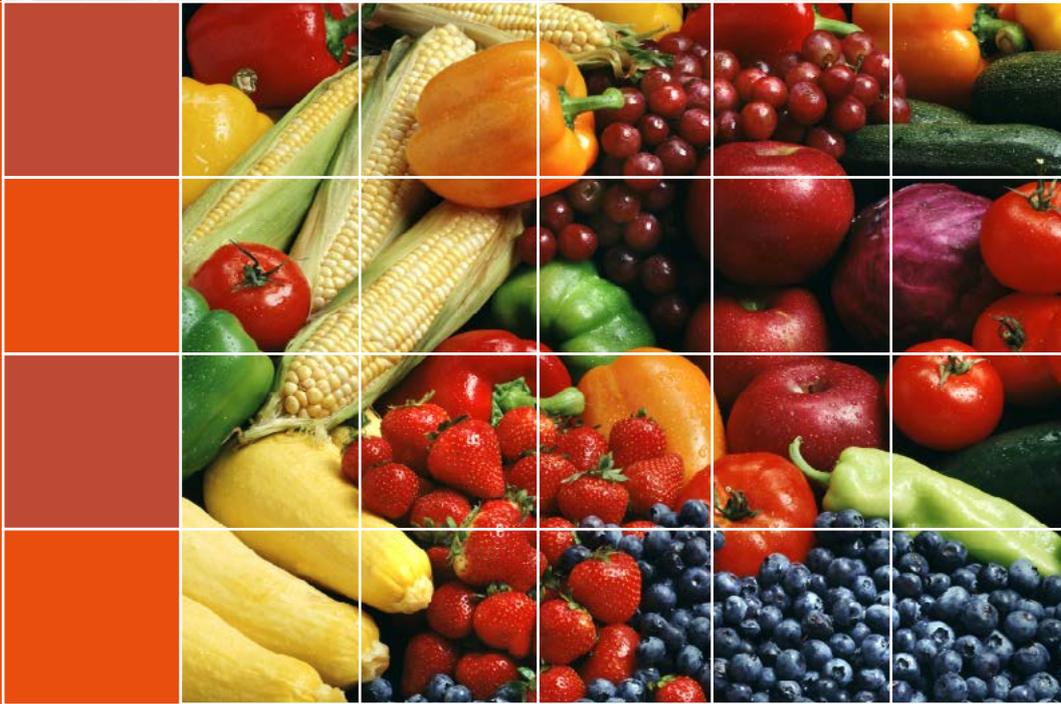




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Food and
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OVERVIEW REPORT

Better HACCP implementation

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**FINAL OVERVIEW REPORT REPORT ON THE STATE OF IMPLEMENTATION OF
HACCP IN THE EU AND AREAS FOR IMPROVEMENT**

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Executive Summary

The principles of Hazard Analysis and Critical Control Points (HACCP) are present in a range of European legislation for food and feed which require food and feed business operators to put in place, implement and maintain a permanent safety management system based on HACCP principles.

The HACCP approach is science based and systematic, it identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool for establishing a control system to focus on prevention rather than relying mainly on end-product testing.

Previous assessments of the implementation of procedures based on the HACCP principles by the Food and Veterinary Office (FVO) were undertaken on a sector specific basis.

The HACCP project aimed to assess HACCP from a cross-sectoral perspective in order to get an overview of the state of implementation and control of procedures based on the HACCP principles across Member States and across sectors and to identify and exchange good practice and common approaches to addressing problems encountered.

The project comprised a series of fact-finding missions to nine Member States, a questionnaire to the competent authorities (CAs) in the non-visited Member States (19) and a stakeholder consultation.

There is general agreement on the importance and benefits of implementing Food and Feed safety management systems based on HACCP principles. The general experience of Food and Feed Business Operators with HACCP has been generally positive with some commonly raised issues.

The main findings of the project are as follows:

- *HACCP is fundamental to food safety management systems.*
- *In all Member States there is a reasonable level of implementation of HACCP-based procedures.*
- *National control systems check on the implementation of HACCP-based systems on an on-going basis.*
- *National frameworks for implementing HACCP-based systems vary between and within Member States leading to inconsistencies of interpretation and implementation.*
- *Some of the core concepts are not always understood, particularly by small FBOs, and are not applied in a consistent manner.*
- *Flexibility is the least understood HACCP concept and is inconsistently applied and evaluated. This is a particular issue in the feed sector.*
- *There is a demand from national CAs and from stakeholder organisations for improved Commission guidance, including examples, on core concepts, and in particular, on prerequisite requirements, hazard analysis, Critical Control Points,*

verification, validation, monitoring and flexible implementation.

- *More focused training for national control staff would contribute to greater consistency in controls and a more appropriate administrative burden for Small FBOs.*
- *There are gaps in the coverage of officially recognised guides developed by the industry for certain sectors.*
- *There is much common ground between official and stakeholder bodies on the main areas where improvements could be made. There is an eagerness to work together to resolve these difficulties for the benefit of all consumers in the EU and beyond.*

Some examples of good practice with the potential for transfer across Member States are described in the report. These demonstrate possible ways to effectively address the key issues.

The Commission consulted with Member State experts on the results of this project at a meeting in May 2015. A Roadmap for a better implementation of HACCP based procedures was developed at this meeting, to be implemented at EU level, by the Member States, by stakeholder organisations and by FBOs. It is envisaged that progress at each level can be achieved in parallel.

This overview report will also enable the FVO to devise an audit framework for use in future audits by the FVO of HACCP based systems.

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT	
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BE	Belgium
BTSF	Better Training for Safer Food
CA(s)	Competent Authority(ies)
CCP	Critical Control Point
CL	Critical Limit
CODEX	<i>Codex Alimentarius</i> Commission of the Food and Agriculture Organization of the United Nations and World Health Organization
CZ	Czech Republic
DE	Germany
DK	Denmark
EU	European Union
EU Guidance document	EU Guidance document on the implementation of procedures based on the HACCP principles, and facilitation of the implementation of HACCP principles in certain food businesses
FBO(s)	Food and Feed Business Operator(s)
FR	France
FVO	Food and Veterinary Office
FSMS	Food Safety Management System
GHP	Good Hygiene Practices
HACCP	Hazard Analysis and Critical Control Points
MS(s)	Member State(s)
NL	Netherlands
SFBB	Safer Food, Better Business
SI	Slovenia
UK	United Kingdom

1 BACKGROUND

1.1. Introduction

Previous assessments of the implementation of procedures based on the HACCP principles by the Food and Veterinary Office (FVO) were undertaken on a sector specific basis. This overview report relates to a project undertaken by the FVO in order to obtain an overview of the state of implementation and control of procedures based on the Hazard Analysis and Critical Control Points (HACCP) principles across Member States (MSs) and to identify and promote the exchange of good practices and common approaches to addressing difficulties encountered.

1.2. Objectives

The specific objectives of the project were to:

- Evaluate the official controls of procedures based on the HACCP principles
- Obtain overview of the state of implementation of procedures based on HACCP principles across MSs
- Identify good practices applied by Competent Authorities (CAs) for the assessment of procedures based on HACCP principles as a basis for:
 - Development of guidance documents and recommendations.
 - Training organised in the framework of Better Training for Safer Food (BTSF).
 - Development of a standard audit framework for use by the FVO in future audits of procedures based on HACCP principles.

1.3. Scope of the Project

The scope covered, in particular, the implementation of procedures based on the HACCP principles and looked specifically at official controls of the Food and Feed Business Operators (FBOs) involved in production, processing, packaging, distribution and import as well as retailers in food and feed sectors.

1.4. Methodology

In order to provide a cross sectoral overview of the current state of implementation, the project comprised a series of fact-finding missions to nine MSs, supplemented by a questionnaire to the 19 non-visited MSs and consultation with stakeholders. The project evaluated the implementation of applicable European Union (EU) legislation (see Annex II) and, where relevant, the use of relevant guidelines and standards.

The relevant EU Guidelines and Codes of Practice of the Codex Alimentarius Commission of the Food and Agriculture Organisation of the United Nations and World Health Organization (CODEX) are set out in Annex III.

1.4.1. Series of Fact-finding Missions

A pilot mission took place in Ireland in January 2014, followed in 2014 by fact-finding missions to a further eight MSs (Belgium, Czech Republic, Denmark, France, Germany, Netherlands, Slovenia and the United Kingdom). The purpose of these missions was to gather information on the spot.

1.4.2. Questionnaire to the Non-visited Member States

A questionnaire was sent to the 19 non-visited MSs. Responses to the questionnaire were received from 16 MSs (replies were not received from Greece, Italy and Luxembourg).

The purpose of this questionnaire was to supplement the information obtained in the mission series and to promote the exchange of good practice and common approaches to difficulties encountered.

1.4.3. Stakeholder Consultation

A questionnaire was sent to the 45 member organisations of the EU Advisory Group on the food chain and animal and plant health¹, representing farmers, the food and feed industry, retailers and consumer organisations in order to get their opinions on the implementation of HACCP based procedures and to collect comments and suggestions on implementation of these procedures.

Replies were received from the following 12 EU and 2 national stakeholder organisations:

- Association of Poultry Processors and Poultry Import and Export Trade in the European Countries
- Copa-Cogeca: European Farmers European Agri-Cooperatives
- Liaison Centre for the Meat Processing Industry in the European Union
- European Modern Restaurant Association
- European Representation of Retail, Wholesale and International Trade
- European Dairy Association
- The European Feed Manufacturers' Federation
- Food Service Europe
- FoodDrinkEurope
- Federation of Veterinarians of Europe
- The European Livestock And Meat Trades Union

¹ The Advisory Group ensures that the Commission's policies on food and feed safety take account of the opinions and needs of consumers, farmers, the food industry and retailers. It comprises 45 stakeholder organisations representing farmers, the food industry, retailers and consumer organisations

- The European Association of craft, small and medium-sized enterprises
- French confederation of butchers, charcutiers and caterers
- German Bakers' Confederation

2 HACCP – CONTEXT AND WHY IT IS FUNDAMENTAL TO FOOD AND FEED SAFETY

2.1 CONTEXT

HACCP is a science based and systematic approach to the identification of hazards and the assessment of related risks, the implementation of measures for their control and monitoring compliance with the set standards. HACCP is a tool to establish control systems based on a hazard analysis that focuses on prevention rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain. Its implementation should be guided by scientific evidence of risks to human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits: the application of HACCP can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The principles of HACCP are present in a range of European legislation for food and feed which require FBOs to put in place, implement and maintain a permanent procedure based on HACCP principles.

The HACCP system is part of a food safety management system (FSMS) to be implemented by producers of food and feed. Food and feed safety is the primary responsibility of the business operators. Safety may be ensured through a combination of:

- Prerequisite requirements covering premises, equipment, staff and environment to ensure good hygienic practices (e.g. cleaning and disinfection, safe water supply, personal hygiene, safe raw materials and food waste handling, maintenance of the cold chain, safe food handling including wrapping, packaging, storage and transport, appropriate heat treatment);
- Procedures based on HACCP principles which are intended to identify, monitor and control (prevent and take corrective action) in response to specific hazards.

The effectiveness of the HACCP procedures directly depends on the engagement of the management and the skills/experience of the staff responsible for implementation.

The specificity of procedures based on the HACCP principles to each FBO, can be considered at the same time to be strength and a potential weakness:

- A strength because it allows flexibility to adapt to each FBO taking into account the specific level of risk, the specific nature of its activity and the size of the production.

- A potential weakness because of the uncertainty about the correct application as there are no prescribed procedures that can be applied by every FBO.

2.2 CURRENT EU LEGAL REQUIREMENTS

2.2.1 Food

Article 5 of Regulation (EC) No. 852/2004² on the hygiene of foodstuffs requires that FBOs put in place, implement and maintain permanent procedure(s) based on the HACCP principles. This applies to FBOs carrying out production, processing and distribution of food at any stage of the food chain after primary production and associated activities.

Recital 15 of Regulation (EC) No. 852/2004 highlights the need to take into account the principles contained in the *Codex Alimentarius* and to provide flexibility in all situations including in Small FBOs, as follows:

(15) The HACCP requirements should take account of the principles contained in the Codex Alimentarius. They should provide sufficient flexibility to be applicable in all situations, including in small businesses. In particular, it is necessary to recognise that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points. Similarly, the requirement of establishing 'critical limits' does not imply that it is necessary to fix a numerical limit in every case. In addition, the requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses.

The Commission published a "*Guidance document on the implementation of procedures based on the HACCP principles, and facilitation of the implementation of HACCP principles in certain food businesses*". This guidance document provides examples of how HACCP principles can be applied in a flexible and simplified way and is available at:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

Article 7 and Article 9 of Regulation (EC) No. 852/2004 require that MSs encourage the development, dissemination and use of EU and national guides to good hygiene practices (GHP) and for the application of HACCP principles.

A listing of sector specific EU guides and the register of available national guides to GHP is available at:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/good_practice_en.htm

² Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)

2.2.2 Feed

Article 6 of Regulation (EC) No. 183/2005 laying down requirements for feed hygiene requires that feed business operators, other than primary producers and associated activities, shall put in place, implement and maintain a permanent written procedure or procedures based on HACCP principles.

Recital 15 of Regulation (EC) No. 183/2005 indicates that HACCP principles in feed production should take into account the principles contained in *Codex Alimentarius*, but should allow sufficient flexibility in all situations as follows:

(15) HACCP principles in feed production should take into account the principles contained in the Codex Alimentarius, but should allow sufficient flexibility in all situations. In certain feed business, it is not possible to identify critical control points and, in some cases, good practices can replace the monitoring of critical control points. Similarly, the requirement to establish 'critical limits', as set out in the Codex Alimentarius, does not require a numerical limit to be fixed in every case. The requirement to retain documents as set out in the same Code needs to be flexible to avoid undue burdens for very small businesses. It should be ensured that operations carried out by a feed business at the level of primary production of feed, including associated operations, as well as the mixing of feed with complementary feedingstuffs for the exclusive requirements of its own holding, are not obliged to follow the HACCP principles.

Article 20 of Regulation (EC) No. 183/2005 requires that the Commission shall encourage the development of EU guides to good practice for the application of HACCP principles, and, where necessary, MSs shall encourage the development of national guides.

A listing of sectoral guides is available at:

http://ec.europa.eu/food/food/animalnutrition/feedhygiene/guide_goodpractice_en.htm.

2.2.3 Official Controls

Article 3 of Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules requires, MSs to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency.

Article 4 of Regulation (EC) No. 854/2004 requires that the CA carries out official controls to verify the FBO's compliance with the requirements of Regulations (EC) No. 852/2004 and (EC) No. 853/2004.

2.3 PREVIOUS REVIEW OF HACCP

A Commission report (2009) to the European Parliament and to the Council³ (Report from the Commission to the Council and the European Parliament on the experience gained from the application of the hygiene Regulations (EC) No. 852/2004, (EC) No. 853/2004 and (EC) No. 854/2004 of the European Parliament and of the Council of 29 April 2004), identified certain difficulties with their implementation, including in relation to procedures based on the HACCP principles, particularly in small FBOs in most MSs. The main issues included the use of (unsuitable) generic plans not reflecting reality and the level of documentation required. Some stakeholders considered that MSs differed as regards the assessment of procedures based on the HACCP principles, while others indicated that the majority of CAs makes use of flexibility arrangements. The importance of simplified and practical guidance material for small businesses was underlined. The report also noted that record-keeping is perceived by some FBOs as an administrative burden.

Since 2009, the Commission developed two guidance documents on flexibility in general within the hygiene Regulations, including on HACCP, which can be found at:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/index_en.htm

In addition, the Commission supported a revision of the Codex General Principles of Food Hygiene and its Annex on HACCP (CAC/RCP 1-1969) so as to get international recognition on the flexibility for procedures based on the HACCP principles. It continues to encourage private stakeholders and CAs to correctly and proportionally implement and assess implementation of procedures based on HACCP principles.

2.4 BETTER TRAINING FOR SAFER FOOD (BTSF)

In order to help MS CAs in verifying the correct implementation by FBOs of procedures based on the HACCP principles, the Commission launched in 2006 a series of training courses. These comprised of two modules initially aimed at providing MS control staff with a good understanding on the one hand, of how food and feed business operators develop, implement and maintain HACCP-based systems, and on the other hand, how to audit such HACCP systems. This training was performed up to 2011 under this format. In 2012, it was decided to slightly modify the format of the courses. From then, the focus was on developing participants' ability to conduct audits to verify the correct implementation of HACCP-based systems. Since 2006 and up to 2013, more than 160 workshops have been organised on HACCP implementation and audit, gathering around 3200 participants mainly from MSs and candidate countries. In addition, 24 additional five-day training sessions covering relevant aspects applicable to controls to be carried out to verify compliance with general hygiene requirements and HACCP procedures put in place by food operators during the period 2014-2015.

³ http://ec.europa.eu/food/food/biosafety/hygienelegislation/docs/report_act_part1_en.pdf

In addition to the specific training on HACCP mentioned above, this topic was also part of the themes covered as part of training activities organised on the EU feed law framework. In order to address repeated demands from MSs regarding more focused activities on feed hygiene, a specific module for feed control staff was launched on EU feed hygiene rules and HACCP auditing in 2013. Six workshops in total were organised in this regards over the period 2013-14.

In addition to these routine training activities, an e-learning module focusing on basic aspects of HACCP-based systems is planned for release in 2015.

3 THE MAIN ISSUES EMERGING FROM THE PROJECT

This chapter summarises the main issues which emerged from the three strands of the project. In addition, for each of the key issues, it lists some examples of good practice which have been successfully developed, mainly by the CAs, and used by businesses to address most of the main difficulties encountered. These solutions may be transferable across MS and more details are given in Annex IV.

3.1 GENERAL VIEWS ON HACCP

The general experience of business operators with HACCP has been positive in most sectors. It is generally seen as an essential tool to facilitate businesses to meet their responsibility for food/feed safety. Implementation is linked to resources and consequently larger FBOs are more effective at implementing HACCP.

MSs have taken initiatives to improve the understanding of HACCP principles and of its usefulness as a tool to manage safety on a daily basis.

3.2 KEY ISSUE 1-LEGAL PROVISIONS AND GUIDES

The existing EU Guidance document, although widely consulted, was not seen as a source of definitive guidance on all concepts and is interpreted differently by CAs. Most stakeholder organisations consider that additional specific guidance, with clear examples, would be helpful.

There are various approaches to the definition of requirements for compliance with HACCP principles across the MSs. This includes national legislation, National Guides to GHP, developed by the industry and formally approved by the national authorities and other CA guidelines and instructions.

Some GHP Guides are not considered useful by Small FBOs, as they are regarded as being overly technical and complicated. The gaps in the existing Guides, such as identification of hazards other than microbiological, the use of flexibility and instructions geared at Small FBOs, are directly related to problems in their implementation and control.

In addition to producing guidance, some MSs have developed tools to help FBOs to either to develop their own procedures based on HACCP principles or to apply good hygiene practices appropriate to their businesses. Many guidelines focus on catering and retail, meat and dairy sectors. These guidelines have often been found by the Small FBOs to be useful, readable and targeted. In general, Guides which are made available free of charge have a higher chance of being used than those which have to be purchased.

Notwithstanding such initiatives taken by most MSs to improve the understanding of HACCP concepts, these remain unclear to some FBOs, particularly to Small FBOs.

Stakeholders indicated that overly complex guidelines can create difficulties for Small FBOs who may not have suitably trained personnel to develop a HACCP plan. In such situations, Small FBOs often use external consultants to develop a HACCP plan, with the risk that it may not reflect the specific requirements of each business. This could result in complicated HACCP plans which are not understood or seen as useful by the business. This was particularly evident in the catering sector and in other food sectors with a high staff turnover, language barriers and a large variety of products.

The following examples of good practice were selected because they address many of the difficulties encountered.

Some examples of good practice (For more details see Annex IV)

- Safe Catering Guide (IE)
- Safer Food, Better Business (UK)
- Cook safe (UK)
- My HACCP web tool (UK)
- 33 Guides to GHP (BE)

3.2.1 Conclusions

Certain HACCP concepts are not clearly understood by some CAs and businesses. This leads to inconsistencies in implementation and controls. Guides to GHPs do not exist for all sectors and in many cases where they have been developed, they may be overly complicated to be understood and used by Small FBOs.

There is a strong demand for more user-friendly guidelines on terminology and implementing arrangements with clear examples (including on hazard analysis and flexibility).

3.3 KEY ISSUE 2 - PREREQUISITES AND HACCP

Food hygiene is the result of the implementation of prerequisites and procedures based on the HACCP principles. The prerequisites provide the foundation for effective HACCP implementation and should be in place before a HACCP based procedure is established. These requirements are designed to control hazards in a general way and they are clearly prescribed in EU law. They may be further developed in guides to good practices established by the different food sectors.

There is a widespread lack of understanding on the part of both FBOs and CAs of the difference between prerequisites and HACCP and their respective roles. The main difficulties observed by MSs concerned the implementation of HACCP without a prerequisites being in place and the setting of Critical Control Points (CCPs) for hazards which should be controlled through the prerequisites. This demonstrated a lack of understanding that if a particular hazard could be controlled more appropriately through prerequisites, then it would not be necessary to set a CCP. Some MSs expressed concern that the incorrect use of the current CODEX decision tree⁴, could lead to some prerequisites being incorrectly categorised as CCP.

Examples were seen of excessive emphasis being placed by some control authorities on the HACCP part of Food Safety Management System (FSMS) with prerequisites being largely ignored. This is problematic as risks covered by prerequisites could potentially involve greater hazards. One MS stated that, in its experience, 50% of non-compliances emanated from problems with prerequisites.

Stakeholder feedback stressed the importance for businesses to implement basic prerequisites before HACCP, particularly as risks covered by prerequisites could involve greater hazards and there was a greater risk of “things going wrong”. Feedback also pointed out that properly implemented prerequisites could reduce the burden of a HACCP plan.

3.3.1 Conclusions

The lack of a clear understanding on the part of some CAs and businesses of the difference between prerequisites and HACCP and their respective role in ensuring food/feed safety undermines the implementation of suitable and effective HACCP-based systems and their control by CAs.

3.4 KEY ISSUE 3 – IMPLEMENTATION OF CERTAIN HACCP PRINCIPLES

The concept of HACCP is generally considered to be a useful tool to manage and understand the importance of food/feed hygiene and food/feed safety in a systematic way. The HACCP concept helps FBOs to evaluate and control different hazards, throughout the processing chain. The main issues to emerge concerning the implementation of HACCP principles relate to "hazard analysis", setting and monitoring of CCPs and "verification".

3.4.1 Hazard analysis

Identifying the hazards at a sufficient level of detail enables the identification of relevant and appropriate control measures. Section 1 of Annex I of the EU Guidance describes how to proceed with identifying any hazards that must be prevented, eliminated or reduced to acceptable levels.

Most MSs reported that businesses had difficulties with hazard analysis. There is a widespread lack of understanding of how to undertake a hazard analysis correctly and this process creates difficulties particularly for Small FBOs due to lack of available expertise. In many cases, the assessment of the likely occurrence of any hazard and the severity of their adverse health effects was not properly undertaken. In general, operators were better equipped to address microbiological hazards. However, hazard analysis of chemical hazards was either absent or only partially addressed, thus chemical hazards were frequently overlooked. New and emerging risks, particularly in the feed sector, were rarely considered.

Stakeholder feedback confirmed that the systematic methodology of hazard evaluation and HACCP had been very helpful to companies enabling them to focus on the significant hazards. The main difficulty faced by Small FBOs is the lack of qualified personnel to carry out the hazard analysis. This was a particular difficulty in cases where there was the lack of resources or willingness in certain food sectors to develop sector specific Guides to GHP. In such cases the operators may have to rely on other solutions (such as external consultants).

⁴ See Annex 1 of the GUIDANCE DOCUMENT- Implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses

The existing EU guidelines were seen to be too narrowly focused on microbiological hazards and do not provide sufficient guidance to address the problems associated with hazard analysis of other types of hazards.

Some MSs attempted to address these difficulties by developing guidance and other tools for business (see box below). One such initiative was taken by NL who produced a guideline on how to manage hazards in raw materials. It also allows companies to use food chain information to minimise the need for their own controls particularly for raw materials.

Some examples of good practice (For more details see Annex IV)

- Risk Plaza (NL)
- Flexibility for hazard analysis (DE)
- Hazard analysis tool (DK)

3.4.2 Critical Control Points (CCPs)

The EU Guidance document explains that critical limits at CCPs distinguish acceptability from unacceptability for the prevention, elimination or reduction of identified hazards. It indicates that it is essential to establish and implement effective monitoring procedures at CCPs. Section 2 of Annex I of the Guidance document describes how CCPs may be identified. An example of a decision tree is provided. Section 3 of the same Annex describes how each control measure associated with a CCP should give rise to the specification of critical limits.

MSs indicated that the concept of CCPs was widely misunderstood and their identification posed a difficulty for some businesses. In many cases, CCPs were determined using the Codex decision tree. However, in some situations, incorrect use of this tool led to incorrect identification of CCPs which resulted in more CCPs being identified for the HACCP plan than could be adequately managed. The problem is compounded by the inclusion of hazards which should be addressed as part of the prerequisites (see Key issue 2). Responding to the requirements of quality schemes may also result in an excessive number of CCPs as the focus of these may be on quality rather than safety aspects.

Setting valid critical limits for CCPs has also posed difficulties to the operators. In some cases, there is a lack of knowledge/competence in setting critical limits, these are not always validated. In general, critical limits were set based on values provided in literature, national legislation and Guides to GHP. Problems arise where such sources are not available and when dual or multi parameters, such as time and temperature, are required to achieve product safety. In some cases, a specific temperature is determined by the business without defining the holding time. This could lead to situations where the set CCPs did not enable the risks to be properly controlled.

Difficulties are encountered as regards monitoring arrangements for critical limits implemented by businesses, such as failure to determine an appropriate monitoring frequency and/or to implement the set frequency.

Stakeholder feedback highlighted uncertainties as to when exactly a CCP should be identified and whether the analysis should be based on a specific product or a product group. It was considered that specific guidance, with examples, would be useful to ensure that CCPs are correctly chosen.

Some examples of good practice (For more details see Annex IV)

- Flexibility for critical limits (IE)
- Flexibility for monitoring (CZ, DK, IE, NL)

3.4.3 Verification

The EU Guidance document explains that establishing procedures, which shall be carried out regularly, to verify that the measures outlined in the HACCP plan are working effectively, are an important part of each HACCP plan.

Difficulties encountered by some businesses with the concept of verification were raised by most MSs as a serious issue. These issues ranged from a complete absence of verification to failure to repeat the verification of the HACCP plan each time a new product or a new process was introduced. Most issues were due to confusion between the concepts of “monitoring”, “verification” and “validation”.

Stakeholder feedback indicated that additional guidance, with examples, would be helpful to businesses.

Example of good practice (For more details see Annex IV)

- Flexibility for verification (NL)

3.4.4 Conclusions

There is a widespread misunderstanding of how to address hazard analysis, CCP and verification.

An incorrect and incomplete hazard analysis may result in HACCP plans which do not correctly address the relevant hazards. This, together with the establishment of too many CCPs and the selection of inappropriate CLs can result in a HACCP plan which is unsuitable to guarantee the safety of the production. Unnecessary multiplication of CCPs may indicate a lack of understanding of HACCP, lead to a reduced level of safety and impose extra burdens for no extra benefit.

3.5 KEY ISSUE 4 - FLEXIBILITY

Recitals (15) of Regulation (EC) No. 852/2004 and of Regulation (EC) No. 1831/2003 state that HACCP requirements should provide sufficient flexibility to be applicable in all situations.

Section 8 of the EU guidance document provides examples of how HACCP principles can be applied in a flexible and simplified way. The document refers to the provisions in Regulation (EC) No. 852/2004 which allow HACCP based procedures to be implemented with flexibility so as to ensure that they can be applied in all situations.

It recommends businesses to take into account the principles laid down in Annex I to the document when implementing HACCP and clarifies that it is possible to fulfil the obligation laid down in Article 5, paragraph 1 of Regulation (EC) No. 852/2004 in situations where controlling significant hazards on a permanent basis can be achieved by equivalent means, e.g. by the correct implementation of prerequisites, by using guides to GHP or by applying HACCP principles.

One of the main issues identified by MSs is the lack of a common understanding on the interpretation and implementation of the concept of flexibility. A number of factors contribute to this situation, including the absence of or inconsistent national policies on the circumstances and conditions under which flexibility may be granted. The EU Guideline was not seen to provide sufficient clarity. In many situations, flexibility is applied on a case by case basis. Lack of clarity may result in Small FBOs being required to maintain unnecessary levels of documentation.

The visits to MSs and the responses to the questionnaires to CAs indicate that flexibility is often not well understood and is not applied in a consistent and systematic way by control authorities. In some MSs, for certain sectors, flexibility is not permitted at all. Cases were seen where flexibility was permitted by the CA only in cases where an officially adopted Guide to GHP was available. A particular issue arises in the feed sector where the implementation of flexibility is limited. In some MSs there was a policy that flexibility was not permitted in this sector.

The feedback from stakeholders underlined the crucial importance of flexibility, particularly to Small FBOs. There was recognition that flexibility must not compromise safety and that significant hazards which may lead to public health issues need to be managed in an equivalent way. The feedback confirmed that the implementation of flexibility varies across MSs and that there is a lack of common understanding between and within CAs and those differences of interpretation may arise even between individual inspectors. The feed sector was again cited as some CAs may not permit any degree of flexibility in this sector.

Concern was expressed that some CAs may not take account of GHP during official controls and indicated that Small FBOs operating very simple systems based only on prerequisites, can find it difficult to convince the CAs that this approach was sufficient.

A number of examples of good practice are listed in the box below.

Some examples of good practice (For more details see Annex IV)

- Simplified Decision tree (BE)
- National legislation requiring only recording of non-compliances on CCPs (BE)
- National frameworks for Feed and for Food (DE)
- Flexibility for critical limits (IE)
- Flexibility for verification (NL)
- Flexibility allowed for Small FBOs without CCP (CZ,DK)

3.5.1 Conclusion

Although flexibility is inherent to the legal framework for HACCP, there is a wide range of interpretation as to what constitutes flexibility, when it is permissible, and under which conditions it may be granted. This lack of a common interpretation and implementation of the concept of flexibility, together with the absence of clear policy guidance in some MSs leads to uneven application of requirements across the EU.

Due to this widespread lack of understanding, MSs and stakeholders highlighted the need for more practical guidance, including examples, on flexibility which would address at least the following (i) what constitutes flexibility, (ii) where flexibility is permissible, and (iii) under what conditions flexibility may be granted. The latter would need to provide some clarity on the required level of documentation. There is a particular need for guidance in the feed sector.

3.6 KEY ISSUE 5 - OFFICIAL CONTROLS

Article 3 of Regulation (EC) No.882/2004 requires MSs to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency.

Article 4 of Regulation (EC) No.854/2004 requires that the CA carries out official controls to verify the FBO's compliance with the requirements of Regulations (EC) No. 852/2004 and (EC) No. 853/2004.

Regulation (EC) No.882/2004 requires, *inter alia*, that official controls should be carried out by staff who had received appropriate training. It specifies that training is also required in order to ensure that the CAs take decisions in a uniform way, in particular with regard to the implementation of HACCP principles. Article 8(4) of the Regulation enables the Commission to establish guidelines for official controls in accordance with the procedure referred to in Article 62(2). The guidelines may, in particular, contain recommendations concerning official controls on, *inter alia*, the implementation of HACCP principles.

Procedures based on HACCP principles are generally included as part of official food and feed hygiene controls, organised on a risk basis. In most cases, CAs have specific

documentation to assist control staff. Determination of control frequency and scope is generally devolved to the responsible CA and there is a wide variation in approach to controls between MSs, between and within CAs and even between inspectors. In some cases, the guidelines for control staff address prerequisites as well as HACCP.

In addition to differences of approach to controls there were also differences of interpretation of legal requirements, such as on the evaluation of how CCPs were identified.

Examples were observed during the fact finding missions where official controls were not effective, including the failure by inspectors (i) to identify problems related to the hazard analysis undertaken by the business, (ii) to notice deviations in CCPs and (iii) to identify shortcomings as regards verification and validation by the business.

Stakeholder feedback acknowledges the importance of official controls, but there was significant criticism regarding the inconsistent approach to controls adopted by different CAs and individual inspectors. In addition, the stakeholders stated that the national Guides to GHP were not always taken into account by CA inspectors and more account should be taken by the CAs of the specific characteristics of Small FBOs.

A number of bodies consider that as implementation of a detailed HACCP plan is one of the key requirements of Food Safety certification schemes such as ISO 22000, those third party certifications should be taken more into account by CAs when planning/performing official controls on HACCP implementation of certified organisations. This would avoid double checks and reduce costs.

A number of examples of good practice which address some of the above issues are listed in the box below.

Examples of good practice (For more details see Annex IV)

- Multiple outlet approach (NL)
- Primary Authority scheme (UK)
- Advice and knowledge dialogue during official controls (DK)
- Voluntary validation, certification of HACCP by delegated third party (DK,NL)

3.6.1 Conclusions

Generally MSs have in place risk-based systems of official assessment of HACCP based procedures. There is a wide variation in the approach to controls in terms of frequency and content. The absence of a common understanding of certain concepts, the lack of clear national policies for flexible implementation and different approaches and interpretations by individual control staff mean that controls are not consistently applied.

3.7 KEY ISSUE 6 – TRAINING

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

All CA control staff in every MS received some form of training in HACCP principles, although this does not ensure that all inspectors are provided with the required knowledge necessary to deliver an appropriate level of official assessment of HACCP in all specific sectors. This leads to a situation where legislation and guidance are inconsistently interpreted by inspectors. While inspectors receive training and supporting guidance, the FVO found that the level of competence of official control staff varied significantly.

Stakeholder feedback expressed concern about the training of official inspectors for the evaluation of HACCP-based systems, including hazard analysis and flexible implementation. A strong message was given that inspectors undertaking official controls have to be better trained so that they can perform better and more consistent controls. One organisation underlined the importance of ensuring that, in addition to being proficient on the evaluation of prerequisites and HACCP, CA inspectors should have knowledge of the specific process being controlled as this can be complex. Lack of such knowledge carries the risk of superficial inspection (with focus on prerequisites rather than CCPs). In their view, the training of inspectors should include more focus on process technology. This was an issue of particular concern in the feed and dairy processing sectors.

At business level, training was identified as a challenge, particularly in Small FBOs with high staff turnover and where non-native languages were in use for example in the hotels, restaurants and catering sector.

3.7.1 Conclusions

The technical competence of control staff is currently a cause of concern for some stakeholder organisations. Improved training for official control staff would improve the consistency of the approach to controls, ensure a more consistent interpretation of national requirements and improve the overall efficiency of HACCP systems.

The challenge faced by Small FBOs faced with high staff turnover underlines the need to ensure that HACCP plans are understood by the personnel with responsibility for their implementation.

3.8 KEY ISSUE 7 - ADMINISTRATIVE BURDEN

The EU Guidance document indicates that establishing documents and records commensurate with the nature and size of the food business is necessary to demonstrate the effective application of the HACCP principles.

As previously discussed, flexible implementation of HACCP is intended to eliminate the burden of unnecessary record keeping. However, difficulties are experienced by Small FBOs with documentation and record keeping, which, in some cases, are viewed as excessive. A lack of understanding of flexibility results in small FBOs maintaining unnecessary documentation.

Stakeholders recognise the need for HACCP to be seen as a useful and practical tool for the management of safety on a daily basis. In some cases, the production of a HACCP plan is considered by smaller businesses as difficult, complicated and largely irrelevant to the

manufacturing operation. HACCP studies are seen as a chore to “tick a box”. This underlines the need for clear practical guidance.

A number of stakeholders raised the issue of private certification schemes and the extent to which these should be taken into account during official controls. FBOs consider that more account should be taken of the contribution made by such certification to reducing food and feed hazards.

A number of examples of good practice which address some of the above issues is listed in the box below.

Some examples of good practice (For more details see Annex IV)

- Simplified recording of prerequisites (DK)
- Flexibility for monitoring (CZ, DK, IE, NL)

3.8.1 Conclusions

The situation where some operators regard the development of a HACCP plan as a formality in order to satisfy the control authority demonstrates a serious lack of understanding. Unless a FSMS is seen as an essential tool to assist operators to meet their obligation for ensuring food and feed safety, it is unlikely that the system will be effective. Further efforts are needed to communicate to operators, particularly Small FBOs, the need for and usefulness of the HACCP system.

In order to reduce unnecessary administrative burden, further clarity should also be provided to operators on the requirements for record keeping in cases where the FSMS is based on prerequisites and on flexible implementation and the possibility of using Food Chain Information should be promoted.

4 SUGGESTIONS FOR IMPROVEMENT

A number of suggestions for improvement were made by MSs, business operators and stakeholder organisations are listed in Annex I. These are listed without being endorsed by the FVO.

This overview report will enable the FVO to devise an audit framework for use in future audits by of HACCP based systems.

5 OVERALL CONCLUSIONS

The HACCP approach provides a mean to business operators to implement control measures which can reduce to an acceptable level or eliminate hazards along the production chain. There was no criticism of the HACCP approach from any source, only criticism of implementation. This project has identified seven key areas where challenges exist. In all cases, there are examples of good practice which could be used as a basis for improvement.

HACCP is inherently flexible and consequently it is impossible to devise prescriptive guidelines. Overly prescriptive guidance could undermine the scope to apply flexibility on a case by case basis. Nevertheless, many of the difficulties identified result from a lack of understanding or misinterpretation of core concepts. Many contributors asked that more clear guidance be provided together with clear examples. Clarification of core concepts leading to

a common understanding across national control authorities and FBOs would provide a foundation for further improvements.

In addition to differences of interpretation, there are also differences of approach between and within MSs on flexible implementation and on official controls. These issues could have an impact on Small FBOs and could impose unnecessary administrative burdens.

At the level of MSs, improvements would involve national authorities devising a clear policy on the implementation of prerequisites and HACCP, hazard analysis, CCPs and verification which would be consistently applied by all CAs on their territories. Specific training programmes would need to be organised by CAs for their control staff. Some MSs have already introduced such arrangements.

Once the above improvements are in place, attention could focus on the development of additional industry guides which are helpful and understood by their intended audience.

6 ROADMAP FOR A BETTER IMPLEMENTATION OF HACCP BASED PROCEDURES

The Commission convened a dedicated BTSF workshop held at the FVO's offices in Ireland on 5-7 May 2015 in order to consult with Member State experts on the results of this project and to devise an overall roadmap for improvements to be implemented at EU level, by the Member States, by stakeholder organisations and by FBOs.

It is envisaged that progress at each level can be achieved in parallel.

A. JOINT EU AND MEMBER STATES ACTIONS

- Commission and MSs to work towards a common agreement on what each HACCP principle and flexibility means.
 - Guidelines/Tools need to be accessible, understandable and operational with practical examples;
 - Case studies/practical examples need to be provided on Flexibility;
 - When adopted, agreed guidelines need to be widely disseminated by CAs.

B. ACTIONS AT EU LEVEL

B.1 Possible revision of the Guidance document on the implementation of procedures based on the HACCP principles, and on the facilitation for SME's

- Discussions with MSs to clarify existing legal provisions and to improve and harmonize understanding (particularly on terminology, flexibility and CCP, with added **practical** examples).

B.2 Develop a guidance document for CAs on key principles to be taken into account for official controls on HACCP based procedures.

B.3 Possible EU Platform for HACCP

- Consider development of a Website (or a page on CIRCABC) with short explanatory text, but mainly providing links to national guidance/approaches;

B.4 BTSF training

- BTSF HACCP training should continue to include the implementation of HACCP in Small FBOs.
 - Target future BTSF training on the Key Issues identified in this report, with emphasis on Flexibility (including documentation) and identification of hazards and hazard analysis.;
- Further develop the E-Learning module.

B.5 Other initiatives

- Consider inviting EFSA to investigate feasibility of a hazard database (taking account of existing MS models).
- Future FVO (compliance) audits will focus mainly on areas and the Key Issues identified in this Report.
- The Commission will continue to participate in the ongoing work on the Revision of the Codex General Principles of Food Hygiene (CAC/RCP 1-1969) and its HACCP Annex.

C. ACTIONS AT MEMBER STATE LEVEL

C.1 The Regulatory framework

- Ensure a uniform approach to official controls
 - Harmonise approach to understanding and interpretation of HACCP principles across CAs (Multi-CAs/Levels);
 - Ensure that control staff has a common understanding of differences between Prerequisites and HACCP based procedures.
- Adopt a clear **National** framework for the implementation of flexibility

- Clear definition of which FBO may use flexibility, under which conditions and to what extent;
- Disseminate good/useable practical examples for each HACCP principle.

C.2 Guidance

- CAs could take a more pro-active/lead role in the joint development of guides by industry (such guidance provides confidence to FBOs that they will be compliant and provide a common platform for engagement with control authorities);
- Particular attention to focus on the needs of Small FBOs where associations often do not exist and resources are not available to develop guides/tools;
- Identify sectors where there are no guides and work with Industry to identify and fill (priority) gaps;
- The needs of FBOs, particularly of small enterprises, should be taken into account in production of operational/interactive guides/tools by Industry/CAs;
- In order to ensure that guides can be used by FBOs and by CAs with confidence, implement a framework for the regular re-evaluation of National and other guides (self-evaluation/by CA)
 - Criteria for evaluation could be set by CA;
- Guides must be understandable by CAs/FBOs and could be supported with interactive tools;
- Achieve a clear understanding on the **status** of different types of guidance and consequent standards to be used for controls, specifying whether:
 - The guide is suitable to achieve full compliance;
 - The guide only provides technical guidance for implementation of HACCP based procedures (operational guide).

C.3 Training

- Provide more targeted training for inspectors, including on process/technology, to ensure consistent application of the national framework;
- Make sure control staff have a common understanding of the implications of flexibility
- Introduce e-learning and other tools for inspectors with effective cascades to pass on training;
- Consider a national framework for skills/training of staff in certain sectors (e.g. retail/catering).

C.4 Innovative solutions

- Provide some support on hazards (some models already exist);
- Consider using multi-outlet and Primary Authority models (to address needs for technical competence by control staff and consistency);
- Consider taking into account third party certification, subject to quality being assured;
- During Official controls, verify that a person in the FBO is clearly designated for implementing procedures based on HACCP principles.

D. ACTIONS AT THE LEVEL OF INDUSTRY/FEDERATIONS

- Review coverage and **regularly evaluate** and update the content of existing guides, ensuring they are operational;
- Collaborate with CAs to fill gaps and make more interactive tools;
- Focus on staff training.

ANNEX I SUGGESTIONS FOR IMPROVEMENT

Terminology and Guidelines

1. *To review EU guidance on the implementation and control of HACCP, particularly in relation to core terminology, the relationship between prerequisites and HACCP, flexible implementation of HACCP, hazard analysis, setting CCPs, documentation requirements and verification.*
2. *MSs should ensure that a common approach is adopted across all CAs at national level on the interpretation and implementation of HACCP requirements.*
3. *To develop enhanced dialogue between National CAs and FBOs on specific topics ranging from flexibility, hazard analysis, verification etc.*

PR and HACCP

4. *Greater account should be taken of ISO developments – in particular ISO 22000 – and their applicability and application in establishments – particularly the larger industry players. ISO 22000 provides additional definitions of terms and deals with integration of the prerequisite programs.*

Flexibility

5. *MSs should clarify to businesses that flexibility is not limited to situations where formally adopted guides to GHP are being used. Guides developed by the CAs or other parties may be used as a basis for flexibility.*
6. *MSs should ensure that a common approach is adopted across all CAs at national/local level on the FBOs which may apply flexibility and define the conditions under which this is to be implemented by businesses.*
7. *MSs should verify how flexibility is being applied in their territories and control and assess its implementation to ensure that an equivalent level of safety is assured.*

Official controls

8. *To ensure that official controls by MSs do not look at HACCP independently without taking account of prerequisites.*
9. *Official controls by MSs should focus, not only, on the HACCP documentation but should also thoroughly verify its implementation.*

Training

10. *To continue the development of specific training modules within the BTSF courses on flexibility.*

11. *To review BTSF training activities, including possible development an e-learning tool on HACCP based procedures, flexibility and assessment of HACCP based procedures in all MS languages, which would include practical examples, videos, etc. for national inspectors.*
12. *MS should review training to staff on HACCP to include specific elements on flexibility, hazard analysis, verification and provide targeted training on key industrial processes.*
13. *MSs should ensure that the participants attending BTSF training courses are the most suitable candidates, paying particular attention that the inspectors undertaking such tasks are allowed attend.*
14. *Stakeholder organisations could explore development of an e-learning tool for FBOs in a variety of sectors and in different languages including third countries languages e.g. Arabic, Vietnamese, Chinese, Indian languages etc.*

Administrative burden

15. *To explore ways to reduce administrative burdens related to documentation and records, bearing in mind that EU legislation requires only that procedures be in place and that Article 5.2.(g) of Regulation 852/2004 does not make documentation obligatory.*

ANNEX II – APPLICABLE LEGISLATION

Legal Reference	Official Journal	Title
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
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
Reg. 853/2004	<u>OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22</u>	Regulation (EC) No 853/2004 of the European Parliament and the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 183/2005	OJ L 35, 8.2.2005, p. 1-22	Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene
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

ANNEX III- STANDARDS AND GUIDELINES RELEVANT TO THIS PROJECT

Reference number	Full title	Publication details
CAC/RCP 1-1969	General principles of food hygiene (CAC/RCP 1-1969)	http://www.codexalimentarius.net/web/standard_list.jsp
CAC/GL 69-2008	Guidelines for the validation of food safety control measures	http://www.codexalimentarius.net/web/standard_list.jsp
	Implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses. Dated in 16/11/2005.	http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf
	Report from the Commission to the Council and The European Parliament on the experience gained from the application of the hygiene Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004. Dated in 2009	http://ec.europa.eu/food/food/biosafety/hygienelegislation/docs/report_act_part1_en.pdf
	COMMISSION STAFF WORKING DOCUMENT on the Understanding of certain provisions on flexibility provided in the Hygiene Package. Frequently Asked Questions. Guidelines for food business operators. Dated 12/08/2010	http://ec.europa.eu/food/food/biosafety/hygienelegislation/docs/faq_all_business_en.pdf
	COMMISSION STAFF WORKING DOCUMENT on the Understanding of certain provisions on Flexibility provided in the Hygiene Package. Guidelines for the competent authorities. Dated 12/08/2010	http://ec.europa.eu/food/food/biosafety/hygienelegislation/docs/faq_all_public_en.pdf
	FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses.	ftp://ftp.fao.org/docrep/fao/009/a0799e/a0799e00.pdf

ANNEX IV- EXAMPLES OF GOOD PRACTICE

Legal provisions and guides

- *Safe catering Guide (IE)*

This guidance document was developed by the CAs and catering stakeholders. The Guideline is clear and widely used. In addition, the CA had developed several documents to help FBOs implement procedures based on the HACCP principles, such as "What is HACCP? Terminology Explained", or "Catering". These guides are available on the web pages of the CA at:

http://www.fsai.ie/resources_publications.html

- *Safer Food, Better Business(SFBB)(UK)*

SFBB was developed as a practical simple approach, based on HACCP principles to specifically help small independent catering and retail businesses to put in place appropriate food safety management procedures, with proportionate record keeping. It helps FBOs to improve standards, understand food safety, protect consumers and comply with the law. SFBB packs include versions for caterers, retailers, Chinese and Indian cuisine, child minders and there is a Care Homes supplement. The packs and further information can be viewed at:

<http://www.food.gov.uk/business-industry/caterers/sfbb/>

- *Cook safe (UK)*

CookSafe can be considered the Scottish equivalent of SFBB. It has been developed by a technical group. An update to the original version of CookSafe reflects new advice on the control of cross-contamination. CookSafe was also translated into Bengali, Urdu, Chinese and Punjabi. Almost 5,000 copies were produced and food safety trainers from those communities were recruited and trained to coach ethnic businesses in the practical application of CookSafe. An electronic version of CookSafe was also developed, within the same time period, to provide a tool for staff training. The guideline is published at:

<https://www.food.gov.uk/scotland/safetyhygienescot/cooksafe>

- *Retailsafe*

Retailsafe: in 2006 RetailSafe was developed for retailers handling high-risk unwrapped foods. The guideline is available free of charge at:

<https://www.food.gov.uk/scotland/safetyhygienescot/retailsafe>

- *ButcherSafe*

ButcherSafe: in November 2013 a guide was developed for butchers handling both raw and ready-to-eat food. The guideline is available on line at:

<https://www.food.gov.uk/scotland/safetyhygienescot/butchersafe>

- *My HACCP web tool (UK)*

My HACCP is a free to use web-based tool that leads FBOs through the stepwise HACCP process, extracting information from them as they progress through the tool, leading to the production of documented HACCP based controls. It is targeted at small-medium FBOs who need controls beyond those provided by SFBB but probably do not have a dedicated in-house technical HACCP capability. My HACCP is available on-line at:

<https://www.food.gov.uk/business-industry/manufacturers/myhaccp>

- *33 Guides to GHP (BE)*

Some 99% of activities in the food chain were covered by national Guides. There are 33 national 'Self Check' guides which have been established by the professional sectors. The 'Self Check' Guides are detailed and comprehensive and they can be used by an FBO opting to avail of flexibility in the implementation of procedures based on HACCP or full HACCP. Some of them are available free of charge from the CA website at:

<http://www.afsca.be/autocontrole-fr/guides/distribution/>

They cover the following sectors: Bakery, Butchery, Canteens and Care Homes, Canteens in crèches, Hotels and Restaurants, Retail Grocery shops and production and sale of milk products at the farm. All of the other Guides to GHP remain under the control of the relevant sectors / trade associations and are available for purchase.

The 'Self Check' Guides are comprehensive and contain very informative instructions for the user. As an example, the 'Self Check' Guide for kitchens of crèches (No G-041) consists of 164 pages and addresses biological, chemical and physical risks. It provides advice on purchasing food, the use of recognised food contact materials, proper organisation of food in fridges, cooking and distribution of food.

Those FBOs which may apply flexibility and opt to use the Guides can avail of a less onerous approach to monitoring and documenting data.

Hazard analysis

- *Risk Plaza (NL)*

Riskplaza was set up as a public/private initiative by the product board of the Netherlands to identify hazards and control measures for raw materials (see link below). Its primary objective was to provide a transparent common database for hazards, and from an FBO perspective, to prevent duplication of checks of raw materials in the food supply chain, with the principle “once checked, accepted in the whole supply chain”.

This system comprises a risk database and an audit system for suppliers. The system has been expanded to almost all sectors with 50 large companies approved to supply raw materials under the scheme. These companies are certified to global private standards and audited

yearly by a certifying body. This certifying body performs an additional audit at a participating company on top of the existing food safety certificate (HACCP, IFS, BRC, ISO 22000, FSSC 22000 or an approved hygiene code), this is called Riskplaza-audit⁺. This additional Riskplaza-audit⁺ is aimed at assuring the food ingredient safety. An independent expert supervises the certifying bodies.

FBOs receiving supplies from these Riskplaza-audit⁺-certificated companies benefit from not having to undertake hazard analysis or verification of the raw materials or their suppliers.

Risk Plaza is available at: <http://www.riskplaza.nl>

- *Flexibility for hazard analysis (DE)*

(See under "Flexibility")

- *Hazard analysis tool (DK)*

The CA had developed an interactive electronic tool to allow FBOs in the retail sector to identify key hazards and produce a hazard analysis document. Another electronic tool with a list of all known risks and valuable information about them can be used in all sectors. This tool was developed by the CA in conjunction with the Technical University of Denmark in response to the widespread finding that many FBOs had difficulties undertaking the task of “hazard analysis”. In general, the problems identified related to the lack of identification of certain microbiological hazards such as viruses and parasites, and chemical hazards such as those associated with food contact materials. The tool is available at:

https://www.foedevarestyrelsen.dk/_layouts/Netcompany.FVS0001/Pages/FormView.aspx?XsnLocation=/FormServerTemplates/Egenkontrol.xsn

CCPs

- *Modified decision tree (UK)*

A guide on HACCP principles has been developed by Campden BRI. Representatives from the CA declared that the tool “My HACCP” is based on this guide. This guide contains a modified version of the decision tree to identify CCPs proposed by CODEX. The modified decision tree includes an additional question which takes into account the presence of prerequisite programs. Modified decision tree could be found at:

https://myhaccp.food.gov.uk/sites/default/files/resources/campdenbri_guidline42page41.pdf

Critical Limits at CCPs

- *Flexibility for critical limits (IE)*

(See under "Flexibility")

Monitoring

- *Flexibility for monitoring (CZ, DK, IE, NL)*

(See under "Flexibility")

Verification

- *Flexibility for verification (NL)*

(See under "Flexibility")

Flexibility

- *Specific National Legislation for Flexibility (BE)*

National legislation has been enacted which defines the conditions whereby any establishment can, avail of flexibility in the implementation of procedures based on HACCP principles. These conditions are set out in the Ministerial Decree and apply to food and feed. The legislation states that flexibility in the implementation of procedures based on HACCP principles.

The application of the decision tree enables an FBO to determine whether or not it can avail of flexibility in the implementation of procedures based on HACCP principles.

- *National legislation requiring only recording of non-compliances on CCPs (BE)*

The Belgian national legislation states that, in case that a FBO can avail of flexibility, where monitoring of CCPs is required only non-compliances are required to be recorded. In addition, this legislation states that records are required to be kept for six months after the expiry date of the ingredients by FBO that can avail of flexibility instead of two years after the expiry date of the ingredients if full HACCP was implemented.

- *Clearly defined national Framework for flexibility in Food and for Feed (DE)*

Based on the adopted EU guidance document, the competent working group of the German "Länder" has devised a framework for flexibility on the application of HACCP in different **food** businesses in 2006. It is an additional element of the whole system of risk assessment in Germany, fixing criteria for official controls with regard to risk based approaches. One of the main criteria is to assess the reliability of self-control activities of FBO's, e.g. the application of HACCP based procedures.

There are four categories, case to case supported by national sector specific guides of GHP, excluding or including elements of hazard analyses.

Category 1: The FBOs do not carry out manufacturing or processing activities. This category includes market stalls, mobile sales vehicles, small grocery shops, bars, coffee shops, transporters and storage of packed food. These enterprises could control hazards in food by

implementation of pre-requisite requirements. There is no minimum requirement for documentation; however, evidence has to be provided of compliance with the sector specific guide of GHP if it has been prepared by the particular industry sector.

Category 2: The FBOs carry out simple job-specific routine activities. This category includes restaurants, facilities for catering on trains, ships, airplanes, catering facilities, artisanal bakeries, patisseries, butchers and small capacity slaughterhouses. These enterprises could control hazards and demonstrate compliance by using a sector specific guide to GHP. Minimum requirement for documentation is to follow the sector specific guide of GHP including hazard analyses, description and schematic representation of the process steps of different product groups. Each procedure shall be documented individually. In the case of visual checks there is the possibility of only recording deficiencies or deviations.

Category 3: These FBOs carry out similar manufacturing and processing activities in one particular industry sector, such as milk processing establishments, facilities handling fishery products, pasteurised liquid product producers, deep freezers, large scale cooking kitchens and slaughterhouses with conveyor systems. These enterprises could control hazards in food by the use of industrial specific HACCP based procedures relating to the standardized technology applied by the establishment. The hazard analyses are carried out by the FBO, with specific product description of the products produced. The minimum requirement for documentation is to implement the specific industrial guide on HACCP based procedures including GHP, specific products description and schematic representation of the operation with risk assessment. Each procedure has to be documented individually.

Category 4: These FBOs carry out individual manufacturing and processing activities. These enterprises are all FBOs other than category 1-3 and meat processors, meat cutting plants, fishery product plants, vegetable processing plants. These enterprises could control hazards to prepare and implement complete product specific HACCP systems and they have to record all the relevant documentation on HACCP and HACCP based procedures.

In the **feed** sector the competent working group of the “Länder” has also devised a framework for flexibility on the application of HACCP based procedures in different feed businesses. There are also four categories, case to case supported by national sector specific guides of GHP, excluding or including elements of hazard analyses:

Category 1: The feed business operators do not carry out manufacturing or processing activities e.g. traders without a warehouse, third country representatives, transporters, warehouses storing or transporting only packed feed. These enterprises should meet the requirements of Good Practices, in particular, Annex II of Regulation (EC) No 183/2005. The potential risks and their controls have to be described. Documentation requirement is a written declaration by the operator on the evaluation and assessment of processes in the establishment relating to possible risks.

Category 2: Enterprises such as compound feed producers including mobile milling and mixing facilities, compound feed producers without any feed additives, premixes or processed animal proteins, farmers using additives but only on their own premises. These enterprises should develop a simple system based on HACCP principles (Article 6 Regulation (EC) No 183/2005) meeting and respecting the requirements of sector specific guides on good practices. Documentation requirement is to implement sector specific guides on GHP. If

such a guide is not available the enterprises have to implement specific good practices for the establishment.

Category 3: These are complex enterprises such as drying facilities with direct drying, producers of compound feed containing additives, premixes or processed animal proteins, producers of feed additives or premixes without approval requirements. These enterprises should develop comprehensive and establishment specific HACCP systems, considering the requirements of the sector specific HACCP procedures relating to technologies and processes used in the establishment. Documentation requirements are the description and schematic representation of the establishment specific activity profile including hazard analyses, proof of implementation of sector specific guides, and proof of homogeneity.

Category 4: These are critical enterprises such as mobile milling and mixing facilities with the possibility to produce medicated feed, producers of compound feed containing pre-mixes, coccidiostatics and histomonostatics, producers of feed additives or pre-mixes with approval requirements. These enterprises should develop a comprehensive and establishment specific HACCP system, relating to individual technologies and processes used in the establishment. Documentation requirements are the description and schematic representation of the establishment specific activity profile including hazard analyses, proof of implementation of an establishment specific HACCP system, and proof of homogeneity testing and cross-contamination testing.

- *Flexibility for critical limits (IE)*

Guidance Note 11 provides options for flexibility in which the HACCP principles could be implemented. The facilities where hazards may be controlled by pre-requisites are divided into two groups. In group one, it is presumed that pre-requisites are appropriate due to the nature of the business. This option is foreseen for facilities where there is no preparation, manufacturing or processing of food. In the second group, pre-requisites are considered appropriate where such a decision is the result of undertaking a hazard analysis.

For establishments applying the full HACCP based procedure, flexibility is allowed for monitoring and recording of critical limits. If a facility applies different limit to those mentioned in recognised national Guides to GHP (if existing), the FBO is obliged to demonstrate to the HSE that the alternative approach ensures the same level of food safety. This could be demonstrated by using a reputable source, for example CODEX standards, or an own-risk assessment study. Guidance Note 11 establishes a time-frame for the retention of documents and records

- *Flexibility for verification (NL)*

The CAs have foreseen different degrees of flexibility in the application of procedures based on the HACCP principles. These vary from the exclusive implementation of prerequisites (where no cooking is involved), to the use of guides to good hygiene practices, or/and standard recognised critical control points. In such cases flexibility in the implementation of HACCP principles can apply to record keeping, documentation and verification procedures such as verification on raw materials.

In the case where GHPs are used by FBOs (rather than developing their own HACCP plan) the sector representative organisation carries out the hazard analyses and transforms the necessary precautionary measures and CCPs to a guide to good practice, which for some

sectors provides for the above flexibility concerning documentation and recording. The guides are formulated in a language which the FBO understands. Therefore it is not necessary that the analyses chapters are present in the guide, nor that CCP's are recognisable. Verification and evaluation has to be carried out by the owner of the guide (in NL associations).

When a company has implemented a HACCP plan, and does not apply a guide to good practice, no flexibility is allowed.

Flexibility is also applied to smaller establishments, which in some instances are allowed to take less samples on Microbiological Criteria than the larger establishments.

- *Flexibility allowed for Small FBOs without CCP (CZ,DK)*

CZ

Although no specific instructions are in place to deal with flexibility options, in the case of Small FBOs the CA accepts that only prerequisites and GMPs (according 2013 guidelines) are implemented and that solely Principle 1 – identification of hazards,, and Principle 2 - identification of CCPs (or possibly, the assessment that no CCPs have been identified) of HACCP are applied.

DK

In the context of a political agreement to reduce the documentation burden in FBOs the CA does not require the FBOs to have a documented prerequisite programme. Nevertheless, prerequisites are subject to official control and if non-compliances are identified, the CA may request that documented procedures are established.

Official controls

- *Multiple outlet approach (NL)*

The CA has adopted a multiple outlet approach to inspection, covering outlets in catering, bakery, retail, gas stations, and butcheries currently participating. With this approach a random number of outlets within a chain are inspected annually, with results then communicated to head office of the chain. The advantage of this approach is that multiple outlet companies typically have a common food safety system and that dealing with a head office has a greater impact on the implementation rather than individually inspecting all outlets. Structurally good levels of compliance can be achieved mainly through contact with the head office and a number of reality checks to verify on the ground. The focus of this approach is the own responsibility of the FBO for compliance.

<http://www.nvwa.nl/onderwerpen/inspectieresultaten>

- *Primary Authority scheme (UK)*

This scheme gives the right to a company (namely those with multi-outlets or more than one site across the territory), to form a statutory partnership with one local CA (the “Primary Authority”) which can then provide robust and reliable ‘assured’ advice to the company

which other local CAs are required to take into account when carrying out their inspections. The scope of the partnership may cover requirements concerning food hygiene, included those related to HACCP. Primary Authorities can centrally assess multi-site company HACCP plans to avoid the burden of repeated requests for HACCP Plans and inconsistent approaches or interpretation of Plans by the local CA in outlets. The Primary Authority is able to issue advice or guidance to local CAs on their inspection plans for the company, including parts of the company HACCP arrangements to check at a local level. The Primary Authority scheme helps to address variation in local CA assessments of HACCP management systems in multi-site companies and reduces the burden on the business and the local CA. The scheme also helps to improve consumer protection by better coordinating and targeting official controls locally in outlets.

<https://www.gov.uk/government/publications/primary-authority-overview>

- *Advice and knowledge dialogue during official controls (DK)*

The CA's approach to audit HACCP based procedures is described as the “control track” method. This comprises the audit of the implementation of the control measures in place to deal with probable risks. The inspector questions the FBO regarding the hazards present and the controls in place on site. During this exercise the CA provides advice on legislation and implementation of legislation through dialogue with the FBO.

- *Voluntary validation, certification of HACCP by delegated third party*

DK

In DK, the frequency of official controls may be reduced when the FBO is certified by a private third party, if requested by the FBO and approved by the CA. The FBO has the option to inform the CA of this third party certification and on condition that the FBO immediately reports if the certification of its quality management system ceases to exist or if it no longer fulfils the condition accepted by the FBO in the application, the frequency of official controls may be reduced.

NL

This system is targeted at craft enterprises which are primarily supplying the final consumer or retailers. All of the FBOs work with an approved hygiene guide and do not develop their own HACCP plan separately. The CA have a multi-step approval process for private control bodies wishing to be accepted for their scheme. Approval, in general, takes two years and includes random checks of FBOs which have been inspected by an accepted private control body. FBOs must maintain compliance to continue to participate in the private control

scheme. Participation is voluntary for FBOs. The principal advantage for the FBO is that they receive external help and advice from the private control services.

Other advantages are fewer or more adapted inspections from the CA and the results being used as input for publishing on the internet.

Another related development is focused on the industry and the schemes which are used. Overall the way to accept such a scheme is slightly different because of the certification element. In the next years this development will go into practice.

<https://www.nvwa.nl/onderwerpen/toezicht-nvwa-eten-en-drinken/dossier/kwaliteitssystemen-zelfcontrolesystemen-levensmiddelen>

<http://www.inspectieresultaten.vwa.nl/iframe/inspectieresultaten.html>

Administrative burden

- *Simplified recording of prerequisites (DK)*

The CA does not require the FBOs to have a documented prerequisite programme. Procedures preventing cross contamination must be documented. Traceability and product-recall documentation must also be available. The CA applies flexibility regarding documentation of the monitoring of CCPs in the retail sector on a case by case basis.

- *Flexibility for monitoring (DK, IE, NL)*

(See under "Flexibility")

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