

To: Interested parties

26 April, 2007

Reference: OCR 0037

Dear Sir/Madam

EU REGULATION 882/2004 ON OFFICIAL CONTROLS - DRAFT EUROPEAN COMMISSION GUIDELINES ON ANNUAL REPORTS ON IMPLEMENTATION OF NATIONAL CONTROL PLANS (NCPs)

1. Following the recent consultation that we completed on the above Commission Guidelines, I am writing to update you on the on-going EU level discussions. I am also seeking any further comments that you may have on the latest version of the Commission's draft, a copy of which is enclosed at Appendix 1.

2. The final draft of the Guidelines is expected to be presented for an opinion to the Standing Committee on the Food Chain and Animal Health (SCoFCAH) in mid-May (with adoption in June) so I shall be grateful to receive any responses **by 11 May 2007**. My contact details are given below.

EU discussions and latest version of the draft Guidelines

3. Since the consultation was launched in early November last year, there have been two Commission Working Group meetings to consider the Guidelines. The majority of Member States (including the UK) believed that they should provide for a flexible approach that takes account of the diversity of national control systems and with the emphasis on providing an assessment of compliance with the national control plan rather than raw statistical returns.

4. The outcome of the discussions is reflected in the latest version of the draft Guidelines. This is enclosed at Appendix 1 and any further views you may have are welcome. As before, please note that the draft may not necessarily represent the views of the Commission and the document that is presented for formal adoption may differ. As you will see, the text has not changed significantly but the drafting does provide more flexibility.

Further information

5. We will keep you informed of developments but, in the meantime, please contact me or Catriona Stewart on 020 7276 8498 (email: catriona.stewart@foodstandards.gsi.gov.uk) if you wish to discuss any issues related to the Guidelines.

Yours faithfully,

Rufina Acheampong
Official Control Regulation Implementation Team

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COMMISSION OF THE EUROPEAN COMMUNITIES

Grange 11.04.2007
F6(2006)D 660099 Rev 4

Draft

COMMISSION DECISION

of [...]

on guidelines to assist Member States in preparing the annual report on the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council

**WORKING DOCUMENT FOR DISCUSSION PURPOSES ONLY
SUBJECT TO AMENDMENT**

**DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION
SERVICES**

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Draft

COMMISSION DECISION

of [...]

on guidelines to assist Member States in preparing the annual report on the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,
Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules¹, and in particular Article 41 and Article 44 thereof,
Whereas:

- (1) Regulation (EC) No 882/2004 lays down general rules for the performance of official controls by the Community or the competent authority of the Member States to verify compliance with rules concerning feed and food law, animal health and animal welfare rules.
- (2) Article 1(3) of that Regulation (EC) No 882/2004 provides that the said Regulation (EC) No 882/2004 shall be without prejudice to specific Community provisions concerning official controls.
- (3) Article 41 of that Regulation (EC) No 882/2004 provides that each Member State is to prepare a single integrated multi-annual national control plan to ensure the effective implementation of Article 17(2) of Regulation (EC) No 178/2002², of animal health and animal welfare rules and of Article 45 of Regulation (EC) No 882/2002 ('the national control plan').
- (4) The purpose of the single integrated multi-annual national control plans is also to establish a solid basis for Commission inspection services to carry out controls in the Member States.
- (5) Article 27a of Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community³ provides that Articles 41 to

¹ OJ L 165, 30.4.2004, p. 1; corrected version OJ L 191, 28.5.2004, p. 1.

² OJ L 31, 1.2.2002, p.1. Regulation as last amended by Commission regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p 3.)

³ OJ L 169, 10.7.2000, p. 1. Directive as last amended by Commission Directive 2006/35/EC (OJ L 88, 25.3.2006, p. 9).

46 of Regulation (EC) No 882/2004 concerning national control plans, annual reports, and Community controls in Member States and third countries are to apply, as appropriate, in order to ensure the effective implementation of Directive 2002/29/EC.

- (6) Article 43(1)(e) of Regulation (EC) No 882/2004 provides that the Commission is to draw up guidelines encouraging the adoption of best practices at all levels of the control systems.
- (7) Article 43(1)(j) of Regulation (EC) No 882/2004 provides that the Commission is to draw up guidelines laying down the structure and information to be included in the annual reports referred to in Article 44 of that regulation
- (8) Article 44(1) of Regulation (EC) No 882/2004 provides that Member States shall submit to Commission an annual report on the implementation of the multi-annual national control plan; this report shall be submitted annually commencing one year after starting implementation of the national control plan. In addition, Article 44(1) also sets out the contents of the annual reports.
- (9) Article 44(2) of Regulation (EC) No 882/2004 provides that the information to be provided in the annual reports is to take account of the guidelines, drawn up by the Commission in order to promote a consistent presentation of this report. The guidelines are not binding but serve to provide useful guidance to the Member States in the implementation of that Regulation.
- (10) Article 45 of Regulation (EC) No 882/2004 provides that Community audits are to be carried out in the Member States on a regular basis mainly in order to verify that official controls are carried out in accordance with the national control plans and in compliance with Community law
- (11) The Commission is to keep the guidelines set out in this Decision under review and update them, as necessary, following the receipt and examination of the Member States annual reports, in line with conclusions and recommendations contained in the Commission annual report and in the light of the experience of the Member States in implementing Regulation (EC) No 882/2004.
- (12) Having taken account of the ongoing work of Eurostat in the context of the Community Statistical programme in developing a "Control and Monitoring Activities" database which comprises various classification schemes for food safety statistics
- ~~(12)~~(13) The measures set out in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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HAS ADOPTED THIS DECISION

1. The guidelines provided for in Article 44(2) of Regulation (EC) No 882/2004 to be taken into account in the annual reports provided for in Article 44(1) of that Regulation (“the annual report”) are set out in the Annex to this Decision

2. This Decision is addressed to the Member States.

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission

ANNEX

Guidance on legal requirements for Annual Reports on Member States Multi-Annual 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 report on the annual implementation of their single integrated multi-annual 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 multi-annual 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 reports will 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 as required by Article 44 (4 & 6).

3 Legal basis

Article 44 of Regulation (EC) No 882/2004

“1. One year after starting the implementation of multi-annual national control plans, and subsequently every year, Member States shall submit to the Commission a report indicating:

(a) any amendments made to the multi-annual 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 multi-annual control plan;

(c) the type and number of cases of non-compliance identified;

(d) actions to ensure the effective operation of multi-annual national control plans, including enforcement action and its results.

2. In order to promote the consistent presentation of this report and in particular the result 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) of Regulation (EC) No 882/2004.

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, Articles 2 and 3 of Regulation (EC) No 178/2002, Article 2 of Council Directive 2000/29/EC, Commission Decision 2006/677/EC⁴, and Commission Decision XXX of XXX on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation(EC) N0 882/2004 of the European Parliament and the Council⁵ shall apply

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

(a) “annual control programme” means the annual programme for Commission controls referred to in Article 45(4) of Regulation (EC) No 882/2004;

⁴ OJ L 278, 10.10.2006, p. 15

⁵ OJ L.[insert after publication]

- (b) “control strategy” means the approach taken to determine the nature, frequency, time, point/stage of production chain, method and techniques of the official controls (refer to section 3.7.2 of the Annex to Commission Decision XXX of XXX on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation(EC) No 882/2004 of the European Parliament and the Council;
- (c) “national control plan” means the single integrated multi annual national control plan provided for by Article 41 of Regulation (EC) No 882/2004.

5 Scope of the Annual Report

The report should cover the scope of the multi-annual national control plan including plant health insofar 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 reports

The latest date for implementing the single integrated multi-annual national control plan is 1 January, 2007; therefore the first annual reports should be transmitted to the Commission by 30 June 2008 at the latest. For subsequent years reports shall be due by 30 June at the latest.

7 Relationship to other specific reports

As Regulation (EC) No 882/2004 is without prejudice to specific Community provisions concerning official controls, this Annual Report does not replace the annual or other reports on specific control plans or other [eontrolsofficial controls](#) provided for under other Community legislation. However as execution of the [eontrolsofficial controls](#) under these specific plans form an essential part of the overall implementation of the national control plan, the results of these [eontrolsofficial controls](#) are relevant for the purposes of the annual report.

When reporting on ~~controls~~official controls relating to these specific control plans in the Annual Report, it is not necessary to repeat the information contained in the specific reports thereon; a cross reference to the most recent report submitted is sufficient. However the outcome of the official controls carried out in implementation of these 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 legislation are not amended by either Article 44 of Regulation (EC) No 882/2004 or by these guidelines.

8 General Guidance

Regulations (EC) 178/2002 and 882/2004 provide for a systems-based approach to official ~~controls~~controls. An essential part of such an approach is the compilation and analysis of the results of ~~controls~~official controls and drawing conclusions thereon, with a view to the determination of appropriate system-based corrective actions and adjustment or amendment of control plans where necessary. The annual report should therefore be a synthesis of this activity and also take account of the conclusions of the audits carried out under the provisions of Article 4(6) of Regulation (EC) No 882/2004.

A simple statistical account of the number of official controls and audits will not satisfy this requirement. For the purpose of compiling the report Member States should provide an overview of the overall or aggregate national results on which this analysis 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 ~~but~~ ~~the~~ 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 control (including sampling) strategies, audit programmes and performance indicators, set out in the national control plan should be cross-referenced, and where such information is not included in the national control plan, a brief description of these strategies should be provided in the annual report.

The issues to be covered in the overview and analysis are outlined in section 9 of this guideline. The analysis of the 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 covering a number of years and for the purpose of such analysis reference should be made to data relating to previous ~~controls~~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 this 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 for the sector in question. ~~For example in relation to plant health Member States should compile the data in accordance with the requirements of Council Directive 2000/29/EC.~~ 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. ~~For the purposes of the annual report Member States may with regard to official controls on feed and food law and animal nutrition and may~~ decide to continue with earlier arrangements for the compilation of data on official controls in relation to these activities. ~~Where applicable existing arrangements for recording data regarding official controls relating to animal health, animal welfare and plant health legislation may also be continued.~~

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 report. 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 the report.

Member States who wish to develop their systems for classifying and recording control data ~~should may~~ take into account the ongoing work in EUROSTAT on “Food Safety statistics” and in particular, the “Control and Monitoring Activities” database⁶. ~~This work, carried on within the context of the Community Statistical Programme and its annual work programmes, comprises various classification schemes e.g. classification of control activities, indicators of control and monitoring activities, common glossary, definition of sampling strategies and~~

⁶ ~~This work, carried on within the context of the Community Statistical Programme and its annual work programmes, comprises various classification schemes for example classification of control activities, indicators~~

~~classification of products and establishments.~~ In order to ensure coherence and avoid duplication of work, Member States are encouraged to closely cooperate with EUROSTAT in the development of these classification schemes. The results of this cooperation may be reflected in future amendments of this Guideline, as appropriate.

The background data supporting the results and analysis supplied in the report may be required by the Commission for the purposes of Community controls provided for by Article 45 of Regulation (EC) No 882/2004 and should therefore be retained and provided to the Commission on request.

9 Guidance on content and format

The 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 plan - 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 Regulation (EC) No 882/2004 – Section 9.3;
- (d) **Actions to ensure effectiveness** in operating the national control plan – Section 9.4;
- (e) **Statement on the overall performance** of the control system in operating the national control plan – Section 9.5; and
- (f) **Amendments** to the multi-annual national control plan – Section 9.6.

The report should contain overall results of the relevant areas, analysis of those results and conclusions at national level, which may be presented on a sectoral basis, as appropriate. The data supporting this analysis and 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. The corrective

~~of control and monitoring activities, common glossary, definition of sampling strategies and classification of products and establishments.~~

actions or amendments to the national control plan arising from these conclusions should be included as appropriate.

9.1 Official controls

The report should indicate the extent to which annual operational targets, ~~and strategic objectives and strategies~~ foreseen 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 cross-referenced. This should be presented on a sectoral basis in line with the national control plan.

The report should include both planned or ongoing official controls and 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 foreseen in the multi-annual national control plan were achieved should be addressed. In the event that targets for planned official controls are not achieved, an analysis of relevant mitigating and/or contributing factors should be provided. Unplanned official controls⁷ should also be reported – particularly when they have diverted resources from planned official controls – and a brief explanation of the reason for the unplanned ~~control~~official controls should be provided.

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

9.2 Overall compliance by operators and products

The report should provide a description on how the overall compliance (by the operators) was measured during the reporting period as well as an overview of the results. A statement on the overall level of compliance should provide an overview of results covering all sectors, production stages and competent authorities. This statement/conclusion should be based on and supported by the information provided in sections 9.2.1-9.2.3 below.

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9.2.1 Frequency and type of non-compliance

The report should describe the non-compliances observed. The 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 report should compile the non-compliances identified nationally on a sectoral basis and these compiled data should feed into the analysis outlined below.

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 should contribute to determining the subsequent actions to be taken to ensure effectiveness, (refer to section 9.4).

This analysis, in line with best practice, should for each sector consider the occurrence, the risk arising and where relevant the root-causes of non-compliance. Conclusions should be provided on the basis of the following analyses, and should 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

⁷ Official controls that involve a significant temporary departure from the national control plan due to unforeseen circumstances.

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 stages and were there indications of emerging trends?
- c) The type of non-compliances i.e. 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 (e.g. 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 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 the non-compliances. The analysis may include the following:

- a) Identification of non-compliances that have a potentially significant impact on humans, animals, or plants;
- b) Description of the potential serious consequences or 'risk' of these non-compliances;
- c) 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 repeat offences are detected an assessment of possible underlying causes may be carried out. Such an assessment may contribute towards development and continual improvement of control systems in the Member State. While carrying out this analysis, consideration may be given to the following factors:

- a) Lack of awareness by the operators and reasons therefore;
- b) Lack of competence by the operators and reasons therefore;
- c) The cost of compliance;
- d) Insufficient tools and/or resources to enforce requirements;
- e) Lack of effective and/or proportionate and/or dissuasive sanctions.

~~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 controls.~~

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 by Article 4(6) of Regulation (EC) No 882/2004. The results of the audits should be presented on a national ~~sectoral~~ basis, by sector if appropriate, in accordance with the arrangements for such audits in the national control plan. ~~For each sector~~The report should summarise the:

- (a) extent to which the audit programme, developed by the competent authority taking account of the provisions of Commission Decision 2006/677/EC⁸, for the reporting period was achieved;
- (b) extent to which overall compliance with planned arrangements for official controls was achieved;
- (c) Conclusions as to the overall effectiveness of the ~~controls~~official controls applied;
- (d) Conclusions as to the overall suitability of the official control systems to achieve objectives.

⁸ Commission decision of 29 September 2006 setting out guidelines laying down the criteria for the conduct of audits under regulation (EC) No 882/2004 of the European Parliament and the Council on official controls to verify compliance with feed and food law, animal health and welfare rules. (OJ L278, 10.10.2006, p.15)

If the description of the audit arrangements provided 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 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 a consolidated account of the actions taken to ensure effective operation of the single integrated multi-annual national control plan. The report should address actions taken in the following areas.

(a) Actions taken to ensure compliance by feed and food business operators and other relevant producers and business operators as provided for by 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 by Article 4(2) and Article 8(3) of Regulation (EC) No 882/2004, including actions taken in response to audits carried out as provided for Article 4(6) Regulation (EC) No 882/2004, and audits or inspections carried out as provided for by Article 5(3) of Regulation (EC) No 882/2004, where appropriate. In the case of actions taken in response to audit conclusions this may include corrective and preventive action, or improvement action based on the identification of best practice.

~~(c) Community controls in Member States may also identify issues relating to the effective operation of national control plans, therefore actions taken in response to Commission recommendations as provided for by Article 45(5)(a) of Regulation (EC) No 882/2004 may be relevant in this regard. Where such measures require amendment to the national control plan~~

~~they should be addressed in the context of amendments to the plan for which guidance is set out at section 9.6 of these guidelines.~~

9.4.1 Actions to ensure compliance by operators and producers:

The 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 operators for non-compliance (criminal sanctions).

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

Substantial actions taken to ensure effective operation of official control services may require amendment of the national control plan and in such case should be included in section 9.6. However some significant actions might not require an amendment of the national control plan and in such cases should be included at this point in the report, in order to indicate positive actions taken by the Member State. This should be an overview of actions not included as amendments to the national 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.

This 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. This statement should be based on an analysis and synthesis of results of the previous sections and provide descriptions of:

- a) The performance indicators applied to these objectives, where appropriate and
- b) Results for each objective, where appropriate.

9.6 Amendments to the national control plan

The report should outline amendments made to the single integrated national control plan during the year to which the report relates. Particular attention should be paid to the need to ensure that amendments made in response to the factors mentioned 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 Commission Decision XXX of XXX on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation(EC) No 882/2004 of the European Parliament and the Council) should be described.

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

- (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) amendment to the guidelines referred to in Article 43 of Regulation (EC) No 882/2004
- (g) scientific findings
- (h) the outcome of audits 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 882/2004⁹
- (j) the outcome of audits performed by a third country in a Member State
- (k) outcome of root-cause assessment.

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

⁹ 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 States response to the recommendations.