APPENDIX 1

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COMMISSION OF THE EUROPEAN COMMUNITIES

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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

WORKING DOCUMENT FOR DISCUSSION PURPOSES ONLY
SUBJECT TO AMENDMENT

DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

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 rules[1], 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 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 178/2002[2], of animal health and animal welfare rules and of Article 45 of Regulation (EC) No 882/2002 ('the national control plan').

(3) The purpose of the national control plans is also to establish a solid basis for Commission inspection services to carry out controls in the Member States.

(4) 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 Community[3] provides that Articles 41 to 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.

[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).

(5) 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.

(6) 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.

(7) 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.

(8) 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

(9) 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 annual reports and in the light of the experience of the Member States in implementing Regulation (EC) No 882/2004.

(10) The measures set out in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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

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 result 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) furnish evidence of the implementation of the multi-annual national control programme by providing information 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 be utilised by the Commission in:

(a) developing its annual control programmes (desk analysis, audits, inspections), and
(b) 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, Commission Decision 2006/677/EC[4], and Commission Decision (insert reference *MANCP guidelines*) shall apply.
In addition the following definitions apply for the purposes of these guidelines:

[4] OJ L 278, 10.10.2006, p. 15

(a) “annual control programme” means the annual programme for Commission controls referred to in Article 45(4);

(b) “control strategy” means the approach taken to determine the nature, frequency, time, point, method and techniques of the official controls (refer to section 3.7.2 of the Annex to Commission Decision *MANCP guidelines*);

(c) “national control plan” means the single integrated multi annual national control plan provided for by Article 41 of Regulation (EC) No 882/2004.

(d) “sampling strategy” means the approach taken to determine:

a. the nature, frequency, time and point or location for obtaining samples, and
b. the particular test to be performed, where appropriate.

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.

In the event of a Member State commencing to implement their plan before 1 January, 2007, the annual report is due within 6 months of the end of the year to which the report relates, however, as the Commission has to report annually on the implementation of the plans it is suggested that all reports should be based on the previous calendar year and be submitted by 30 June of the following year.

7 Relationship to other specific reports

This Annual Report does not replace the annual or other reports on specific control plans or activities provided for under other Community legislation. However as execution of these specific controls form an essential part of the overall national control plan, the results of these controls are relevant for the purposes of the annual report.

In relation to these control activities it is not necessary to repeat the information contained in the specific reports; a cross reference to the most recent report submitted is sufficient. However the outcome of these official controls 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

The report should be in the form of a synthesis and analysis of the results of the official controls and summary 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 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 stages to be reported on is a matter for the individual Member State to decide but the scope of each sector and stage should be clearly defined and be consistent with the structure of the description of the control systems in the national control plan.

The issues to be covered in such a synthesis 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.

In order to place the results and analysis in context the relevant control and sampling strategies in the national control plan should be cross-referenced, and where such information is not included in the plan, a brief description should be provided.

The detailed information supporting the results and analysis supplied in the report should be available to the Commission on request. In this regard Member States may decide to continue with earlier arrangements for the compilation of data on official controls in relation to feed and food hygiene, and where applicable of animal health, animal welfare and plant health.

Member States who wish to develop their systems for classifying and recording control data should take into account the ongoing work in Eurostat on the “Food Safety Database” and in particular, the “Control and Monitoring Activities” module of that database. This work comprises various classification schemes e.g. classification of control activities, indicators of control and monitoring activities, common glossary, definition of sampling strategies and 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.

9 Guidance on content and format

The report should include the following sections:

(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.*

Sections 9.1 – 9.3 should contain overall results of the relevant subject headings, analysis of those results and conclusions at national level, which may be subdivided to sectoral level, 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 actions or amendments to the national control plan arising from these conclusions should be included in sections 9.4 and 9.6, as appropriate.

9.1 Official controls

The report should indicate the extent to which annual operational targets foreseen in the national control plan were achieved. A 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 or audit 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 controls[5] should also be reported – particularly when they have diverted resources

[5] Controls that involve a significant temporary departure from the national control plan due to unforeseen circumstances.

from planned official controls – and an explanation as to why they were carried out should be provided.

9.2 Overall compliance by operators

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 a synthesis of results across sectors 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.

9.2.1 Frequency and type of non-compliance

The purpose of this section is to describe the non-compliances observed. The report should where appropriate:

(a) describe the type and number of non-compliances identified,

(b) classify the non-compliances detected by type,

(c) describe or define the classification used.

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

9.2.2 Analysis of non-compliance

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

9.2.2.1 Occurrence of non-compliance

The purpose of this section is to provide an analysis of the frequency and type of non-compliances broken down by sectors and/or competent authorities, as appropriate. The analysis may 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 kind of clustering?
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 information on the potential consequences of the non-compliances. The analysis may include the following:

a) Identify non-compliances that have a potentially significant impact on humans, animals, or plants;
b) Describe the potential consequences or ‘risk’ of these non-compliances;

c) describe whether the risk is related to a specific hazard only or a general increase in risk (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 should be carried out. This 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.

9.3 Audits

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

This section deals exclusively with 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, in accordance with the national control plan. For each sector summarise the:

(a) extent to which the audit programme as outlined in the national control plan was achieved;
(b) extent to which overall compliance with planned arrangements was achieved;
(c) Conclusions as to the overall effectiveness of the controls applied;
(d) Conclusions as to the overall suitability of the official control systems to achieve objectives.

If not included in the national control plan, the methods for measuring compliance, effectiveness and suitability should be described 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 audits or inspections of control bodies, as provided for in the national control plan were 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 the report should also include actions taken in response to Commission recommendations as provided for by Article 45(5)(a) of Regulation (EC) No 882/2004.

9.4.1 Actions to ensure compliance by operators and producers:

The report should include an overview of:

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 to operate a feed or food business,
c) administrative fines and other administrative sanctions,
d) prosecutions 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

9.4.3 Actions taken in response to recommendations arising from Commission controls

The report should include an overview of:

a) all Commission recommendations made during the reporting period,
b) all outstanding recommendations from previous reporting periods,

c) the proposed response of the competent authority to the recommendation,
d) the progress to date in implementing the recommendation and any alterations to deadlines given in the original response.

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 Regulation (EC) No 882/2004.

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, as appropriate, broad descriptions of:

a) The performance indicators applied to these objectives; and
b) Results for each objective.

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 *MANCP guidelines*) 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 882/2004
(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 in sections 9.3-9.5 of this guideline and include cross-references to the relevant section(s), as appropriate.

LIST OF INTERESTED PARTIES

Heads of Service, all UK local authorities
Agricultural Industries Confederation
AIC Scottish Council
Association of British Abattoir Operators
Association of Independent Meat Suppliers
Association of Meat Inspectors
Association of Port Health Authorities
Association of Public Analysts
Association of Public Analysts Scotland
Association of Veterinary Surgeons Practising in NI
Assured British Meat
Bee Farmers Association
British Association of Feed Supplement & Additives Manufacturers Ltd.
British Beekeepers Association
British Egg Industry Council
British Goat Society
British Hospitality Association
British Meat Processors Association
British Ports Association
British Poultry Council
British Retail Consortium
British Trout Association
British Veterinary Association
Business Gateway
Carp Society
Central Science Laboratory
Chartered Institute of Environmental Health
Chilled Food Association
CIEH Northern Ireland
CIEH Wales
Convention of Scottish Local Authorities
Corporation of London
COSLA
Country Land & Business Association
Crop Protection Association
Dairy Hygiene Inspectorate
Dairy Industry Federation
Dairy UK, Northern Ireland
Dairy UK, Scotland
Farm Animal Welfare Council
Farmers Union of Wales
Federation of Agricultural Co-operatives
Food and Agriculture Group for Wales
Food and Drink Federation
Food Commission
Food Industry Forum
Foodaware
Freight Transport Association Ltd
GAFTA
General Consumer Council
General Consumer Council for Northern Ireland

Halal Food Authority
Humane Slaughter Association & Council of Justice to Animals
Institute of Auctioneers and Appraisers Scotland
International Meat Trade Association
Laboratory of the Government Chemist
LACORS
LACORS (Welsh Officer)
Livestock & Meat Commission, Northern Ireland
Livestock Auctioneers Association
Livestock Auctioneers Association, Northern Ireland
Local Government Association
Meat and Livestock Commission
Meat Hygiene Service (Scottish Office)
National Association of Catering Butchers
National Beef Association
National Beef Association, Scottish Council
National Consumer Council
National Consumer Federation
National Council of Women
National Dried Fruit Trade Association
National Farmers Union
National Farmers Union Scotland
National Federation of Meat and Food Traders
National Office of Animal Health
National Pig Association
National Sheep Association
NFU Cymru
Northern Ireland Agricultural Producers Association
Northern Ireland Food and Drink Association
Northern Ireland Grain Trade Association
Northern Ireland Local Government Association
Northern Ireland Meat Exporters Association
Northern Ireland National Beef Association
Northern Ireland Poultry Federation
Organic Farmers and Growers
Pet Food Manufacturers' Association
Quality Meat Scotland
Royal College of Veterinary Surgeons
Royal Environmental Health Institute of Scotland
Royal Pharmaceutical Society of Great Britain
Royal Welsh Agricultural Society
Salmon and Trout Association
Scottish Association of Meat Wholesalers
Scottish Audit Advisory Committee
Scottish Beekeepers Association
Scottish Civil Forum
Scottish Consumer Council
Scottish Enterprise
Scottish Environment Protection Agency
Scottish Executive Environment and Rural Affairs Department
Scottish Federation of Meat Traders Association
Scottish Food and Drink Federation
Scottish Food Enforcement Liaison Committee
Scottish Food Safety Officers Association
Scottish Game Gamedealers and Processors Association

Scottish Salmon Producers Organisation
Sea Fish Industry Authority
Shellfish Association of Great Britain
Small Business Service
Society of Chief Officers of Environmental Health Officers in Scotland
Society of Chief Officers of Trading Standards
Soil Association
Sustain
The Audit Commission
The National Audit Office
Trading Standards Institute
UK Association of Frozen Food Producers
Ulster Beekeepers Association
Ulster Farmers Union
Ulster Shellfish Association
UNISON
Veterinary Laboratories Agency
Welsh Beekeepers Association
Welsh Consumer Council
Welsh Local Government Association
Which?