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COMMISSION OF THE EUROPEAN COMMUNITIES

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Draft

COMMISSION DECISION

of […]

setting out the guidelines to assist Member States in preparing the single integrated multi-annual national control plan further to the provisions of 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

WORKING DOCUMENT FOR DISCUSSION PURPOSES SUBJECT TO AMENDMENT

DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

Draft

COMMISSION DECISION

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setting out the guidelines to assist Member States in preparing the single integrated multi-annual national control plan further to the provisions of 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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95 and 152(4)(b) thereof,

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 43(1) thereof,

Having consulted the Standing Committee on the Food Chain and Animal Health,

Whereas :

(1) Under 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, and in particular Article 41 thereof, each Member State is required to prepare a single integrated multi-annual national control plan.

(2) By virtue of Article 59 of Regulation (EC) No 882/2004, Articles 41 to 46 of that Regulation apply, as appropriate, for the purposes 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) The purpose of the single integrated multi-annual national control plan is to ensure effective implementation in each Member State of Article 17(2) of Regulation (EC) no 178/2002, of animal health and of animal welfare rules and as appropriate of plant health law, and to establish a solid basis for Commission inspection services to carry out controls in the Member States.

[1] OJ L 191, 28.05.2004, p. 1

(4) Article 45 of Regulation (EC) No 882/2004 specifies that Community audits in Member States shall be carried out on a regular basis with the main purpose to verify that, overall official controls take place in Member States in accordance with the multi-annual national control plans and in compliance with Community law

(5) Article 42 of Regulation (EC) No 882/2004 specifies principles for the preparation of the plan and in particular the general information that should be contained in the plan.

(6) Under Article 43 of the said Regulation, the Commission is required to draw up guidelines on the single integrated multi-annual national control plan to, inter alia, promote a consistent, comprehensive and integrated approach to official controls of food and feed, animal health and animal welfare legislation and embrace all sectors and all stages of the feed and food chain, including import and introduction.

(7) Under Article 43 (1) the multi-annual control national control plan shall take account of guidelines to be drawn up by the Commission. The guidelines are not binding but serve to provide useful guidance to the Member States in the implementation of Regulation (EC) No 882/2004.

(8) Article 43(1) subparagraphs (a) to (k) of the said Regulation set out specifically the purpose and content of the guidelines on the multi-annual national control plans.

(9) Certain matters can only be developed in the light of experience gained from the implementation of the single integrated multi-annual national control plans, from the audits carried out by the competent authorities under Article 4(6) and by Commission experts under Article 45 and from the information included in the annual reports submitted by the Member States under Article 44 of the said Regulation. It is therefore appropriate to take a phased approach in developing the guidelines.

(10) In this first phase, the guidelines concentrate on the elements of the single integrated multi-annual national control plan which should be in place in the Member States in order to meet the minimum requirements of Regulation (EC) No 882/2004, in particular the requirements of Article 42, and to provide a basis for Commission inspection services to carry out controls in the Member States.

(11) Further guidelines addressing specific issues shall, where appropriate be developed progressively in the light of experience.

(12) The guidelines laying down criteria for the conduct of the audits referred to in Articles 4(6) and 43(1)(i) of the said Regulation are set out in the annex to Commission Decision 2005/XXX/EC.

(13) The guidelines laying down the structure of, and information to be contained in, the annual report required in Article 44 of the said Regulation are set out in the annex to Commission Decision 2005/YYY/EC.

(14) The Commission will keep the guidelines under review and will update them, as necessary, following receipt and examination of the Member States single integrated multi-annual national control plan and in the light of the experience of the Member States in implementing the provisions of Regulation (EC) No 882/2004.

HAS ADOPTED THIS DECISION:

Article 1

The guidelines for the single integrated multi-annual national control plans referred to in Article 41 of Regulation (EC) No 882/2004 are established as provided in the Annex

This Decision is addressed to the Member States.

Done at Brussels, […]

For the Commission
[…]
Member of the Commission

ANNEX

Guideline for single integrated multi-annual national control plans

Contents

5. Guidance on the scope of multi-annual national control plans

1. PURPOSE AND SCOPE OF THE GUIDELINES

These guidelines are to assist Member States in preparing the single integrated multi-annual national control plan referred to in Article 41 of Regulation (EC) No 882/2004. They provide guidance on the requirements for the plan as set out in Article 42(2) of Regulation (EC) No 882/2004.

~~The purpose of this plan is to ensure the effective implementation of Article 17 (2) of Regulation (EC) No 178/2002[2], of animal health and of animal welfare rules and of Article 45 of Regulation (EC) No 882/2004 and as appropriate of plant health law.~~

The guidelines are applicable to all official controls coming within the scope of Regulation (EC) no 882/2004, that is feed and food law and rules applicable to animal health and animal welfare. In accordance with the provisions of Article 59 of Regulation (EC) No 882/2004 the plan also covers plant health insofar as that Article requires.

2. 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 and ~~the definitions~~ in Articles 2 and 3 of Regulation (EC) No 178/2002, shall apply.

The following definitions should be noted

*"**Food law**" means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food and also of feed produced for, or fed to, food producing animals."(Article 3(1) of Regulation (EC) No 178/2002)*

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

*"**Feed Law**" means the laws, regulations and administrative provisions governing feed in general and feed safety in particular, whether at Community or national level; it covers all stages of production, processing and distribution of feed and the use of feed. (Article 2(3) of Regulation (EC) No 882/2004)*

*"**Official control**" means any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules. (Article 2(1) of Regulation (EC) No 882/2004)*

*"**Competent authority**" means the central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country. (Article 2(4) of Regulation (EC) No 882/2004.*

*"**Control body**" means an independent third party to which the competent authority has delegated certain control tasks (Article 2(5) of Regulation (EC) No 882/2004).*

"***Control plan**" means a description established by the competent authority containing general information on the structure and organisation of its official control system (Article 2 (20) of Regulation (EC) No 882/2004)*

For the purpose of these guidelines,

With regard to plant health

"Competent authority" includes the "Single Authority" and other "Responsible Official Bodies" as defined in Articles 1(4) and 2(1)(g) of Council Directive 2000/29/EC[3]*, and*

"Control body" includes "legal persons" with delegated tasks as defined in Article 2(1)(g) of Council Directive 2000/29/EC.

With regard to organic production of agricultural products (Council Regulation (EEC) No 2092/91[4] (as amended)

[3] 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 in the Community. (OJ L 169, 17.07.2000, p.1)

[4] Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs. (OJ L 198, 22.7.1991, p. 1)

"Competent authority" includes the authority designated for the reception of notifications referred to in Article 8(2) of Regulation (EEC) No 2092/91 and the designated authority responsible for the approval and supervision of private inspection bodies referred to in Article 9(4) of Regulation (EEC) No 2092/91, and

"Control Body" includes an approved private body in accordance with Article 9 of Regulation (EEC) No 2092/91.

With regard to the protection of geographical indications and designations of origin for agricultural products and foodstuffs (Council Regulation (EEC) No. 2081/92[5] (as amended)

"Competent authority" includes the designated inspection authorities referred to in Article 10 of Regulation (EEC) No 2081/92 save where such authorities are private bodies.

"Control Body" includes an approved private body in accordance with Article 10 of Regulation (EEC) No 2081/92.

With regard to certificates of specific character for agricultural products and foodstuffs (Council Regulation (EEC) No. 2082/92[6] (as amended)

"Competent authority" includes the designated inspection authorities referred to in Article 14 of Regulation (EEC) No 2082/92 save where such authorities are private bodies.

"Control Body" includes an approved private body in accordance with Article 14 of Regulation (EEC) No 2082/92.

*"**risk**" means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard" (Article 3 (9) of Regulation (EC) No 178/2002).*

In addition to the definitions set out above the following definitions shall apply for the purpose of this guideline –

[5] Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin of agricultural products and foodstuffs (OJ L 208, 24.7.1992, p. 1)

[6] Council Regulation (EEC0 No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs (OJ L 208, 24.7.1992, p. 9)

*"c**oordination**" means any action(s) taken to ensure that the designated competent authorities are planning and implementing their controls in a coherent and consistent manner in order to effectively contribute to the common objective(s).*

*"**production chain**" means the full chain of production incorporating all 'stages of production, processing and distribution', as defined in Article 3(16) of Regulation (EC) No 178/2002. Where appropriate this also includes all stages of non-food chain related animal and plant production.*

*"**production stage**" means any stage in the production chain for a commodity, including import, from and including the primary production up to and including processing, manufacture, storage, transport, distribution sale or supply to the final consumer.*

***"critical production stage"** means a production stage in the production chain identified by the competent authority as one where compliance must be verified in order to ensure that a hazard is prevented, eliminated or reduced to an acceptable level.*

***"sector**" means the full production chain for a particular commodity or group of commodities and which may involve the activities of one or more competent authorities.*

3. GUIDANCE ON LEGAL REQUIREMENTS FOR MULTI-ANNUAL NATIONAL CONTROL PLANS

Note re citation of Community legislation

In these guidelines a reference to a Directive, Regulation or Decision means, unless a contrary intention is indicated, a reference to that Directive, Regulation or Decision as last amended.

3.1. Single Integrated Multi-Annual National Control Plans`

3.1.1. Legal obligation

Article 41 of Regulation (EC) No 882/2004

"In order to ensure the effective implementation of Article 17(2) of Regulation (EC) No 178/2002, of animal health and animal welfare rules and of Article 45 of this Regulation, each Member State shall prepare a single integrated multi-annual national control plan".

3.1.2. Guidance/definition of requirement

3.1.2.1. Scope of the single integrated multi-annual national control plan

The plan should cover the full legislative scope of Regulation (EC) No 882/2004 including plant health insofar as the provisions of Article 59 of that Regulation requires. Note that with regard to feed and food law, animal health and animal welfare legislation the plan is required to cover all official controls relating to all relevant Community legislation not just those relating to feed and food hygiene and safety.

Therefore with regard official controls on feed and food the plan should cover all feed and food law including, for example, feed and food hygiene, materials in contact with food, genetically modified organisms (GMOs), irradiation, quality and compositional requirements of feed and food law, labelling, nutritional aspects, organic farming[7], protection of geographic indications and designations of origin for agricultural products and foodstuffs[8], certificates of specific character of agricultural products and foodstuffs[9] etc. In relation to animal health all diseases and issues regulated by Community law should also be included.

For further clarification on the scope see point 5 of these guidelines.

3.1.2.2. Application to Plant Health

Some of the requirements of the plan, as specified in Article 42 of Regulation (EC) No 882/2004 refer to provisions of the Regulation that are not applicable to plant health. These requirements relate to the information requested at Articles 42(2)(f) to (k)~~points~~

~~Article 42(2)(g) - operational criteria for which guidance is set out in section 3.9~~

~~Article 42(2)(j) - operational contingency plans for which guidance is set out in section 3.12~~

However, where a requirement of Regulation (EC) No 882/2004 has an equivalent or corresponding requirement in Council Directive 2000/29/EC information on the arrangements to meet the requirements of that Directive should be provided in respect of plant health.

[7] Council Regulation (EEC) 2092/91 as amended
[8] Council Regulation (EEC) 2081/92 as amended
[9] Council Regulation (EEC) 2082/91 as amended

Article 42(2)(f)- delegation of ~~control~~ tasks to control bodies for which guidance is set out at section 3.8,

Article 42(2)(h)- training of ~~control~~ staff performing official controls for which guidance is set out at section 3.10

Article 42(2)(i)- documented procedures for which guidance is set out in section 3.11

Article 42(2)(k)- organisation of cooperation and mutual assistance for which guidance is set out in section 3.12

The guidance on the requirements of Article 42(2) subparagraphs (c), (d) and (e) contain some additional references to provisions of Regulation (EC) No 882/2004 which are not applicable to plant health. When addressing these requirements it is not necessary to apply these aspects of the guidance to plant health. For example the guidance at section 3.6 refers to audits of competent authorities as required by Article 4(6) of Regulation (EC) No 882/2004 which are not applicable to plant health. However if Member States operate such audits, or apply other non-obligatory provisions of the guidance in relation to official controls in respect of plant health they may provide this information on a voluntary basis in their description of their control system for plant health.

3.1.2.3. Single Integrated Plan

Each Member State should produce a single integrated multi-annual national control. This plan should be applicable to, the official control activities of all the designated competent authorities at all levels (central, regional and local) for each of the following areas feed and food law, animal health, and animal welfare and plant health law. The plan should cover all relevant sectors and commodities, including non-food commodities of animal and plant origin, and all ~~stages of~~ production stages, ~~processing and distribution~~ (including importation, primary production, processing, manufacture up to and including storage, transport, distribution and sale or supply to the final consumer)

For Member States with decentralised administrations the plan should outline how the coordination of the integrated control systems of the individual administrations is ensured in order to arrive at a single integrated national control plan.

A simple compilation of individual competent authority or sectoral plans which does not address the integration and coordination of controls across competent authorities and sectors will not satisfy the requirement for a single integrated national control plan.

National competent authorities should devise appropriate systems for the integrated planning, development and coordination of activities regarding the plan. This process should include putting in place arrangements for the transmission of a single plan to the Commission and the identification of a single contact point in the Member State for communications regarding the plan.

When preparing a single integrated multi-annual national control plan, Member States should provide that during its implementation sufficient evidence of compliance is gathered, retained and made available to allow verification of its effective implementation. Such evidence should include written procedures, documentation and records of controls.

3.1.2.4. Periodicity (length of planning cycle)

The period of validity/duration of the plan is a matter for the Member State to decide and may be set to correspond with other national planning activities such as the budgetary cycle. The reasons for selecting the chosen duration should be briefly stated in the plan.

It is suggested that in order to be multi-annual the plan should cover a minimum of three years. In view of the difficulty for planning ahead in an evolving environment it is suggested that a single planning cycle should not exceed five years.

Uncertainties and constraints will dictate the level of detail on official control activities that can be provided for each year of the plan. In particular operational goals/objectives for control activities may have to be set provisionally for the later years of the plan and updated on an ongoing basis in conjunction with the preparation of the annual report required under Article 44(1) of Regulation (EC) No 882/2004. In this connection attention is drawn to the provisions regarding the adjustment or amendment of the national control plan as laid out in Article 42 (3) of Regulation (EC) No 882/2004.

3.2. General requirements for Multi-Annual National Control Plans

3.2.1. Legal obligation

Article 42(2) of Regulation (EC) No 882/2004

"Each multi-annual national control plan shall contain general information on the structure and organisation of the systems of feed and food control, and of animal health and animal welfare control in the Member State concerned, in particular on…."

3.2.2. Guidance/definition of requirement

The plan is required to contain general information on the structure and organisation of the Member States systems of official controls covering all sectors and all stages of the feed and food production chain, animal health, animal welfare and, as is provided for by Article 59 of Regulation (EC) No 882/2004, amending Council Directive 2000/29/EC, plant health. Although general in nature the plan is required to include information on the specific issues set out in subparagraphs (a) to (k) of Article 42(2) of Regulation (EC) No 882/2004. Guidance on these specific issues is set out in the following sections of these guidelines.

Specific control plans, ~~see following paragraph,~~ provided for under other Community legislation are not replaced by the multi-annual national control plan. However, the multi-annual national control plan should integrate the planning and implementation of these specific plans into the overall national control plan. A general description of the controls for each of the specific areas should be included in the overall description of the structure and organisation of the control systems applied to the relevant sectors and this description may cross-reference the specific plans.

~~The specific control plans referred to above are those required in accordance with the following legislation.~~

~~Council Directive 96/23/EC[10] of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products. Regulation (EC) No 999/2001[11] of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.~~

~~Regulation (EC) No 2160/2003 [12]of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other food-borne zoonotic agents.~~

[10] OJ L 125, 23.5.1996, p. 10, Directive as last amended by Regulation (EC) No 806/2003 (0J L)
[11] OJ L 147, 31.5.2001, p. 1, Directive as last amended by Regulation (EC) No 806/2003 (OJ L 333, 20.12.2003,p. 28)
[12] OJ L 325, 12.12.2003, p. 1.

~~Council Directive 86/362/EEC[13] of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals.~~

~~Council Directive 90/642/EEC[14] of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables.~~

~~Commission Directive 92/1/EEC[15] of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption.~~

~~Commission Directive 92/2/EEC[16] of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption.~~

~~Regulation (EC) No1082/2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 of the European Parliament and the Council as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals~~

3.3. Strategic Objectives of the Plan

3.3.1. Legal obligation

Article 42(2)(a) of Regulation (EC) No 882/2004

"The strategic objectives of the plan and on how the prioritisation of controls and allocation of resources reflect these objectives"

3.3.2. Guidance/definition of requirement

Bearing in mind that the main objective of Regulation (EC) 882/2004 is to ensure effective enforcement of feed and food law and rules applicable to animal health, animal welfare, and insofar as the provisions of Article 59 require, plant health, and the general obligation on

[13] OJ L 221,7.8.1986, p. 37, Directive as last amended by Commission Directive 2004/2/EC (OJ L 14, 21.1.2004, p. 10)

[14] OJ L 350, 14.12.1990, p. 7,1 Directive as last amended by Commission Directive 2004/2/EC.

[15] OJ L 34, 11.2.1992, p. 28.

Member States to enforce Community law, Member States should develop appropriate strategies to achieve this purpose. These strategic objectives should form the basis of, and be briefly set out in the single integrated multi-annual national control plan

The strategy adopted may involve the concentration or prioritisation of controls or allocation of resources on certain activities or at certain stages of the production chain. Where this is the case such priorities and reasons therefor, should be indicated.

3.4. Risk Categorisation

3.4.1. Legal Obligation

Article 42(2)(b) of Regulation (EC) No 882/2004

"The risk categorisation of the activities concerned"

3.4.2. Guidance/definition of requirement

Bearing in mind that Article 3(1) of Regulation (EC) No 882/2004 requires official controls to be carried out on a risk basis with appropriate frequency, the plan should indicate the risk categorisation, if any, assigned to the various activities subject to official controls. A brief description of the process of risk categorisation used by the Member State may be included if desired.

This information may at a future date contribute to the development of guidelines concerning the identification of risk-based priorities and the most effective control procedures as provided for by Article 43(1)(b) of Regulation (EC) no 882/2004.

3.5. Designation of Competent authorities

3.5.1. Legal Obligation

Article 42(2)(c) of Regulation (EC) No 882/2004

"The designation of competent authorities and their tasks at central, regional and local level, and on the resources available to these authorities"

[16] OJ L 34, 11.2.1992, p. 30

3.5.2. Guidance/definition of requirement

The plan should provide a comprehensive overview of the structure and tasks of the competent authorities. This should:

- identify the organisations, or, where appropriate, the categories of organisations, that are designated as competent authorities responsible for the purposes of official controls. All competent authorities, or where appropriate the category of competent authority, at all levels, i.e. central, regional and local level should be identified, as should all independent third party control bodies to which certain control tasks have been delegated in relation to plant health,
- describe the allocation of official control tasks and responsibilities for the entire feed and food production chain, and for animal health, animal welfare and plant health,
- indicate the resources (see guidance below), available to the competent authorities,
- list the laboratories designated, in accordance with Article 33(1) of Regulation (EC) No 882/2004, as national reference laboratories, the areas for which they are designated as responsible and the competent authority responsible for the laboratory,

This information may be illustrated in the form of an integrated national-level organigramme of the competent authorities and their respective tasks/ responsibilities.

The description of resources should include human resources and supporting facilities and services such as specialist IT systems and laboratory, diagnostic, research and training facilities/services as applicable. Human resources should be described in terms of authorised full or whole time equivalent posts. Facilities and services available may be quantified in terms of level of service, laboratory capacity and range of analytical activities etc. and if appropriate may be provided on a national or regional level indicating the number of competent authorities sharing the facilities.

A full list of laboratories designated to carry out analysis on samples taken during official controls is not required to be included in the plan but should be maintained by the competent authority and made available for audit/inspection purposes.

When addressing this requirement Member States should include the organisations equating with competent authorities under Articles 1(4) and 2(1)(g) of Council Directive 2000/29/EC,

Article 8(2) of Council Regulation (EEC) No 2092/91, Article 14 of Council Regulation (EEC) No 2081/92 and Article 10 of Council Regulation (EEC) No 2082/92

3.6. General Organisation and Management

3.6.1. Legal Obligation

Article 42(2) (d) of Regulation (EC) No 882/2004

"The general organisation and management of official controls at national, regional and local level, including official controls in individual establishments"

3.6.2. Guidance/definition of requirement

This section should provide a general description of the organisation and structure of each organisation designated as a competent authority, at all levels taking account of the specific requirements of Regulation (EC) No 882/2004 where applicable. A generic description may be provided for the same category of competent authority at regional and, or, local level when the organisation and structure of the authorities is essentially similar. The plan should describe how official controls, including import controls, are organised and managed at national, regional and local level.

For the purpose of completing the plan the descriptions of the organisation and management of official controls may be provided under the headings of feed and food law, animal health, animal welfare and plant health law.

This should include a general description of:

- the organisation of the competent authorities,
- the hierarchical relationships and reporting arrangements within and between competent authorities, and with control bodies with delegated tasks,
- the supervision to which all the designated competent authorities and control bodies are subject,
- arrangements for inspection and/or verification and/ or supervision to ensure the quality, impartiality, consistency and effectiveness of official controls at all levels

within and across competent authorities including across all regional and /or local authorities as required by Article 4(4) of Regulation (EC) No 882/2004,

- for plant health the authority (legal and administrative powers) that the competent authorities and control bodies have to enforce the applicable legislation,(for other areas this aspect is covered under section 3.9)
- the procedure for the designation of laboratories for the analysis of samples and the arrangements to ensure that such laboratories conform to and operate in accordance with the standards referred to in Article 12.2 of Regulation (EC) No 882/2004,
- the arrangements to ensure that laboratories designated, in accordance with Article 33(1) of Regulation (EC) No 882/2004, as national reference laboratories conform to and operate in accordance with the requirements of Article 33 of Regulation (EC) No 882/2004,

The plan should describe how the audits of competent authorities, to ensure effectiveness and suitability of official controls, as required by Article 4(6) of Regulation (EC) No 882/2004 are organised and managed at national, regional and local level. This should include a description of the arrangements in place

- for internal or external audits of competent authorities,
- to ensure that competent authorities take appropriate measures in the light of the results of these audits,
- to ensure that these audits are subject to independent scrutiny and are carried out in a transparent manner.

These arrangements should take account of the guidelines laying down the criteria for the conduct of audits [Insert reference to decision on audit guidelines]

3.7. Control Systems and Coordination of Activities

3.7.1. Legal Obligation

Article 42(2)(e) of Regulation (EC) No 882/2004

"Control systems applied to different sectors and coordination between the different services of competent authorities responsible for official controls in these sectors"

3.7.2. Guidance/definition of requirement

3.7.2.1. Organisation of official controls

The organisation of official control systems should take account of:

- the need to determine the nature, frequency, time and point of control in order to maximise compliance with feed and food law, animal health, animal welfare and plant health law.
- the role of prioritisation in determining the balance between tasks and resources.
- the specific control plans or programmes prescribed by Community legislation
- any specific national disease control or eradication plans
- any relevant risk categorisations

The plan should describe:

- the control systems applied to different sectors, in particular
    - the control methods and techniques used and where and when applied that is monitoring, surveillance, verification, audit, permanent supervision, inspection, sampling and analysis etc, taking account of the requirements of Articles 10 and 11 of Regulation (EC) No 882/2004,
    - The frequency, or as appropriate, the criteria for determining the frequency and nature of official controls, and
    - the extent and operation of official controls on import of all feed and food, animals and products of animal origin.
- how the risk categories referred to in section 3.4.1 are applied to target control actions effectively,
- how the control arrangements for horizontally applicable legislation and the specific control plans mentioned in section 3.2.2 are integrated into the specific controls applicable to each relevant sector or sub-sector. Where more than one sector or sub-sector is involved appropriate linkages should be established between the different sectors or sub-sectors

3.7.2.2. Coordination and cooperation

Arrangements should be in place to ensure effective coordination of activities and cooperation within and between competent authorities, especially in relation to issues which involve joint action or cooperation between different services within a competent authority or between

different competent authorities. These arrangements should also contribute to ensuring the quality, impartiality, consistency and effectiveness of official controls .In particular information should be provided on the general measures to manage the relationship between the different competent authorities responsible for different sub-sectors or different stages of the production chain and on the arrangements to ensure efficient and effective cooperation where competence is conferred on, or shared with regional and, or, local competent authorities.

The plan should describe

- the arrangements to ensure effective and efficient cooperation and co-ordination of activities within a competent authority, between two or more competent authorities involved in the same sector, and in particular where a Member State confers competence to carry out official controls on an authority other than a central competent authority between the relevant central, regional and local authorities , as laid down in Article 4 (3) and Article (5) of Regulation (EC) No 882/2004 and Article 2(1)(g) of Council Directive 2000/29/EC. For example formal arrangements for coordination of activities and ensuring consistency of controls such as meetings, joint committees and liaison groups, requirements for joint agreements or actions etc.,
- shared training initiatives for staff involved in official controls, such as technical skills, supervision of control services, quality management and auditing if applicable,
- sharing access to laboratory and diagnostic facilities if applicable,
- management and use of shared national databases if applicable, and
- the areas where coordination and communication between competent authorities is an important issue, and
    - the measures in place to ensure the effective operation of this activity so there is no breakdown in control actions,
    - how the necessary information is exchanged between competent authorities to ensure the continuity and consistency of controls and to enable traceability systems to operate effectively.

3.8. Delegation to Control Bodies

3.8.1. Legal Obligation

Article 42(2)(f) of Regulation (EC) No 882/2004

"Where appropriate the delegation of tasks to control bodies"

3.8.2. Guidance/definition of requirement

The plan should where appropriate:

- identify the competent authorities that delegate control tasks to control bodies,
- list the specific tasks delegated to each category of control body
- describe the arrangements in place to ensure that delegating competent authorities and control bodies meet the requirements of
    - Article 5(2) points (b), (c), (d) and (f) and Article 5(3)of Regulation (EC) No 882/2004,
    - Annex II, Chapter II point 2 of Regulation (EC) No 882/2004
    - Article 2(1)(g) of Council Directive 2000/29/EC ,
    - Article 9 of Council Regulation (EEC) No 2092/91
    - Article 10 of Council Regulation (EEC) No 2081/92, and
    - Article 14 of Council Regulation (EEC) No 2082/92, as applicable.

Where the same control task is delegated to a number of control bodies the delegation of such tasks may, for the purposes of the plan be described in terms of category of control body. Where this option is taken the relevant competent authorities should maintain a comprehensive and up-to-date list of control bodies to whom control tasks are delegated and make this list available for audit and, or, inspection purposes.

3.9. Compliance with Operational Criteria

3.9.1. Legal Obligation

Article42(2) (g) of Regulation (EC) No 882/2004

"Methods to ensure compliance with the operational criteria of Article 4(2)"

3.9.2. Guidance/definition of requirement

The plan should describe the methods employed to ensure that organisations designated as competent authorities are effectively implementing the requirements of Article 4(2) of Regulation (EC) No 882/2004

In particular the plan should describe the arrangements in place to ensure the following in respect of all competent authorities..

- That, as required by Article 4(2)(a) of Regulation (EC) No 882/2004, effective and appropriate official controls are applied at all stages of production, processing and distribution of animals, food, feed and plants and to the use of feed).
- That, as required by Article 4(2)(b) of Regulation (EC) No 882/2004, measures are in place to ensure that staff carrying out official controls are free from any conflict of interest which could impair their objectivity and independence or compromise their professional judgement and to deal with any potential conflict of interest which may arise. Where external or contract staff are used the measures in place to ensure that they have the same degree of independence and accountability as permanent staff regarding their official control duties should also be described.
- That, as required by Article 4(2)(c) of Regulation (EC) No 882/2004, all competent authorities have, or have access to, adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively.
- That, as required by Article 4(2)(d) of Regulation (EC) No 882/2004, all competent authorities have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively.
- That, as required by Article 4(2)(e) and taking account of the requirements of Articles 8(2), 54 and 55 of Regulation (EC) No 882/2004, there are adequate legal powers to carry out official controls, including power to enter onto premises, to inspect animals, plants, products, records or other documents including computing systems, to take samples, and to take appropriate actions in the case of suspicion or detection of non-compliances including the imposition of effective, proportionate and dissuasive sanctions.
- That, as required by Article 4(2)(f) of Regulation (EC) No 882/2004, there are contingency plans in place, and competent authorities are prepared to operate such plans in the event of an emergency.

- That, as required by Article 4(2)(g) of Regulation (EC) No 882/2004, feed and food business operators are obliged to undergo any inspection carried out in accordance with Regulation (EC) No. 882/2004 and to assist staff of the competent authority in the accomplishment of their tasks.

3.10. Training of Staff Performing Official Controls

3.10.1. Legal Obligation

Article 42(2)(h) of Regulation (EC) No 882/2004

"The training of staff performing official controls referred to in Article 6".

3.10.2. Guidance/definition of requirement

The plan should describe the systems or arrangements in place to ensure that staff carrying out official controls receive, or have received the training, referred to in Article 6 of Regulation (EC) No 882/2004.

For all sectors, including plant health the plan should also describe the arrangements to ensure that all staff carrying out official controls have the necessary qualifications, training and competencies to carry out official controls in an effective manner and in particular meet the requirements of Article 2(1)(i) of Council Directive 2000/29(EC) and paragraphs 1 and 2 of the Annex to Commission Directive 98/22/EC [17] if applicable.

The plan should, for all sectors, set out the systems or arrangements in place to:

- identify the training needs for staff performing official controls,
- provide and evaluate such training,
- document such training for audit purposes.

The documentation of training by the competent authorities should include recording the subject and level of training, number of days training, and the number of participants. These records should be maintained up-to-date and be available for audit and, or, inspection purposes.

[17] OJ, L126 of 28.4.1998 p26

3.11. Documented Procedures

3.11.1. Legal Obligation

42(2) (i) of Regulation (EC) No 882/2004 "The documented procedures referred to in Articles 8 and 9"

3.11.2. Guidance/definition of requirement

The plan should describe the systems or arrangements in place to ensure the effective implementation of the requirements of Articles 8(1) and 8(3) of Regulation (EC) No 882/2004 regarding documented procedures and Article 9 of Regulation (EC) No 882/2004 regarding reports on official controls.

For plant health the plan should, in particular, describe the systems or arrangements in place to ensure the effective implementation of points (a) and (b) of paragraph 1 of the Annex to Commission Directive 98/22/EC

For all sectors, including plant health, the plan should describe the systems or arrangements in place to ensure that:

- The relevant documented procedures are readily accessible to;
    - all staff performing official controls,
    - the competent authorities concerned,
    - the central competent authority,
    - any audit body involved,
    - the Commission upon request.
- documented procedures are reviewed and updated at appropriate intervals.

A comprehensive list or index of documented procedures should be maintained by the competent authority and be available for audit and, or, inspection purposes.

For all sectors, , the plan should describe the systems or arrangements in place to provide for the recording of the performance and outcome of official controls, as prescribed by Articles 9(1) and (2) of Regulation (EC) No 882/2004, the filing of such records, and for ensuring that such records are readily accessible to:

- all staff performing those official controls,
- the competent authority concerned,
- the central competent authority,
- any relevant audit body,
- the Commission upon request.

3.12. Operational Contingency Plans

3.12.1. Legal Obligation

Article 42(2) (j) of Regulation (EC) No 882/2004

"The organisation and operation of contingency plans for animal or food borne disease emergencies, feed and food contamination incidents and other human health risks"

3.12.2. Guidance/definition of requirement

This section applies in particular to the contingency plans referred to in Articles 4(2)(f) and 13(1) of Regulation (EC) No 882/2004 but reference should also be made to other contingency plans required under Community legislation, such as

- Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever,
- Council Directive 2003/85/EC of 29 September on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EC and amending Directive 92/46/EEC and
- Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease.

The plan should:

- indicate each of the sectors for which specific contingency plans are in place,
- indicate the scope of each such contingency plan,
- in relation to each such contingency plan, identify the body or bodies responsible for their preparation and maintenance,
- describe the system or arrangements in place for dissemination of the contingency plans and for appropriate training in relation to their implementation.

however, it is not necessary to append a copy of the individual contingency plans.

If appropriate these arrangements may be described using an organigramme or table or other easily presented format.

3.13. Organisation of Cooperation and Mutual Assistance

3.13.1. Legal Obligation

Article 42(2) (k) of Regulation (EC) No 882/2004

- *"The organisation of cooperation and mutual assistance"*

3.13.2. Guidance/definition of requirement

The plan should:

- describe the general arrangements in place to ensure that the requirements of Articles 34 to 39 of Regulation (EC) No 882/2004 are met.
- identify the designated liaison body or bodies and their respective areas of responsibility or competence.
- for plant health describe the arrangements in place to comply with Articles 12(4), 13c (2)(c) and 16 of Council Directive 2000/29/EC,

3.14. Adjustment of Multi-Annual National Control Plans

3.14.1. Legal Obligation

Article 42(3) of Regulation (EC) No 882/2004

"Multi annual national control plans may be adjusted during their implementation. Amendments may be made in the light of, or in order to take account of factors including

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) The results of Member States' official controls
e) The results of Community controls carried out in accordance with Article 45
f) any amendment of the guidelines referred to in Article 43

g) Scientific findings

h) The outcome of audits performed by a third country in a Member State"

3.14.2. Guidance/definition of requirement

Member States are reminded of their obligation to consider adjustments to the single integrated multi-annual national control plan during its implementation in the light of the factors set out under Articles 42(3), 44(5) and 45(5) of Regulation (EC) No 882/2004 and for the inclusion of any subsequent adjustments in the Annual report referred to in Article 44 (1) of Regulation (EC) No 882/2004.

The plan should therefore describe

- the process for the review of the operation of the single integrated multi-annual national control plan. This review should take place annually as a contribution to the annual report {refer to separate guideline} on the implementation of the plan,
- how the outcome of the audits of national competent authorities required under Article 4(6) of Regulation (EC) No 882/2004 shall feed into this process.

4. GUIDANCE ON FORMAT OF SINGLE INTEGRATED MULTI-ANNUAL NATIONAL CONTROL PLAN

In order to have a consistent and comprehensive approach to the organisation and implementation of official controls the single integrated multi-annual national control plan should be presented in accordance with the following format.

4.1. Title:

Single integrated multi-annual national control plan presented by ……..[Member State] for the period from …… to ……..[period of validity of the plan].

4.2. Contact point in Member State: [for communication regarding the plan]

Contact point: [may be a unit or office of a named administration and not necessarily a named individual official]	
Address:	
Email address:	
Telephone:	
Fax:	

4.3. Content of plan

4.3.1 Overall national strategic objectives

4.3.2 Designation, of the competent authorities, national reference laboratories and delegated control bodies

4.3.3 Organisation and management of official controls by competent

4.3.4 Contingency plans & mutual assistance

4.3.5 Arrangement for audit of competent authorities

4.3.6 Measures to ensure compliance with the operational criteria of Regulation (EC) No. 882/2004.

4.3.7 Review and adjustment of the plan

4.3.1. Overall national strategic objectives

Reference Guidance: Section 3.1 Single integrated national control plans

Section 3.3 Strategic objectives of the plan

List Strategic objectives e.g.
Objective 1
Objective 2
Objective 3 etc.

4.3.2. Designation of the competent authorities, national reference laboratories and delegated control bodies

Reference Guidance: Section 3.5 Designation of competent authorities

Section 3.8 Delegation to control bodies

Designated competent authorities [designation, structure and organisation on a national basis]

Provide an overview of the:

- Areas of competence/ scope of responsibilities
- Reporting and communication channels

Organisational charts or tables may be used to describe the structure, responsibilities, ~~resources~~, reporting or communication channels, etc above as appropriate.

Delegation of control tasks to control bodies

Competent authority responsible	Control bodies or category of control body as appropriate	Control tasks delegated

Describe the arrangements to ensure that the legislative requirements regarding delegation of tasks to control bodies ~~y requirements~~ are met

National reference laboratories:[18]

National reference laboratories	Competent authority responsible	Designated analytical activities

Describe the arrangements to ensure the responsibilities of national reference laboratories are addressed

Describe the quality control or management systems applied in each reference laboratory

Describe arrangements for the planning and conduct of ~~ring~~ proficency tests and the programme for proficency~~ring~~ tests during the duration of the plan.

[the arrangements to ensure that laboratories designated, in accordance with Article 33(1) of Regulation (EC) No 882/2004, as national reference laboratories conform to and operate in accordance with the requirements of Article 33 of Regulation (EC) No 882/2004,]

4.3.3. Organisation and management of official controls by competent authorities

Reference Guidance: Section 3.2 Multi-annual national control plans
Section 3.4 Risk categorisation
Section 3.6 General organisation and management
Section 3.7 Control systems and coordination of activities
Section 3.9 Compliance with operational criteria
Section 3.10 Training of staff performing official controls
Section 3.11 Documented procedures

Competent authority [*complete individually for each designated competent authority however this information may be aggregated at national or regional level for the same category of local or municipal competent authorities]*]

Describe the:

- internal organisation and structure in general terms
- human resources available for the purpose of carrying out official controls [full time equivalents]
- resources supporting official control actions
    - laboratory facilities
    - other resources/infrastructure

as applicable

[18] Note, National Reference Laboratories are not prescribed by Plant Health Law

The information on competent authorities may be presented on a sectoral basis (Food/Feed/Animal Health/Animal Welfare/ Plant Health) e.g.

Sector(i.e.Food/Feed/Animal Health/Animal Welfare/Plant Health as appropriate)

Central Competent Authorities(CCA)

Competent Authority CCA 1

Competent Authority CCA 2

Etc.

Regional (e.g. Federal/Provincial) Competent Authorities(RCA)

Competent Authority RCA 1

Competent Authority "RCA Category 1"

Etc.

Local (e.g. District/Municipal)Competent Authorities(LCA)

Competent Authority LCA Category A

Competent Authority LCA Category B

Etc.

Laboratories [other than national reference laboratories]:

Describe procedures for:

- designation of laboratories
- ensuring requirements applicable to official laboratories are met

Control systems [*by sector, including horizontal arrangements where applicable*]

For each of the following sectors describe:

- The control methods and techniques used and where and when applied
- Control priorities, resource allocation and how they relate to risk categorisation
- Supervision and verification of planned arrangements including reporting arrangements
- Arrangements for the application of horizontal legislation across different sectors/sub-sectors
- How specific control plans or programmes required by community legislation are integrated into the control systems for the relevant sectors or sub-sectors as appropriate

1.Control System for Food Law

2.Control system for Feed Law

3.Control System for Animal Health Law

4.Control System for Animal Welfare Law

5.Control System for Plant Health Law

In relation to the control systems describe the measures to:

- manage coordination between competent authorities with related responsibilities
- ensure efficient and effective cooperation both within and between competent authorities
- ensure all areas where coordination and cooperation are required both within and between competent authorities are addressed
- ensure the appropriate integration of control activities

Training arrangements [*these may be included under each competent authority or per category of competent authority where there are equivalent systems, as appropriate. If appropriate the descriptions of training arrangements may be orgainsed on a sectoral basis*]

Describe the arrangements for:

- Identification of training needs
- Implementing training plan(s)
- Recording and evaluating training

4.3.4. Contingency plans and mutual assistance

Reference Guidance: Section 3.12 Operational contingency plans

Section 3.13 Organisation of cooperation and mutual assistance

This section should be completed on a national basis

Contingency plans:

Describe the:

- Sectors/subjects/areas where contingency plans are in place
- Scope of each plan
- Body responsible
- Arrangements for dissemination and training to ensure effective implementation including simulation exercises

Arrangements for mutual assistance:

Liaison body/bodies	Area of responsibility

4.3.5. Arrangements for audit of competent authorities

Reference Guidance: Section 3.6 General Organisation and Management

Describe the arrangements for:

- internal or external audits of competent authorities including the frequency and nature of the audits
- ensuring that competent authorities take appropriate measures in the light of results of these audits
- ensuring that these audits are subject to independent scrutiny and are carried out in a transparent manner

4.3.6. Measures to ensure compliance with the operational criteria of Regulation (EC) No. 882/2004. (Not applicable to plant health)

Reference Guidance: Section 3.9 Compliance with Operational Criteria

Section 3.11 Documented procedures

Describe the arrangements to ensure the following:

- Impartiality, quality and consistency of controls
- Staff are free from conflict of interest
- Adequate laboratory capacity
- Sufficient number of suitably qualified & experienced staff
- Adequate facilities & equipment
- Adequate legal powers
- Food & Feed business operators co-operate with staff performing official controls
- Documented procedures are available
- Records are maintained

4.3.7. Review and adjustment of the plan

Reference Guidance: Section 3.14 Adjustment of multi-annual national control plans

Describe the process for the review of the operation of the single integrated multi-annual national control plan.

5. GUIDANCE ON THE SCOPE OF THE SINGLE INTEGRATED MULTI-ANNUAL NATIONAL CONTROL PLAN

The arrangements for all official controls coming within the scope of Regulation (EC) No 882/2004 should be addressed in the plan. An indication of the range of legislation/topics to be addressed in the plan is set out in the following tables. Requirements of both primary legislation and implementing measures should be taken into account

ANIMAL HEALTH LAW INCLUDES

	Includes
Live Animals	Aquaculture
	Bovine
	Equine
	Ovine and Caprine
	Porcine
	Poultry and Hatching Eggs
	Pets etc.
	Others
Semen, Ova and Embryos	Bovine
	Equine
	Ovine and Caprine
	Porcine
Animal Diseases	Control measures
	• *specific diseases*
	• *general*
	Eradication and monitoring
	Animal Disease notification System
	Animo/Traces
	Community Reference Laboratories
Animal identification	Bovine
	Equine
	Ovine and Caprine
	Porcine
	Pets
Import controls	in all above categories as appropriate

ANIMAL WELFARE LAW INCLUDES

Welfare on farm	
Welfare during transport	
Welfare at slaughter	

PLANT HEALTH LAW INCLUDES

	Includes
Harmful organisms	Control measures
	Intra EU trade
	Third Country imports

FOOD AND FEED LAW INCLUDES

	Includes
General Food Law	Responsibilities and procedures operators
	Official controls
	Traceability
	Rapid Alert System
Food Labelling and Nutrition	Food Labelling
	Health and Nutrition Claims
	Nutrition Labelling
	Mineral waters
	Food supplements
	Addition of Vitamins and Minerals
	Dietetic Food
	Food for Infants and Young Children
	Food for weight reduction
	Food for Sports People
	Foods for Diabetics
	Specific food products
Biological Safety	Food Hygiene (general all sectors and commodities)
	- primary production
	- processing
	- manufacture
	- storage
	- distribution
	- transport
	- retail
	Sampling and analysis
	Approval of establishments
	Salmonella and food-borne diseases
	Food Hygiene (food of animal origin)
	- meat/meat products/preparations etc.
	- game meat/products/preparations etc.
	- milk and milk products
	- fish /fishery products
	- aquaculture
	- bivalve molluscs
	-other products

	TSE's
	Animal by-products (also animal health issue)
Chemical safety	Food Additives
	Food Flavourings
	Novel Foods
	Contaminants
	Residues
	- medicinal products
	- pesticides
	Hormones/prohibited substances in products of animal origin
	Food Contact Materials
Community reference Laboratories	Chemical and biological
Irradiation	
Biotechnology	GM Food and Feed
	GM plants and Seeds
Other Food Law	Organic farming
	Specific Character Agricultural Products and Foodstuffs
	Geographic Indications and Designations of Origin
Fraudulent practices	
Animal Nutrition	Feed Materials
	Certain products used in animal nutrition– "Bioproteins"(Council Directive 82/471?EEC)
	Feed Additives
	Compound feedingstuffs (including petfood)
	Medicated feed
	Undesirable substances
	Methods of sampling and analuysis
	Feed Hygiene