THE FOLLOWING GIVES AN EXAMPLE OF THE STRUCTURE OF AN AUDIT PLAN AND A PRE-MISSION QUESTIONNAIRE.

STRUCTURES WILL VARY SIGNIFICANTLY AS THEY DEPEND ON THE LEGAL FRAMEWORK AND THE SCOPE OF THE AUDIT.

PLAN FOR THE AUDIT TO BE CARRIED OUT IN (COUNTRY) FROM (START DATE) TO (FINISH DATE) IN ORDER TO (TITLE OF AUDIT)

Note to the competent authority

This plan is designed to provide information on the objectives, scope, and organisation of the planned audit, and indicates the main areas that the audit team will wish to examine. It is intended to assist both national authorities and DG Health and Food Safety in the planning and preparation of the audit.
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ANNEX I: APPLICABLE EUROPEAN UNION STANDARDS
Audit plan

1. **OBJECTIVES OF THE AUDIT**
   
   Objectives specific to the audit concerned.

2. **LEGAL BASIS FOR THE AUDIT**
   
   The audit will be carried out under the general provisions of European Union (EU) legislation. Legislation specific to the audit concerned.
   
   Annex I comprises a full list of EU legislation relevant to the objectives of this audit.

3. **AUDIT SCOPE**
   
   The audit will address the ability of the competent authorities to deliver the required standards and will cover the following sector (specific to the audit concerned).
   
   The audit team will also examine the implementation of controls on (specific to the audit concerned) The audit will be conducted through data and document review, interviews with officials and, where appropriate, other parties concerned, and system verifications on-the-spot.

4. **PREPARATION AND ORGANISATION OF THE AUDIT**
   
   The audit will take place from (start) to (finish).

4.1. Preliminary information required for the audit
   
   In order to assist in the effective preparation and execution of the audit, the information requested in the attached questionnaire should be made available as soon as possible, preferably before (audit specific date). It would be greatly appreciated if this information could be provided in English.

4.2. Availability of competent authority representatives
   
   The audit team should be accompanied throughout the audit by a representative of the central competent authority. In addition, the availability of representatives of the relevant (sub)departments during this period should be assured. The competent authorities are also advised that during the visits to premises (e.g. establishments, farms etc), the regional/local authority official responsible for carrying out official controls on these premises should be present, and that the relevant control records should be available for inspection by the audit team.
4.3. **Meetings and sites to be visited**

A suitable itinerary should be prepared, covering the following points:

**For example:**

- An **opening meeting** and a **closing meeting** between the audit team and your services including the competent authorities responsible for: *(Audit specific)*

- **Visits to:**
  - Laboratories;
  - Regional/local authority offices;
  - Various food or feed business operators *(Audit specific)*;
  - Importers/Exporters *(Audit specific)*
  - Distributors of veterinary medicinal products *(Audit specific)*
  - Etc.

The table below is intended as a **guide** for the competent authorities to assist them in drawing up the itinerary:

<table>
<thead>
<tr>
<th>EXAMPLE</th>
<th>Meeting/Visit</th>
</tr>
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<tbody>
<tr>
<td>AM</td>
<td></td>
</tr>
<tr>
<td>Sun</td>
<td>Arrival of audit team, preparation of audit team</td>
</tr>
<tr>
<td>Mon</td>
<td>Day 1 Opening meeting with CCAs</td>
</tr>
<tr>
<td>Tue</td>
<td>Day 2 Laboratory 1 Regional competent authority x</td>
</tr>
<tr>
<td>Wed</td>
<td>Day 3 Food business operator 1 Food business operator 2</td>
</tr>
<tr>
<td>Thu</td>
<td>Day 4 Food business operator 3 Importer/Exporter</td>
</tr>
<tr>
<td>Fri</td>
<td>Regional competent authority y Closing meeting</td>
</tr>
<tr>
<td>Sat</td>
<td>Departure of audit team</td>
</tr>
</tbody>
</table>

The timetable above is only a suggestion of how the audit could be scheduled in order to cover all of the relevant areas within nine working days. The competent authorities do not need to follow this precise model but should ensure that the relevant sites are included in the itinerary.

The proposed itinerary should be e-mailed to the lead auditor at: *(specific e-mail address)* as soon as possible, preferably before *(date)*, in order to facilitate the practical arrangements for the audit. It would be helpful if when drawing up the itinerary, that estimated travel times could be indicated.

Please note that the audit team may need to modify the proposed itinerary as a consequence of the response to the pre-audit questionnaire, or in light of further information received.

5. **Language to be used during the audit**

The language to be used during the course of the audit will be English. *(Interpreters depending on the language of the country and if EU Member State or Non-EU countries)*
6. **CONFIDENTIALITY REQUIREMENTS**

The finalised audit report will be made available to the European Parliament, Member States and consumers, subject to the provisions of Article 339 of the Treaty on the functioning of the European Union and in accordance with applicable DG Health and Food Safety procedures.

7. **PROCESSING AND DISTRIBUTION OF THE AUDIT REPORT**

The draft audit report will be produced within 20 working days of completion of the audit. The competent authority will receive a copy of the draft report for comment. Comments should be provided within 25 working days of receipt of the draft report. The report will be finalised after receipt of the competent authority comments.

8. **INFORMATION TO BE PROVIDED DURING THE OPENING MEETING**

The competent authority is invited to compile the relevant data and make concise and focussed presentations on the following areas (highlighting in particular amendments in the organisation and or procedures implemented after the last DG Health and Food Safety audit in *(year)* which will be discussed during the initial meeting.

- A presentation on the competent authority - focussing on its role (and the role of its subordinate departments) – in controlling:…… *(audit specific).*

- An explanation of the present **planning process** for official controls on…. (audit specific) throughout the organisation of the competent authority.

- Information on the **training** of official staff, carrying out official controls and the **written instructions** in place guaranteeing consistent performance in this respect.

- Information on the co-ordination role of the competent authority and its **supervision** of implementation of official controls on…. *(audit specific).*

- A description on how **information** is **transmitted** between the various actors of the competent authority *(audit specific).*
9. **APPENDIX: PRE-AUDIT QUESTIONNAIRE**

The following questions have been tailored to take into account information already held by DG Health and Food Safety on the functioning of ...(audit specific information) in (country audited). The competent authorities will also have an opportunity to provide supplementary information and an overview of the operation of these controls during the initial meeting (see point 8).

If the information requested in the following questions has not changed from that described in the Mission Report (No of audit) there is no need to provide a full response – simply refer to the relevant documents. Where changes have occurred (e.g. reorganisation, new legislation, new staff instructions etc), a full response is necessary.

### 9.1. ROLE OF THE COMPETENT AUTHORITY

#### 9.1.1. *For example: PLANNING OF OFFICIAL CONTROLS*

1. Please describe….

#### 9.1.2. *For example: IMPLEMENTATION OF OFFICIAL CONTROLS*

2. Please list all **written instructions** for staff …… Copies of these should be provided (preferably) electronically at the latest at the opening meeting.

3. Please provide an overview on relevant training provided to staff (the overview should include: date of training, duration, scope covered, number of participants, evaluation of effectiveness of the training provided).

4. Please explain the reason(s) for …….1.

#### 9.1.3. *For example: FOLLOW-UP INVESTIGATIONS, ADMINISTRATIVE AND LEGAL SANCTIONS, FURTHER SAMPLING ETC.*

5. Are there **written instructions** for staff responsible for carrying out investigations when non-compliant results have been found …… Copies of these instructions should be provided at the opening meeting.

6. 

### 9.2. For example: LABORATORIES

7. In order to enable the audit team to clearly evaluate the competence and capability of each of the residue laboratories involved in the national residue monitoring plan, please provide the following information………..

8. 

9. 

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Pre-audit questionnaire Page 1
9.3. *(OTHER AUDIT SPECIFIC TOPICS)*

9.3.1. *(OTHER AUDIT SPECIFIC TOPICS)*

<p>| | |</p>
<table>
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<tbody>
<tr>
<td><strong>10.</strong></td>
<td>Please provide information on….</td>
</tr>
<tr>
<td><strong>11.</strong></td>
<td></td>
</tr>
</tbody>
</table>
**Audits by the Commission Services**


**Food Law**


*(Other audit specific legislation)*