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GENERAL REPORT OF A MISSION SERIES
CARRIED OUT IN
SIX MEMBER STATES
IN THE PERIOD NOVEMBER 2009 TO MARCH 2010
IN ORDER TO GATHER INFORMATION REGARDING THE APPLICATION OF THE
HYGIENE REGULATIONS IN SMALL ESTABLISHMENTS PRODUCING MEAT AND MEAT
PRODUCTS OF MAMMALS AND DAIRY PRODUCTS

EXECUTIVE SUMMARY

These missions took place from November 2009 to March 2010 and formed part of a fact-finding mission series to six Member States (MS):

- *to collect information concerning the implementation of the Regulations (EC) No 178/2002, No 852/2004, No 853/2004, and No 854/2004 in small establishments¹;*
- *to review any special measures taken by the Competent Authorities (CA) to provide flexibility in the implementation of some of this legislation for small establishments, in particular in relation to structures, layout, equipment, operational practices, Food Business Operator's (FBO) obligations and their controls; and*
- *to identify within the context of these measures, "best practices" with a view to their wider dissemination.*

Based on the information collected during these six missions the following can be concluded:

The level of application of flexibility measures was very different in the six MS visited: whereas for example the United Kingdom, Austria and Germany had made use of many flexibility provisions other MS such as the Czech Republic had only made very limited use of flexibility measures.

In some cases the CCA has provided guidelines for application of national measures to its authorities. In other MS it was solely left to the local authorities to apply flexibility at local level using the provisions already provided in the Hygiene Regulations without adoption of additional national measures.

Also within MS the flexibility measures applied were different between the regions and the CCA was not always aware about the details of the flexibility measures applied in all parts of the MS.

The majority of provisions in place relate to the meat sector (structure, equipment, official supervision, microbiological testing). In the dairy sector flexibility was mainly applied in relation to food products with traditional characteristics and food businesses that were situated in regions subject to geographical constraints (mountainous areas).

Notification of flexibility was not consistently applied and not all draft national measures/national measures had been notified or informed of as required.

The documentation of the application of flexibility measures in individual establishments did not in all cases allow for verification on-the spot.

In some MS visited the measures provided for seem to go beyond the provisions currently foreseen in the Hygiene Regulations.

In a number of other areas where flexibility could provide ad-hoc solutions in small capacity establishments the CA have so far not taken any action. The result was, however, that in small establishments visited which could not benefit from flexibility measures non-compliance was more frequent.

This overview report identifies best practice and makes recommendations of a wider nature to the MS.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
CA	Competent Authority (ies)
CCA	Central Competent Authority
DG SANCO	Health and Consumers Directorate General
EU	European Union
FBO	Food Business Operator
FVO	Food and Veterinary Office
HACCP	Hazard Analysis and Critical Control Points
Hygiene Regulations	Regulation (EC) No 852/2004, No 853/2004 and No 854/2004
MS	Member State(s)
OV	Official Veterinarian
SCC	Somatic cell count
SH	Slaughterhouse
TPC	Total plate count

1. INTRODUCTION

The missions took place from November 2009 to March 2010. The six Member States (MS) visited were Austria, the Czech Republic, Finland, Germany, the United Kingdom and Spain. An overview of the individual missions is provided in the following table:

Country visited	Mission dates
Germany	1 to 5 March 2010
United Kingdom	8 to 12 February 2010
Spain	1 to 5 February 2010
Austria	18 to 22 January 2010
Finland	18 to 22 January 2010
Czech Republic	30 November to 4 December 2009

The missions were undertaken as part of the Food and Veterinary Office's (FVO) planned mission programme.

The mission teams were in all cases accompanied throughout the missions by representatives of the Central Competent Authorities (CCA) of each MS and if applicable by the relevant regional and local competent authorities. National Experts of the MS involved in this series of fact-finding missions accompanied the mission teams on each of the missions.

2. OBJECTIVES OF THE MISSIONS

The objectives of the missions were:

- to collect information concerning the implementation of the Regulations (EC) No 178/2002, No 852/2004, No 853/2004 and No 854/2004 in small establishments¹;
- to review any special measures taken by the CA to provide flexibility in the implementation of Regulations (EC) No 852/2004, No 853/2004, No 854/2004 and No 2074/2005 in small establishments, in particular in relation to structures, layout, equipment, operational practices, FBO's obligations and their controls; and
- to identify within the context of these measures, "best practices" with a view to their wider dissemination.

In particular, production of meat of domestic ungulates, farmed game, wild game, minced meat, meat preparations, mechanically separated meat, meat products raw milk and dairy products in the framework of Regulations (EC) No 852/2004, No 853/2004, No 854/2004, and (EC) No 1162/2009 were subject to this evaluation.

¹ "Small establishments" mainly comprised establishments that were allowed before 1 January 2006 to place food of animal origin on the national market (slaughterhouses, cutting plants, meat product establishments) but also small slaughterhouses and establishments producing minced meat and meat preparations in small quantities (Chapter 3.2. of Regulation (EC) No 2073/2005) and milk-processing establishments with a low throughput. It could however also be establishments using traditional methods or being situated in regions that are subject to special geographic constraints (Article 10 of Regulation (EC) No 853/2005). The decisive criterion was however not the size or throughput of the establishment but whether the competent authority had decided to apply flexibility.

3. LEGAL BASIS FOR THE MISSIONS

The missions were carried out in agreement with the Competent Authorities involved and under the general provisions of Community legislation.

A full list of the legal instruments referred to in this report is provided in Annex I. Legal acts quoted in this report refer, where applicable, to the last amended version.

4. BACKGROUND

The Hygiene Regulations allows the CA to take national measures to provide flexibility for the implementation of this legislation, in particular in relation to structures, layout, equipment operational practices, FBO's obligations and their controls.

In agreement with the MS, the FVO carried out a series of fact-finding missions in six MS on the implementation of flexibility measures. In this mission series attention was paid to small establishments as competent authorities and stakeholders had highlighted that the implementation of Regulations (EC) No 852/2004, No 853/2004 and No 854/2004 was particularly demanding for small establishments.

5. FINDINGS

5.1. National measures in relation to flexibility

The national measures were introduced through Regulations, Ordinances, Decrees, administrative Regulations, guidelines issued by the CAs and guidelines issued by professional organisations.

Some CA have issued guidance documents – directed towards FBO or official control staff to introduce and explain flexibility measures and provide guidance for official controls.

5.1.1. Notifications

The majority of the MS visited had not notified one or more national measures as required and also in relation to national measures for food with traditional characteristics (simple information) cases were seen where no information about the national measure had been notified to other MS and to the Commission services.

In relation to national measures requiring notification prior to adoption of these measures it could be seen that national measures introduced through law were usually notified whereas national measures that were only contained in national implementing provisions or guidelines occasionally were not notified.

5.1.2. Activities excluded from the scope of Regulation (EC) No 853/2004

Four of the six MS visited have established national rules in legislation or guidelines in relation to Articles 1.4 and 1.5 of Regulation (EC) No 853/2004. Mainly these rules are related to:

- direct supply by the producer of small quantities of primary products, and by hunters of small quantities of game, to the final consumer or local retail establishments directly supplying the final consumer;
- the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail

establishments directly supplying such meat to the final consumer as fresh meat;

- hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.

Some MS, such as Germany or Austria have defined 'small quantities of meat from poultry and lagomorphs' or 'small quantities of wild game or wild game' whereas for example the United Kingdom have not defined the quantities that can be produced under the national rule. Likewise some MS have defined the term 'local retail establishment' or have provided a definition of 'marginal, localised and restricted'.

Moreover additional precisions concerning Article 1.5, point b(ii) of Regulation (EC) No 853/2004 were introduced by defining what constitutes a 'retail establishment' or 'supplying other retail establishments'.

5.1.3. National measures

A wide range of national measures – mainly adaptations of the Annex to Regulations (EC) No 852/2004, 853/2004 and 854/2004 are available in the six MS visited.

The most widely used national measures relate to the adaptation of requirements on the construction, layout and equipment of establishments.

Flexibility for (small capacity) slaughterhouses (SHs) in relation to:

- the availability of a lairage,
- the availability of a separate sick pen,
- a separate place for cleaning of live animal transporters on the spot,
- a separate chiller for confiscated meat, carcasses and animal by-products,
- general exemptions permitting separation in time of activities in abattoirs such as the slaughter of different species, clean and dirty operations including the emptying and cleaning of green offal,
- separation in time of activities is allowed when constant progress of the product cannot take place in cutting and processing facilities,
- use of the same room for the different slaughter operations and/or cutting provided the activities are separated in time,
- a locker for the official veterinarian (OV) instead of separate facilities,
- provisions for the use of common shared facilities between officials and the FBOs,
- the storage of cleaning agents and disinfectants in a lockable cupboard,
- less stringent requirements allowing the use of facilities such as lavatories and changing rooms outside of approved food establishments,
- exemptions for the refrigerated storage of packaged and exposed meat together
- use of alternative procedures when loading or unloading facilities are absent,
- utilisation of simple hand wash and boot wash facilities instead of hygiene lobbies between changing rooms and food handling areas,
- the use of wooden surfaces such as cutting blocks as food contact surfaces,
- the use of alternative procedures for restraining animals when the layout of the lairage does not facilitate ante-mortem and identification of the animals,
- absence of adequate surface drainage of the cutting room floor, if protection of exposed meat from contamination by drainage and wash water can be ensured by alternative

means.

Flexibility for dairy establishments in relation to:

- use of copper vats for cheese coagulation or use of non-corrosion resistant material for surfaces or equipment if it can be ensured that the food products are not affected negatively;
- use of alternative heat-treatment methods if it can be ensured that the heat-treated milk and milk products fulfil the food safety requirements of Regulation (EC) No 2073/2005.

The CAs in the Czech Republic, Germany, United Kingdom and in particular Austria have defined throughout of establishments and/or species for which these national measures can be applied.

Flexibility provisions pursuant to Article 7 of Regulation (EC) No 2074/2005 for FBOs producing food products with traditional characteristics were used in four MS visited in relation to:

- manufacturing of traditionally dried reindeer meat,
- use of rooms with tiles or porous natural stone in walls, ceilings and floor or other natural material in the floor,
- use of natural caves or stone cellars for ripening of milk products,
- use of equipment made of wood for smoking of naturally fermented raw sausages and raw smoked meat products,
- use of copper vats, equipment made of wood, and of wrapping material made of natural fibres or other material of plant origin in the production, storage and wrapping of milk products,
- use of non-corrosion resistant material for surfaces or equipment if it can be ensured that the food products are not affected negatively.

Flexibility measures to accommodate the needs of food businesses situated in regions that are subject to special geographic constraints:

In one MS flexibility is provided for FBOs producing cheese with a ripening time of more than 60 days in mountainous areas (in *the Alms*). The flexibility provisions cover the use of hand wash basins, ducting of drainage, and testing method of raw milk for somatic cell counts (SCC) and Total Plate Counts (TPC).

The guidelines for processing milk on the “*Alms*” in another MS allows the following possibilities for flexibility:

- absence of changing room (however, clean working clothes and shoes must be used);
- use of concrete as floor (although tiles are recommended);
- use of wood (walls, windows, doors) especially in cheese ripening rooms;
- use of wooden churns and other equipment for butter production, provided these can be sterilised with heat-treatment;
- use of copper for the cheese ripening vat;
- continuous temperature registration can be replaced by manual measurements.

Flexibility with regard to the implementation of procedures based on the HACCP principles in four of the visited MS

In one MS the mission team was informed that the main difficulties with the implementation of the Hygiene Regulations in small establishments was linked to the correct application of own checks and HACCP programmes.

The CAs had dealt with this mainly by promoting the drafting and use of generic guides by the industry and allowing for lighter requirements concerning HACCP documentation (e.g. registering only deviations and/or non-compliances).

Flexibility in implementing Hazard Analysis Critical Control Points (HACCP) principles by following guides of good hygiene practices including generic HACCP guidelines, establishing the HACCP team and reducing documentation and verification was provided for in the United Kingdom.

In Austria the following measures were introduced:

- It is not necessary for all types of establishments to have in place a programme based on HACCP. This can be replaced in some cases by good hygiene practices;
- The FBO does not have to include the sampling of water in the establishment into their own control programme, if the water used is from the public water network and the test results of the official water testing are available;
- It is sufficient that cleaning and disinfection of a SH is carried out according to a plan and that the success of these actions are controlled by the veterinarian or official auxiliary before the start of the next slaughter;
- The results of temperature monitoring in the framework of own controls have to be documented only if they deviate from the expected temperature range.

Flexibility with regard to the implementation of Regulation (EC) No 2073/2005:

- Several MS had introduced national measures with regard to implementation of microbiological controls. In one MS, less stringent requirements for the carcass testing in smaller SHs were set up, e.g. sampling of 5 bovine carcasses once every 4 weeks if slaughtering less than 20 000 per year, once every 12 weeks if slaughtering less than 7 500, once every year if slaughtering less than 1 500 and no sampling required if slaughtering less than 500 (the limits for pigs, sheep and goats are 5 times higher).
- Another MS provided for a derogation for low throughput establishments producing less than 2 tonnes of minced meat and meat preparations per week provides for the exemption from microbiological sampling.
- In one region of another MS the CA is authorising reduced sampling frequencies for carcass sampling in small SHs (defined as slaughtering approximately up to 1000 heads of bovine/year, or equivalent for other species) and small meat preparations and minced meat establishments (defined as processing approximately up to 260 tonnes/year).

The reduced frequency would be authorised if sampling results had been satisfactory or adequate. For small SHs the reduced frequency would result in a carcass sampling frequency of once every 2 months. For small meat preparations and minced meat establishments the reduced frequency would mean a sampling of once every month. This authorisation requires annual renewal.

- In another MS, scope for flexibility is available under national law and in relation to bacteriological sampling programmes.

Flexibility in relation to official controls was noted in five MS visited and comprised the following measures:

- Flexibility in relation to the presence of an OV during ante-mortem and slaughter of

farmed even-toed game in establishments with a low throughput (establishments which do not slaughter or kill, or supply for slaughter more than 50 animals annually). Meat derived from such animals shall be labelled with a special round stamp.

- The guidance document is targeted at the CAs responsible for the establishment supervisions and audits and comprises flexibility rules in relation to the HACCP principles, depending on which risk category the FBO belongs to.
- The OV or the official auxiliary do not have to be permanently present during slaughter in establishments that have permanent slaughter premises, if during the ante-mortem examination no unusual observations were made and it is ensured that all parts of the carcass are subjected to a post-mortem examination and these parts can be allotted to the respective carcasses. However, the post-mortem examination must always be carried out within 6 hours of the slaughter of the first animal and ended within 3 hours of the slaughter of the last animal. Official auxiliaries, who were authorised to carry out post-mortem and meat examinations before 1 January 2006 are entitled to carry out the final slaughter and meat examinations, if no abnormalities have been detected during ante- and post-mortem examinations. The OV must make the final decision in relation to slaughter and meat examination should abnormalities be detected.
- Flexibility in relation to official controls for slaughter of farmed game, if the farmed game meat is produced only for direct sale or for local retail shops, to be sold further for the final consumer and the animal keeper has a contract which ensures that the holding is under veterinary supervision. In this case the head of the regional CA can authorise that the ante-mortem control is replaced by the control carried out and documented by the animal keeper, provided he has been properly trained (the training must also be documented); the animals on the holding have been inspected during the previous 28 days by an OV and during this inspection no signs of abnormalities are detected which could cause the meat to be unfit for human consumption; the holding is not subject to restrictions in relation to infectious animal diseases; and the post-mortem controls are carried out by the CA within 3 hours of the slaughter of the last animal. The authorisation can be withdrawn if it is noted during the official controls that the requirements are not adhered to. The authorisation must be in writing.
- A general exemption, delegated to each OV is provided from the requirement in Regulation (EC) No 854/2004, Annex I, Section I, Chapter II, D, 3 to require carcasses of domestic swine over 4 weeks old to be submitted for post-mortem inspection split lengthways into half carcasses down the spinal column.
- A draft proposal foresees partial evisceration (for kids and lambs still being milk fed, piglets, rabbits, some poultry and small game).
- The authorities in one MS have developed a guideline, referring to "cold inspection" in red meat SHs and providing flexibility measures in relation to Regulation (EC) No 854/2004. This guideline allows for the absence of the OVs during the dressing procedures and for the post-mortem inspection to be delayed and being performed "cold" at a later stage. This has not been notified to the Commission and the MS.
- In one MS seeking approval as a region presenting negligible risk of *Trichinella*, *Trichinella* testing is only required on samples collected from breeding sows and boars. The authorities continue to test all breeding sows, boars, horses and feral wild boar processed in approved establishments. This is not a formal derogation or national measure adopted by legislation already implemented although the case for approval as a region presenting negligible risk of *Trichinella* is not completed. *Trichinella* testing of wild boars from the hunters' supply of small quantities of wild game or wild game meat directly to the final consumer or local retail establishments directly supplying the final consumer is voluntary.

- Sale of reindeer meat not subject to ante-mortem or post-mortem inspection directly to the final consumer.

Flexibility in relation to temperature requirements for meat and milk

Flexibility is provided in one MS in relation to minced meat (point 1. (a), Chapter III, Section V of Annex III to Regulation (EC) No 853/2004). The flexibility provision allows the production of minced meat of pork origin from not cooled pig carcasses and pork meat, provided the minced meat is placed on the market within four hours of production, is provided only for direct sale for the final consumer or to local retail establishments directly supplying such meat to the final consumer. The latter derogation applies only to certain districts in the MS.

Specifications in relation to the implementation of the Hygiene Package in MS included several derogations:

- One MS has introduced the possibility to deviate from the 2°C cooling requirement for minced meat, which has been produced in the country and is targeted only for direct consumption or local retail. The maximum temperature limit for such meat is 4°C.
- In another MS, one proposal relating to the transport temperature of foodstuffs has been implemented.

Flexibility in relation to the restrictions in time for the use of meat

The following possibility for flexibility covering the meat sector was documented at the level of guidelines in one MS:

- A derogation allows the use of fresh meat from animals other than poultry for a longer period instead of within the no more than 6 days of their slaughter (Regulation (EC) No 853/2004, Annex III, Section V, Chapter III, 2(b)(ii)).

5.1.4. National Rules

National rules in relation to Article 10.8 (a) of Regulation (EC) No 853/2004 restricting or prohibiting the placing on the market of raw milk or raw cream intended for direct human consumption were seen in several MS visited. These rules usually restrict the sale of raw milk or raw cream.

Flexibility is provided in one MS by establishing a national derogation provided for in Article 13 (5) of Directive 2000/13/EC and Annex III, Section IX, Chapter V, paragraph 2. of Regulation (EC) No 853/2004 in relation to the labelling requirement for milk and milk products in reusable glass bottles.

Another MS has established national rules which specifies the requirements concerning:

- emergency slaughter and the corresponding “Local” special health mark; and
- for the use of milk not complying with the criteria of Annex III, Section IX of Regulation (EC) No 853/2004 as regards plate count and somatic cell count for production of cheeses with ripening period of at least 60 days (Article 10.8 (b) of Regulation (EC) No 853/2004).
- slaughter and placing on the market of meat from bull fighting animals is regulated by Royal Decree 260/2002, which also prescribes a characteristic health mark and it must be sold only as fresh meat and cannot be converted into meat products, or meat

preparations or minced meat.

One regional CA indicated that its understanding of Article 4 of Regulation (EC) No 852/2004 implied that the sampling plans prescribed by Regulation (EC) No 2073/2005 should be applied also to retail butcher shops that produce minced meat and/or meat preparations.

5.1.5. National measures possibly affecting the achievement of the objectives of the Hygiene Regulations

A number of national measures have been introduced which possibly affect the achievement of the objectives of the Hygiene Regulations. Examples seen include:

- Sale of uninspected wild game meat to the final consumer,
- Voluntary testing for Trichinella in wild boar,
- 'Cold inspection',
- Absence of carcass sampling or reduced carcass sampling,
- Reduced/absent microbiological sampling in minced meat,
- HACCP replaced by GHP.

5.2. On-the-spot-visits

In each of the six MS the mission team visited about six small establishments with approvals as red meat establishments (slaughterhouses, cutting plants, meat products plants, game processing establishments) and milk-processing establishments.

The establishments had been chosen by the CAs as examples of establishments where provisions providing flexibility under the Hygiene Regulations were in application.

5.2.1. Approvals

The CA in the MS visited handled the approval and documentation of flexibility measures at the level of individual establishments differently.

In one MS, the local authority documented for each individual establishment which flexibility provisions were applied in the approval file.

In another MS, the authorities stated that for small establishments the flexibility rules as provided for at guideline level do not need to be specified in the approval documents. The establishments can automatically benefit from these derogations, whereas derogations granted based on national legislation will be specified in the approval.

In other cases no provisions existed that the use of national measures need to be documented for each individual establishment in the relevant establishment file.

5.2.2. Use of flexibility rules in the establishments visited

The most commonly used flexibility measures in the establishments visited are listed below:

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- replacement of HACCP by good hygiene practices; in some areas the relevant documentation was very limited or non-existent (for example, documentation on cleaning and disinfection of equipment or on pest control, documentation on

- temperature checks of chillers),
- the level of detail of HACCP-based own-check programmes,
- a lighter microbiological sampling programme for final products.

Slaughterhouses, cutting plants and meat processing establishments as applicable:

Commonly applied

- the absence of a lairage or waiting pen,
- absence of a sick pen in the lairage,
- the absence of a facility for the cleaning and disinfection of livestock transport vehicles,
- the absence of a designated chilling room for detained carcasses or meat,
- the changing rooms and toilets not adjacent to the slaughter/cutting/processing premises,
- direct access to production rooms from the outside,
- separation in time for different activities in cutting and meat processing and authorisation of slaughter operations in one identical physical place.

Occasionally applied

- the absence of a room for the OV,
- flexibility was applied for cleaning and disinfection of equipment (use of immersion coil instead of steriliser),
- absence of a gut room,
- presentation of porcine carcasses that are not split for post-mortem inspection,
- not performing Trichinella testing in integrated production of fattening pigs,
- absence/reduction of microbiological sampling of carcasses and minced meat, meat preparations and meat products in low throughput SH and other meat establishments,
- "cold inspection" in red meat SHs, allowing for the absence of the OVs and auxiliaries during the dressing procedures and for the post-mortem inspection to be delayed and being performed "cold" at a later stage,
- documentation of temperature measurements only when deviations of the allowed temperature range occurred.

Dairy establishments:

- separation of different activities in time, for example use of a common room for cutting, wrapping, vacuuming and packing cheeses with a time separation of the activities,
- structure of cheese maturing facilities (i.e. use of wooden shelves, walls porous),
- in relation to the HACCP principles,
- authorisation of an alternative temperature/time relation for transport of raw milk for cheese production due to technological reasons,
- alternative protective measures taken when progressing work flows are not possible,
- authorisation to share equipment between the dairy plant and the restaurant attached.

5.2.3. Compliance issues which could have been addressed through flexibility measures

During the visits in the establishments the mission team identified some compliance issues in different areas which could have been addressed appropriately by providing flexibility to small establishments relating to:

General

- separation between retail and EU-eligible activities,
- separation in time of different activities carried out in the same place,
- the availability of changing rooms and a hygiene barrier at the entry to the facilities,
- the access from changing rooms to working rooms,
- storage of cleaning and disinfection equipment,
- temperature registration,
- the requirement to establish HACCP-based procedures,
- documentation of own controls,
- sampling programme in relation to potable water.

Slaughterhouses, cutting plants and meat processing establishments as applicable

- the housing of live animals before being slaughtered,
- carrying out all dressing operations in the same place,
- carrying out post-mortem examination after the carcass is cut in quarters,
- correct temperature of the meat during cutting and the temperature in the cutting rooms,
- freezing of meat after maturation,
- the exit of the meat from the establishments in the absence of docking facilities,
- the storage of animal by-products,
- the location of SHs within the perimeter of a farm/animal holding.

Dairy establishments:

- double testing of raw milk for antibiotics – in the first establishment and in the second where the raw milk was however only processed after the result from the first establishment became available,
- antibiotic testing of the milk processed in a dairy establishment using only the milk from its own farm.

Establishments and their operations showed more deficiencies where national measures for flexibility were not available. This became obvious in the Czech Republic where both CCA and regional authorities stated that they would find it difficult to provide for flexibility in relation to equipment, operational practices, FBOs' obligations or their controls now as they have had to be quite strict during the upgrading process preceding the accession to the EU.

5.3. Implementation of hygiene rules in the establishments

The establishments visited in the six MS visited had in general adequate facilities, structures, equipment and operational hygiene.

Nevertheless shortcomings were noted in some establishments, mainly in relation to inadequate maintenance, poor cleaning and disinfection of the premises and equipment and insufficient pest control.

Occasionally due to lack of space several activities took place in the same room without clear separation in time, also exposed raw meat and wrapped/packed products were stored close to each other and contamination of exposed product could not be excluded.

Condensation due to insufficient ventilation was seen. Slaughter hygiene was not satisfactory in individual cases and carcasses were contaminated with faeces. Carcasses were not sufficiently cooled.

Regular observations were made in relation to HACCP programmes:

- HACCP did not cover all production or had not been updated to cover current production.
- In the implementation of HACCP programs occasionally no documentation could be shown to adequately demonstrate good control over the milk pasteurisation parameters, likewise other documentation in relation to the control of critical control points was not complete or absent.
- In several cases, microbiological sampling of products or carcasses was not in line with the provisions of Regulation (EC) No 2073/2005:
 - The microbiological sampling of pig carcasses in one SH visited covered only Salmonella.
 - The sampling frequency of carcasses was based on guidelines of the Association of Butchers and depended on the throughput. Establishments which slaughter less than 20 pigs or bovines annually should have analyses of five carcasses a year for aerob mesophilic bacteria, enterobacteriaceae and salmonella.
 - Labelling of products (beef labelling), traceability and identification marking was not correctly implemented, in particular in establishments that performed approved activities as well as non-approved activities. The identification mark was occasionally used on production which was not approved but for example destined for a restaurant/canteen or for direct sale to the final consumer.
 - The CCA stated that if the establishment receive potable water from the public water network, it is sufficient to receive the water analysis in the network. According to the guidelines established by the CAs it is not necessary to take official samples from the establishment net.
 - One facility was seen during this mission round where the flexibility measures provided led to hygiene implications: the facility had received a national derogation for de-hiding, post-mortem examinations and cooling outside of an EU-approved game processing establishment. The facility consisted of one single large room. All the operations were carried out without proper separation (physical or time), and satisfactory guarantees in relation to hygiene could not be provided.
 - In one other case the establishment had not updated HACCP based procedures when modifying the production to raw milk products.

Shortcomings were pointed out on-the-spot and CAs were asked to address them individually with the FBOs.

6. BEST PRACTICES

In light of the practical implementation of flexibility measures in the six MS visited the following best practices could be seen:

- Notification of national measures (including national measures introduced through guidelines) done correctly in line with the provisions of the Hygiene Regulations.
- The national measures implemented to not affect the achievement of the objectives of the Hygiene Regulations.
- National measures are introduced where required in order to avoid that in particular small establishments are non compliant with the provisions of the Hygiene Regulations, suffer from economic investments which are not necessary to achieve the objectives of the Hygiene Regulations or prevent closure of establishments because CA do not provide for flexibility.
- The national measures that are availed of are documented in the approval file of the establishment or the official file and the CA are fully aware of the individual flexibility measures granted.
- The FBO and CA receive guidance on what flexibility measures are available at national level – both in relation to requirements in establishments and in relation to official controls.
- In a few MS the situation in some small establishments - taking into account flexibility measures - was particularly outstanding, for example, in one sheep SH visited, the mission team found excellent facilities, very small but with a suitable layout perfectly adapted to the throughput of the establishment. The level of maintenance and cleanliness was very high and the FBO was extremely motivated.

7. MEMBER STATES PROPOSALS

The CAs and the organisations representing the different FBOs met expressed the following concerns and needs for possible flexibility rules in relation to:

Cattle living semi-wild

- To apply a derogation for dangerous cattle living semi-wild so that it could be categorised as farmed game, as it is sometimes not possible to transport these animals to a SH in a way that would ensure the safety and welfare of the animals and the staff handling them.

Laboratories for trichina analysis

- Some CA were of the opinion that the requirement to accredit all laboratories analysing trichina samples according to ISO 17025 was too costly and suggested that other means of quality control would suffice to guarantee the validity of the testing (for example obligatory participation in proficiency testing, training etc).

Farmed game, wild game

- Flexibility should be allowed in relation to the requirements to have an OV carrying out the ante-mortem examination of farmed game within 24 hours before slaughter and to have an OV present during slaughter of farmed game;
- To permit the use of plant staff in game handling establishments to carry out the post-mortem inspection in line with the possibilities provided for in the white meat sector;

- Flexibility should be allowed in relation to the obligation that evisceration of farmed game can only take place at the place of origin and only in the presence of a veterinarian (point 3 (h) of Section III, Annex III to Regulation (EC) No 853/2004), as delayed evisceration might endanger the hygienic quality of the carcass;
- One FBO handling farmed and wild game meat emphasised that flexibility arrangements in relation to OV controls on farmed game should not limit the sale of such farmed game to domestic market only as this limitation would hamper the livelihood of some establishments which currently trade with other Member States.

Minced meat

- An organisation representing the red meat small establishment sector stated that the requirement to chill minced meat to 2°C is creating problems to some FBOs and that 4°C upper limit would be sufficient.

Trichinella examination

- A risk assessment should be carried out of the risks associated with visual meat inspection of pigs that have been reared outdoors. The background for the suggestion is that the SH in the MS concerned receive different batches (outdoor/ indoor) during the same slaughter day making the effective redeployment of officials difficult.

Traceability

- In one MS the organisation representing the red meat small establishment sector stated that there is sometimes a problem when the FBO would like to return meat and meat products from his/her own retail shop to the approved establishment as they cannot be returned if the traceability cannot be guaranteed (the packages have been opened).

The Commission services undertook to review these proposals and discuss them with MS as appropriate.

8. OVERALL CONCLUSIONS

The level of application of flexibility measures was very different in the six MS visited: for example whereas the United Kingdom, Austria and Germany had made use of many flexibility provisions other MS such as the Czech Republic had only made very limited use of flexibility measures.

In some cases the CCA has provided guidelines for application of national measures to its authorities. In other MS it was solely left to the local authorities to apply flexibility at local level using the provisions already provided in the Hygiene Regulations without adoption of additional national measures.

Also within MS the flexibility measures applied were different between the regions and the CCA was not always aware of the details of the flexibility measures applied in all parts of the MS.

The majority of provisions in place relate to the meat sector (structure, equipment, official supervision, microbiological testing). In the dairy sector flexibility was mainly applied in relation to food products with traditional characteristics and food businesses that were situated in regions subject to geographical constraints (mountainous areas).

Notification of flexibility was not consistently applied and not all draft national measures/national measures had been notified or informed of as required.

The documentation of the application of flexibility measures in individual establishments did not, in all cases, allow for verification on-the spot.

In some MS visited the measures provided for seem to go beyond the provisions currently foreseen in the Hygiene Regulations. However, there were very few cases where flexibility as applied could lead to possible health risks.

In a number of other areas where flexibility could provide ad-hoc solutions in small establishments the CA have so far not taken any action. The result was, however, that in the small establishments visited, which could not benefit from flexibility measures, non-compliance was more frequent. In particular in the MS visited that had acceded to the EU some years ago, CA find it difficult to provide for flexibility now, whereas CA had to be strict during the upgrading of establishments pre-accession.

9. RECOMMENDATIONS

The following recommendations of a wider nature are made, with a view to addressing the issues arising from this round of fact-finding missions:

1. To introduce flexibility measures more widely and to encourage their implementation.
2. To notify national measures as required.
3. To provide guidance to all levels of the competent authorities, in particular the CA in charge of approval and supervision of establishments.
4. To document in the establishment approval file or in official documents the flexibility granted to individual establishments.
5. To ensure that the objectives of the Hygiene Regulations are achieved despite implementation of flexibility measures, in particular in relation to implementation of microbiological criteria such as food safety and process hygiene criteria and post-mortem inspection.

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
Reg. 1162/2009	OJ L 314, 1.12.2009, p. 10-12	Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 2075/2005	OJ L 338, 22.12.2005, p. 60-82	Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for Trichinella in meat
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	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
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

Legal Reference	Official Journal	Title
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	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