OVERVIEW REPORT OF A SERIES OF AUDITS IN MEMBER STATES

IN ORDER TO ASSESS THE OFFICIAL CONTROL SYSTEMS IN PLACE FOR FOOD HYGIENE (within the meaning of Regulation (EC) No 852/2004), TRACEABILITY, LABELLING AND BOTTLED WATER
EXECUTIVE SUMMARY

This is an overview report on a series of audits undertaken between 2007 and 2010 by the European Commission’s Food and Veterinary Office (FVO). The series consisted of 25 audits to Member States (MSs) to assess the official control systems in place for food hygiene for food of non-animal origin and composite products at all stages of processing and distribution, as well as food of animal origin at retail level and evaluate the implementation of the EU legislation in the area of traceability, labelling and bottled water in particular the recognition procedure of natural mineral water sources and official control of bottled water for human consumption. The reports on these audits are available on http://ec.europa.eu/food/fvo/ir_search_en.cfm. This report presents an overview of the main issues of interest and concern common to some or all individual reports.

Competent authorities (CAs) within the scope of the audit were designated but a lack of co-ordination within and between CAs was frequently observed.

- Official controls in the area of food hygiene have been implemented in all visited MSs and the inspections confirmed that inspectors were confident in assessing prerequisites for hygiene. However, in relation to the assessment of Hazard Analysis and Critical Control Points (HACCP) considerable weaknesses were encountered in most MSs. In addition, the level of implementation of procedures based on HACCP principles was relatively low and a lack of adequate training at all levels of the CAs was observed particularly in relation to assessment of HACCP and labelling. An enhanced effort to improve the understanding of HACCP principles and their assessment is essential to ensure an effective implementation of HACCP.

- In relation to Natural Mineral Waters (NMW) most MSs complied fully with EU legislation. Where discrepancies were noted, they were generally minor and did not necessarily pose immediate food safety risks.

- With regard to the control of labelling by inspectors, two areas of weakness were noted; the correct control of the labelling of allergens and NMW. In particular, inspectors lacked detailed knowledge on the labelling requirements of allergens.

- Attendance at the Better Training for Safer Food (BTSF) courses was highly regarded and sought after. However, with very few places available per MS, the training was often undertaken by managerial staff at central and regional level and the subsequent cascade training did not necessarily filter through to operational inspectors at the local level.

- Where appropriate recommendations aimed at corrective measures are being pursued with the MSs concerned.
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<td>Better Training For Safer Food</td>
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<td>CA(s)</td>
<td>Competent Authority(ies)</td>
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<td>DG (SANCO)</td>
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<td>FBO</td>
<td>Food Business Operator</td>
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<td>FNAO</td>
<td>Food of Non-Animal Origin</td>
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<td>GHP</td>
<td>Good Hygiene Practice</td>
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<td>GMP</td>
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<td>ISO</td>
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<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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1. **INTRODUCTION**

This series of audits was undertaken from 2007 to 2010 by the Food and Veterinary Office (FVO) of the European Commission's Directorate-General for Health and Consumers (SANCO). The series consisted of 25 audits to Member States (MSs) to assess the official control systems in place for food hygiene for food of non-animal origin and composite products at all stages of processing and distribution, as well as food of animal origin at retail level and evaluate the implementation of the EU legislation in the area of traceability, labelling and bottled water in particular the recognition procedure of natural mineral water sources and official control of bottled water for human consumption. Most audits were of one week and a half and usually consisted of a team of two inspectors and one national expert from a MS authority. The programme involved meetings with central and regional/local Competent Authorities (CA), visits to several food premises (typically one restaurant, two supermarkets, one natural mineral water (NMW) plant and one food producing company), and visits to official laboratories undertaking microbiological and NMW official analysis.

Reports on individual audits are available on SANCO's website: http://ec.europa.eu/food/fvo/index_en.htm

Details on specific reports (MS, audit references, dates and status of action plan) are available in Annex I.

2. **OBJECTIVES OF THE SERIES OF AUDITS**

The audits targeted food of non-animal origin (FNAO) and composite products at all stages of processing and distribution, as well as food of animal origin at retail level, to evaluate

- the implementation of Regulation (EC) No 852/2004 on the hygiene of foodstuffs and Regulation (EC) No 882/2004 on official controls;
- the implementation of EU legislation regarding the general principles and requirements of Article 18 of Regulation (EC) No 178/2002 regarding traceability;
- the implementation of Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;
- the transposition and implementation of Directive 54/2009/EC and Directive 98/83/EC, in particular the recognition procedure of NMW sources and official inspections and controls carried out in relation to bottled water for human consumption;
- the transposition and implementation of Directive 2000/13/EC relating to labelling, presentation and advertising of foodstuffs, in particular the implementation of provisions addressing the labelling of allergens.

3. **LEGAL BASIS FOR THE AUDITS**

The audits were carried out under the general provisions of EU legislation, in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.
A full list of the legal instruments referred to in this report is provided in the Annex II and refers, where applicable, to the last amended version.

4. BACKGROUND

4.1. Summary of previous FVO audit series results

A previous series of audits was carried out to 25 MSs from June 2004 to October 2005 with the objective of evaluating EU legislation on controls on the hygiene of foodstuffs. These audits also evaluated certain aspects of the veterinary legislation, in so far as they were applicable to butchers shops.

The overview report of this series of audits is available on the Directorate-General Health and Consumers (DG SANCO) Internet site at:

http://ec.europa.eu/food/fvo/specialreports/index_en.htm

5. FINDINGS AND CONCLUSIONS

5.1. Legislation

Findings

In all MSs the CAs stated that all relevant EU legislation in the context of these audit has been transposed into national legislation.

Nine MSs have additional legislation in place regarding microbiological standards, four MSs have set up national temperature control limits, and six MSs have in place national legislation on NMW. In six MSs there is additional national legislation concerning food hygiene requirements for retailers or catering. In two cases there is national legislation for the direct supply by the producer of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer. Four MSs applied national or regional rules for sampling; in one case national legislation provides the framework for dealing with food borne epidemics.

In all MSs there are nominated CAs responsible for transposition and publication of relevant legislation.

Conclusions

The relevant EU legislation in the context of the series of audits is transposed. Legislation is made available to the public. In some MSs, there is additional national or regional legislation in force in the context of this audit series.
5.2. Competent Authorities

5.2.1. Designation of Competent Authorities

Legal Requirements

Article 4(1) of Regulation (EC) No 882/2004 requires MS(s) to designate the CA responsible for official controls.

Findings

All MSs visited have official services designated with responsibility for official control of the hygiene of foodstuffs within the scope of this series of audits.

There are three organisational levels in the majority of MSs; central, regional and local. The central level is mainly responsible for policy making, preparation of legislation and co-ordination of the regional levels. The regional level is principally responsible for coordination of the local level, auditing and training. The local level is in general responsible for enforcement of legislation.

This structure differs in nine MSs, where there are only two organisational levels, where the central level has the same role as above and the local or regional level is enforcing the legislation. In two MSs, there are four levels of organisation – federal, state, regional and local. The role of the federal level is policy making, legislation, risk assessment and the state level has the responsibility for preparation of legislation and co-ordination of regional level. The responsibilities of regional and local level are similar to 3 levels systems.

The number of authorities involved in the official control systems varies between one and six. Typically the Ministry of Health or the Ministry of Agriculture had the primary responsibility. In ten MSs there are independent Food Authorities or Agencies established, with the main role of co-ordination of official control activities and risk assessment.

Conclusions

All MSs have designated the competent authorities in the context of this series of audits as required by Article 4(1) of Regulation (EC) No 882/2004. Organisational structures vary significantly between MSs, reflecting different administrative cultures. There is no "one-size fits-all" structure.

5.2.2. Co-operation between and within Competent Authorities

Legal Requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination and co-operation between CAs.

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a CA, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.
Findings

Cooperation within and between CAs is essential to ensure that the whole food chain is covered and controls are effectively implemented.

In 16 out of 23 MSs where competence is shared between different CAs, the cooperation between them is provided by written or oral agreements. In seven MSs, there are coordination groups or bodies established, tasked with the coordination of official controls, the preparation of coordinated plans and new legislation.

In 15 MSs there are regular meetings organised between CAs at the central level. The frequency of such meetings varies between once a year to once a month.

In six MSs overlaps were identified in the activities of CAs in the context of food hygiene and in the FVO’s reports recommendations were given to improve coordination between the CAs involved in official controls. The problems in coordination in seven MSs concern lack of exchange of information and non coordinated control activities of different CAs.

In eleven MSs regular meetings are organised within the CAs, with the frequency ranging between once a year to twice a month. In the majority of the MSs, there is an ad hoc exchange of information within the CA, by means of intranet, letters, phone and e-mails. The exchange of information concerns the RASFF, complaints, instructions and guidelines. In one MS problems were identified in the cooperation within one CA.

Conclusions

There are significant differences between MSs in the approach towards co-operation within and between CAs.

There are generally adequate procedures established for the horizontal and vertical coordination, however these are not always followed by the CAs at various levels.

5.3. Resources and performance of controls

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and that there is an obligation on FBOs to undergo inspection by the CAs. Article 8 of the above Regulation requires that CAs have the necessary powers of access to food business premises and documentation.

Findings

In all visited MSs there are provisions in place to ensure legal powers to carry out official controls, including powers for inspectors to gain entry to establishments and access to FBO's documentation.

Conclusions
Legal provisions are in place to ensure that CAs have the necessary legal powers to carry out controls in all visited MSs as required by Articles 4 and 8 of Regulation (EC) No 882/2004.

5.3.1. Staffing provision and facilities, staff qualification, and training

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the CA to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Article 6 of Regulation (EC) No 882/2004 requires that CAs ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Findings

In all MSs the CAs have access to a suitably qualified staff, in six MSs the CAs stated that there are some shortages in the number of staff.

In all visited MSs provisions were in place to ensure that staff performing controls are free of any conflict of interest.

In all visited MSs appropriate and properly maintained facilities are available to CAs, but in four MSs, shortage of equipment was identified in particular calibrated thermometers.

In 13 MSs insufficient training was identified. The FVO audits noted that the most frequent training needs were in the assessment of the procedures based on Hazard Analysis Critical Control Points (HACCP) principles (10 MSs). Some staff from the central level participated in the SANCO program Better Training for Safer Food (BTSF) on HACCP. However the cascade transmission of knowledge to colleagues not attending courses was insufficient. In two MSs, insufficiencies were noted in training on NMW, traceability and food hygiene. In one MS training needs were identified to improve expertise on labelling.

Conclusions

Legal and administrative provisions in all visited MSs are in place to ensure that CAs have access to suitable qualified staff, free of any conflict of interest.

In a minority of MSs staff shortages were identified by the CAs.

Not all CAs in visited MSs have appropriate equipment available as required by Article 4 of Regulation (EC) No 882/2004.

The training received by the CA's staff in some MSs was insufficient in particular assessment of the procedures based on HACCP principles, labelling, traceability, food hygiene and NMW.
5.4. Organisation and implementation of official controls

5.4.1. Registration of food business operators

Legal Requirements

Article 31 of Regulation (EC) No 882/2004 requires MS to establish procedures for the registration/approval of food and feed business operators, for reviewing compliance with conditions of registration and for the withdrawal of approvals.

Findings

In all visited MSs, FBOs are required to register their food business establishments with the appropriate CA (central or local level). There was only one MS where such a system was not in operation at the time of FVO audit.

In seven MSs, FBOs are obliged to undergo an approval procedure (issuing the certificate on the basis of on the spot visit). In two MSs, approval procedure is obligatory only for wholesale or retail facilities.

In another seven MSs the CAs are responsible for registering or approving the facilities on the basis of on the spot visits. If deemed necessary, an inspection is conducted before completion of registration in two MSs.

Conclusions

In all visited MSs with exception of one there are provisions in place for registration of FBOs as required by Article 6 of Regulation (EC) No 852/2004. These provisions differ substantially between MSs.

5.4.2. Prioritisation of official controls

Legal Requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. Controls shall be carried out at any of the stages of the production and processing chain and, in general, are to be carried out without prior warning. Controls shall be applied with the same care to exports from the EU, imports into the EU and to product placed on the EU market.

Findings

Normally, official control plans are developed at the central level and are implemented at the local level. The frequency of inspections is based on a risk categorisation of food premises and on the FBO’s past records in 19 MSs. In these MSs controls are performed regularly. In six MSs the officials controls are not carried out regularly and are not risk based. In one of them officials controls are planned according to the number of staff available for controls. In five MSs the controls are not planned for some types of facilities such as butcher shops, NMW production and facilities with lower risk. The planned frequency of official controls
varies between four times per year up to one in 16 years. In two MSs the planned frequency of controls was not achieved.

In five MSs the audit team was informed that official controls are not announced, in one MS inspections are usually announced in advance. In eight MSs only audits or controls focused on HACCP are announced.

**Conclusions**

The frequency of controls is risk based and takes into account the results of previous controls in most of the MSs. The majority of MSs achieved their planned targets, but in others the frequency of controls is inadequate.

Generally controls are unannounced; however in some MSs the audits or official controls of procedures based on HACCP principles are announced.

5.4.3. *Sampling and official control laboratories*

**Legal Requirements**

Article 10.1 of Regulation (EC) No 882/2004 requires that tasks related to official controls shall, in general, be carried out using appropriate control methods and techniques such as among others, sampling.

Article 11.1 of Regulation (EC) No 882/2004 requires that sampling methods used in the context of official controls shall comply, in principle, with relevant EU rules.

Article 3 of Regulation (EC) No 2073/2005 requires FBOs to ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I to the same Regulation.

Article 1 of Regulation (EC) No 2073/2005 requires the CAs to verify compliance with the implementing rules and microbiological criteria laid down in this Regulation in accordance with Regulation (EC) No 882/2004.

Article 4(2)(c) of Regulation (EC) No 882/2004 requires CAs to ensure that they have access to an adequate laboratory capacity.

Article 11 of Regulation (EC) No 882/2004 requires that sampling and analysis methods used in the context of official controls shall comply with relevant EU rules.

Article 12 of Regulation (EC) No 882/2004 requires CAs to designate laboratories that may carry out the analysis of samples taken during official controls.

**Findings**

In all visited MSs plans are in place to verify microbiological criteria set-out in EU legislation. Sampling is one of the control methods used. In 14 MSs, guidelines are used for official sampling. In one MS, two different versions of the same guideline are used leading to inconsistencies. In two MSs, there are no guidelines developed for sampling.
Sampling for official control was observed in each visited MS. In four MSs the method of the sampling and delivery to the laboratory did not ensure the microbiological integrity of the sample for the laboratory analysis.

In 19 visited MSs, there were procedures in place to ensure that FBOs obtained sufficient numbers of samples for supplementary opinion. In three MSs, there was no such procedure in place.

In all visited MSs designated laboratories were carrying out the analysis of official samples. In all MSs, the CAs had access to adequate laboratory capacity with one exception that had no laboratory for testing allergens in foodstuffs. In the majority of visited MSs the laboratories were accredited to ISO EN 17025.

In 14 MSs, the method of analysis used complied fully with the relevant EU rules. In seven MSs, deficiencies were identified in the method of analysis, in particular the measurement of uncertainty and the sample temperature, method used for NMW analysis, quality management system, and the method used for the determination of Bacillus cereus and reporting results. In 18 MSs, the laboratories participated in proficiency tests with good results, in one MS visited the laboratory did not participate in any inter-laboratory comparison.

**Conclusions**

In all visited MSs, sampling is one of the official control methods; in some MSs the sampling method was not appropriate.

All visited MSs have designated laboratories for the majority of the requirements laid down in EU legislation in the scope of food hygiene. Some laboratories were not accredited and some used methods that did not comply with relevant EU rules.

5.4.4. *Procedures for performance and reporting of control activities*

**Legal Requirements**

Article 8 of Regulation (EC) No 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 of the above Regulation requires competent authorities to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

**Findings**

Documented procedures for official controls have been developed in 25 MSs, however, in one MS these guidelines were not available to inspectors. In three MSs some procedures are missing in particular for assessment of procedures based on HACCP principles, labelling and NMW.
After each official control a report is drawn up and a copy is provided to the FBO concerned in 15 MSs. In 3 MSs, such report is drawn up only when non-compliances are reported and in one case when non-compliances are significant.

Conclusions

In the majority of MSs there are procedures for official controls developed and used. In some MSs procedures do not cover all control methods as required by Annex II, Chapter II of Regulation (EC) 882/2004.

Generally procedures are in place for drawing up reports at least in the case of non-compliances in all visited MSs.

5.5. Enforcement measures

5.5.1. Measures in the case of non-compliance and sanctions

Legal Requirements

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

Article 55 of Regulation (EC) No 882/2004 states that MSs shall lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Findings

All visited MSs have sufficient powers to enforce compliance with relevant legislation. When a non compliance is identified the CAs have a number of measures in place such as prohibition of activities, withdrawal or destruction of the products, suspension of FBO's activities. These measures are mainly imposed by CAs, only in one MS were these measures implemented through the courts. However in one MS, measures did not cover infringements in relation to Article 5 of Regulation (EC) No 852/2004. In two MSs, the legal basis for measures in case of infringement to Regulations (EC) 882/2004 and 852/2004 has not been amended yet.

In all visited MSs, there are legal provisions in place to impose the sanctions for infringements in connection with food hygiene. In 21 MSs, the sanction is imposed by the CA, in six MSs, by the court or prosecutor. In two MSs, penalties could be imposed by CA or by the court depending on the type of infringement.

Conclusions

In all visited MSs there are, in the context of this series of audits, legal provisions in place which provide for a range of measures in the event of non compliance as required by Articles 54 and 55 of Regulation (EC) No 882/2004. Some MSs were not in line with the current EU legislation.
5.6. Verification of official controls

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the CAs to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective actions and to update documentation where needed.

Findings

In 20 MSs there are procedures in place regarding verification of the effectiveness of official controls carried out. On the spot visits are used for verification in 14 MSs. In two MSs, such visits are done on the basis of the results of documentary checks. In 9 MSs documentary checks are done to verify the quality of official controls. In two MSs, the CAs stated that there are no such procedures in place. In two MSs these procedures are not applied to controls carried out by municipalities, in one MS due to inadequate legal powers for such verification. In four MSs, there is an incomplete system of verification applied e.g. verification is not performed in certain CAs or not at all levels (central / regional) of a CA, or FNAO is not covered.

In 21 MSs there are audit systems in place. However fully operational systems are only in place in 5 MSs, the remainder having incomplete systems. The systems are in a very preliminary stage in 5 MSs, in the rest of the visited MSs each level of CAs is not covered or does not cover each CA, or is focused only on food of animal origin.

Conclusions

There are functional systems in several visited MSs in place to verify the quality and effectiveness of official controls.

There are audit systems in place; however the system is complete and fully operational in only a few MSs.

5.7. Recognition of natural mineral waters

Legal Requirements

Directive 2009/54/EC relating to the exploitation and marketing of NMWs (recast of the Council Directive 80/777/EEC) concerns waters extracted from the ground of a MS and recognized by the responsible authority of that MS as NMWs satisfying the provisions of Annex I, Section I. This Directive also concerns waters extracted from the ground of a TC, imported into the EU and recognized as NMWs by the responsible authority of a MS.
Findings

The procedures for the official recognition of NMWs were clearly established in the visited MSs. In all cases official recognitions were reported to the Commission.

The non compliances detected relating to the recognition of NMWs included; incomplete laboratory analysis e.g. failure to test the level of dry residues at 260°C, analysis for cyanide and incorrect volume used for testing for absence of pathogens, map used for geological and hydrological surveys of the catchment area with the scale higher than required by legislation and incorrect labelling.

Conclusions

Mechanisms for the official recognition of NMWs are well established in the visited MSs and the Commission is informed when such recognitions are granted.

5.8. General hygiene requirements

Legal Requirements

Article 4.2 of Regulation (EC) No 852/2004 requires that FBO carrying out any stage of production, processing and distribution of food subsequent to the primary production and those associated operations shall comply with the general hygiene requirements laid down in Annex II to the same Regulation.

Article 10.2.c of Regulation (EC) No 882/2004 requires that official controls on food shall include, inter alia, the checks on the hygiene conditions in food businesses.

Findings

Overall the hygiene inspections observed in restaurants, supermarkets and industrial sites were undertaken to a high standard with inspectors being well trained and equipped and making appropriate use of check lists.

The main shortcomings observed were due to the inspector(s) not always having appropriate equipment (thermometers) during the inspection or being appropriately equipped but failing to verify the FBOs temperature records with the inspectors' calibrated thermometers.

Conclusions

The official hygiene inspections of food establishments observed are of a high standard but had some shortcomings mainly in relation to verification of temperature records.
5.9. Hazard Analysis and Critical Control Points

Legal Requirements

Article 5.1 of Regulation (EC) No 852/2004 requires that FBOs shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

Article 5.2.g of Regulation (EC) No 852/2004 requires that the HACCP principles shall consist, among other things, of establishing documentation and records commensurate to the nature and the size of the food business.

Article 5.5 of Regulation (EC) No 852/2004 allows the adoption of arrangements to facilitate the implementation of the HACCP requirements by certain food business operators. These include the use of guides for the application of HACCP principles.

Article 10.2.d of Regulation (EC) No 882/2004 requires that official controls on food shall include, inter alia, the assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP) and HACCP, taking into account the use of guides established in accordance with EU legislation.

Findings

The level of implementation of a permanent procedure or procedures based on the HACCP principles by FBOs was variable. But the following trend could be applied to the majority of MSs visited. The larger FBOs e.g. industrial manufacturers and processors tended to have full HACCP systems in place. The majority of smaller FBOs had difficulties with implementation of HACCP based principles and frequently did not fully understand the concepts of critical control points, corrective actions and the documentation requirements for record keeping. Frequently inspectors did not fully comprehend the difference between prerequisites and HACCP. In addition inspectors did not always understand and apply the concept of the flexible approach to HACCP provided for under current EU legislation when assessing smaller establishments.

The non-compliances observed were mainly concerned with inspectors not having sufficient knowledge to assess systems based on HACCP principles. Consequently whether or not the HACCP system was appropriate for the FBO was rarely evaluated in the inspections observed.

Conclusions

A considerable number of non compliances were observed in relation to the assessment of HACCP by inspectors. There is a low level of implementation of HACCP based principles by small FBOs. Flexibility provisions in relation to HACCP for smaller establishments is poorly understood.
5.10. Guides to Good Hygiene Practice

Legal Requirements

Article 7 of Regulation (EC) No 852/2004 requires that MSs shall encourage the development of national guides to GHP and for the application of HACCP principles in accordance with Article 8. Article 8 of the same Regulation requires MSs to assess national guides and forward to the Commission national guides complying with the requirements of this Article.

Article 10.2d of Regulation (EC) No 882/2004 requires that official controls on food shall include, inter alia, the assessment of procedures on GMP, GHP and HACCP, taking into account the use of guides established in accordance with EU legislation.

Findings

More than half the MSs had prepared and implemented GHPs in an appropriate manner. However, in five instances the old legislation was still being used, in one case the country had failed to notify the Commission about their guides. There were two instances of guides being available but FBOs not being aware of them or failing to use them. In other cases the problems detected were a combination of failing to prepare GHPs or inspectors failing to ask if they were in use as part of the inspection approach.

Conclusions

Some significant shortcomings were observed in relation to the availability and use of approved guides to GHP as required by Article 7 of Regulation (EC) No 852/2004.

5.11. Traceability and labelling

Legal Requirements

Article 18 of Regulation (EC) No 178/2002 requires that the traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

Article 6 of Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs requires that ingredients shall be listed in accordance with this Article and Annexes I, II, III and IIIa.

Findings

Traceability difficulties were detected in three MSs and were associated with failing to check for documentary evidence to confirm the supply chain. It was noted that nine MSs did not control labelling correctly. In two MSs incorrect labelling of NMWs was noted and five MSs failed to check that the presence of allergens was appropriately labelled.
Conclusions
Non compliances in labelling were observed, particularly in relation to allergens and NMWs.

6. RECOMMENDATIONS

To Member State authorities

The following is a list of the main recommendations made to MSs. The number of MSs with the related recommendation is indicated in brackets.

1) Ensure that HACCP systems are fully assessed by CAs as required by Article 10.2(d) of Regulation (EC) No 882/2004 (13x)

2) Ensure that all guides to GHP comply with the requirements of Article 8 of Regulation (EC) No 852/2004 (10x)

3) Ensure that staff performing official controls receive appropriate training as required in Article 6 and Annex II to Regulation (EC) No 882/2004 (8x)

4) Ensure that official controls are carried out with appropriate frequency following the requirements of Article 3(1) of Regulation (EC) No 882/2004 (8x)

5) Ensure that all designated laboratories are accredited to EN ISO 17025 as required by Article 12(2) of Regulation (EC) No 882/2004 (7x)

6) Ensure that labelling is fully assessed by CAs as required by Article 10.2(b) of Regulation (EC) No 882/2004 (7x)

7) Ensure that the MANCP contains all information as required by Article 42(2) of Regulation (EC) No 882/2004 (7x)

8) Ensure that CAs have appropriate and properly maintained equipment as required by Article 4(2)(d) of Regulation (EC) No 882/2004 (6x)

9) Ensure that the recognition procedure for NMWs fully follows the requirements of Annex I to Directive 2009/54/EC (6x)

10) Ensure that a sufficient number of staff is available in order to carry out official controls with appropriate frequency as required by Article 3 of Regulation (EC) No 882/2004 (5x)

11) Ensure efficient and effective coordination between all CAs involved in official controls on food according to Article 4(3) of Regulation (EC) No 882/2004 (5x)

12) Ensure that contingency plans comply with Article 4(2)(f) and 13 of Regulation (EC) No 882/2004 (5x)
13) Ensure that the method of sampling used in the context of official controls ensures the microbiological integrity for the laboratory analysis according Article 11(7) of Regulation (EC) No 882/2004 (5x)

14) Ensure that audits are carried out and that they meet all the requirements of Article 4(6) of Regulation (EC) No 882/2004 (5x)

7. **ACTION TAKEN BY COMMISSION SERVICES**

7.1. **Follow-up of audit recommendations**

For each audit a copy of the final report was sent to the national CAs with a request for an action plan indicating the steps envisaged to address the report’s recommendations.

A deadline was set for the receipt of these plans and the response of the CAs was analysed. Where it was considered that a response did not address the issues raised, the Commission’s services actively pursued the matter with the authorities concerned. The vast majority of issues raised by the FVO were adequately addressed by the CAs.

8. **OVERALL CONCLUSIONS**

Competent authorities (CAs) within the scope of the audit were adequately designated but a lack of co-ordination within and between CAs was frequently observed.

Official controls in the area of food hygiene have been implemented in all visited MSs and the inspections observed confirmed that inspectors were competent in assessing prerequisites for hygiene. However, in relation to the assessment of Hazard Analysis and Critical Control Points (HACCP) considerable weaknesses were encountered in most MSs. In addition, the level of implementation of HACCP principles was relatively low and a lack of adequate training at all levels of the CAs was observed particularly in relation to HACCP and labelling. An enhanced effort to improve the understanding of HACCP principles and their assessment is essential to ensure effective implementation of HACCP.

In relation to Natural Mineral Water (NMW) most MSs had complied fully with EU legislation. Where discrepancies were noted, they were generally minor and did not pose immediate food safety risks.

With regards to the control of labelling by inspectors, two areas of weakness were noted; the correct control of the labelling of allergens and NMW. In particular, inspectors lacked detailed knowledge on the labelling requirements of allergens.

Attendance at the Better Training for Safer Food (BTSF) courses was highly regarded and sought after. The training was often undertaken by managerial staff at central and regional level and the subsequent cascade training was not always filtering through to operational inspectors at the local level.
## ANNEX I

### DETAILS OF AUDITS UNDERTAKEN

<table>
<thead>
<tr>
<th>Audit reference number</th>
<th>Member State</th>
<th>Dates of audit</th>
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## ANNEX II

### Table of legislation

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