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## ANNEX

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

### 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<sup>(1)</sup> 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.

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## 9.2. Overall compliance by operators and products

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-

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compliances related to self-controls, administrative aspects or documentation (for 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<sup>(2)</sup>;
- (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) Official controls that involve a significant temporary departure from the national control plan due to unforeseen circumstances.
- (2) 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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