categories)) and the last column of the tables indicates the actions/measures taken by the competent authorities to restore compliance under two categories: "Administrative" and "Judicial".

Where applicable, under the text boxes "Fraudulent and deceptive practices", Member States should provide a summary of the non-compliances identified during official controls performed to identify possible intentional violations of the rules referred to in Article 1(2) of Regulation (EU) 2017/625, perpetrated through fraudulent or deceptive practices, and taking into account information regarding such violations shared through the mechanisms of administrative assistance provided for in Articles 102 to 108 of Regulation (EU) 2017/625 and any other information pointing to the possibility of such violations.

When providing the summary above, the Member States should take into account the definition of "food fraud notification" in Article 2(21) of Commission Implementing Regulation (EU) 2019/1715 (12), which is a non-compliance notification concerning suspected intentional action by businesses or individuals for the purpose of deceiving purchasers and gaining undue advantage therefrom, in violation of the rules referred to in Article 1(2) of Regulation (EU) 2017/625.

Optional text boxes, for free text, are provided after the tables for any comments deemed necessary on the quantity and type of non-compliances detected and actions/measures initiated, namely any specific context, background or constraints that merit to be highlighted.

B. Information per section

Section 1. Food and food safety, integrity and wholesomeness at any stage of production, processing and distribution of food, including rules aimed at ensuring 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

Section 1 of Part II is composed of:

- a text box numbered 1.1, for free text, for the overall conclusion on the level of compliance achieved;
- three tables for the official controls performed, numbered 1.2, 1.3 and 1.4;
- an optional text box numbered 1.5, for free text, for comments;
- a table for the non-compliances and actions/measures numbered 1.6, and
- an optional text box numbered 1.7, for free text, for comments.

The text box 1.1 should be completed following the guidance in Section A.1.

For table 1.2 on official controls, Member States should take into account the guidance in Section A.2.

⁽¹²⁾ Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components ('the IMSOC Regulation') (OJ L261, 14.10.2019, p. 37).

| | How to complete table 1.2 |
|--|---|
| For approved establishments | |
| Column "Number of establishments" | Total number of approved establishments, used for planning the official controls (most likely at the beginning of the year), for the different categories. |
| Column "Number of official controls performed" | Total number of official controls carried out during the reporting year, in the different categories of approved establishments. |
| For registered operators/establishments | |
| Column "Number of operators/ establishments" | Total number of operators/establishments, used for planning the official controls (most likely at the beginning of the year), for the different categories. |
| Column "Number of official controls performed" | Total number of official controls carried out during the reporting year, in the different categories of operators/establishments. |
| For establishments producing food contact | ct materials |
| Column "Number of establishments" | Total number of establishments, used for planning the official controls (most likely at the beginning of the year), for this category. |
| Column "Number of official controls performed" | Total number of official controls carried out during the reporting year, in this category of establishments. |

The categories of operators/establishments were divided in "approved" and "registered", following the rules of Article 6 of Regulation (EC) No 852/2004 of the European Parliament and of the Council (13) and Article 4 of Regulation (EC) No 853/2004 (14).

In the case of "approved" establishments, the categories in table 1.2 (and consequently in table 1.6) were drawn from the Annex II of the "Technical Specifications in Relation to the Master List and the Lists of EU Approved Food Establishments and Certain other Specified Food Establishments" (15).

In the case of "registered" operators/establishments, the categories in table 1.2 (and consequently in table 1.6) were agreed by the Commission Expert group during the development of Implementing Regulation (EU) 2019/723. In addition, to facilitate the categorisation of the operators/establishments, the Statistical classification of economic activities in the European Community (NACE) (16), by means of their codes, can optionally be used. The following table illustrates how the NACE codes relate to the defined categories:

| Categories of registered operators/ establishments | NACE codes |
|---|-----------------------------------|
| Growing of crops | 01.11 to 01.14 and 01.19 to 01.28 |
| Animal production | 01.41 to 01.49 |
| Mixed farming | 01.50 |
| Hunting | 01.70 |

⁽¹³⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

⁽¹⁴⁾ 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 (OJ L 139, 30.4.2004, p. 55).

⁽¹⁵⁾ https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_eu_food_establishments-techspecs_en.pdf, with modification introduced by https://webgate.ec.testa.eu/Ares/renditionDownload.do?itemId=090166e5a58a9c2d (point A.01 of the Summary Report)

⁽¹⁶⁾ http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=LST_NOM_DTL&StrNom=NACE_REV2&StrLanguageCo-de=EN&IntPcKey=&StrLayoutCode=HIERARCHIC

| Fishing | 03.11 and 03.12 |
|--|---|
| Aquaculture | 03.21 and 03.22 |
| Processing and preserving of fruit and vegetables | 10.31, 10.32 and 10.39 |
| Manufacture of vegetable oils and fats | 10.41 and 10.42 |
| Manufacture of grain mill products, starches and starch products | 10.61 and 10.62 |
| Manufacture of bakery and farinaceous products | 10.71 to 10.73 |
| Manufacture of other food products | 10.81 to 10.86 and 10.89 |
| Manufacture of beverages | 11.01 to 11.07 |
| Wholesale | 46.31, 46.34, 46.36, 46.37 and 46.39 |
| Retail | 47.11, 47.21 to 47.25, 47.29, 47.76, 47.81, 47.91 and 47.99 |
| Transport and storage | 49.20, 50.20, 50.40, 51.21 and 52.10 |
| Food and beverage service activities | 55.10, 56.10, 56.21, 56.29 and 56.30 |
| Others | No code associated |

The category "Establishments producing food contact materials" is added to the end of table 1.2 to cover the official controls performed on manufacturers of materials and articles intended to come into contact with food.

The table 1.3 on official controls relates to those controls requiring continuous or regular presence of staff or representatives of the competent authorities on the operator's premises.

| How to complete table 1.3 | | | |
|--|--|--|--|
| Column "Number of establishments" | Total number of establishments, used for planning the official controls (most likely at the beginning of the year), for the different categories. | | |
| Column "Number of official controls performed" | Total number of official controls carried out during the reporting year, in number of carcasses or weight per tonnes, in the different categories of establishments. | | |
| Column "Rejections" | Total number of immediate actions taken by the competent authority to prevent meat unfit for human consumption to be placed on the market subsequent to the official controls performed. | | |

The approach to counting this type of official controls is based on Article 13(3) of Regulation (EU) 2017/625, where written records of these official controls, are to be produced with a frequency that enables the competent authorities and the operator to be:

- Regularly informed of the level of compliance; and
- Promptly informed of any case of non-compliance identified through the official controls.

The type of official controls mentioned above relate only to *ante-mortem* and *post-mortem* inspection in slaughterhouses. Official controls should be reported in relation to the number of carcasses inspected or in relation to the weight (in tonnes). Member States can add an explanation in the optional text box 1.5 on how they have counted the official controls performed. The categories of establishments are linked to the categories of "approved" establishments mentioned in table 1.2.

In table 1.4, Member States should report the total number of official controls performed only on products/goods during the reporting year, by food categories and by horizontal rule categories.

The food categories were divided using the food classification and description system "FoodEX2" of the European Food Safety Authority (namely its "Table A3: Facet descriptors for the groups defined in Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives" (17) in Appendix A), while incorporating the food categories associated to the "approved" establishments in table 1.2, as optional categories to be filled. The latter are identified by a (*).

The category "food contact materials" is added to the end of table 1.4 to cover the manufacture, labelling and use of materials and articles intended to come into contact with food.

In the category "Others", Member States can also report the official controls performed for verifying food integrity and wholesomeness.

The horizontal rule categories derive from specific Union provisions concerning official controls in the area of Article 1(2)(a) of Regulation (EU) 2017/625. The intention of table 1.4 is to have an overview of the number of times the horizontal rules were controlled by the competent authorities, in relation with the food categories listed.

A non-exhaustive indicative list of rules, meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(a) of Regulation (EU) 2017/625 is provided in Annex I.

More specifically, the following table indicates for the horizontal rules in tables 1.4 and 1.6:

- a non-exhaustive indicative list of rules, meant as a guidance with regard to the information on official controls and non-compliances to be reported for the area in Article 1(2)(a) of Regulation (EU) 2017/625, and
- where the official controls and non-compliances provided for in Member States' national legislation relevant to Article 1(2)(a) of Regulation (EU) 2017/625 should be reported.

| Horizontal rule in tables 1.4 and 1.6 | Union legislation |
|---------------------------------------|--|
| 1icrobiological criteria | Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, namely Article 14 on Food safety requirements |
| | Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs |
| Pesticides in food | Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant or animal origin |
| | Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food |
| Contaminants in food | Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs |

⁽¹⁷⁾ https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2015.EN-804

| Residues of veterinary medicinal products in food | Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists |
|--|--|
| | Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products |
| | Decision 97/747/EC fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products |
| | Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin |
| | Regulation (EC) No 1760/2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products (Title II) |
| | Directive 2001/110/EC relating to honey |
| | Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters |
| | Regulation (EC) No 1924/2006 on nutrition and health claims made on foods |
| Labelling, nutritional and health claims | Regulation (EC) No 543/2008 of 16 June 2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultry meat |
| | Regulation (EC) No 361/2008 amending Regulation (EC) No 1234/2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products |
| | Regulation (EC) No 617/2008 laying down detailed rules for implementing Regulation (EC) No 1234/2007 as regards marketing standards for eggs for hatching and farmyard poultry chicks (Articles 3 to 6) |
| | Regulation (EU) No 1169/2011 on the provision of food information to consumers |
| | Regulation (EU) No 29/2012 on marketing standards for olive oil |
| | Regulation (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs |
| | Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products (articles 74 to 91) |
| | Regulation (EU) No 1337/2013 laying down rules for the application of Regulation (EU) No 1169/2011 as regards the indication of the country |



| | of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry |
|---|--|
| | Regulation (EU) No 1379/2013 on the common organisation of the markets in fishery and aquaculture products (Chapter IV) |
| | Regulation (EU) No 665/2014 supplementing Regulation (EU) No 1151/2012 with regard to conditions of use of the optional quality term "mountain product" |
| | Regulation (EC) No 1829/2003 on genetically modified food and feed |
| Genetically Modified Organisms (GMOs) | Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms |
| n food | Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation |
| | Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements |
| | Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods |
| | Regulation (EC) No 1332/2008 on food enzymes |
| Improvement agents (additives, enzymes, flavourings, processing aids) | Regulation (EC) No 1333/2008 on food additives |
| | Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on food |
| | Directive 2009/32/EC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients |
| Irradiation | Directive 1999/2/EC on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation |
| irradiation | Directive 1999/3/EC on the establishment of a Community list of foods and food ingredients treated with ionising radiation |
| | Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food |
| Contamination by/migration of food contact materials | Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food |
| | Regulation (EU) No $10/2011$ on plastic materials and articles intended to come into contact with food |

Directive 98/83/CE on the quality of water intended for human consumption (relevant rules for water put into bottles or containers)

Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, namely Article 18 on traceability

Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters

Regulation (EC) No 852/2004 on the hygiene of foodstuffs

Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin

Regulation (EC) No 2074/2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 and for the organisation of official controls under Regulation (EC) No 854/2004

Directive 2009/39/EC on foodstuffs intended for particular nutritional uses

Directive 2009/54/EC on the exploitation and marketing of natural mineral waters

Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters

Commission Implementing Regulation (EU) No 931/2011 on the traceability requirements set by Regulation (EC) No 178/2002 for food of animal origin

Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

Regulation (EU) No 1379/2013 on the common organisation of the markets in fishery and aquaculture products

Regulation (EU) 2015/1375 laying down specific rules on official controls for Trichinella in meat

Regulation (EU) 2015/2283 on novel foods

National legislation

Others

| How to complete the colum | nn "Non-compliances of operators/establishments" in table 1.6 |
|---|--|
| Column "Detected during official controls performed" | Total number of non-compliances detected during the reporting year, in the different categories of approved and registered operators/establishments. |
| Optional column "Total number of controlled operators/establishments" | Total number of operators/establishments for the different categories of operator/establishments where the competent authorities have carried out official controls during the reporting year. |
| Optional column "Number of controlled operators/establishments where non-compliances were detected" | Total number of operators/establishments for the different categories of operators/establishments where the competent authorities have carried out official controls and detected non-compliances (related only to the operator or establishment, either structural or operational) during the reporting year. |
| | |
| How to complete | the column "Non-compliances of food" in table 1.6 |
| Column "Non-compliances detected during official controls performed" and seven sub-columns comprising horizontal rules | Total number of non-compliances in the different categories of food and horizontal rules that the competent authorities detected while performing official controls during the reporting year. |
| | |
| How to complete the colu | mn "Non-compliances related to horizontal rules" in table 1.6 |
| Column "Non-compliances detected during official controls performed" | Total number of non-compliances in the different categories of horizontal rules that the competent authorities detected while performing official controls during the reporting year. |
| | |
| How to comp | plete the column "Actions/measures" in table 1.6 |
| Column "Administrative" | Total number of actions/measures initiated by the competent authorities during the reporting year, in the different categories of operators/ establishments, food, and horizontal rules to restore compliance with the rules in the areas referred to in Article 1(2)(a) of Regulation (EU) 2017/625 |
| Column "Judicial" | Total number of actions/measures that were sent by the competent authority to the judicial authority, during the reporting year, to restore compliance with the rules in the areas referred to in Article 1(2)(a) of Regulation (EU) 2017/625. |

Section 2. Deliberate release into the environment of Genetically Modified Organisms (GMOs) for the purpose of food and feed production

Section 2 of Part II is composed of:

- a text box numbered 2.1, for free text, for the overall conclusion on the level of compliance achieved;
- a table for the official controls numbered 2.2;
- an optional text box numbered 2.3, for free text, for comments;
- a table for the non-compliances and actions/measures numbered 2.4, and
- an optional text box numbered 2.5, for free text, for comments.

The text box 2.1 should be completed following the guidance in Section A.1.

In this Section 2, Member States should report all relevant information on official controls performed in relation to the deliberate release into the environment of GMOs for the purpose of food and feed production, in particular in the following three categories:

 Commercial cultivation of GMOs for the purpose of food and feed production (Part C of Directive 2001/18/EC of the European Parliament and of the Council (18))

Commercial cultivation of GMOs requires an EU wide authorisation, which includes specific conditions, meaning obligations for the operators such as labelling requirements, risk management measures or monitoring of environmental effects. Commercial cultivation for the purpose of food and feed production concerns only GMOs that can be used as food, feed or raw material for the production of food and feed. Member States, where GMOs are cultivated, should report the official controls and the results of those controls in accordance with the guidance provided below. Member States without GMOs cultivation should report the absence of GMOs cultivation in this section of the Annual Report together with any legal reason for doing so (opt-out, safeguard measure, national law etc.).

— Experimental releases of GMOs related to food and feed production (Part B of Directive 2001/18/EC)

Experimental releases of GMOs are authorised at national level, in accordance with Directive 2001/18/EC. Experimental releases of GMOs related to food and feed production concern experimental releases of GMOs which, when commercialised, can be used as food, feed or raw material for the production of food and feed products. Member States that have granted consents for such experimental releases, should report the official controls and the results of those controls in accordance with the guidance provided below.

Seeds and vegetative propagating material for the purpose of food and feed production

Seeds and vegetative propagating material for the purpose of food and feed production concern seeds for planting, which produce plants, and vegetative propagating material that can then be used for the production of food and feed products. Member States should report the official controls on authorised Genetically Modified (GM) seeds and vegetative propagating material as well as the official controls on conventional seeds and vegetative propagating material for the presence of GM material (authorised or unauthorised). Under Article 4(5) of Directive 2001/18/EC, the official controls must be carried out at any stage of placing on the market (such as internal market, exports).

For table 2.2 on official controls, Member States should take into account the guidance in Section A.2 and the description of the three categories above.

| How to complete table 2.2 | | | |
|--|---|--|--|
| Column "Number of official controls performed" | Total number of official controls carried out during the reporting year, in the three categories described for deliberate release into the environment of GMOs for the purpose of food and feed production. | | |

A non-exhaustive indicative list of rules, meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(b) of Regulation (EU) 2017/625 is provided in Annex II.

The table for the non-compliances 2.4 is divided in two main columns, one for "Non-compliances" and another for "Actions/measures". Member States should take into account the guidance in Section A.3 when completing this table.

| How to complete the column "non-compliances" in table 2.4 | | | |
|---|--------|----------|---|
| Column "Detected controls performed" | during | official | Total number of non-compliances detected during the reporting year, in the five categories described for deliberate release into the environment of GMOs for the purpose of food and feed production. |

⁽¹⁸⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration (OJ L 106, 17.4.2001, p. 1).

| How to complete the column "non-compliances" in table 2.4 | | |
|--|--|--|
| Optional column "Total number of controlled operators" | Total number of operators for the five categories described for deliberate release into the environment of GMOs for the purpose of food and feed production, where the competent authorities performed official controls during the reporting year. | |
| Optional column "Number of controlled operators where non-compliances were detected" | Total number of operators for the five categories described for deliberate release into the environment of GMOs for the purpose of food and feed production, where the competent authorities performed official controls and detected non-compliances during the reporting year. | |

| How to complete the column "Actions/measures" in table 2.4 | | |
|--|--|--|
| Column "Administrative" | Total number of actions/measures initiated by the competent authorities during the reporting year, in the five categories described for deliberate release into the environment of GMOs for the purpose of food and feed production, to restore compliance with the rules in the areas referred to in Article 1(2)(b) of Regulation (EU) 2017/625. | |
| Column "Judicial" | Total number of actions/measures that were sent by the competent authority to the judicial authority, during the reporting year, for deliberate release into the environment of GMOs for the purpose of food and feed production, to restore compliance with the rules in the areas referred to in Article 1(2)(b) of Regulation (EU) 2017/625. | |

Section 3. Feed and feed safety at any stage of production, processing and distribution of feed and the use of feed, including rules aimed at ensuring fair practices in trade and protecting consumer health, interests and information

Section 3 of Part II is composed of:

- a text box numbered 3.1, for free text, for the overall conclusion on the level of compliance achieved;
- one table for the official controls, numbered 3.2;
- an optional text box numbered 3.3, for free text, for comments;
- a table for the non-compliances and actions/measures numbered 3.4, and
- an optional text box numbered 3.5, for free text, for comments.

The text box 3.1 should be completed following the guidance in Section A.1.

For table 3.2 on official controls, Member States should take into account the guidance in Section A.2.

| How to complete table 3.2 | | |
|--|--|--|
| Column "Number of establishments" | Total number of establishments, used for planning the official controls (most likely at the beginning of the year), for the different categories of establishments. | |
| Column "Number of official controls performed" | Total number of official controls carried out during the reporting year, in the different categories of establishments or in the different categories of horizontal rules. | |

The official controls performed on the different categories of establishments cover mainly feed hygiene requirements laid down in Regulation (EC) No 183/2005 of the European Parliament and of the Council (19) (e.g. registration/approval, structure, hygiene, maintenance, own-checks).

⁽¹⁹⁾ Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

For the establishments in the category of "Establishments approved in accordance with Article 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council", Member States can report official controls under the additional optional row "Primary producers approved according to Article 10 of Regulation (EC) No 183/2005", identified by a (*). This optional category includes on-farm mixers.

For the establishments in the category of "Establishments registered in accordance with Article 9 of Regulation (EC) No 183/2005, with the exclusion of primary production", Member States can report official controls under the additional optional row "Primary producers registered in accordance with Article 9 of Regulation (EC) No 183/2005 and complying with provisions in Annex I to that Regulation", identified by a (*).

The category "Operators (farmers) using feed" relates to farmers that keep production animals (animals that eventually will be destined for the food chain), that buy feed (all kinds) and then give that feed to their animals. Official controls on these operators focus on, for example, the feed used in the farms, the equipment used for distributing the feed and the storage of feed (taking into account Article 7 and Chapters I to IV of Annex IV to Regulation (EC) No 999/2001 (20) and Annex III of Regulation (EC) No 767/2009 (21) both of the European Parliament and of the Council).

The horizontal rule categories derive from specific Union provisions concerning official controls in this area of Article 1(2):

- Official controls on "Labelling of feed" covers requirements of Regulation (EC) No 767/2009 and points 8 and 9 of section "Production" in Annex II to Regulation (EC) No 183/2005 and of Regulation (EC) No 1831/2003 of the European Parliament and of the Council (²²). Controls on the ingredients of feed should also cover identification of any undeclared ingredients.
- Official controls on "Traceability of feed" covers requirements of Article 18 of Regulation (EC) No 178/2002 and, in particular, those of point 4 of section "Quality Control", point 5 of section "Dioxin Monitoring for Oils, Fats and Derived Products" and point 2(b) of section "Record-Keeping", all of Annex II to Regulation (EC) No 183/2005.
- Official controls on medicated feedingstuffs covers the requirements of Article 13 of Council Directive 90/167/EEC (²³) laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community.

A non-exhaustive indicative list of rules, meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(c) of Regulation (EU) 2017/625 is provided in Annex III.

The table 3.4 is divided in two main columns, one for "Non-compliances" and another for "Actions/measures". Member States should take into account the guidance in Section A.3 when completing this table.

| How to complete table 3.4 Non-compliances | | |
|---|---|--|
| Column "Detected during official controls performed" | Total number of non-compliances detected during the reporting year, for the different categories of establishments. | |
| Optional column "Total number of controlled establishments" | Total number of establishments for the different categories of establishments where the competent authorities have carried out official controls during the reporting year. | |

⁽²⁰⁾ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

⁽²¹⁾ Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1).

⁽²²⁾ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

⁽²³⁾ Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (OJ L 92, 7.4.1990, p. 42).

| How to complete table 3.4 Non-compliances | | |
|---|--|--|
| Optional Column "Number of controlled establishments where non-compliances were detected" | Total number of establishments for the different categories of establishments where the competent authorities have carried out official controls and detected non-compliances (related only to the establishment, either structural or operational) during the reporting year. | |
| Column "Number of non-compliances found" | Total number of non-compliances in the different categories of horizontal rules that the competent authorities detected while performing official controls during the reporting year. | |

The non-compliances in the horizontal rule categories derive from specific Union provisions concerning official controls in this area of Article 1(2). Product safety non-compliances relate to microbiological criteria applicable to feed (Chapter I, of Annex X to Commission Regulation (EU) No 142/2011 (24) for feed materials of animal origin and Regulation (EC) No 999/2001 for animal protein) and to the results of the analysis for the official control of feed carried out under the rules of Article 3 of Commission Regulation (EC) No 152/2009 (25), and Articles 4 and 5 of Commission Regulation (EU) No 619/2011 (26).

| How to complete the column "Actions/measures" in table 3.4 | | |
|--|--|--|
| Column "Administrative" | Total number of actions/measures initiated by the competent authorities during the reporting year, in the different categories of establishments and horizontal rules to restore compliance with the rules in the areas referred to in Article 1(2)(c) of Regulation (EU) 2017/625 | |
| Column "Judicial" | Total number of actions/measures that were sent by the competent authority to the judicial authority, during the reporting year, in the different categories of establishments and horizontal rules, to restore compliance with the rules in the areas referred to in Article 1(2)(c) of Regulation (EU) 2017/625. | |

For the establishments in the category of "Establishments approved in accordance with Article 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council", Member States can report non-compliances and actions/measures under the additional optional row "Primary producers approved according to Article 10 of Regulation (EC) No 183/2005", identified by a (*). This optional category includes on-farm mixers.

For the establishments in the category of "Establishments registered in accordance with Article 9 of Regulation (EC) No 183/2005, with the exclusion of primary production", Member States can report non-compliances and actions/measures under the additional optional row "Primary producers registered in accordance with Article 9 of Regulation (EC) No 183/2005 and complying with provisions in Annex I to that Regulation", identified by a (*).

Section 4. Animal health requirements

This is Section 4 of Part II and is composed of:

- a text box numbered 4.1, for free text, for the overall conclusion on the level of compliance achieved;
- a table for the official controls numbered 4.2;

⁽²⁴⁾ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

⁽²⁵⁾ Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

⁽²⁶⁾ Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired (OJ L 166, 25.6.2011, p. 9).

- an optional text box numbered 4.3, for free text, for comments;
- a table for the non-compliances and actions/measures numbered 4.4, and
- an optional text box numbered 4.5, for free text, for comments.

The text box 4.1 should be completed following the guidance in Section A.1.

In the area of Animal Health, namely in relation to identification and registration of certain animals, there are existing reporting requirements and defined models for the reports (27) (28). Those models have been integrated in one single table in this Section of the Annual Report, which covers more than reporting requirements for identification and registration of certain animals. Therefore, for table 4.2 on official controls, Member States should take into account the guidance in Section A.2.

| How to complete table 4.2 | | |
|---|--|--|
| Column "Number of holdings/establishments" | Total number of holdings for the two categories in the first two rows, at the beginning of the reporting year. Total number of establishments for the rest of the categories, used for planning the official controls (most likely at the beginning of the year). | |
| Column "Number of official controls performed" | Total number of official controls carried out during the reporting year, in the different categories of holdings/establishments. | |
| Column "Number of animals registered (at the beginning of the reporting period or other national reference date for animal statistics)" | Total number of animals registered for the categories related to identification and registration of bovine animals at the beginning of the reporting period or other national reference date for animal statistics. | |
| Column "Number of animals registered (at the beginning of the reporting period or other national reference date for animal statistics)" | Total number of animals registered for the categories related to identification and registration of ovine and caprine animals at the beginning of the reporting period or other national reference date for animal statistics. | |
| Column "Number of animals checked" | Total number of animals checked for the categories related to identification and registration of bovine, ovine and caprine animals, during the reporting year. | |

For the establishments in the categories of "Approved aquaculture establishments", "Semen collection centres", "Semen storage centres" and "Embryo collection/production teams", Member States can report official controls under the additional optional rows provided (related to animal species for which specific Union provisions exist), identified by a (*).

A non-exhaustive indicative list of rules, meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(d) of Regulation (EU) 2017/625 is provided in Annex IV.

The table for the non-compliances 4.4 is divided in two main columns, one for "Non-compliances" and another for "Actions/measures". Member States should take into account the guidance in Section A.3 when completing this table.

⁽²⁷⁾ Article 7 and Annex to Regulation (EC) No 1505/2006 implementing Council Regulation (EC) No 21/2004 as regards the minimum level of checks to be carried out in relation to the identification and registration of ovine and caprine animals (OJ L 280, 12.10.2006, p. 3).

⁽²⁸⁾ Article 5(1) and Annex I to Regulation (EC) No 1082/2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals (OJ L 156, 25.6.2003, p. 9).

Under the column "Non-compliances", Member States should complete the table as follows:

| How to complete the column "Non-compliances" in table 4.4 | | |
|---|---|--|
| Column "Number of holdings/ establishments with non- compliances" | Total number of holdings/establishments where non-compliances were detected during the reporting year, in the different categories. | |

For the establishments in the categories of "Approved aquaculture establishments", "Semen collection centres", "Semen storage centres" and "Embryo collection/production teams", Member States can report non-compliances under the additional optional rows provided (related to animal species for which specific Union provisions exist), identified by a (*).

Under the column "Actions/measures", Member States should take into account that the actions/measures taken are a consequence of the non-compliances detected (and not of suspicion or confirmation of disease, or cessation of activities).

| How to complete the column "Actions/measures" in table 4.4 | | |
|--|--|--|
| Column "Administrative" | Total number of actions/measures initiated by the competent authorities during the reporting year, in the different categories of establishments and horizontal rules to restore compliance with the rules in the areas referred to in Article 1(2)(d) of Regulation (EU) 2017/625 | |
| Column "Judicial" | Total number of actions/measures that were sent by the competent authority to the judicial authority, during the reporting year, to restore compliance with the rules in the areas referred to in Article 1(2)(d) of Regulation (EU) 2017/625. | |
| Column "Restriction of movements o | f individual animals": | |
| Column "Affected animals" | Total number of individual bovine animals that had their movements restricted, by the competent authorities, during the reporting year. | |
| Column "Affected holdings" | Total number of bovine holdings that were affected by movement restrictions of individual bovine animals imposed by the competent authorities, during the reporting year. | |
| Column "Restriction of movements o | f all animals": | |
| Column "Affected animals" | Total number of individual bovine animals that had their movements restricted because of an imposed restriction of movements of all animals in the holding, by the competent authorities, during the reporting year. | |
| Column "Affected holdings" | Total number of bovine holdings that were affected by movement restrictions of all bovine animals of the holding, imposed by the competent authorities, during the reporting year. | |
| Column "Destruction of animals": | | |
| Column "Affected animals" | Total number of individual bovine animals that were slaughtered or killed, by order of the competent authorities, during the reporting year. | |
| Column "Affected holdings" | Total number of bovine holdings that were affected by the slaughter or killing of bovine animals of the holding, by order of the competent authorities, during the reporting year. | |

For the establishments in the categories of "Approved aquaculture establishments", "Semen collection centres", "Semen storage centres" and "Embryo collection/production teams", Member States can report actions/measures under the additional optional rows provided (related to animal species for which specific Union provisions exist), identified by a (*).

Section 5. Prevention and minimisation of risks to human and animal health arising from animal by-products and derived products

Section 5 of Part II is composed of:

- a text box numbered 5.1, for free text, for the overall conclusion on the level of compliance achieved;
- one table for the official controls, numbered 5.2;
- an optional text box numbered 5.3, for free text, for comments;
- a table for the non-compliances and actions/measures numbered 5.4, and
- an optional text box numbered 5.5, for free text, for comments.

The text box 5.1 should be completed following the guidance in Section A.1.

For table 5.2 on official controls, Member States should take into account the guidance in Section A.2.

| How to complete table 5.2 | | |
|--|---|--|
| Column "Number of establishments/ plants" | Total number of establishments/plants, used for planning the official controls (most likely at the beginning of the year), for the different categories of establishments/plants. | |
| Column "Number of official controls performed" | Total number of official controls carried out during the reporting year, in the different categories of establishments/plants or in the different categories of horizontal rules. | |

The official controls performed on the different categories of establishments/plants cover mainly hygiene requirements laid down in Regulation (EC) No 1069/2009 of the European Parliament and of the Council (29) (e. g. registration/approval, structure, hygiene, maintenance, own-checks).

The official controls to be performed in accordance with the horizontal rule derive from specific Union provisions concerning official controls in this area of Article 1(2), namely labelling and traceability of animal by-products/derived products under Regulation (EC) 1069/2009.

For clarity purposes, in order to concentrate the reporting of official controls on animal by-products/derived products in one section, the following guidance should be followed:

- Official controls on animal by-products/derived products (such as identification and collection), when verified at operators that handle (but do not process or transport) animal by-products/derived products, should be reported under the "By horizontal rule" column in table 5.2. Consequently, non-compliances detected during these official controls should be reported under the "By horizontal rule" column in table 5.4.
- Official controls on animal by-products/derived products (such as transport, treatment, use and disposal), when verified at establishments or plants that process animal by-products/derived products, should be reported under the "By establishment/plant" column in table 5.2. Consequently, non-compliances detected during these official controls should be reported under the "By establishments/plants" column in table 5.4.

⁽²⁹⁾ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

A non-exhaustive indicative list of rules, meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(e) of Regulation (EU) 2017/625 is provided in Annex V.

The table for the non-compliances and actions/measures 5.4 is divided in two main columns, one for "Non-compliances" and another for "Actions/measures". Member States should take into account the guidance in Section A.3 when completing this table.

| How to complete table 5.4 Non-compliances | | |
|--|---|--|
| Column "Detected during official controls performed" | Total number of non-compliances detected during the reporting year, for the different categories of establishments/plants. | |
| Optional column "Total number of controlled establishments/plants" | Total number of establishments/plants for the different categories of establishments/plants where the competent authorities have carried out official controls during the reporting year. | |
| Optional column "Number of controlled establishments/plants where non-compliances were detected" | Total number of establishments/plants for the different categories of establishments/plants where the competent authorities have carried out official controls and detected non-compliances (related only to the establishment or plant, either structural or operational) during the reporting year. | |
| Column "Number of non-compliances found" | Total number of non-compliances in the different categories of horizontal rules that the competent authorities detected while performing official controls during the reporting year. | |

The non-compliances in the horizontal rule categories derive from specific Union provisions concerning official controls in this area of Article 1(2)(e). The non-compliances with the rules on safety of animal by-products/derived products relate to the results of official controls carried out under the rules of Chapter VII of Regulation (EU) No 142/2011.

For the category of "Product non-compliance", Member States can report non-compliances under the additional optional rows provided (related to the categories of animal by-products for which specific Union provisions exist), identified by a (*).

| How to complete the column "Actions/measures" in table 5.4 | |
|--|---|
| Column "Administrative" | Total number of actions/measures initiated by the competent authorities during the reporting year, in the different categories of establishments/plants and horizontal rules, to restore compliance with the rules in the areas referred to in Article 1(2)(e) of Regulation (EU) 2017/625. |
| Column "Judicial" | Total number of actions/measures that were sent by the competent authority to the judicial authority, during the reporting year, to restore compliance with the rules in the areas referred to in Article 1(2)(e) of Regulation (EU) 2017/625. |

For the category of "Product non-compliance", Member States can report actions/measures under the additional optional rows provided (related to the categories of animal by-products for which specific Union provisions exist), identified by a (*).

Section 6. Welfare requirements for animals

Section 6 of Part II is composed of:

- a text box numbered 6.1, for free text, for the overall conclusion on the level of compliance achieved;
- a table for the official controls, non-compliances and measures taken by the authorities on animal welfare on farms, numbered 6.2;
- a text box numbered 6.3, for free text, for the analysis and action plan for animal welfare on farms;
- a table for the official controls, non-compliances and measures taken by the authorities on animal welfare during transport, numbered 6.4;
- a text box numbered 6.5, for free text, for the analysis and action plan for animal welfare during transport;
- a text box numbered 6.6, for free text, for the animal welfare at the time of killing, and
- an optional text box numbered 6.7, for free text, for comments.

The text box 6.1 should be completed following the guidance in Section A.1.

In the area of animal welfare on farms, and in order to fulfil the obligations under Articles 6(2) of Council Directive 98/58/EC (30), 8(2) of Council Directive 1999/74/EC (31), 7(2) of Council Directive 2007/43/EC (32), 7(3) of Council Directive 2008/119/EC (33) and 8(3) of Council Directive 2008/120/EC (34), Member States should submit the information included in table 6.2. This table's purpose is to present the official controls performed, the types and number of non-compliances and measures taken by competent authorities, which are considered most useful for indicating the level of compliance with animal welfare rules on farms.

Official controls on chickens kept for meat production are included as a separate category in table 6.2 because Directive 2007/43/EC also requires annual reporting of controls on these animals.

| How to complete table 6.2 | |
|--|---|
| Column "Number of production sites" | Total number of production sites, used for planning the official controls (most likely at the beginning of the year), for the different categories of animals. |
| Column "Number of official controls performed" | Total number of official controls carried out during the reporting year, in the different categories of animals. |
| Column "Non-compliances": | |
| Optional column "Total number of controlled production sites*" | Total number of production sites for the different categories of animals where the competent authorities have carried out official controls during the reporting year. |
| Column "Number of controlled production sites where non-compliances were detected" | Total number of production sites for the different categories of animals where the competent authorities have carried out official controls and detected non-compliances during the reporting year. |

⁽³⁰⁾ Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (OJ L 221, 8.8.1998, p. 23).

⁽³¹⁾ Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens (OJ L 203, 3.8.1999, p. 53).

⁽³²⁾ Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production (OJ L 182, 12.7.2007, p. 19).

⁽³⁾ Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves (OJ L 10, 15.1.2009, p. 7).

⁽³⁴⁾ Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs (OJ L 47, 18.2.2009, p. 5).

| Column "Actions/measures": | |
|----------------------------|--|
| Column "Administrative" | Total number of actions/measures initiated by the competent authorities during the reporting year, in the different categories of animals to restore compliance with the rules in the areas referred to in Article 1(2)(f) of Regulation (EU) 2017/625 |
| Column "Judicial" | Total number of actions/measures that were sent by the competent authority to the judicial authority, during the reporting year, to restore compliance with the rules in the areas referred to in Article 1(2)(f) of Regulation (EU) 2017/625. |

In the row "Other (specify)" Member States should identify one or more of the species listed in the drop down menu which have not been specified in the previous rows. Any official controls of other species carried out to fulfil the objective specified in the MANCP should also be listed in the table, under this row.

Member States should use the data submitted in table 6.2 as part of the analysis of the most serious findings of non–compliance. These analyses should be the basis for a national action plan that addresses these findings to prevent or decrease their occurrence for the forthcoming years. In accordance with Articles 6(2) of Directive 98/58/EC, 8(2) of Directive 1999/74/EC, 7(2) of Directive 2007/43/EC, 7(3) of Directive 2008/119/EC and 8(3) of Directive 2008/120/EC, as amended respectively by Articles 151(2)(b), 152(1)(b), 156(2)(b), 157(2)(b) and 158(2)(b) of Regulation (EU) 2017/625, Member States should provide the analyses and the national action plans in text box 6.3.

In the area of animal welfare during transport, and in order to fulfil the obligations under Article 27(2) of Council Regulation (EC) No 1/2005 (35), Member States should submit the information included in table 6.4. This table's purpose is to present the official controls performed, the types and number of non-compliances and measures taken by competent authorities, which are considered most useful for indicating the level of compliance with animal welfare rules during transport. The scope of official controls on animal welfare during transport includes place of departure, during transport (including at control posts and exit points), place of destination and controls after the transport has been completed.

| How to complete table 6.4 | |
|--|--|
| Column "Number of official controls performed" | Total number of official controls on the protection of animals during transport, carried out during the reporting year, by animal species. |
| Column "Number and category of non-compliances": | |
| Column "1. Fitness of animals" | Total number of non-compliances detected by the competent authorities, by animal species, related to fitness of animals for transport (Article 3(b), Chapter I and paragraph 1.9 of Chapter VI of Annex I to Regulation (EC) No 1/2005). |
| Column "2. Transport practices, space allowance, height" | Total number of non-compliances detected by the competent authorities, by animal species, related to transport practices, space allowances and internal height (Article 3(d), (e) and (g), paragraph 1.2 of Chapter II and Chapters III and VII of Annex I to Regulation (EC) No 1/2005). |
| Column "3. Means of transport" | Total number of non-compliances detected by the competent authorities, by animal species, related to means of transport and additional provisions for livestock vessels or vessels transporting sea containers and for long journeys (Article 3(c) and (h), and Chapters II, IV and VI of Annex I to Regulation (EC) No 1/2005). |

⁽³⁵⁾ Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).

| Column "4. Water, feed, journey and resting times" | Total number of non-compliances detected by the competent authorities, by animal species, related to watering and feeding, journey times and resting periods (Articles 3(a), (f) and (h), and Chapter V of Annex I to Regulation (EC) No 1/2005). |
|--|---|
| Column "5. Documents" | Total number of non-compliances detected by the competent authorities, by animal species, related to transport documentation, transporters' authorisations, driver's certificates of competence and approval of means of transport and journey logs, other than non-compliances referred to under category 4 (Articles 4, 5(4), 6(1), (5) and (8), and 17(2), and Annex II to Regulation (EC) No 1/2005). |
| Column "6. Other" | Total number of non-compliances detected by the competent authorities, by animal species, not included in the previous categories. |
| Column "Actions/measures": | |
| Column "Administrative" | Total number of actions/measures initiated by the competent authorities during the reporting year, in the different categories of establishments and horizontal rules to restore compliance with the rules in the areas referred to in Article 1(2)(f) of Regulation (EU) 2017/625 |
| Column "Judicial" | Total number of actions/measures that were sent by the competent authority to the judicial authority, during the reporting year, to restore compliance with the rules in the areas referred to in Article 1(2)(f) of Regulation (EU) 2017/625. |

Member States should use the data submitted in table 6.4 to analyse the major deficiencies detected. Member States should provide in text box 6.5 the analysis and, where appropriate, an action plan, to address these deficiencies. The animal welfare controls and deficiencies reported in IMSOC should also be covered by the analysis and action plan submitted in text box 6.5. Member States can explain further the number of penalties imposed by competent authorities, by animal species, in accordance with rules laid down in national legislation pursuant to Article 25 of Regulation (EC) No 1/2005 and the number of emergency measures, infringements and notifications of infringements taken by the competent authorities, by animal species, in accordance with Articles 23 and 26 (until 14 December 2022) of Regulation (EC) No 1/2005.

In the area of animal welfare at the time of killing, Council Regulation (EC) No 1099/2009 (36) does not contain a specific requirement for reporting official controls of animal welfare at slaughter (i.e. killing animals for human consumption). However, if official controls to verify compliance with this regulation are made under the provisions of Member States' MANCPs, they should be reported here as required by Article 113(1)(b) of Regulation (EU) 2017/625.

Therefore, in the text box 6.6, Member States should provide an overview of the results of official controls carried out by the competent authorities and the type and number of cases of non-compliance detected during the reporting year.

A non-exhaustive indicative list of rules, meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(f) of Regulation (EU) 2017/625 is provided in Annex VI.

Section 7. Protective measures against pests of plants

Section 7 of Part II is composed of:

— a text box numbered 7.1, for free text, for the overall conclusion on the level of compliance achieved;

⁽³⁶⁾ Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).

- a table for the official controls numbered 7.2;
- an optional text box numbered 7.3, for free text, for comments;
- a table for the non-compliances and actions/measures numbered 7.4, and
- an optional text box numbered 7.5, for free text, for comments.

The text box 7.1 should be completed following the guidance in Section A.1.

For the table 7.2 on official controls, Member States should take into account the guidance in Section A.2.

| How to complete table 7.2 | |
|--|---|
| Column "Number of operators" | Total number of operators, used for planning the official controls (most likely at the beginning of the year), for the different categories of operators. |
| Column "Number of official controls performed" | Total number of official controls carried out during the reporting year, in the different categories of operators. |

The category "Operators authorised to issue plant passports" includes professional operators that have implemented a pest risk management plan approved in accordance with Article 91 of Regulation (EU) 2016/2031 of the European Parliament and of the Council (37) and professional operators with premises located in a demarcated area established in accordance with Article 18(1) of Regulation (EU) 2016/2031.

A non-exhaustive indicative list of rules, meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(g) of Regulation (EU) 2017/625 is provided in Annex VII.

The table 7.4 is divided in two main columns, one for "Non-compliances" and another for "Actions/measures". Member States should take into account the guidance in Section A.3 when completing this table.

| How to complete the column "Non-compliances" in table 7.4 | |
|--|---|
| Column "Detected during official controls performed" | Total number of non-compliances detected during the reporting year, in the different categories of operators. |
| Optional column "Total number of controlled operators" | Total number of operators for the different categories of operators where the competent authorities have carried out official controls, during the reporting year. |
| Optional column "Number of controlled operators where non-compliances were detected" | Total number of operators for the different categories of operators where the competent authorities have carried out official controls, and detected non-compliances during the reporting year. |

Non-compliances, in this section, are any deviation from the phytosanitary requirements of Regulation (EU) 2016/2031, namely the ones in Articles 90 and 98.

| How to complete the column "Actions/measures" in table 7.4 | |
|--|---|
| Column "Administrative" | Total number of actions/measures initiated by the competent authorities during the reporting year, in the different categories of operators to restore compliance with the rules in the areas referred to in Article 1(2)(g) of Regulation (EU) 2017/625. |

⁽³⁷⁾ Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

Section 8. Requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides, with the exception of pesticides application equipment

Section 8 of Part II is composed of:

- a text box numbered 8.1, for free text, for the overall conclusion on the level of compliance achieved;
- a table for the official controls numbered 8.2;
- an optional text box numbered 8.3, for free text, for comments;
- a table for the non-compliances and actions/measures numbered 8.4, and
- an optional text box numbered 8.5, for free text, for comments.

The text box 8.1 should be completed following the guidance in Section A.1.

For the table 8.2 on official controls, Member States should take into account the guidance in Section A.2.

| How to complete table 8.2 | |
|--|--|
| Column "Number of operators" | Total number of operators (an estimation in case no national obligation to register operators exist), used for planning the official controls (most likely at the beginning of the year), for the different categories of operators marketing and using plant protection products. |
| Column "Number of official controls performed" | Total number of official controls carried out during the reporting year, in the different categories of operators marketing and using plant protection products. |

The category "Entry points" means the points of entry into the Union, under Article 44(3)(a) of Regulation (EU) 2017/625, which have access to the appropriate control facilities for different types of products/goods. The official controls performed in these points of entry that should be reported are the ones provided for in Article 44(1) of Regulation (EU) 2017/625.

For the category of "On use of PPPs and sustainable use of pesticides", Member States can report the number of operators and the number of official controls performed under the additional optional rows provided (related to the categories of "Agricultural users" or "Other professional users"), identified by a (*).

A non-exhaustive indicative list of rules, meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(h) of Regulation (EU) 2017/625 is provided in Annex VIII.

The table 8.4 is divided in two main columns, one for "Non-compliances" and another for "Actions/measures". Member States should take into account the guidance in Section A.3 when completing this table.

| How to complete the column "Non-compliances" in table 8.4 | |
|--|--|
| Column "Detected during official controls performed" | Total number of non-compliances detected during the reporting year, in the different categories of operators marketing and using plant protection products. |
| Optional column "Total number of controlled operators" | Total number of operators for the different categories of operators marketing and using plant protection products where the competent authorities have carried out official controls, during the reporting year. |
| Optional column "Number of controlled operators where non-compliances were detected" | Total number of operators for the different categories of operators marketing and using plant protection products where the competent authorities have carried out official controls and detected non-compliances during the reporting year. |

| How to complete the column "Actions/measures" in table 8.4 | |
|--|---|
| Column "Administrative" | Total number of actions/measures initiated by the competent authorities during the reporting year, in the different categories of operators marketing and using plant protection products to restore compliance with the rules in the areas referred to in Article 1(2)(h) of Regulation (EU) 2017/625. |
| Column "Judicial" | Total number of actions/measures that were sent by the competent authority to the judicial authority, during the reporting year, in the different categories of operators marketing and using plant protection products to restore compliance with the rules in the areas referred to in Article 1(2)(h) of Regulation (EU) 2017/625. |

For the category of "On use of PPPs and sustainable use of pesticides", Member States can report the non-compliances and actions/measures initiated under the additional optional rows provided (related to the categories of "Agricultural users" or "Other professional users"), identified by a (*).

Section 9. Organic production and labelling of organic products

Section 9 of Part II is composed of:

- a text box numbered 9.1, for free text, for the overall conclusion on the level of compliance achieved;
- templates provided for in Annexes XIIIb and XIIIc to Regulation (EC) No 889/2008 (38), and
- an optional text box numbered 9.3, for free text, for comments.

The text box 9.1 should be completed following the guidance in Section A.1.

A non-exhaustive indicative list of rules, meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(i) of Regulation (EU) 2017/625 is provided in Annex IX.

Section 10. Use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed

Section 10 of Part II is composed of:

- a text box numbered 10.1, for free text, for the overall conclusion on the level of compliance achieved;
- a table for the official controls numbered 10.2;

⁽³⁸⁾ Commission Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1).

- an optional text box numbered 10.3, for free text, for comments;
- a table for the non-compliances and actions/measures numbered 10.4, and
- an optional text box numbered 10.5, for free text, for comments.

The text box 10.1 should be completed following the guidance in Section A.1.

For the table 10.2 on official controls, Member States should take into account the guidance in Section A.2.

| How to complete table 10.2 | | |
|--|---|--|
| Column "Number of official controls performed" | Total number of official controls carried out during the reporting year, in the categories "Pre-market", "Conventional market" and "Electronic commerce". | |

A non-exhaustive indicative list of rules, meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(j) of Regulation (EU) 2017/625 is provided in Annex X.

The table 10.4 is divided in two main columns, one for "Non-compliances" and another for "Actions/measures". Member States should take into account the guidance in Section A.3 when completing this table.

| How to complete the column "Non-compliances" in table 10.4 | | |
|---|--|--|
| Column "Detected during official controls performed" | Total number of non-compliances detected during the reporting year, in the categories "Pre-market", "Conventional market" and "Electronic commerce". | |
| Column "Total number of controlled operators" | Total number of operators in the categories "Pre-market", "Conventional market" and "Electronic commerce" where the competent authorities have carried out official controls during the reporting year. | |
| Column "Number of controlled operators where non-compliances were detected" | Total number of operators in the categories "Pre-market", "Conventional market" and "Electronic commerce" where the competent authorities have carried out official controls and detected non-compliances during the reporting year. | |

| How to complete the column "Actions/measures" in table 10.4 | | |
|---|---|--|
| Column "Administrative" | Total number of actions/measures initiated by the competent authorities during the reporting year, in the categories "Pre-market", "Conventional market" and "Electronic commerce", to restore compliance with the rules in the areas referred to in Article 1(2)(j) of Regulation (EU) 2017/625. | |
| Column "Judicial" | Total number of actions/measures that were sent by the competent authority to the judicial authority, during the reporting year, to restore compliance with the rules in the areas referred to in Article $1(2)(j)$ of Regulation (EU) $2017/625$. | |

ANNEX I

Non-exhaustive indicative list of rules meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(a) of Regulation (EU) 2017/625

| Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food | Tables 1.4 and 1.6 |
|--|------------------------------|
| Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists | Tables 1.4 and 1.6 |
| Directive $96/23/EC$ on measures to monitor certain substances and residues thereof in live animals and animal products – provisions which remain applicable in accordance with the transitional provision in Article 150 of Regulation (EU) $2017/625$ | Tables 1.4 and 1.6 |
| Decision 97/747/EC fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products | Tables 1.4 and 1.6 |
| Directive 98/83/EC on the quality of water intended for human consumption (relevant rules for water put into bottles or containers) | Tables 1.4 and 1.6 |
| Directive 1999/2/EC on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation | Tables 1.4 and 1.6 |
| Directive 1999/3/EC on the establishment of a Community list of foods and food ingredients treated with ionising radiation | Tables 1.4 and 1.6 |
| Regulation (EC) No $1760/2000$ establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products (Title II) | Tables 1.4 and 1.6 |
| Directive 2001/110/EC relating to honey | Tables 1.4 and 1.6 |
| Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety | Tables 1.2 and 1.6 |
| Directive 2002/4/EC on the registration of establishments keeping laying hens, covered by Council Directive 1999/74/EC | Tables 1.4 and 1.6 |
| Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements | Tables 1.4 and 1.6 |
| Directive 2002/99/EC laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption | Tables 1.3, 1.4 and 1.6 |
| Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters | Tables 1.4 and 1.6 |
| Regulation (EC) No 1829/2003 on genetically modified food and feed | Tables 1.4 and 1.6 |
| Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms | Tables 1.4 and 1.6 |
| Regulation (EC) No 852/2004 on the hygiene of foodstuffs | Tables 1.2, 1.3, 1.4 and 1.6 |

| | , |
|--|------------------------------|
| Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin | Tables 1.2, 1.3, 1.4 and 1.6 |
| Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation | Tables 1.4 and 1.6 |
| Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food | Tables 1.2, 1.4 and 1.6 |
| Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant or animal origin | Tables 1.4 and 1.6 |
| Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs | Tables 1.4 and 1.6 |
| Regulation (EC) No 2074/2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 and for the organisation of official controls under Regulation (EC) No 854/2004 | Tables 1.4 and 1.6 |
| Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs | Tables 1.4 and 1.6 |
| Regulation (EC) No 1924/2006 on nutrition and health claims made on foods | Tables 1.4 and 1.6 |
| Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods | Tables 1.4 and 1.6 |
| Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food | Tables 1.2, 1.4 and 1.6 |
| Regulation (EC) No 543/2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultry meat | Tables 1.4 and 1.6 |
| Regulation (EC) No 361/2008 amending Regulation (EC) No 1234/2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products | Tables 1.4 and 1.6 |
| Regulation (EC) No 617/2008 laying down detailed rules for implementing Regulation (EC) No 1234/2007 as regards marketing standards for eggs for hatching and farmyard poultry chicks | Tables 1.2., 1.4 and 1.6 |
| Regulation (EC) No 1332/2008 on food enzymes | Tables 1.4 and 1.6 |
| Regulation (EC) No 1333/2008 on food additives | Tables 1.4 and 1.6 |
| Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on food | Tables 1.4 and 1.6 |
| Directive 2009/32/EC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients | Tables 1.4 and 1.6 |
| Directive 2009/39/EC on foodstuffs intended for particular nutritional uses | Tables 1.4 and 1.6 |
| Directive 2009/54/EC on the exploitation and marketing of natural mineral waters | Tables 1.4 and 1.6 |

| Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin | Tables 1.4 and 1.6 |
|---|--------------------|
| Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters | Tables 1.4 and 1.6 |
| Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food | Tables 1.4 and 1.6 |
| Regulation (EU) No $931/2011$ on the traceability requirements set by Regulation (EC) No $178/2002$ for food of animal origin | Tables 1.4 and 1.6 |
| Regulation (EU) No 1169/2011 on the provision of food information to consumers | Tables 1.4 and 1.6 |
| Regulation (EU) No 29/2012 on marketing standards for olive oil | Tables 1.4 and 1.6 |
| Regulation (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs (Title IV: optional quality terms) | Tables 1.4 and 1.6 |
| Regulation (EU) No 228/2013 laying down specific measures for agriculture in the outermost regions of the Union | Tables 1.4 and 1.6 |
| Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control | Tables 1.4 and 1.6 |
| Regulation (EU) No 1306/2013 on the financing, management and monitoring of the common agricultural policy | Table 1.6 |
| Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products (articles 74 to 91) | Table 1.6 |
| Regulation (EU) No 1337/2013 laying down rules for the application of Regulation (EU) No 1169/2011 as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry | Tables 1.4 and 1.6 |
| Regulation (EU) No $1379/2013$ on the common organisation of the markets in fishery and aquaculture products (Chapter IV) | Tables 1.4 and 1.6 |
| Regulation (EU) No 179/2014 supplementing Regulation (EU) No 228/2013 with regard to the register of operators, the amount of aid for the marketing of products outside the region, the logo, the exemption from import duties for certain bovine animals and the financing of certain measures relating to specific measures for agriculture in the outermost regions of the Union | Tables 1.4 and 1.6 |
| Regulation (EU) No 665/2014 supplementing Regulation (EU) No 1151/2012 of the European Parliament and of the Council with regard to conditions of use of the optional quality term "mountain product" | Tables 1.4 and 1.6 |
| Regulation (EU) 2015/1375 laying down specific rules on official controls for Trichinella in meat | Tables 1.4 and 1.6 |
| Regulation (EU) 2015/2283 on novel foods | Tables 1.4 and 1.6 |
| Regulation (EU) $2019/624$ concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) $2017/625$ | Tables 1.4 and 1.6 |
| Regulation (EU) 2019/627 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 and amending Regulation (EC) No 2074/2005 as regards official controls | Tables 1.4 and 1.6 |

| Regulation (EU) 2019/1139 amending Regulation (EC) No 2074/2005 as regards official controls on food of animal origin in relation to requirements concerning food chain information and fishery products and to the reference to recognised testing methods for marine biotoxins and to testing methods for raw milk and heat-treated cow's milk | Tables 1.4 and 1.6 |
|--|--------------------|
| Regulation (EU) 2019/2090 supplementing Regulation (EU) 2017/625 regarding cases of suspected or established non-compliance with Union rules applicable to the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or with Union rules applicable to the use or residues of prohibited or unauthorised pharmacologically active substances | Tables 1.4 and 1.6 |

ANNEX II

Non-exhaustive indicative list of rules meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(b) of Regulation (EU) 2017/625

| Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms | Tables 2.2 and 2.4 |
|--|--------------------|
| Regulation (EC) 1829/2003 on genetically modified food and feed | Tables 2.2 and 2.4 |
| Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms | Tables 2.2 and 2.4 |
| Regulation (EC) 1946/2003 on transboundary movements of genetically modified organisms | Tables 2.2 and 2.4 |
| Recommendation 2004/787/EC on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003 | Tables 2.2 and 2.4 |
| Regulation (EC) No $65/2004$ establishing a system for the development and assignment of unique identifiers for genetically modified organisms | Tables 2.2 and 2.4 |
| Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation | Tables 2.2 and 2.4 |
| Regulation (EU) $619/2011$ laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired | Tables 2.2 and 2.4 |
| Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory | Tables 2.2 and 2.4 |
| All legal acts on authorisation for individual products, as can be found in the EU GMO Register: Genetically Modified Organisms - European Commission (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm) | Tables 2.2 and 2.4 |

ANNEX III

Non-exhaustive indicative list of rules meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(c) of Regulation (EU) 2017/625

| Directive $90/167/EEC$ laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (until 27 January 2022) | Tables 3.2 and 3.4 |
|--|--------------------|
| Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety | Table 3.2 |
| Directive 2002/32/EC on undesirable substances in animal feed | Tables 3.2 and 3.4 |
| Regulation (EC) 1829/2003 on genetically modified food and feed | Tables 3.2 and 3.4 |
| Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms | Tables 3.2 and 3.4 |
| Regulation (EC) No 1831/2003 on additives for use in animal nutrition | Tables 3.2 and 3.4 |
| Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation | Tables 3.2 and 3.4 |
| Regulation (EC) No 183/2005 laying down requirements for feed hygiene | Tables 3.2 and 3.4 |
| Regulation (EC) No $396/2005$ on maximum residue levels of pesticides in or on food and feed of plant or animal origin | Tables 3.2 and 3.4 |
| Directive 2008/38/EC establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes | Tables 3.2 and 3.4 |
| Regulation (EC) No $152/2009$ laying down the methods of sampling and analysis for the official control of feed | Tables 3.2 and 3.4 |
| Regulation (EC) No 767/2009 on the placing on the market and use of feed | Tables 3.2 and 3.4 |
| Regulation (EU) No 619/2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired | Tables 3.2 and 3.4 |
| Regulation (EU) No 68/2013 on the Catalogue of feed materials | Tables 3.2 and 3.4 |
| Regulation (EU) 2019/4 on the manufacture, placing on the market and use of medicated feed (from 28 January 2022) | Tables 3.2 and 3.4 |
| Regulation (EU) 2019/2090 supplementing Regulation (EU) 2017/625 regarding cases of suspected or established non-compliance with Union rules applicable to the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or with Union rules applicable to the use or residues of prohibited or unauthorised pharmacologically active substances | Tables 3.2 and 3.4 |

ANNEX IV

Non-exhaustive indicative list of rules meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(d) of Regulation (EU) 2017/625

| List of acts in Article 270(2) of Regulation (EU) 2016/429 (until 20 April 2021), in particular: Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species Directive 89/556/EEC on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species Directive 90/429/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species Directive 92/65/EEC laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC Regulation (EC) No 21/2004 establishing a system for the identification and registration of ovine and caprine animals Directive 2006/88/EC on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals | Tables 4.2 and 4.4 |
|--|--------------------|
| Regulation (EC) No $1255/97$ concerning Community criteria for control posts and amending the route plan referred to in the Annex to Directive $91/628/\text{EEC}$ | Tables 4.2 and 4.4 |
| Regulation (EC) No $494/98$ laying down detailed rules for the implementation of Regulation (EC) No $820/97$ as regards the application of minimum administrative sanctions in the framework of the system for the identification and registration of bovine animals | Tables 4.2 and 4.4 |
| Regulation (EC) No $1760/2000$ establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products | Tables 4.2 and 4.4 |
| Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies | Tables 4.2 and 4.4 |
| Regulation (EC) No $1082/2003$ laying down detailed rules for the implementation of Regulation (EC) No $1760/2000$ as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals | Tables 4.2 and 4.4 |
| Regulation (EC) No 1505/2006 implementing Regulation (EC) No 21/2004 as regards the minimum level of checks to be carried out in relation to the identification and registration of ovine and caprine animals | Tables 4.2 and 4.4 |
| Regulation (EU) 2016/429 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ("Animal Health Law") (from 21 April 2021) | Tables 4.2 and 4.4 |

ANNEX V

Non-exhaustive indicative list of rules meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(e) of Regulation (EU) 2017/625

| Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption | Tables 5.2 and 5.4 |
|---|--------------------|
| Regulation (EU) No $142/2011$ implementing Regulation (EC) No $1069/2009$ and implementing Directive $97/78/EC$ as regards certain samples and items exempt from veterinary checks at the border under that Directive | Tables 5.2 and 5.4 |

ANNEX VI Non-exhaustive indicative list of rules meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(f) of Regulation (EU) 2017/625

| Regulation (EC) No 1255/97 concerning Community criteria for control posts and amending the route plan referred to in the Annex to Directive 91/628/EEC (namely Articles 6(1) and 6b) | Table 6.4 and text box 6.7 |
|---|----------------------------|
| Directive 98/58/EC concerning the protection of animals kept for farming purposes | Table 6.2 and text box 6.3 |
| Directive 1999/74/EC laying down minimum standards for the protection of laying hens | Table 6.2 and text box 6.3 |
| Regulation (EC) No 1/2005 on the protection of animals during transport and related operations | Table 6.4 and text box 6.5 |
| Directive 2007/43/EC laying down minimum rules for the protection of chickens kept for meat production | Table 6.2 and text box 6.3 |
| Directive 2008/119/EC laying down minimum standards for the protection of calves | Table 6.2 and text box 6.3 |
| Directive 2008/120/EC laying down minimum standards for the protection of pigs | Table 6.2 and text box 6.3 |
| Regulation (EC) No 1099/2009 on the protection of animals at the time of killing | Text box 6.6 |
| | |

ANNEX VII

Non-exhaustive indicative list of rules meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(g) of Regulation (EU) 2017/625

| Regulation (EU) 2016/2031 on protective measures against pests of plants | Tables 7.2 and 7.4 |
|---|--------------------|
| Regulation (EU) 2019/66 on rules on uniform practical arrangements for the performance of official controls on plants, plant products and other objects in order to verify compliance with Union rules on protective measures against pests of plants applicable to those goods | |

ANNEX VIII

Non-exhaustive indicative list of rules meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(h) of Regulation (EU) 2017/625

| Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market | Tables 8.2 and 8.4 |
|--|--------------------|
| Directive 2009/128/EC establishing a framework for Community action to achieve a sustainable use of pesticides | Tables 8.2 and 8.4 |

ANNEX IX

Non-exhaustive indicative list of rules meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(i) of Regulation (EU) 2017/625

| Regulation (EC) No $834/2007$ on organic production and labelling of organic products (until 31 December 2020) | Annex XIIIc of Regulation (EC) No 889/2008 |
|---|--|
| Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control | Annex XIIIc of Regulation (EC) No 889/2008 |
| Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries | Annex XIIIc of Regulation (EC) No 889/2008 |
| Regulation (EU) No $392/2013$ amending Regulation (EC) No $889/2008$ as regards the control system for organic production | Annex XIIIc of Regulation (EC) No 889/2008 |
| Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products | |
| Regulation (EU) 2018/848 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (from 1 January 2021) | |

ANNEX X Non-exhaustive indicative list of rules meant as a guidance with regard to the information on official controls to be reported for the area referred to in Article 1(2)(j) of Regulation (EU) 2017/625

| Regulation (EC) No 178/2002 (Article 53) | Tables 10.2 and 10.4 |
|--|-------------------------|
| Regulation (EC) No $110/2008$ on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks | Tables 10.2 and 10.4 |
| Regulation (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs | Tables 10.2 and 10.4 |
| Regulation (EU) No $251/2014$ on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products | Tables 10.2 and 10.4 |
| Regulation (EU) No 664/2014 supplementing Regulation (EU) No 1151/2012 with regard to the establishment of the Union symbols for protected designations of origin, protected geographical indications and traditional specialities guaranteed and with regard to certain rules on sourcing, certain procedural rules and certain additional transitional rules | Tables 10.2 and 10.4 |
| Regulation (EU) No 668/2014 laying down rules for the application of Regulation (EU) No 1151/2012 | Tables 10.2 and 10.4 |