
Changes to legislation: There are currently no known outstanding effects for the Commission Decision of 24 July 2008 on guidelines to assist Member States in preparing the annual report on the single integrated multiannual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council (notified under document number C(2008) 3756) (Text with EEA relevance) (2008/654/EC), ANNEX. (See end of Document for details)

ANNEX

Guidelines for annual reports on the implementation of Member States national control plans

1. PURPOSE OF THE GUIDELINES

The purpose of these guidelines is to promote and assist the consistent presentation by the Member States of their annual reports on the implementation of their national control plans and in particular the results of their official controls.

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 44(1) of Regulation (EC) No 882/2004;
- (b) outline progress on the implementation of the national control plan and make an assessment of the effectiveness of the control arrangements and the control systems based on the results and outcomes of official controls in the Member State.

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

The information provided in the annual reports should also be utilised by the Commission in:

- (a) developing its annual control programmes (desk analysis, audits, inspections); and
- (b) the preparation of the Commission's report to the European Parliament and the Council in accordance with Article 44(4) and (6) of Regulation (EC) No 882/2004.

3. LEGAL BASIS

Article 44 of Regulation (EC) No 882/2004 provides:

1. One year after starting the implementation of multiannual national control plans, and subsequently every year, Member States shall submit to the Commission a report indicating:
 - a any amendments made to the multiannual national control plans to take account of the factors referred to in Article 42(3);
 - b the results of official controls and audits conducted in the previous year under the provisions of the multiannual control plan;
 - c the type and number of cases of non-compliance identified;
 - d actions to ensure the effective operation of multiannual national control plans, including enforcement action and its results.

2 In order to promote the consistent presentation of this report and in particular the results of official controls, the information referred to in paragraph 1 shall take account of guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 62(2).

3 Member States shall finalise their reports and transmit them to the Commission, within six months of the end of the year to which the reports relate.

4. DEFINITIONS

For the purpose of these guidelines the definitions laid down in the relevant Community legislation and, in particular, the definitions in Article 2 of Regulation (EC) No 882/2004,

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Articles 2 and 3 of Regulation (EC) No 178/2002, Article 2 of Directive 2000/29/EC, Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules⁽¹⁾, and Commission Decision 2007/363/EC of 21 May 2007 on guidelines to assist Member States in preparing the single integrated multiannual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and the Council⁽²⁾ shall apply.

In addition the following definitions apply for the purposes of these guidelines:

- (a) 'annual control programme' means the annual programme for Community controls referred to in Article 45(4) of Regulation (EC) No 882/2004;
- (b) 'control strategy' means the approach taken to determine the nature, frequency, time, point/stage of the production chain, method and techniques of official controls (refer to Section 3.7.2 of the Annex to Decision 2007/363/EC);
- (c) 'national control plan' means the single integrated multiannual national control plan provided for in Article 41 of Regulation (EC) No 882/2004.

5. SCOPE OF THE ANNUAL REPORT

The annual report should cover the scope of the national control plan, including plant health, in so far as Article 27a of Directive 2000/29/EC provides for plant health matters to be included in that plan.

6. REPORTING PERIOD AND SUBMISSION OF ANNUAL REPORTS

Pursuant to Article 42(1)(a) of Regulation (EC) No 882/2004 the latest date for implementing the national control plan for the first time is 1 January 2007. Pursuant to Article 44(3) of that Regulation Member States are to finalise their reports and transmit them to the Commission, within six month of the end of the year to which the reports relate. Therefore the first annual reports are to be transmitted to the Commission by 30 June 2008, at the latest, and for subsequent years those reports are to be submitted by 30 June at the latest.

7. RELATIONSHIP TO OTHER SPECIFIC REPORTS

Regulation (EC) No 882/2004 is without prejudice to specific Community provisions concerning official controls. Therefore, the annual reports do not replace the annual or other reports on specific control plans or other official controls provided for under other Community legislation. However, as the performance of the official controls under those specific control plans form an essential part of the overall implementation of the national control plans, the results of those official controls are relevant for the purposes of the annual reports.

When reporting on official controls relating to those specific control plans in the annual reports, it is not necessary to repeat the information contained in the specific reports thereon; a cross reference to the most recent specific report submitted is sufficient. However, the outcome of the official controls carried out in implementation of those specific control plans should be integrated into the analysis of results in general terms, in the context of reviewing the overall outcome of official controls in the relevant sector.

The dates specified for submission of such specific reports in the relevant Community legislation are not amended by either Article 44 of Regulation (EC) No 882/2004 or by these guidelines.

8. GENERAL GUIDANCE

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Regulations (EC) No 178/2002 and (EC) No 882/2004 provide for a systems-based approach to 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 national control plans where necessary. The annual report should therefore be a synthesis of that activity and also take account of the conclusions of the audits carried out in accordance with Article 4(6) of Regulation (EC) No 882/2004.

A simple statistical account of the number of official controls and audits will not satisfy that requirement. For the purpose of 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, presented on the basis of sectors and stages in the production chain. The choice of sectors and production stages to be reported on is a matter for the individual Member State to decide. The scope of each sector and production stage should be clearly defined and be consistent with the structure of the description of the control systems in the national control plan. In order to place the results and analysis in context, the relevant official control (including sampling) strategies, audit programmes and performance indicators, set out in the national control plan should be referred to by means of cross-references, and where such information is not included in the national control plan, a brief description of those strategies should be provided in the annual report.

The issues to be covered in the overview and analysis of the results of official controls are outlined in Section 9 of these guidelines. The analysis of those results should identify trends and comment on their significance and possible future consequences for official controls. The identification of trends may require the review of data on results of official controls covering a number of years and for the purpose of such analysis reference should be made to data relating to previous official controls where appropriate. Taking account of Article 43(1)(e) of Regulation (EC) No 882/2004 these guidelines provide some guidance as to how that analysis may be carried out.

For the purposes of compilation of the raw control data, where Community legislation prescribes the data to be collected for the purpose of specific reports, in relation to feed or food law, animal health, animal welfare or plant health, these data should form the basis of the analysis of the results of official controls for the sector in question. Where there are no such provisions Member States are free to decide the appropriate means of data collection and compilation appropriate to their national systems and may decide to continue with earlier arrangements for the compilation of data on official controls in relation to those activities.

For the purposes of classifying non-compliances, where Community 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 are free to decide a classification system appropriate to their requirements and should briefly describe the system used in their annual reports.

Member States who wish to develop their systems for classifying and recording control data may take into account the ongoing work in Eurostat on 'food safety statistics' and in particular, the 'control and monitoring activities' database⁽³⁾. In order to ensure coherence and avoid duplication of work, Member States are encouraged to closely cooperate with Eurostat in the development of those classification schemes. The results of such cooperation may be reflected in future amendments of these guidelines, as appropriate.

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 Community controls provided for in Article 45 of Regulation (EC) No 882/2004 and should therefore be retained and provided to the Commission on request.

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9. GUIDANCE ON CONTENT AND FORMAT OF THE ANNUAL REPORT

The annual report should cover the following areas:

- (a) *official controls* performed by the Member State as provided for in Article 3 of Regulation (EC) No 882/2004 and national control plans — Section 9.1;
- (b) *overall compliance* with feed and food law, animal health and animal welfare rules — Section 9.2;
- (c) *audits* carried out as provided for in Article 4(6) of Regulation (EC) No 882/2004 including, where appropriate, the results of audits or inspections of control bodies as provided for in Article 5(3) of that Regulation — Section 9.3;
- (d) *actions to ensure effectiveness* in operating the national control plans — Section 9.4;
- (e) *statement on the overall performance* of the control system in operating the national control plans — Section 9.5;
- (f) *amendments* to the national control plans — Section 9.6.

The annual report should contain the overall results of the performance of official controls in the relevant areas, analysis of those results and conclusions at national level, which may be presented on the basis of sectors and production stages, and/or on the basis of the structure established in the national control plan of the Member State, as appropriate. A summary of the data supporting that analysis and those conclusions may be given as a separate Annex, if necessary, and the level of detail of such data is left to the Member State to decide bearing in mind that the background data should be retained as indicated in the seventh paragraph of Section 8. The corrective actions or amendments to the national control plan arising from those conclusions should be included as appropriate.

9.1. Official controls

The annual report should indicate the extent to which annual operational targets (where Member States have established such operational targets), and strategic objectives set out in the national control plan were achieved. A brief description of relevant performance indicators and/or operational targets applied should be included here, unless provided in the national control plan, in which case they should be referred to by means of cross-references. This should be presented on a sectoral basis in line with the national control plan.

The annual report should include both planned or ongoing official controls and, where applicable, specific control activities focused on a particular issue. For planned official controls the extent to which the frequency or intensity and nature of official controls set out in the national control plan were achieved should be addressed. In the event that operational targets for planned official controls are not achieved, an analysis of relevant mitigating and/or contributing factors should be provided. Unplanned official controls⁽⁴⁾ should also be reported — particularly when they have diverted resources from planned official controls — and a brief explanation of the reason for the unplanned official controls should be provided.

With regard to official controls relating to animal health and plant health, this section of the annual report should include the results of official controls carried out for the purpose of disease monitoring, surveillance, eradication or control, including official controls to verify or determine health status with regard to a particular disease.

9.2. Overall compliance by operators and products

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The annual report should provide a description on how the overall compliance with food and feed law, animal health and animal welfare rules and plant health law (by the food and feed business operators and other relevant producers and business operators or of products) was measured during the reporting period as well as an overview of the results. A statement or conclusion on the overall level of compliance should provide an overview of results on the basis of sectors, production stages and competent authorities. That statement or conclusion should be based on and supported by the information provided in Sections 9.2.1-9.2.2.

9.2.1. Frequency and type of non-compliance

The annual report should describe the non-compliances observed. The annual report should, where appropriate:

- (a) describe or define the classification used;
- (b) classify the non-compliances detected by type;
- (c) describe the type and number of non-compliances identified.

The annual report should compile the non-compliances identified nationally on a sectoral basis and these compiled data should feed into the analysis outlined in Section 9.2.2.

9.2.2. Analysis of non-compliance

Analysis of non-compliance is an integral part of determining the appropriate corrective measures to be taken to ensure effective operation of control systems. This section includes examples of factors which may be taken into account in the performance of such an analysis and which may contribute to determining the subsequent actions to be taken to ensure the effectiveness of the national control plans (refer to Section 9.4).

That analysis of non-compliance, in line with best practice, may for each sector consider the occurrence, the risk arising and where relevant the root causes of non-compliance. Conclusions may be provided on the basis of the following analyses, and may assess the potential significant consequences of the non-compliances in terms of risks to humans, animals or plants, and where relevant the root causes of these non-compliances. In order to carry out such analysis it may be necessary to consider data collected over a period of years, and if appropriate, reference may be made to previous official controls.

9.2.2.1. Occurrence of non-compliance

The purpose of this section is to provide some guidance as to how an analysis of the frequency and type of non-compliances may be performed. The analysis may be broken down by sectors and/or competent authorities, as appropriate. The analysis may, where appropriate, provide answers to questions such as:

- (a) what was the frequency of non-compliances in various sectors? This is particularly relevant in cases where significant deviations from the overall compliance are evident in some sectors or in official controls carried out by certain competent authorities;
- (b) were the non-compliances randomly distributed in time and space or was there some clustering at particular points or production stages and were there indications of emerging trends?
- (c) the type of non-compliances, that is whether they were related to structural, operational or end-product related requirements? Other types may include non-compliances related to self-controls, administrative aspects or documentation (for

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example traceability). Non-compliances may also be categorised as major/minor, systematic/sporadic etc.;

- (d) were the non-compliances scattered all along the feed and food chain or concentrated at primary production or further down the chain?
- (e) were there possibly multiple clusters of non-compliances along certain chains?
- (f) does the pattern of non-compliances indicate that there are critical control stages along the production chain(s)?
- (g) are there any patterns indicating that different (types) of food and feed business operators and other relevant producers and business operators or production chains were more compliant than others?

9.2.2.2. Nature of the risk arising from non-compliance

The purpose of this section is to provide some guidance on the analysis required to provide information on the potential consequences of non-compliances. The analysis may include the following:

- (a) the identification of non-compliances that have a potentially significant impact on humans, animals or plants;
- (b) the description of the potential serious consequences or 'risk' of those non-compliances;
- (c) the description as to whether the risk is related to a specific hazard only or a general increase in risk arising from the incidence of multiple hazards or hazard-groups.

9.2.2.3. Root cause(s) of non-compliance

Where relevant, and in particular, where patterns of significant non-compliances or repeated offences are detected, an analysis of possible underlying causes may be carried out. Such analysis may contribute towards development and continual improvement of control systems in the Member State. While carrying out that analysis, consideration may be given to the following factors:

- (a) the lack of awareness by the food and feed business operators and other relevant producers and business operators and reasons therefor;
- (b) the lack of competence by the food and feed business operators and other relevant producers and business operators and reasons therefor;
- (c) the cost of compliance;
- (d) the insufficient tools and/or resources to enforce requirements;
- (e) the lack of effective and/or proportionate and/or dissuasive sanctions.

9.3. Audits

9.3.1. Audits carried out as provided for in Article 4(6) of Regulation (EC) No 882/2004

This guidance refers exclusively to the audits provided for in Article 4(6) of Regulation (EC) No 882/2004. The results of such audits should be presented on a national basis, by sector if appropriate, in accordance with the arrangements for such audits in the national control plan.

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Taking account of the provisions of Decision 2006/677/EC the annual report should summarise the following:

- (a) the extent to which the audit programme, developed by the competent authority, for the reporting period was achieved;
- (b) the extent to which overall compliance with planned arrangements for official controls by the competent authorities was achieved;
- (c) the conclusions as to the overall effectiveness of the official controls applied by the competent authorities;
- (d) the conclusions as to the overall suitability of the official control systems operated by the competent authorities to achieve the objectives.

If the description of the audit arrangements set out in the national control plan, does not indicate the methods or performance indicators used for measuring compliance, effectiveness and suitability of the official controls a brief description should be included in the annual report.

9.3.2. Audits and inspections of control bodies — Article 5(3) of Regulation (EC) No 882/2004

Describe to what extent the programme for audits or inspections of control bodies, was achieved, and summarise the conclusions of these audits or inspections.

9.4. Actions to ensure effectiveness

This should be an account of the actions taken to ensure effective operation of the national control plan. The annual report should address actions taken in the following areas. This information may be presented on the basis of sectors or production stages.

- (a) Actions taken to ensure compliance by food and feed business operators and other relevant producers and business operators as provided for in Article 31(2)(e), Article 54(2) and Article 55 of Regulation (EC) No 882/2004.
- (b) Actions taken to ensure the effective operation of official control services as provided for in Article 4(2) and Article 8(3) of Regulation (EC) No 882/2004, including actions taken in response to audits carried out in accordance with Article 4(6) of Regulation (EC) No 882/2004, and audits or inspections carried out in accordance with Article 5(3) of that Regulation, 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 best practice.

9.4.1. Actions to ensure compliance by food and feed business operators and other relevant producers and business operators

The annual report should include an overview of actions taken. These may include:

- (a) restrictions or prohibitions on the placing on the market, import, export or use of feed, food or animals;
- (b) withdrawal or suspension of approval or registration to operate a feed or food business;
- (c) administrative fines and other administrative sanctions;
- (d) prosecution of food and feed business operators and other relevant producers and business operators for non-compliance (criminal sanctions).

9.4.2. Actions taken to ensure the effective operation of official control services

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Substantial actions taken to ensure effective operation of official control services may require amendment of the national control plan and should in such case be included in Section 9.6. However, some significant actions might not require an amendment of the national control plan and should in such cases be included in this point in the annual report, in order to indicate positive actions taken by the Member State. This information may be presented on the basis of sectors or production stages and should cover actions not included as amendments to the national control plan, such as:

- (a) new, updated or revised control procedures;
- (b) training initiatives;
- (c) provision of additional resources;
- (d) reallocation of existing resources following review of priorities;
- (e) special control initiatives;
- (f) changes to the organisation or management of competent authorities;
- (g) provision of guidance or information to feed and food business operators;
- (h) new legislation;
- (i) suspension or withdrawal of delegation in the case of control bodies.

9.5. Statement on the overall performance

Assess the overall:

- (a) progress towards achievement of the strategic objectives as described in the national control plan;
- (b) effectiveness of the official controls carried out under the national control plan and their suitability to achieve the objectives of Article 17(2) of Regulation (EC) No 178/2002, Regulation (EC) No 882/2004, animal health, animal welfare and, as applicable, plant health rules.

That self-assessment should also address issues like overall effectiveness, coordination between and within competent authorities, delivery of a farm-to-fork approach and overall risk-based targeting of official controls. The statement on the overall performance should be based on an analysis and synthesis of results of the previous sections and provide descriptions of:

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

9.6. Amendments to the national control plan

The annual report should outline amendments made to the national control plan during the year to which that report relates. Particular attention should be paid to the need to ensure that amendments made in response to the factors referred to in Article 42(3), Article 44(5) and Article 45(5)(a) of Regulation (EC) No 882/2004 are addressed and explained. In particular relevant changes to the official control systems as described in the national control plan and relevant changes to the risk categorisation of activities (refer to Section 3.4 of the Annex to Decision 2007/363/EC) should be described.

The annual report should describe the nature and reasons for such amendments. For example, and where applicable:

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- (a) new legislation;
- (b) the emergence of new diseases or other health risks;
- (c) significant changes to the structure, management or operation of the competent authorities;
- (d) significant changes to the agri-food production sector;
- (e) the results of Member States' official controls;
- (f) any amendment of the guidelines referred to in Article 43 of Regulation (EC) No 882/2004;
- (g) scientific findings;
- (h) the outcome of audits carried out in accordance with Article 4(6) of Regulation (EC) No 882/2004;
- (i) the outcome of Community controls carried out in accordance with Article 45 of Regulation (EC) No 882/2004⁽⁵⁾;
- (j) the outcome of audits performed by a third country in a Member State;
- (k) outcome of root-cause analysis.

The amendments should be consistent with the analysis and conclusions provided for in Sections 9.3-9.5 of these guidelines and include cross-references to the relevant section(s), as appropriate.

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- (1) OJ L 278, 10.10.2006, p. 15.
- (2) OJ L 138, 30.5.2007, p. 24.
- (3) This work, carried on within the context of the Community Statistical Programme and its annual work programmes, comprises various classification schemes like the classification of control and monitoring activities, the data dictionaries of products and activities of the establishments, a common glossary, the definition of sampling strategies and indicators of control and monitoring activities.
- (4) Official controls that involve a significant temporary departure from the national control plan due to unforeseen circumstances.
- (5) Community controls in Member States may identify issues for which the corrective or preventative actions taken in response to the Commission recommendations require amendment to the national control plan. Such amendments should be included in the annual report, notwithstanding that they may also be covered by a Member State's response to the recommendations.

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