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ASSESSMENT OF FOOD SAFETY IN FOOD SERVICE ESTABLISHMENTS

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Que la memoria titulada “Food safety assessment in foodservice establishments” presentada por Doña Ana Catalina Chinchilla Lee, Licenciada en Ciencia y Tecnología de los Alimentos, ha sido realizada en la en el Área de Tecnología de los Alimentos bajo la dirección del Doctor Jordi Rovira Carballido, Profesor titular del Área y la sub-dirección de la Doctora Pieternel Luning, Profesora adjunta de la Universidad de Wageningen, y en representación del Consejo de Departamento, autoriza su presentación para ser defendida como Tesis Doctoral.

Y para que conste, y a efectos oportunos, firmo el presente certificado en Burgos, a siete de octubre de dos mil nueve.

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INFORMAN:

Favorablemente la presentación de dicha tesis, ya que reúne las condiciones necesarias para su defensa en cuanto a la realización de la fase experimental y la elaboración de la memoria

Y para que así conste y a los efectos oportunos, firmamos el presente informe en Burgos a siete de octubre de dos mil nueve

Para la realización de la tesis, Ana Catalina Chinchilla Lee, recibió una beca concedida por el Ministerio de Asuntos Exteriores y Cooperación – Agencia Española de Cooperación Internacional y otra beca otorgada por el Proyecto Europeo PathogenCombat: Contract No. Food –CT-2005-07081 PathogenCombat "Control and prevention of emerging and future pathogens at cellular and molecular level throughout the food chain".

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INTRODUCCIÓN

Las enfermedades transmitidas por alimentos se han convertido en un problema de salud pública debido al aumento de reporte de brotes alrededor del mundo en las últimas décadas. La organización mundial de la salud ha establecido una incidencia global en países industrializados del 30% de la población que ha sufrido anualmente enfermedades transmitidas por alimentos (WHO, 2007). La Autoridad Europea de Seguridad Alimentaria reportó que en 2006, 22 miembros estado habían tenido 5,719 enfermedades transmitidas por alimentos incluyendo un total de 53,568 personas y resultando en 5,525 hospitalizaciones (10.3%) y 50 muertes (0.1%). La mayoría de los estudios epidemiológicos relacionados han indicado que el principal lugar de transmisión es el hogar (41%) seguido por establecimientos de restauración (FSE) como restaurantes, hoteles, bares, etc (29% en países industrializados, 54% en el Reino Unido, 25% en España) (Olsen et al., 2000; López & Martín, 2004; WHO, 2007; Hughes et al., 2007). Estos datos demuestran que los sistemas de gestión de seguridad alimentaria implementados en los establecimientos de restauración aún tienen margen de mejora.

El objetivo global de ésta investigación es evaluar la seguridad alimentaria en los establecimientos de restauración a través del cumplimiento de cinco objetivos principales. (I) analizar las dificultades de la aplicación de los estándares/guías actuales de seguridad alimentaria en los establecimientos de restauración, (II) comprender el contexto en el que los establecimientos de restauración deben implementar sus sistemas de gestión de seguridad alimentaria, (III) evaluar el rendimiento de los sistemas de gestión de seguridad alimentaria actualmente implementados y entender los factores que pueden contribuir a dicho rendimiento, (IV) encontrar los puntos débiles de los sistemas de gestión de seguridad alimentaria actualmente implementados en los establecimientos de restauración, y (V) proponer recomendaciones para mejorar dichos puntos débiles.

La seguridad alimentaria depende tanto del producto, como de las personas que lo manejan. A su vez, las características del producto dependen de las condiciones tecnológicas que se aplican (tipo de proceso, equipo, instalaciones, medición, etc) para controlar la variación intrínseca del producto; mientras que el comportamiento del personal depende de las condiciones administrativas (gestión) que ofrece el establecimiento (tipo de relaciones organizativas, disponibilidad de información, sistemas de comunicación, formación, etc) para influir en la toma de decisiones de los

empleados (Luning & Marcelis, 2006). Por lo tanto, el enfoque que se utilizó en ésta investigación fue un enfoque tecnológico-administrativo con el objetivo de buscar medidas efectivas para lograr la seguridad alimentaria en establecimientos de restauración.

Ésta investigación está desarrollada en seis capítulos para cumplir con los objetivos propuestos. El primer capítulo analiza las dificultades de aplicación de los estándares/guías actuales de seguridad alimentaria en los establecimientos de seguridad alimentaria. Consiste en una visión general de los principales peligros microbiológicos que hay en establecimientos de restauración, un análisis del contexto tecnológico, administrativo y externo en el que debe trabajar éste sector en comparación con el sector de industrias alimentarias, una descripción de los requerimientos básicos que deben tener los sistemas de gestión de seguridad alimentaria en los establecimientos de restauración, y una revisión de algunos estándares/guías que han sido modificadas para mejorar su implementación en éste sector. Todos los aspectos se describen mediante revisión literaria.

Considerando que los sistemas de gestión de seguridad alimentaria necesitan mejoras, se hace necesario evaluar los factores que influyen en su rendimiento microbiológico. La forma más común de evaluar rendimientos de sistemas de gestión de seguridad alimentaria es a través de auditorías donde se chequea si los requerimientos del estándar se cumplen (Cornier et al., 2007; Wallace et al., 2005). Con el objetivo de evaluar el rendimiento de los sistemas de gestión de seguridad alimentaria sin considerar un estándar específico y tomando en cuenta el contexto en el que debe operar el establecimiento de servicio de alimentos se utilizó un herramienta desarrollada por Luning y co-autores (Luning, et al., 2008; 2009a, submitted 2009b, submitted 2009c). El segundo capítulo, analiza la utilidad de ésta herramienta: instrumento de diagnóstico para evaluar el sistema de gestión de la seguridad alimentaria (FSMS-DI) mediante búsqueda literaria para después utilizarla como medio de evaluación del rendimiento de los sistemas de gestión de seguridad alimentaria aplicados en establecimientos de restauración.

El tercer capítulo evalúa funcionamiento real de los sistemas de gestión de seguridad alimentaria en 50 establecimientos de restauración localizados en Burgos utilizando el instrumento de diagnóstico (FSMS-DI) modificado. Los datos analizados con

herramientas estadísticas permitieron identificar las actividades de control y aseguramiento que se ejecutan a niveles bajos o básicos considerando el contexto en el que los establecimientos de restauración deben llevarlas a cabo. Los resultados obtenidos en éste capítulo son el primer paso para identificar los puntos débiles de los sistemas de gestión de seguridad alimentaria.

El capítulo cuatro es una evaluación combinada (que incluye la aplicación del instrumento de diagnóstico FSMS-DI modificado y la realización de análisis microbiológicos de platos) llevada a cabo en 10 establecimientos de restauración con el objetivo de conocer el estado microbiológico real en los que operan los sistemas de gestión de seguridad alimentaria implementados y entender los factores que puedan influir en dicho estado.

El capítulo cinco se enfoca en el análisis de las actividades que se ejecutan a niveles bajos o básicos en vista de los resultados obtenidos con el instrumento de diagnóstico (FSMS-DI) modificado y con los análisis microbiológicos de los platos. Este capítulo analiza las prácticas higiénicas de los empleados y su efecto sobre el nivel de contaminación microbiana de las superficies de contacto y manos.

Después de obtener los resultados del instrumento de diagnóstico, los análisis microbiológicos de los platos, superficies de contacto y manos, y las observaciones de las prácticas higiénicas de los empleados, en el capítulo seis se proponen algunas recomendaciones para mejorar las actividades de control y aseguramiento que se ejecutan a niveles bajos o básicos considerando el contexto en el que deben realizarse. De ésta manera, los sistemas de gestión de seguridad alimentaria implementados en los establecimientos de restauración pueden ser más predecibles y controlables para lograr una mayor seguridad alimentaria de los platos.

INTRODUCTION

Foodborne diseases have become a major public health concern throughout the world in the last few decades. The World Health Organization surveillance program for control of foodborne infections and intoxications established a global incidence of 30% of industrialized countries population that have suffered foodborne diseases each year (WHO, 2007). The European Food Safety Authority reported that in 2006, 22 countries member states had 5,719 foodborne outbreaks involving a total of 53,568 people resulting in 5,525 hospitalisations (10.3%) and 50 deaths (0.1%). The report also identified *Salmonella* as the most common agent responsible for foodborne outbreaks, followed by foodborne viruses and then by *Campylobacter* (EFSA, 2007). More in detail, in the US, the foodborne outbreaks caused 76 millions of gastrointestinal problems per year, of which 325,000 required hospitalization and 5,000 resulted in death (Swanger & Rutherford, 2004; Mead et al., 1999). In England and Wales it was estimated 2,366,000 cases per year, 21,138 hospitalizations and 718 deaths (Adak et al., 2002).

Most of the foodborne disease surveillance studies have shown that the main place that causes foodborne outbreaks is the private home, followed by food service establishments (FSE) like restaurants, hotels, bars, etc. (Olsen et al., 2000). More specifically, the World Health Organization (2007) has reported that 29% of the foodborne illness has emerged in restaurants, hotels, bars and cafeterias. Similarly, the European Food Safety Authority reported that out of 3,737 foodborne outbreaks, private homes and restaurants/cafes/pubs/bars/hotels were the most commonly reported location of exposure with percentages of 46,4% and 19,8% respectively (EFSA, 2007). Hughes, and co-authors (2007) reported in their surveillance study in England and Wales during the period 1992-2003 that 54% of the outbreaks were associated with restaurants, hotels, canteens, pubs and caterers. In Castilla y Leon, Spain, between 1987 and 2003, the percentage of outbreaks in restaurants and bars was 23.12%, and between 4% and 2% in other food service establishments like dining halls, camping, elder residences, sanitary centres, or closed institutions (López & Martín, 2004). Moreover, food service establishments have been found to be a major source of salmonellosis and campylobacteriosis in various European countries (Cowden et al, 1989; Effler et al, 2001).

The aim of this study is to assess food safety in the sector of Food Service Establishments through the accomplishment of five major objectives. (I) analyse the applicability of current QA standards/guidelines in FSE, (II) comprehend the contextual situation in which FSE must implement their FSMS, (III) assess actual performance of FSMS understanding the factors that may contribute to that performance, (IV) find the weak points of the FSMS applied in FSE and (V) propose recommendations to improve those weak points.

The research on this study is based upon a technological-managerial (T-M) approach because the food safety in FSE is highly dependent on the product and the people who prepare the meals. More in detail, the characteristics of the food products depend on a food production system with certain technological conditions (process, storage conditions, equipment, facilities, measurement) that control the intrinsic variation of the food and make the product to have desired properties (Luning & Marcelis, 2006). On the other hand, people have individual characteristics and make different and unpredictable decisions. In the same way that the product depends on the technological conditions, also people depend on the managerial conditions (organisational relationships, available information, procedures, communication systems, training) that influence their decision-making (Luning & Marcelis, 2006).

In order to achieve the proposed goals, this study is divided in six chapters.

Chapter 1 analyse the applicability of QA-standards/guidelines by detecting the situations that may interfere with an adequate implementation in the FSMS of FSE. It consists of an overview of the main microbiological hazards found in FSE, an analysis of the technological, managerial and environmental conditions that may affect the implementation of QA-standards/guidelines into the FSMS operated in FSE in comparison to the food manufacturing industries, a description of the basic requirements that FSMS of FSE must have, and a review of some current QA-standards/guidelines that were modified to improve its application in the FSMS of FSE. All the aspects described were analysed with literature review.

Considering that FSMS implemented in FSE still need improvements, it becomes necessary to get insight of the factors that influence the performance of the FSMS of FSE (second objective of the study). The common way to evaluate the performance of

FSMS is by audits where the requirements of a QA standard are checked for its compliance (Cornier et al., 2007; Wallace et al., 2005). In order to assess the performance of FSMS without considering a specific QA standard and taking into account the context wherein the FSE must implement their FSMS, a recently developed Food Safety Management System- Diagnostic Instrument (FSMS-DI) created by Luning and co-authors was used (Luning, et al., 2008; 2009a, submitted 2009b, submitted 2009c). Chapter 2 analyse the usefulness of the FSMS-DI for FSE through literature search with the aim of obtaining a tool to assess the performance of FSMS in FSE.

Chapter 3 comprises the assessment of the performance of the FSMS of 50 FSE located in Burgos, Spain through the application of the FSMS-DI modified for FSE. Data analysis by means of statistical tools helped to identify those core control and assurance activities that are performed at low or basic levels in view of the context wherein FSE must implement their FSMS. The results obtained with this chapter are the first step to identify the weak points of the FSMS of FSE.

Chapter 4 describes a combined assessment (using the modified FSMS-DI and carrying out microbiological analyses of meals) done in 10 FSE in order to know actual performance of FSMS in terms of microbiological safety and to understand the factors that may contribute to that performance.

Chapter 5 focuses on the specific activities that were performed at low or basic levels in the FSMS of FSE in light of the results obtained from the modified FSMS-DI and from the microbiological data of meals. These activities are related to the avoidance of cross contamination by contact surfaces and employees. This chapter analyses actual hygienic practices in effect of the microbiological performance of food contact surfaces and hands.

After obtaining the results from the modified FSMS-DI, the microbiological analyses of final meals and contact surfaces, and the actual hygienic practices of employees, Chapter 6 propose some recommendations to improve those core control and assurance activities that were performed at low or basic levels in view of the context so the FSMS implemented in FSE may become more predictable and controllable to ascertain food safety of meals.

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CAPÍTULO 1

Dificultades en la aplicación de los estándares/guías actuales de seguridad alimentaria en establecimientos de restauración

Introducción

Actualmente existe un amplio rango de estándares de aseguramiento de higiene y seguridad alimentaria que se utilizan como base para el desarrollo de los sistemas de gestión de calidad de las empresas tales como códigos de Buenas Prácticas, programas de prerrequisitos, análisis de peligros y puntos críticos de control, estándares de la Organización de Estandarización Internacional (ISO), Buenas Prácticas Agrícolas (EUREP-GAP), Consorcio Británico de Detallistas (BRC), Seguridad, Calidad, Alimentos (SQF), o Estándares Internacionales de Alimentos (IFS) (Luning and Marcelis, 2009; Jacxsens, DeVlieghere and Uyttendaele, 2009). La implementación de éstos estándares ha sido efectiva en los eslabones de la cadena alimentaria dedicados a la transformación de alimentos (Ropkins and Beck, 2000; Efstratiadis, Karirti, and Arvanitoyannis, 2000; Codex Alimentarius Commission, 2003; Wallace et al., 2005). Sin embargo, en los establecimientos de restauración (FSE, Food Service Establishments) no parece que se haya conseguido dicha efectividad, posiblemente debido a que estos estándares han sido diseñados para aplicarse en industrias y porque existen diversas diferencias de contexto entre ambos sectores (Mortlock et al, 1999; Panisello & Quantick, 2001; Rodgers, 2005a; Airey & Greaves, 2005). Por lo tanto se propone que los estándares actuales de calidad deben ser mejor adaptados a la situación de los establecimientos de restauración para que sus sistemas de gestión sean más efectivos.

El objetivo de este estudio es resaltar las situaciones contextuales de los establecimientos de restauración que afectan el diseño y la operación de los sistemas de gestión de seguridad alimentaria (FSMS, Food Safety Management Systems), y cómo deben tomarse en cuenta para aplicar los estándares de seguridad alimentaria en el sistema de gestión de los establecimientos. El estudio inicia con una descripción de los principales peligros microbiológicos y las fuentes de contaminación más comunes dentro de los FSE. Seguidamente se analizan las situaciones contextuales para ver cómo pueden influir en el rendimiento de los sistemas de gestión. A partir de éste análisis, se

proponen algunos requerimientos básicos que pueden usarse para desarrollar estándares de seguridad alimentaria más aplicables a los FSE. Finalmente, se analizan algunos estándares/guías de seguridad alimentaria que han sido propuestos por otros autores y se usan actualmente para verificar si cumplen con los requerimientos propuestos.

Peligros microbiológicos típicos de los establecimientos de restauración

Los principales microorganismos que se han reportado como causantes de las enfermedades transmitidas por alimentos por establecimientos de restauración son *Salmonella, Campylobacter*, *Escherichia coli, Listeria monocytogenes*, *Shigella*, *Yersinia*, *Bacillus cereus*, *Clostridium perfringens* y *Staphylococcus aureus*. Los alimentos mayormente implicados son carnes, pescados, mariscos, pollo, ensaladas, sándwiches, huevos y lácteos (Sharp & Reilly, 1994; Olsen et al, 2003; Hernández, Roig & Rodríguez, 2003; Dalton et al, 2004).

Las principales causas de contaminación microbiológica que típicamente ocurren en los establecimientos de restauración son materia prima contaminada, materiales de contacto sucios, malas prácticas higiénicas, temperaturas de almacenamiento inadecuadas, y cocción insuficiente (Notermans & Verdegaal, 1992; Hilton, 2002; Käferstein, 2003; Griffith & Clayton, 2005; Jones et al., 2008). Por lo tanto el control de estas fuentes de contaminación deben considerarse explícitamente en los sistemas de gestión de seguridad alimentaria de los establecimientos de restauración (FSE).

Entre los materiales de contacto que mayormente pueden ocasionar contaminación cruzada si no se encuentran limpios son los trapos de cocina, manos, tiradores de frigoríficos y hornos, tablas de cortar y equipos que tenga contacto directo con los alimentos (Gorman et al., 2002; Beumer & Kusumaningrum, 2005; Gibbons, Adesiyun, Seepersadsingh, & Rahaman, 2006).

El almacenamiento a temperaturas adecuadas es esencial para prevenir enfermedades transmitidas por alimentos porque reduce el crecimiento de microorganismos patógenos como *Bacillus cereus*, *Staphylococcus aureus*, *Salmonella* y *Listeria monocytogenes* (Johnson, 1999; Unicomb et al., 2003; Dierick et al., 2005; ILSI, 2005).

Las prácticas higiénicas del personal que manipula los alimentos, también son importantes para disminuir las enfermedades transmitidas por los mismos porque

pueden ser una fuente de contaminación, especialmente para aquellos platos que tienen alto grado de manipulación y ausencia de alguna intervención, como el calentamiento, que reduzca la carga microbiana, como por ejemplo las ensaladas (Lee, et al, 1996; Clayton et al., 2002; Walker et al., 2003; Worsfold & Griffith, 2003; Ethelberg, 2004; Cenci-Goga, et al., 2005; Kir et al., 2006; Bolton et al., 2008).

La contaminación inicial de la materia prima es un punto importante que se debe considerar en los establecimientos de restauración pues también se ha encontrado como causa de enfermedades transmitidas por alimentos (Panisello et al., 2000; Kivi et al, 2007).

La temperatura interna de los alimentos, tanto en el proceso de cocción como de mantenimiento de la misma antes del servicio, también es un factor de riesgo importante para la aparición de enfermedades transmitidas por alimentos, porque es el paso en el que se reduce la carga microbiana (cocción) y evita el crecimiento de microorganismos patógenos (mantenimiento en caliente) (Panisello et al., 2000; McCabe-Sellers, 2004; Ochiai et al, 2005).

Características del contexto de los establecimientos de restauración

Se asume que el contexto en el que trabajan los establecimientos de restauración es considerablemente diferente al que tiene la industria de alimentos. Dicho contexto se refiere a los hechos dados que no se pueden cambiar a corto plazo e influyen en el rendimiento de los sistemas de gestión de seguridad alimentaria. Los factores que se consideran para definir éste contexto son el contexto tecnológico que se relaciona con los productos y el sistema de preparación de platos, el contexto organizativo que crea ciertas condiciones para tomar decisiones dentro del establecimiento, y el contexto externo que viene dado fundamentalmente por los requerimientos legislativos y la relación con los proveedores y las las demandas de los clientes (Luning and Marcelis, 2007).

El contexto tecnológico se ha evaluado describiendo las características de los productos, del proceso de preparación y el diseño de las instalaciones; el contexto organizativo mediante las características de la estructura organizacional, competencia del personal, disposición de la organización y el sistema de información; y el contexto externo a través de las características de los requerimientos legales, y las relaciones con los

proveedores y clientes. Los tres tipos de contexto se han analizado comparándolos con la industria alimentaria.

Contexto tecnológico

Con respecto al contexto tecnológico, los establecimientos de restauración ofrecen una gran variedad de platos con riesgos diferentes e impredecibles que incluyen carne, pescado, mariscos, productos avícolas, lácteos y alimentos listos para consumir. Esto induce a la manipulación de muchos ingredientes y platos al mismo tiempo y sobre las mismas superficies de contacto creando condiciones que facilitan la contaminación cruzada (Sun & Ockerman, 2005). A diferencia de ésta situación, la industria alimentaria usualmente trabaja con un número restringido de productos y con varias líneas de producción específicas para cada grupo de productos.

Asimismo, los establecimientos de restauración tienen mayor número de productos (platos) que la industria alimentaria porque es la estrategia para retener el interés del cliente y muchas veces dichas innovaciones tienen enfoques principalmente artísticos e intuitivos a diferencia de la industria cuyo proceso de innovación de productos es más largo y complejo (Van Kleef, Trijp & Luning, 2005; Rodgers, 2007). La variedad de ingredientes y productos que se manipulan en los establecimientos de restauración limita la aplicación de un análisis de peligros sistemático y directo especialmente en la asignación de puntos de control, mientras que en la industria alimentaria el análisis de peligros y asignación de puntos de control de la materia prima y el proceso son bien conocidos y claros (Panisello & Quantick, 2001; Salvat and Fravalo, 2004; Domenech, Escriche, & Martorell, 2007; Luning et al., 2009).

Otra característica típica de los establecimientos de restauración es la producción en pequeños lotes donde el muestreo y control estadístico no es factible (Rodgers, 2005a). Además, la gran variedad de platos, el servicio simultáneo a un gran número de personas y la incertidumbre de no conocer el pedido exacto de los clientes por la naturaleza del sector, requiere la preparación con antelación y el almacenamiento de materia prima y productos en preparación (Gilbert et al., 1996; Worsfold, 2001). Esta situación demanda al sistema de gestión de seguridad alimentaria considerar la capacidad de las instalaciones de almacenamiento y recalentamiento.

Otra característica típica es que durante el proceso de preparación hay un alto nivel de manipulación con las manos de los alimentos, por parte del personal, comparado con los procesos automatizados en la industria alimentaria. Esto puede convertirse en un gran riesgo de contaminación que exige requerimientos extremos en el lavado de manos e higiene del personal (Bidawid, Farber & Sattar, 2000; Clayton & Griffith, 2004; Smith, Kanas, McCoubrey & Belton, 2005).

Otra diferencia con la industria alimentaria es que ésta aplica múltiples técnicas de reducción de carga microbiana mientras que los establecimientos de restauración solamente tienen el calentamiento y el lavado con químicos como medidas de reducción (Anderson, Shuster, Hansen, Levy and Volk, 2004; Bolton & Maunsell, 2004; Griffith and Clayton, 2005; Rodgers, 2005a; Luning et al, 2008).

La mayoría de establecimientos de restauración son pequeñas y medianas empresas con un presupuesto limitado para invertir en instalaciones sofisticadas por lo que el personal debe preparar los alimentos en cocinas pequeñas llenas de personal y equipo, donde las superficies de contacto son las mismas para todos los tipos de alimentos, y muchas veces el diseño no ha sido evaluado para verificar si cumple con las condiciones específicas de producción y efectividad de limpieza (Panisello & Quantick, 2001; Rodgers, 2005a; Montes et al.,2005).

Las diferencias entre el sector de restauración y la industria alimentaria demanda al sistema de gestión de seguridad alimentaria a adoptar medidas factibles que se adapten a las características típicas. Por ejemplo, la gran variedad de materia prima y productos requiere medidas flexibles como agrupamiento de platos en tipos de procesos para realizar el análisis de riesgos, o procedimientos más estrictos de limpieza para sobrellevar las limitaciones del diseño de las instalaciones de las cocinas.

Contexto organizativo

La primera diferencia es que los establecimientos de restauración son usualmente pequeñas y medianas empresas y por lo tanto tienen una estructura organizativa menos formal y simple, comparada con la industria de alimentos que tiene visión, misión, objetivos, políticas y valores bien establecidos (Yapp & Fairman, 2006). Esta característica hace que los procedimientos escritos y el uso de registros se consideren

una carga, y por consiguiente se utilice solamente la comunicación verbal como medio para gestionar el establecimiento (Taylor, 2001).

Una característica que comúnmente se encuentra sólo en el sector de la restauración es la presión para preparar gran cantidad de platos en un período corto de tiempo, y eso puede influir negativamente en la actitud del personal hacia las prácticas higiénicas y crear una brecha entre conocimiento y actuación (Howes et al, 1996; Taylor, 1996; Angelillo et al, 2000; Clayton et al, 2002; Wordsfold, 2001). Otra consecuencia de éste factor es que es necesario preparar platos con antelación y eso puede incrementar los riesgos de crecimiento de microorganismos patógenos (Wordsfold, 2001; Sun and Ockerman, 2005; Eves & Dervisi, 2005).

Usualmente en los establecimientos de restauración no hay un procedimiento de selección de personal tan sofisticado como en la industria alimentaria y se escoge al personal en base a su experiencia. Esto resulta en un equipo de trabajo con diferentes niveles de formación y competencias y por lo tanto dificultades en la comunicación (Oteri & Ekanem, 1992; Taylor, 1996; Panisello & Quantick, 2001). Otro inconveniente es el alto grado de rotación y la contratación temporal del personal, lo cual complica el desarrollo de un programa regular de formación y requiere una gestión más estricta para asegurar que el personal cumple con los controles de higiene y seguridad alimentaria (Burch & Sawyer, 1991; Worsfold, 2001; Jones & Angulo, 2006; Jones et al., 2008).

Contexto externo

Con respecto a los requerimientos legislativos tanto los establecimientos de restauración como la industria de alimentos están obligados a cumplir con los principios del autocontrol APPCC (Reglamento 852/2004 CE).

Las relaciones con los proveedores son diferentes entre el sector de restauración y la industria alimentaria. En el primer caso, aunque los cocineros puedan tener poder para determinar las especificaciones de la materia prima, generalmente éste no es suficiente para influir en el sistema de gestión de seguridad alimentaria de los proveedores, como lo tiene la industria alimentaria. Ésta situación crea dependencia hacia los proveedores para tener materia prima con niveles microbiológicos aceptables y por lo tanto requiere mayor control en la entrada de materia prima (Luning et al, 2002; Polo & Cambra, 2007).

Las relaciones con los clientes también son diferentes entre los establecimientos de restauración y la industria alimentaria. Ésta última sistemáticamente analiza las necesidades de sus clientes y adapta sus productos para cumplir con esas expectativas (Polo & Cambra, 2007), mientras que el sector de restauración abarca a toda la población que incluye a grupos vulnerables como niños, ancianos y personas inmuno-comprometidas (McCabe-Sellers & Beattie, 2004). Asimismo, los clientes en los establecimientos de restauración muchas veces esperan un servicio rápido sin considerar que un alimento seguro requiere suficiente tiempo para que alcance temperaturas seguras y se usen superficies limpias, lo cual aumenta la presión de tiempo para el personal en la cocina.

Requerimientos de los estándares de gestión de seguridad alimentaria para establecimientos de restauración

Un sistema de gestión de seguridad alimentaria apropiado para los establecimientos de restauración debe considerar medidas de control que mantengan los riesgos microbiológicos bajo límites seguros; que dichas medidas cubran las rutas de contaminación más frecuentes como materia prima contaminada, materiales de contacto sucios, malas prácticas higiénicas, almacenamiento inadecuado e insuficiente cocción; y que sean diseñadas considerando el contexto típico en el que trabaja éste sector.

Se propone entonces que los estándares de seguridad alimentaria para los establecimientos de restauración deben permitir el desarrollo de un sistema de gestión que sea fiable, simple y flexible. Debe ser **fiable** para asegurar que los alimentos se encuentran dentro de límites microbiológicos seguros. Un criterio para asignar una medida como fiable es que ésta haya sido validada en términos de efectividad para prevenir, reducir o controlar un nivel microbiológico dado, que esté escrita como procedimiento, y verificada para su cumplimiento. Debe ser **simple** para que su aplicación esté en concordancia con el contexto típico de los establecimientos de restauración. La simplicidad de operación del sistema de gestión de seguridad alimentaria es necesaria para sobrellevar la diversidad del nivel de formación del personal y así todos puedan aplicar los procedimientos y realizar las tareas adecuadamente. Esto requiere la implicación del personal en el desarrollo del sistema pues se ha demostrado que los planes de APPCC se desarrollan mejor cuando la participación del personal es alta (Taylor & Kane, 2005). Finalmente debe ser **flexible**

para que se adapte al contexto de complejidad de preparación, menús, tipos de alimentos, equipo e instalaciones disponibles, etc (Seward, 2000; Sun & Ockerman, 2005).

Evaluación de sistemas de gestión de seguridad alimentaria que se aplican actualmente en establecimientos de restauración

Entre los sistemas de gestión de seguridad alimentaria que se aplican actualmente en establecimientos de restauración están los códigos de buenas prácticas que son generales y no específicos para cada situación u operación por lo que su interpretación puede resultar muy variada. También se utiliza en EEUU el manual de uso voluntario de los principios de APPCC para operadores de establecimientos de restauración desarrollado por la FDA (Food and Drug Administration). En éste manual se agrupan los diferentes tipos de preparación en tres tipos de procesos resultando en una identificación y control de peligros más simple. Las guías de control de seguridad alimentaria en restaurantes europeos creadas por la Red de Información de la Unión Europea de Análisis de Riesgos (EU-RAIN) describe cómo deben controlarse los peligros en una cocina con mucho trabajo. Entre los puntos que se recomienda controlar están el enfriamiento, almacenamiento, descongelado, cocción, mantenimiento en caliente y recalentamiento. También explica cómo se puede verificar y llevar los registros de los pre-requisitos. Se considera como un sistema fiable y simple pero no flexible porque no considera las condiciones específicas de cada cocina. El sistema "Alimentos más seguros, mejor negocio" es una guía desarrollada por la Universidad de Salford y la Agencia de Estándares de Alimentos en el Reino Unido. En ésta guía se considera que deben controlarse cuatro pasos en la cocina: cocción, limpieza, enfriamiento y la contaminación cruzada. Asimismo, considera el compromiso de la administración porque incluye una quinta sección que requiere que el responsable de la cocina lleve un diario para asegurarse que los cuatro pasos esenciales se cumplan. Dado que cada control que se desarrolla en este sistema es desarrollado con el apoyo del personal, en base a su situación específica y validándolo se puede considerar éste sistema como fiable, simple y flexible. Estos sistemas pueden alcanzar a llenar la brecha entre sistemas de gestión diseñados para industrias alimentarias y los desarrollados más acorde al contexto en que deben trabajar los establecimientos de restauración. Sin

embargo, el grado en que estas guías son adoptadas por los establecimientos de restauración en los diferentes países es muy variable.

El análisis de literatura mostró que la aplicación de los estándares/guías de seguridad alimentaria depende del contexto en el que deben implementar los establecimientos sus sistemas de gestión de seguridad alimentaria. Para poder evaluar el rendimiento de los sistemas de gestión de seguridad alimentaria se propone utilizar el instrumento de diagnóstico desarrollado por Luning y co-autores (2008, 2009a, submitted 2009b, submitted 2009c) porque esta herramienta permite evaluar los sistemas de gestión independientemente del estándar/guía que se haya utilizado para diseñarlo y porque toma en cuenta el contexto en el que se debe implementar.

CHAPTER 1

Applicability of current Quality-Assurance guidelines/standards in Food Service Establishments

Abstract

Although nowadays quality assurance standards and guidelines are widely applied in the food industry its application in food service establishments yet lacks behind. The objective of this study was to analyse the applicability of current standards and guidelines to the Food Service Establishments (FSE) sector. This paper describes the typical microbiological hazards that are commonly found at food service establishments, the contextual situation wherein the food service establishments work in comparison to the manufacturing industries, the requirements that food safety management systems (FSMS) for food service establishments must have, and some current standards/guidelines that have been tailored for the food service establishments. It was found that major pathogen microorganisms involved in foodborne outbreaks from food service establishments are *Salmonella, Campylobacter, Escherichia coli, Listeria monocytogenes, Shigella, Yersinia, Bacillus cereus, Clostridium perfringens* and *Staphylococcus aureus*; and that FSE work within a complex contextual situation that may hinder the applicability of current QA-standards. It was proposed that a guideline/standard (that will be translated into the FSMS) must be reliable to control the microbial hazards, simple to be easily applicable, and flexible to adapt to own circumstances. Some guidelines/standards, such as “Safer food, Better business”, have those requirements and had good results but are not widely adopted.

1. Introduction

The safety of the food chain supply is of concern due to the persistence of foodborne outbreaks that had reached up to 30% of prevalence in developed countries (WHO, 2007). Being a public health issue, food safety has been integrated along the food chain taking into account the sectors of government, industry and consumers (Kaferstein, 2003). An effort to improve food safety is the implementation of various Quality-Assurance (QA) standards such as Good Practice codes, Prerequisite Programmes (PRP), Hazard Analysis of Critical Control Points (HACCP), International Standardisation Organisation (ISO), Euro Retailer Produce – Good Agricultural Practice (EUREP-GAP), British Retail Consortium (BRC), Safety, Quality, Food (SQF), or International Food Standard (IFS) within the Food Safety Management Systems (FSMS) of the different sectors in the food chain (Luning and Marcelis, 2009; Jacxsens et al., 2009). The standards differ in various characteristics such as their focus, approach, level of detail, legislative status, and certification possibilities (Kussaga et al, 2009). The sector of food manufacturing industries have showed better performance of the application of these QA-standards (Ropkins and Beck, 2000; Efstratiadis, Karirti, and Arvanitoyannis, 2000; Codex Alimentarius Commission, 2003; Wallace et al., 2005). However, the last part of the food chain referring to the Food Service Establishments (FSE) has become one of the main sources of foodborne outbreaks with percentages of 29% of the total of foodborne outbreaks in developed countries (WHO, 2007) showing that current QA standards have not supported an effective food safety management system.

The objective of this study is to get insight in the applicability of some QA standards/guidelines in the development of more effective FSMS within the sector of food service establishments.

Various studies have discussed that the context, wherein a company operates, has implications for the quality management system (Van der Spiegel, et al., 2005a, 2006; Luning et al, submitted 2009b). More specifically, the design and operation of a company's food safety management system should be adapted to its context to be effective (Luning et al., submitted 2009b, submitted 2009c). The context of a food service establishment is considerably different from companies in agribusiness and food

manufacturing industry. Therefore, the chapter analyse the context of FSE in comparison to the food manufacturing industry.

The chapter starts with a concise description of major microbial hazards, common contamination sources and major contamination routings that may occur in FSE because are the aspects that any QA-standard/guideline used by food service establishments should control. The focus is on microbial hazards, because they are of major concern to be controlled and assured in FSE as compared to chemical and physical hazards. Subsequently, the typical context circumstances of FSE that could influence the microbial performance of their food safety management system were analysed. From this analysis, some basic requirements that QA standards/guidelines for the FSE sector should have were proposed. Finally, some currently available QA standards/guidelines that have been modified for the catering and restaurant situation were analysed to check its applicability.

2. Typical microbiological hazards at Food Service Establishments (FSE)

The major pathogens of concern, their major sources and contamination routes were briefly analysed as a first step to get insight in which basic requirements are necessary to make QA standards applicable for FSE. *Salmonella, Campylobacter, Escherichia coli, Listeria monocytogenes, Shigella, Yersinia, Bacillus cereus, Clostridium perfringens* and *Staphylococcus aureus* are generally considered as major pathogen species involved in foodborne outbreaks. Salmonellosis is the most frequently reported foodborne disease in Europe, USA, and Australia, whereby meats, fish, seafood, salad, sandwiches, and eggs are the most often implicated foods (Sharp & Reilly, 1994; Olsen et al, 2003; Hernández, Roig & Rodríguez, 2003; Dalton et al, 2004). Likewise, *Campylobacter jejuni, Staphylococcus aureus, Clostridium perfringens,* and *Bacillus cereus* have been found as main causes of foodborne diseases in many European countries and Japan (Gorman, Bloomfield & Adley, 2002; Joann & Fang, 2003; Lukinmaa, Takkunen & Siitonen, 2002). *Campylobacter jejuni* has been commonly identified in poultry products due to undercooking or cross-contamination from raw chicken (Luber et al., 2006). The presence of *Staphylococcus aureus* is normally associated with meat, poultry, fish, shellfish and milk products (Soriano et al., 2002) and is commonly used as an indicator of correct employee's hand practices (Aarnisalo et al., 2006; Jacxsens et al., 2009). Since *Clostridium perfringens* is ubiquitous in the environment it can easily contaminate any food, but it has often been found in meat and poultry (Ochiai, 2005). *Bacillus cereus* has been isolated in meat, soups, sauces, vegetables, milk products, desert mixes, spices, seafood, and rice (Ankolekar et al., 2009). For other bacterial foodborne diseases as shigellosis, yersiniosis, *Escherichia coli* infections, and listeriosis, reported annual incidence rates are lower (FAO/WHO, 2002) but due to its severe consequences, it is important to consider them as relevant for FSE.

Major contamination sources and routings of microbiological hazards in FSE was briefly analysed with literature to get insight in which control measures are crucial for FSE and should thus be addressed in QA standards/guidelines for the FSE sector. The main causes of microbiological contamination and growth typically occurring in food service establishments that have been found and/or discussed are *contaminated supplies, dirty food contact materials, poor personnel hygiene practices, inappropriate storage*

temperatures, and *insufficient cooking* (Notermans & Verdegaal, 1992; Hilton, 2002; Käferstein, 2003; WHO, 2007; Jones et al., 2008). This picture corresponds with data collected from 1993 until 1998, by the World Health Organization, who reported that major causes of foodborne outbreaks at food preparation were inadequate use of temperature (44%), contaminated supplies (20%), and unacceptable handling (14%) (Griffith & Clayton, 2005).

More in detail, *contaminated supplies* is considered as a major concern in food service establishments. A surveillance study made from 530 outbreaks that took place in England and Wales between 1992 and 1996 revealed that the use of contaminated raw material is a contributory factor for outbreaks. It appeared that the use of contaminated raw material represented 22% of the outbreaks. The main food associated were sauces and desserts that contained raw shell eggs, raw seafood like oysters and other bivalves, and unpasteurised milk (Panisello, Rooney, Quantick, and Stanwell-Smith, 2000). Another study that was initiated due to an increase of *Salmonella Typhimurium* DT104 in The Netherlands during September-November 2005 showed that the risk factor causing the outbreak was imported contaminated beef that was served undercooked as "filet américain" at mobile caterers (Kivi et al, 2007).

With respect to the cross contamination from *dirty food contact materials*, Gorman and co-authors (2002) found that *Campylobacter*, *Salmonella*, *Escherichia coli* and *Staphylococcus aureus* caused cross contamination in 12% of dishcloths, 24% of hands, 4% of refrigerator door handles, 20% of oven door handles, 24% of counter-tops and 32% of draining boards. Also equipment can be a potential source of contamination if not adequately cleaned and sanitized (Notermans & Verdegaal, 1992). A study about contamination of *Listeria* spp of ready-to-eat meat products reported that adequate sanitary practices on food contact surfaces reduces the risk of contamination with this pathogen, since the contact surface may continually contaminate finished products (Gibbons, Adesiyun, Seepersadsingh, & Rahaman, 2006). A well designed establishment with hygienically designed and reliable equipment will help in maintaining hygienic conditions, facilitate cleanliness and control pest infestations (Panisello & Quantick, 2001).

Other researchers suggested the importance of reducing *poor personnel hygiene practices* as basic condition for the decrease of foodborne illnesses caused in FSE (Lee,

et al, 1996; Worsfold & Griffith, 2003; Clayton et al., 2002; Manask, 2002; Walker et al., 2003; Kir et al., 2006; Bolton et al., 2008). For example, an outbreak of *Salmonella typhymurium,* affecting 390 persons, occurred in Denmark during July and August of 2003. The source of contamination was found to be the contact of food with an assistant chef who was infected by the epidemic strain of *Salmonella typhymurium* (Ethelberg et al., 2004). Hygienic food handling is even more important when dealing with meals with no interventions to reduce microbial contamination, and/or with meals that are eaten raw (like salads) (Cenci-Goga, et al., 2005).

Many broad surveillance studies of foodborne diseases have underpinned that *inappropriate storage temperatures* are a main cause of foodborne diseases (Panico et al., 2006; McCabe-Sellers et al., 2004; Daniels et al., 2002). It has been argued that adequate refrigeration may avoid production of the Bacillus cereus toxin at high levels (Dierick et al., 2005). Moreover, it is well known that, foods, like dairy products, mayonnaise or potato salad can serve as culture for *Staphylococcus aureus* when are left at room temperature (Johnson, 1999). Similarly, Unicomb and co-authors (2003), reported that an outbreak of Salmonellosis in 2002 in a restaurant in Australia was caused by contaminated egg-based dressings that were stored under inadequate conditions. Furthermore, the temperature abuse during storage may exacerbate the growth of *Listeria monocytogenes*, which can grow during refrigerated storage in certain foods, and thus, must be maintained at 4.4ºC or lower (ILSI, 2005).

Several studies have related inadequate use of temperature (*insufficient cooking* or *poor hot holding*) as a risk factor that causes foodborne diseases at food preparation. The surveillance study, mentioned by Panisello and co-authors (2000) revealed that improper heating represented 42% of the causes of outbreaks. A study about an outbreak in 2002 in a Japan Maritime Self-Defence Force base that affected 81 members, demonstrated that *Clostridium perfringens* was found in braised chop suey (typical Japanese meal with pork and vegetables) that was not adequately held above 65ºC (Ochiai et al, 2005). Similarly, McCabe-Sellers and co-authors (2004) have reported that an improper holding temperature is a leading factor of foodborne outbreaks due to the overgrowth of *Clostridium perfringens* and *Bacillus cereus*.

The studies described above underpin that various serious pathogens may occur at FSE and that contaminated supplies, dirty food contact surfaces, poor personnel hygiene

practices, inadequate temperature of storage, and insufficient cooking or hot holding are major sources of pathogens in Food Service Establishments. The control of these critical sources should be explicitly addressed in the QA-standards/guidelines used to develop food safety management systems for FSE. The high risk foods handled in FSE, the numerous contamination routes, the fact that large groups of people may have contact with pathogens (due to the nature of the business in FSE) and the severity of the associated foodborne outbreaks require that the QA standards/guidelines for FSE specifically support in developing **reliable** and effective control measures to prevent contamination and growth of pathogens. Typical issues that should, therefore, be addressed are adequate incoming control program to reduce safety problems due to too high initial contamination of raw materials, specific cleaning and disinfection program to support prevention of contamination via dirty contact surfaces, tailored procedures and training programs to enhance compliance to hygienic food handling practices, and simple but reliable systems to support storage at safe temperatures and heating and hot-holding processes at appropriate temperatures.

The next step in the analyses of this study is aimed at analysing in more detail the typical context wherein food safety management systems of food service establishments have to operate as compared to food industries, in order to get insight in why the current QA standards/guidelines might be less applicable in this specific sector.

3. Characterisation of typical context of Food Service Establishments

The context expressed as contextual factors in the perspective of this study has been defined as a condition, characteristic or situation, which is a given fact or cannot be easily changed on the short term, but which can have an influence on the system performance (Luning et al., submitted 2009b, submitted 2009c).

A recently developed concept on food quality management (FQM) functions underpinned that food quality is realised by technological and managerial FQM functions that interact, within an organisation in its environment. It was discussed that the characteristics of the food production system itself and its inherent technology dependent activities influence the realisation of certain desired product properties, whereas organisational characteristics affect food quality, by creating certain conditions for decision-making processes. The environment on its turn affects food quality by influencing decision-making by the organisation through interests and power (Luning and Marcelis, 2007). Moreover it was proposed that when analysing complex food quality management issues, both technological and managerial factors should be systematically analysed (Luning and Marcelis, 2006, 2009). These viewpoints were basically used to analyse typical technological as well as managerial and environment contextual factors in FSE as compared to manufacturing industry that could influence the FSMS performance.

Technological contextual factors

Technological contextual factors typically refer to inherent characteristics of the products and processes of a company, which can not be easily changed but which could influence food safety, and therewith put demands on the design and operation of the food safety management system of the company (Luning et al., 2008; Luning et al., submitted 2009b). In line with this description, the focus used to analyse the technological contextual factors of FSE was a comparison between food manufacturing industries and food service establishments of the characteristics of *product assortment, product composition, process,* and *typical layout and conditions of facilities* (Table 1).

The characteristics of *product assortment* refer to the variety of raw materials and meals handled in the establishment. It is common to find food service establishments manipulating a highly differentiated assortment of meals with different and

unpredictable risk levels, including meat, fish, poultry, dairy products and ready-to-eat meals (Montes et al., 2005). Managing a large assortment induces the preparation of many ingredients and meals at the same time with the same facilities, utensils and surfaces creating conditions that may facilitate cross contamination (Sun and Ockerman, 2005). On the other hand, manufacturing industries usually work with restricted number of product groups, and are usually able to work with several production lines specific for each product group, which can be separately cleaned and disinfected in order to avoid any possibility of cross contamination (Van der Spiegel et al, 2005b). Furthermore, the rate of development of new products is commonly rather high at food service establishments as compared to manufacturing industries and those innovations are "by trial" with artistic and intuitive approaches in order to retain customer interest (Rodgers, 2007). Additionally the same meal can be prepared in different ways depending on the cook who is preparing it (Montes et al., 2005). In the food industry, however, this takes much longer and usually products and processed are developed based on a systematic analysis of, amongst others, opportunities for new products, potential target market, lab and pilot products, consumer preferences, and market survival (Luning and Marcelis, 2009; Van Kleef, Trijp & Luning, 2005).

The characteristics of *product composition* refer to the variation in the composition of the products produced/delivered by the company. In the case of FSE, the products refer to the meals that are served to consumers. Typical for their products is that for one meal often many different ingredients and raw materials are used for preparation. They usually have to deal with many different ingredients and raw materials with different (microbial) hazards with various risks (Panisello & Quantick, 2001; Montes et al., 2005). For example, meals containing both cooked (crustaceans) and raw items (molluscs), or served lightly cooked or raw (sushi) are commonly found and may generate several opportunities for cross contamination from the raw foods or the food preparation surfaces to the cooked items (Mossel, Jansen & Struijk, 1999; Worsfold, 2001). In FSE were many different ingredients and raw materials are used, a systematic risk assessment is very complex (Bemrah et al, 2003; Montes et al., 2005; Lievonen, Ranta, and Maijala, 2007), which could hinder a straightforward assignment of control points. Furthermore, due to the diversity of raw materials, there will be more hazards, control points, critical control points, and monitoring tasks to do in order to maintain the safety of the product in comparison to the manufacturing industries that often have clear

lethal steps or combinations of various process steps to eliminate or reduce the hazards of their products (Panisello & Quantick, 2001; Luning et al., 2008). Moreover, manufacturing industries commonly deal with less different raw materials and ingredients, which enables them to assess hazards and risks and to identify clear critical control points (Salvat and Fravalo, 2004; Domenech, Escriche, and Martorell, 2007).

The *process* characteristics refer to typical properties of the processes that may have an influence on the final FSMS performance, by being more or less vulnerable to for example microbial spoilage (Luning et al., 2008). Process features are considerably different between food service establishments and manufacturing industries. Firstly, the production processes to make meals at FSE are typified by small quantity batches (Rodgers, 2005a), where statistically sampling and systematic process control is not really feasible. This situation is remarkable different at manufacturing industries where (semi) continuous production lines allow the application of statistical process control using control charts, and automated feedback systems (Luning and Marcelis, 2009).

Another difference is the way in which ingredients and materials are stocked. Manufacturing industries often have logistic systems like "Just In Time" delivery (Luning & Marcelis, 2009, Kannan & Choon, 2005) that enables low stocks of ingredients, raw materials, and products. Meanwhile at food service establishments, the high assortment of meals to comply with the need of serving large number of people simultaneously and the uncertainty of not knowing the exact client orders due to the nature of the business (Montes et al., 2005), force the establishment to have a high and variable stock of raw materials, ingredients, and partly prepared meals and meal components (like sauces) in order to satisfy the clients and to save time during preparation (Gilbert et al., 1996; Worsfold, 2001). This typical situation put demands on the FSMS of FSE by, for example, requiring advanced cooling and reheating equipments and facilities, and highly hygienic working conditions to maintain microbiological safety.

Another characteristic in food service establishments is that processes are usually manual where direct product handling and direct contact with food is common. This induces a large risk of contamination via people as compared to automated processes, and puts, for example, extremely high requirements on hand washing practices and personal care and health (Bidawid, Farber & Sattar, 2000; Clayton & Griffith, 2004;

Smith, Kanas, McCoubrey & Belton, 2005). Food manufacturing industries increasingly tend to use automated processes to avoid handling implicating direct food contact with hands, thereby, they rely more on safety and cleanliness of equipment alone and less on hygienic handling and personnel hygiene (Davidson et al., 1999; Cogan et al., 2002; Wachtel et al., 2003).

Furthermore, manufacturing industries commonly have a broad set of intervention strategies and methods available to reduce microbial contamination, such as heat treatment, high pressure, use of chemical additives, reduction of pH, etc. (Luning et al, 2008), while at food service establishments the available techniques for that objective are only heat treatment and washing with approved chemicals when the meal is a fresh type food such as a salad (Anderson et al., 2004; Bolton & Maunsell, 2004; Griffith and Clayton, 2005; Rodgers, 2005a).

The characteristics of *typical layout and conditions of facilities* refer to the design and layout of facilities and equipment that determine the working flows and influence the FSMS measures related to sanitation procedures and avoidance of cross contamination from contact surfaces or environment. Food service establishments are usually small and medium enterprises with restricted budget for investment in sophisticated kitchen facilities. Commonly, personnel must prepare all kind of meals in a small kitchen crowded with people and machinery to satisfy occasional workload and where the contact surfaces are the same, increasing the risk of cross contamination (Panisello & Quantick, 2001). It is also usual to find kitchens without enough storage space that may not ascertain that core temperature is within limits, or not designed for easy unloading of raw material (Worsfold, 2001). Furthermore, there is lack of objective quantitative approaches to evaluate if the layout of equipment has been designed to comply with sanitation and the specific production conditions of the FSE (Rodgers, 2005a). Also kitchens with high ambient temperature may facilitate growth of micro-organisms, or with facilities where external contamination or plagues may easily enter into the kitchen may cause contamination (Montes et al., 2005). On the other hand, manufacturing industries commonly use specific hygiene criteria for the design and layout of its equipment and facilities, such as the requirements given by the European Hygienic Engineering Design Group (EHEDG) (Doménech, Escriche & Martorell, 2008).

The differences in characteristics of the technological contextual factors of FSE and food manufacturing industries underpin that FSE require **flexible** measures in their FSMS that can deal with the specific characteristics of product assortment, process and conditions of facilities. For example, the high assortment of raw materials and meals require flexible measures, such as grouping of different types of preparation processes to assess critical control points instead of implementing a HACCP system based on the process for each meal. Another example is the requirement of very strict cleaning procedures to overcome that fact that equipment and facilities in FSE are commonly not hygienically designed.

Organisational contextual factors

The organisational contextual factors refer to the managerial processes and organisational arrangements that are typical for the company. Organisational characteristics affect people's decision-making behaviour in food safety management systems (Luning & Marcelis, 2007, 2009). Important aspects to consider are the *organisational structure* (which reflects authorities & responsibilities), the *information system structure* (to support decision making), *organisational arrangements* (which concerns assignment of tasks, procedures and instructions to direct peoples decision-making behaviour), and *quality of workforce* (which reflects competences and skills of personnel) (Luning & Marcelis, 2007, 2009). Similarly, the differences in organisational characteristics of FSE versus food manufacturing industry were analysed (Table 2).

The *organisational structure* refers to the system of relationships that establishes the tasks to be done (Luning & Marcelis, 2009). There are evident differences in this aspect between food service establishments and manufacturing industries. First of all, since FSE are usually small and medium enterprises, they are commonly not so formally and strictly organised as compared to manufacturing food industry where vision, mission, goals, policies and values are properly established and implemented, regular staff meetings are held and formal maintenance systems are in place (Yapp & Fairman, 2006). This fact may show lack of management commitment toward safety.

Considering the size of the company, the organisation chart is also different between food service establishments and manufacturing industries. At micro-sized food service establishments with few hierarchic levels including the manager, chief cook, cooks,

cleaning and service employees, the paperwork and use of written procedures is considered a burden and therefore making the verbal communication a major resource to successfully manage the business (Taylor, 2001). On the other hand, at manufacturing industries the number of departments and persons need a more complex and bureaucratic organisation chart with a functional, division or network structure that requires efficient horizontal and vertical communication between each department with a formalised information system, where everything done is written on procedures to assure that the information flow is adequate, reliable and available enough to facilitate the decision-making toward food safety (Luning & Marcelis, 2009). Therefore, it can be said that the *information system structure* in FSE is based in oral communication and simple posters pasted on walls to remind tasks while in manufacturing industries the information system is formalised with the use of written procedures and specialised information management systems.

With respect to the *organisational arrangements*, there is another fact commonly found at food service establishments and not at manufacturing industries. It is that FSE are a fast-moving environment where time is always limited and people prioritise tasks according to their own perception of importance (Panisello & Quantick, 2001). The pressure to prepare meals in a short period of time may influence negatively the attitude toward safe practices, making an evident gap between knowledge and practices (Howes et al, 1996; Taylor, 1996; Angelillo et al, 2000; Clayton et al, 2002; Wordsfold, 2001). Because of the time pressure, FSE usually prepare meals or meal components in advance, which include greater risks on growth of pathogens (Wordsfold, 2001; Sun and Ockerman, 2005; Eves & Dervisi, 2005). Observation studies have demonstrated the consequences of time pressure on food handler behaviour. For example, an outbreak of *Campylobacter jejuni* in a restaurant of England led to a study based on observation of personnel practices. This study showed that personnel usually washed their hands between raw and cooked or ready-to-eat food, but when they were under pressure they avoided the washing step increasing the risk of cross contamination and possible foodborne illness (Brown et al., 1988). Additionally, some researchers have argued that the knowledge of food hygiene has less impact on food safety controls than the commercial pressure to prepare meals above the designed capacity of the establishments (Luby et al., 1993; Powell et al., 1997; Jones et al., 2008). Different from this situation, at food manufacturing industries the tasks and responsibilities commonly described for

each job position, and a structured production planning is followed with less time pressure (Panisello & Quantick, 2001; Taylor, 2001).

The *quality of the workforce* refers to the competences, knowledge, experience and skills of the employees. There are obvious differences between food service establishments and food manufacturing industries. At FSE there is usually no systematic selection procedure and employees are chosen according to their experience, resulting in different education levels, competences and skills between workmates and difficulties with communication (Oteri & Ekanem, 1992; Taylor, 1996; Panisello & Quantick, 2001). Furthermore, the workforce is composed mostly by young employees who have little background training in food safety (Jones & Angulo, 2006). A relatively high turn-over of personnel or temporary staff is another characteristic of food service establishments, which may complicate the development of a regular training program and cause problems like poor handling practices, or would require stronger management to assure that staff adhere to food safety controls (Burch & Sawyer, 1991; Worsfold, 2001; Jones & Angulo, 2006; Jones et al., 2008). On the other hand, the food manufacturing industries usually have a systematic selection procedure for acquiring personnel, where required knowledge, experience and competences for each job position are established in a job profile that each new hired person must comply with (Airey & Greaves, 2005), although also in food industries appropriate safety knowledge is still a point of concern (Ramnauth, et al, 2008) Furthermore, the company usually offers continuous training and the opportunity for the person to develop within the company making the job positions more stable and with less turn-over rates (Houghton & Portougal, 2005).

The simple organisational structure of the FSE, where safety policies are not adequately implemented, trusts the direction of the decision-making mainly on oral communication and not on a formalised information system with written procedures. This aspect, along with the characteristic of a low quality of workforce composition, requires the FSMS to have **simple** measures that may enable employees to follow them and constant training to assure that they have an internalised behaviour toward safety, even at rush hours with time pressure and without the need of supervising the compliance to good handling practices.

Environmental contextual factors

Environmental contextual factors typically refer to the chain environment wherein a company operates. In the chain environment, stakeholders like government (legislative requirements), suppliers (supplier relationships) and customers can put specific demands on the FSMS (Luning & Marcelis, 2007; Luning et al., 2008). Therefore, the aspects to consider are *legislative requirements, supplier* and *customer relationships*. As done in the other sections, the differences between FSE and food manufacturing industry were analysed (Table 3).

The *legislative requirements* refer to the list of commands that legislation demands. In food service establishments and food manufacturing industries, legislation requires a FSMS based on HACCP principles because are regulated by the 852/2004 EC Regulation, effective since January 2006, that indicates that it is compulsory to have a system based on the HACCP principles. Furthermore, the increase of foodborne outbreaks caused in FSE has increased the legal requirements within the European Union that mandate that staff must be supervised, instructed or trained to follow HACCP practices (Jones et al., 2008). For instance, the World Health Organisation developed the *Ten Golden Rules for Safe Food Preparation*, which were widely translated and reproduced and then introduced the *Five Keys to Safer Food* poster in 2001 that incorporates the messages of the *Ten Golden Rules for Safe Food Preparation* under simpler headings: keep clean, separate raw and cooked, cook thoroughly, keep food at safe temperature, and use safe water and raw materials. This poster has also been translated into more than 40 languages and is used to train about food hygiene (WHO, 2006).

The *supplier relationships* refer to the extent of the power to influence on the quality specifications of the raw materials and on the management systems of the suppliers. When the characteristics of supplier relationships are compared it can be found that especially the big food manufacturing industries have stable relationships with sophisticated systems of supplier's selection and control, and lists of preferred suppliers. In such situations, the food companies have a considerable power position and can put clear demands on the safety and quality level of the supplies and even on the quality management system of the suppliers (Luning & Marcelis, 2009; Polo & Cambra, 2007). This facilitates the control of incoming materials since it is less strict due to the

confidence that the company has on the suppliers. The food service establishments can be able to influence the quality and handling practices of the foods before they enter the kitchen and assure that meat, produce and other foods are obtained from high-quality suppliers (Jones & Angulo, 2006). However, it is common for the food service establishments to have many small suppliers with few consistent relationships so they depend more on the suppliers to have raw material with low or acceptable microbial load. This dependency also allows the suppliers to deliver their products at hours where it cannot be properly checked. This fact was observed as potential hazard according to an observational study made by Worsfold (2001).

The *customer relationships* refer to degree in which the company has influence on the use of the product by the customers and also refer to the level of demand by the customers toward the product. Within this aspect, the customers of food service establishments and manufacturing industries have different characteristics. The manufacturing industries commonly put efforts in getting insight in their target customers and have indications about their demands and necessities to adapt the technical quality of their products to the customer's specific needs (Polo & Cambra, 2007). On the other hand, consumers at food service establishments are covering the whole population, including vulnerable groups like children, elder and immune-compromised people (McCabe-Sellers & Beattie, 2004; Swanger & Rutherford, 2001). It is important to consider this fact because the decline in the immune system function increases the incidence of foodborne illness and death (Sneed et al., 2004). Furthermore, FSE consumers usually expect to have a quick service without considering that a safe food requires enough time to be appropriately cooked and to be prepared on contact surfaces that are well cleaned and disinfected. Moreover, consumers should avoid consumption of high-risk foods, such as undercooked eggs or undercooked ground beef (Jones & Angulo, 2006).

An explicit requirement in a FSMS is that it must be based on HACCP principles in order to comply with legislation. Considering that part of the FSE customers include vulnerable groups, the FSMS must be **reliable** enough to ascertain safety of the final meals. The dependence on suppliers to have raw materials with acceptable microbial load requires the FSMS to have stricter control at the time of receiving them, or stricter intervention process to reduce the microbial load. Furthermore, the fact that the

customers of FSE ask for a quick service demands the FSMS to consider measures that can ascertain safety of meals that are prepared on advance; and processes to obtain safe core temperatures in a few time, plus cleanliness of surfaces if those are used for different types of food.

4. Requirements of QA-standards/guidelines to support effective Food Safety Management Systems in Food Service Establishments

A suitable QA-standard/guideline to develop an effective FSMS in FSE should consider control measures to maintain microbiological hazards under safe limits, and the measures must cover the most common and critical routes of contamination in food service establishments, like contaminated supplies, dirty contact materials, poor personnel practices, inappropriate storage, and insufficient cooking. Furthermore, these measures should be designed in such a way that they fit with the typical organisational context of FSE, which is considerably different from food manufacturing industries where most of the QA standards and guidelines are aimed for. It is then proposed that a QA standard for a FSE should enable the development of a **reliable**, **flexible**, and **simple** FSMS. These characteristics are considered as basic requirements for tools to support the implementation of effective FSMS in the FSE sector. This section discusses those basic requirements.

An important criteria to assign a measure as **reliable** is that the measure must be validated in terms of effectiveness to prevent, reduce, monitor, or minimise a certain microbiological contamination level; it must be written as a procedure and checked for its compliance; and it must be verified to assure that it is operated correctly (Luning et al., 2009a). The validation is used to demonstrate that the measures are effective to control food safety hazards and assure that products are safe (Codex Alimentarius Commission, 2003). The requirement of the food hygiene legislation (EC Regulation 852/2004) is that businesses should provide evidence that the food they make or sell is safe and it is written down (FSA, 2006). The documentation should be designed to show all parties, including the enforcement authorities, that the system is appropriate, comprehensive, based on risk assessment and HACCP principles and is capable of being communicated to all staff (Worsfold, 2001). The verification involves the methods, procedures and tests to confirm the effectiveness of the system (Codex Alimentarius Commission, 2003).

The need of a **flexible** FSMS has been emphasised also by other authors, they mentioned reasons like the complexity of recipes, menus, food types, changing products or processes, assortment of amounts during preparation, sizes of the food service establishments, diverse employee competences, and the different types of food service

preparations (Seward, 2000; Sun & Ockerman, 2005). Furthermore, the Codex Food Hygiene Committee has initiated the production of guidance documents to promote flexibility in the interpretation of the HACCP standards for small and medium sized enterprises (WHO/FAO 2000). In addition, the European Commission Regulation (EC No 852/2004) establishes flexibility for small businesses when applying the HACCP principles since it describes that record-keeping and documentations should be proportionate to the size and nature of the business, describes that critical limits can be sensory evaluated, and that some critical limits may be replaced by good hygienic practices (Airey & Greaves, 2005). First of all, any FSMS in a FSE has to deal with a high assortment of raw materials and meals with different hazards, and this hinders a systematic risk assessment for each individual meal. Therefore, the control of hazards must be based on common preparation processes. Furthermore, the need of providing large quantities of cooked meals demands innovation in preparation methods, equipment design and production planning (Rodgers, 2005b). For example, the chief cook must plan a smooth work with minimum preparation and holding times, and no overloading of critical equipment as refrigerators (Worsfold, 2001). Another aspect that requires flexibility is the small quantity batches production where statistically control is not feasible. It requires the FSMS to adopt more flexible measures to control safety without the use of statistical tools but with the use of validated processes that are only verified with an acceptable frequency. Since the FSE are generally small or medium enterprises with low budget to invest on hygienically designed facilities they must have more flexible measures to find ways to improve the features of the facilities and make them safer without investing too much money; or develop a stricter cleaning and disinfection procedure to counteract the deficiencies of design of the facilities.

Another requirement is that the QA standards should be **easily applicable** (**simple**) in the typical FSE context. A consequence of the different educational level among personnel in FSE is that the FSMS must be **simple** so all personnel can be able to apply procedures and perform tasks adequately. It would require employee involvement because if the measures are done by the people who will execute them, those measures would be more understandable. It has been shown that the better HACCP plans were developed in organisations where employee involvement is high (Taylor & Kane, 2005). Furthermore, the inadequate selection procedure, the lack of culture related to safety within the company, the lack of written procedures, the different educational

level of employees, and the high turn-over rate demands a FSMS operated in food service establishments to have stricter measures to guide personnel behaviour toward safety, and to develop more efficient training that all employees can understand and follow up and therefore may help to increase motivation, change their attitude, and level their knowledge in order to lower the turn-over rate and improve team work toward safety (Clayton & Griffith, 2004). As established before, the information system in FSE, especially in micro-business, is based mainly on oral communication (Taylor, 2001). Then a simple measure to guide personnel toward safety is to have a chief cook who continuously trains good handling practices until all the employees show that they have internalised a safe behaviour. An example of a simple measure is found at quick service restaurants where the use of laminated, icon-based procedural guides posted at operating stations is a measure that complies with the requirement of making the control steps simpler and clearer (Seward, 2000).

5. Evaluation of current QA-standards/guidelines modified for Food Service Establishments

The final inquiry of this analysis is to know if there are current food safety guidelines/standards that support the design of a reliable, simple and flexible FSMS, and then determine the degree in which these standards are adopted. Therefore, the following section discusses the principles, its suitability for FSE, and the degree of adoption of some of them, including good practices codes, FDA-Manual for the voluntary use of HACCP principles for operators of food service and retail establishments, EU-RAIN guidelines for food safety control in European restaurants, and Safer Food Better Business (Table 4).

The *good practices codes* are guidelines used to accomplish acceptable minimum standards and conditions to handle and store food. These guidelines are not legally compulsory but are required as a basic condition to apply systems like HACCP. This QA standard is rather general and not specific for each situation or operation carried out in the company. Therefore, its interpretation and application to operational procedures or actions may become very different. For example, the guideline prescribing that heated or cooked products or ingredients should be cooled as quickly as possible to below 8ºC does not specify how much time is considered quickly or not (Luning, Marcelis & Spiegel, 2006). It is reliable since is the basis to implement the HACCP system and helps to control all the sources of contamination. It can also be simple due to the fact that the requirements are general and thus easily applicable. However, it is not flexible because it does not consider the own circumstances of the establishment at the time of developing the FSMS. It is widely adopted as a component in food safety management systems operated in the food supply chain, and due to its simplicity these measures are the first to be adopted in small and medium enterprises as the FSE (Aruoma, 2006).

The *Manual for the voluntary use of HACCP principles for operators of food service and retail establishments* developed by the US Food and Drug Administration and based on the FDA Food Code is a QA standard that identifies hazards among three types of processes in order to obtain a simpler monitoring and corrective action process approach (www.cfsan.fda.gov). This QA standard was developed in order to deal with the problem of complexity of processes, and product and raw material assortment that

food service establishments have. Therefore, it is a guideline that describes how to prepare safe food. This QA standard is an example of applying simplicity to the FSMS but since it uses a generic HACCP approach due to the grouping of processes, it may be considered as not as reliable as the one applied to food manufacturers (Airey & Greaves, 2005). However, due to the fact that it includes steps of validation and verification and is based on the HACCP principles and the pre-requisite programs, it was considered as reliable in this study. Despite this, it is adopted only in the United States.

The *guidelines for food safety control in European restaurants* created by European Union Risk Analysis Information Network (EU-RAIN), is a guideline that describes how food safety hazards should be controlled in a busy catering kitchen. It recommends that effective prerequisite procedures to control hazards associated with food service environment should be followed up before the HACCP plan is implemented. It also outlines potential critical control points that should be taken into account in the catering kitchen, describing their critical limits, monitoring measures and corrective actions. Those points include chilling, chilled storage, frozen storage, thawing, cooking, hot holding, and reheating. Furthermore, it explains how to verify and keep records of the prerequisites and HACCP plan (Bolton & Maunsell, 2004). The guideline can be considered as reliable and simple since it proposes feasible measures, based on HACCP principles, to control potential hazards commonly found in catering kitchens. However, it is not flexible because it does not consider the own circumstances of the establishments. This guideline is adopted in Ireland.

The system *Safer food, Better business* is a guideline developed by the Salford University and the UK Food Standards Agency in order to create different approaches for different sorts of business (Airey & Greaves, 2005) and is a shortened version of Menu-Safe (Taylor & Taylor, 2006) for very small FSE. It considers the main steps that must be controlled in a kitchen: cook, clean, chill and cross contamination avoidance (Griffith & Clayton, 2005). It also takes into account management commitment since the fifth section of the guideline requires that the responsible of the kitchen must fill in and manage a diary where the compliance of these four C´s is checked (Taylor, et al, 2006). The critical control points in this case are safety points that establish validated tasks, making the system reliable. It also describes why those safety points must be

controlled with the aim of doing it simpler. Finally, it explains how it is done, according to the situation of the establishment giving then flexibility to the FSMS. In this way, the personnel may understand easily the reason for each control measure (Airey & Greaves, 2005). Another advantage of the system is that the monitoring measures are practical and visual. For example: instead of measuring the core temperature each time of cooking, a visual test is used and the temperature is measured with certain frequency to assure that the visual test and procedure of cooking results in safe food (Taylor, et al, 2006). The standard can be considered as reliable because each measure must be demonstrated to be a safe method and complies with the HACCP principles, flexible since the safety points are selected and tailored according to the own characteristics and necessities of each kitchen, and simple developing measures as the visual tests. This method has had effects on the UK Government's perception of the FSE sector and subsequent policy, and has become a benchmark worldwide to adapt HACCP principles in small and less developed business according to FAO/WHO guidance to governments (FAO/WHO, 2006; Taylor & Taylor, 2008).

The aforementioned safety standards are reliable but have some drawbacks such as lack of flexibility to adapt to the own conditions of the establishment, and complexity of implementation. For instance, the FDA- Manual for the voluntary use of HACCP principles for operators of food service and retail establishments or the EU-RAIN guidelines are considered as simple QA-standards/guidelines because they propose practical measures that are expected to be more accepted and have more success of implementation. However, these guidelines do not have the flexibility found in Safer food, Better business. By using this guideline, the employees themselves select the measures that comply with its own situation and validate other measures that may not be included in the guideline. These standards may bridge the gap between FSMS based on standards designed mainly for manufacturing industries and FSMS developed more accordingly to the context situation of the FSE. However, these standards/guidelines are not widely adopted in all industrialised countries.

6. Conclusions

The current standards and guidelines are not easy to implement in FSE because were designed for manufacturing industries. There are differences between these sectors that may constraint an adequate implementation such as high assortment of raw materials, preparation processes and meals prepared on the same areas with many routes of cross contamination, small volume batches, commonly hand contact with food, not formalised organisations with high turn-over rate and low competent employees, a fast-moving environment where the time pressure may restraint good hygienic practices, and dependency on the suppliers and customers.

In order to bridge the gap due to the characteristics of the FSE, the QA-standards/guidelines to be used in this sector must allow the development of a FSMS that is **reliable** to ascertain the effectiveness of the measures to control microbial hazards, **flexible** to adapt them to the own circumstances of the establishment, and **simple** to apply them in accordance to the educational level of employees. There are tailored guidelines/standards that support a reliable, flexible and simple such as Safer food, Better business but are not widely adopted. This fact requires the development of tools to increase the adoption of QA-standards/guidelines that can be translated into reliable, flexible and simple FSMS suitable for the FSE sector.

The literature analysis showed that the applicability of a QA-standard/guideline depends on the contextual situation wherein the company/establishment must implement its FSMS, and that there are various QA-standards/guidelines with unknown performance or not widely adopted. In order to assess actual performance of FSMS, it is proposed to use the Food Safety Management System-Diagnostic Instrument (FSMS-DI) developed by Luning and co-authors (2008, 2009a, submitted 2009b, submitted 2009c) because this tool is independent of the QA-standard/guideline that is used to design a FSMS and because it takes into account the context.

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Table 1: Technological contextual factors of food service establishments and manufacturing industries.

Factors	*Food service establishments*	*Manufacturing industries*
Product assortment	Different types of food handled in the same production line	Commonly one type of food or different production lines
	High rate development of new products	Development of new products takes a longer time
Product composition	Meals with different risks	Products with one known risk which is predictable and stable
Process characteristics	Not standardized batch production of small quantities where statistically sampling is not feasible	Standardized and continuous production lines that can be controlled with statistical-based tools like control charts or process capability
	High stock of food prepared in advance that must be safely stored and reheated	Low stocks due to planned logistics or systems like “just in time”
	Manual process that requires hand manipulation making the hand washing step critical for safety	Commonly automated process relying safety mainly on cleanliness of equipment and not on hand washing
	The common methods used to reduce microbial contamination are only heat treatment and washing of fresh products	All types of preservation methods to reduce microbial contamination to safe limits
Facilities	Small and medium enterprises with low budget to invest in adequate facilities that may facilitate cross contamination or restrain the maintenance of food within safe temperatures.	Adequate facilities that are properly maintained and cleaned and thus help to apply the safety measures.

Table 2: Organisational contextual factors of food service establishments and manufacturing industries.

Factors	*Food service establishments*	*Manufacturing industries*
Organisational structure	Small and medium enterprises where the organisational culture is not well developed, specially policies related to safety	Company committed to establish an organisational culture where vision, mission, goals, policies and values related to safety are developed and implemented
	Simple organisation chart with maximum three hierarchic levels	Complex and bureaucratic organisation chart with a functional structure that requires efficient communication between each department
Information system structure	The viability of using only oral communication lead to the lack of written procedures	Formalised information system with the use of written procedures and specialised information management systems.
Organisational arrangements	Pressure of time to prepare meals that influence negatively the attitude toward safe practices, making an evident gap between knowledge and practice. It also requires preparing meals in advance which add more risks to the process.	All the tasks and responsibilities are commonly described and established for each job position
Quality of workforce	Usually there is no selection procedure so personnel is chosen mainly by experience bringing about different educational level between the workmates and difficulties in communication	The selection of new personnel is through a systematic written procedure where required knowledge, experience and abilities for each job position are established in a job profile that each hired person must comply with
	High turn over rate of personnel	More stable job positions where continuous training and development within the company is common

Table 3: Environmental contextual factors of food service establishments and manufacturing industries.

Factors	*Food service establishments*	*Manufacturing industries*
Legislative requirements	Food Safety Management Systems must be based on HACCP principles.	Food Safety Management Systems must be based on HACCP principles and their products must comply with other specific legislative requirements.
Supplier relationships	High dependency on the supplier allowing the chance of having supplies with unpredictable quality and safety	Stable and developed relationships with suppliers that give power to influence the quality and FSMS of the supplier.
Customer relationships	Consumers that may be part of the vulnerable groups	Target customers that choose the product based on the label information or specifications
	One of their main requirements is a quick service	

Table 4: Principle, suitability and degree of adoption of current QA-standards/guidelines modified for food service establishments.

Food safety management system	*Principle*	*Suitability*	*Degree of adoption*
Good practices codes	Guidelines that help to accomplish acceptable minimum standards and conditions to handle and store food. They are not legally compulsory but are required as basic condition to apply systems like HACCP.	Too general and not specific for each situation or operation carried out in food service establishments.	Widely adopted
Manual for the voluntary use of HACCP principles for operators of food service and retail establishments	It is a manual for the voluntary use of HACCP principles for operators of food service and retail establishments created by the US Food and Drug Administration. The operations done in the food service establishments are grouped in three common processes to make the HACCP system more efficient.	It is an option to solve the problem of product assortment and process complexity since it simplifies the hazard analysis. However the grouping of the processes may decrease the reliability of the hazard assessment. It does not consider own characteristics of the establishment.	Adopted in US
Guidelines for food safety control in European restaurants	Guide created by EU-RAIN to help the catering sector to implement prerequisites and HACCP plan. It proposes critical limits, monitoring measures and corrective actions of potential critical control points commonly found at food service establishments.	Is reliable since the measures recommended to control microbial hazards are based on HACCP principles, and is simple because the measures to control potential critical control points are feasible.	Adopted in Ireland
Safer food, Better Business	System adopted by UK Food Standards Agency that integrates the HACCP system with prerequisites programs. Requires the collaboration of the kitchen personnel to establish the security points and monitoring measures. Includes the control of the four C which correspond to Cook, Clean, Chill and Cross contamination avoidance.	The measures used to control the safety of the dishes are practical and visual instead of using complex or time-consuming methods. Is flexible since the security points are selected according to the own characteristics and necessities of the restaurant.	Adopted in UK

CAPITULO 2

Modificación del instrumento de diagnóstico del sistema de gestión de seguridad alimentaria para establecimientos de restauración

Introducción

Con el objetivo de evaluar el rendimiento de los sistemas de gestión de seguridad alimentaria Luning y co-autores (2008, 2009a, submitted 2009b, submitted 2009c) desarrollaron un instrumento de diagnóstico que es independiente del estándar de calidad que utilice el sistema. Asimismo, toma en cuenta el contexto en el que trabaja la compañía que se evalúa. El instrumento consiste en un cuestionario en el que se relacionan una serie de indicadores con los factores contextuales del establecimiento y las actividades clave de control y aseguramiento que influyen sobre la seguridad alimentaria. La valoración se realiza empleando una escala con descripciones de tres diferentes situaciones contextuales (situaciones de menor riesgo 1, situación de riesgo moderado 2, y situación de riesgo alto, 3), y cuatro diferentes niveles de rendimiento de las actividades clave de control y aseguramiento (nivel bajo 0, nivel básico 1, nivel promedio 2, nivel avanzado 3). De ésta manera se evalúa sistemáticamente en qué nivel se diseña y opera el sistema de gestión de acuerdo al riesgo que debe afrontar la empresa en función de sus características contextuales (Luning et at., 2008).

El contexto en el instrumento de diagnóstico está descrito por las características de producto, características de proceso, características de organización y características del ambiente externo. Las actividades de control incluyen el diseño de las medidas preventivas, del proceso de intervención y del sistema de monitoreo, y la operación de dichas actividades. Las actividades de aseguramiento consisten en determinación de requerimientos del sistema, validación, verificación, y documentación y sistema de mantenimiento de registros como se muestra en la Figura 1 del Capítulo 2.

Modificaciones del instrumento de diagnóstico del sistema de gestión de seguridad alimentaria

Con el objetivo de adaptar el instrumento de diagnóstico para que evalúe el sistema de gestión de seguridad alimentaria en base al sector de establecimientos de restauración (FSE), cada indicador de los factores contextuales y de las actividades de control y

aseguramiento se evaluó con la bibliografía existente, para verificar su relevancia en éste sector. Las modificaciones que se realizaron para adaptar el instrumento a los establecimientos de restauración se explican a continuación. Para ver la lista de indicadores y la escala de situaciones contextuales y niveles de rendimiento se hace referencia a la Figura 1 y a las Tablas 1, 2 y 3 del Capítulo 2.

El indicador de “riesgo de productos” se modificó a “riesgo de platos” debido a que en el sector de restauración el producto final es el plato servido al cliente. Asimismo, para facilitar la asignación en las tres diferentes situaciones, éstas se modificaron de manera que la situación 1 incluye platos que se sirven al cliente sin ninguna manipulación (por ejemplo productos empacados como yogures), la situación 2 incluye platos que llevan un paso de cocción y se sirven inmediatamente, y la situación 3 incluye platos que no tienen ningún paso de intervención (como las ensaladas) o se mantienen en caliente antes de servirse al cliente.

El indicador de “contribución del empaque para la seguridad” se descartó del instrumento de diagnóstico porque en el sector de restauración no se utiliza el empaque como medio para contribuir en la seguridad del plato final.

La escala de situaciones del indicador de “alcance de los pasos de intervención” fue modificada para facilitar la ubicación de situación. Por lo tanto, los platos que conllevan cocción y se sirven inmediatamente se asignan en la situación 1, los platos que se cocinan, almacenan y se recalientan se asignan en la situación 2, y los platos que no llevan pasos de intervención con cocción como las ensaladas se asignan en la situación 3.

El indicador de “cambios del proceso de producción” fue modificado a “proceso de preparación de platos” para que sea más específico al sector de restauración, ya que se espera que en una cocina no exista la automatización que se encuentra en la industria alimentaria y existen muchos cambios de tipo de preparación o alimento que requiere más pasos de limpieza o adaptación del equipo para cada tipo de alimento. La escala de situaciones también fue modificado por lo que la situación 1 está descrita por bajo número de recetas que permite el uso de equipo y superficies solamente para un tipo de alimentos (por ejemplo residencias de estudiantes), la situación 2 está caracterizada por un número medio de platos que permite suficiente tiempo para limpiar el equipo y

superficies después de cada cambio de tipo de alimento, y la situación 3 se define por un alto número de platos donde no hay suficiente tiempo para limpiar o ajustar el equipo para los diferentes tipos de alimentos especialmente durante horas pico de trabajo.

El indicador de “grado de cambio de productos/procesos” fue modificado a “grado de cambio de menús”. Dado que en los establecimientos de restauración el desarrollo de nuevos menús o recetas es mayor que en la industria alimentaria, la escala de situaciones fue modificada con respecto a la frecuencia de cambios. De manera que la situación 1 se presenta cuando los cambios se hacen una vez al año, la situación 2 se describe cuando los cambios son por cada estación, y la situación 3 es evidente cuando los cambios se hacen varias veces durante cada estación o temporada.

El indicador de “relaciones con los clientes” se descartó del instrumento de diagnóstico porque, debido a la naturaleza del negocio del sector de restauración, no hay probabilidad de poder de influencia sobre el cliente con respecto al uso del producto.

El indicador de “medidas de prevención específicas para el producto” fue modificado a tres actividades que se hacen específicamente en los establecimientos de restauración “conservación de platos”, “método de descongelado” y “método de mantenimiento en caliente”. La conservación de platos que se preparan con antelación es un paso de prevención comúnmente encontrado en el sector de restauración que incluye el uso de equipo de enfriamiento rápido, almacenamiento en condiciones de refrigeración y empaque al vacío. El método de descongelado es importante considerarlo porque puede convertirse en un punto de sobrecrecimiento de microorganismos. Asimismo el método de mantenimiento en caliente es importante para prevenir el crecimiento de microorganismos patógenos y por consiguiente la prevalencia de enfermedades transmitidas por alimentos. El grado en que éstas medidas de preservación son diseñadas en concordancia con requerimientos legales y verificados en cuanto a su efectividad determina la situación en que deben ubicarse dentro de la escala. Por lo tanto, si las medidas fueron diseñadas en base a la experiencia se asignan en el nivel 1, si están basadas en legislación o guías válidas se ubican en el nivel 2, y si están verificadas y probadas se consideran en el nivel 3.

El indicador de “capacidad real del equipo de mantenimiento en caliente” fue añadido al instrumento de diagnóstico para evaluar la capacidad real del equipo. En la escala, el

nivel 1 está descrito por rendimiento regularmente inestable con variaciones significativas de temperatura, ausencia de mecanismos para medir automáticamente la temperatura y falta de información acerca de la temperatura interna del producto. El nivel 2 se caracteriza por rendimiento más o menos estable, control automático de temperatura pero ausencia de análisis de desviaciones e información de temperatura interna del producto en algunas ocasiones. El nivel 3 se define por rendimiento estable, medición automática de temperatura e información constante de la temperatura de los productos.

El indicador de “rendimiento real del equipo analítico” fue descartado del instrumento de diagnóstico porque comúnmente no se utiliza equipo analítico en el sector de restauración.

Con éste instrumento de diagnóstico modificado se puede proceder a evaluar el rendimiento de los sistemas de gestión de seguridad alimentaria en función del contexto en el que los establecimientos de restauración tengan que ejecutarlo.

Como consecuencia del estudio detallado de las características específicas del sector de la restauración, y el apoyo de la bibliografía se ha realizado una adaptación del FSMS-DI, propuesto por Luning et al. (2008, 2009a, submitted 2009b, submitted 2009c), para los establecimientos de restauración (FSE), que permitirá evaluar el rendimiento de los sistemas de gestión de seguridad alimentaria en este tipo de establecimientos. Este FSMS-DI adapatado al sector de la restauración podrá ser utilizado tanto por los propios propietarios de establecimientos, como por empresas auditoras o la propia administración, con el fin de detectar deficiencias en el sistema de gestión de la seguridad alimentaria.

CHAPTER 2

Evaluation of the usefulness of the Food Safety Management System-Diagnostic Instrument (FSMS-DI) for Food Service Establishments

Abstract

The percentage of foodborne outbreaks from Food Service Establishments (FSE) indicates that their Food Safety Management Systems (FSMS) have weak points that need improvement. In order to assess actual performance of FSMS Luning and co-authors (2008, 2009a, submitted 2009b, submitted 2009c) developed a FSMS-Diagnostic Instrument (FSMS-DI) that evaluates FSMS independently of the QA-standard that has been used. This tool takes into account the context wherein the company operates. The objective of this study was to evaluate the usefulness of the FSMS-DI for food service establishments by analysing its relevance with support of literature. As a final result, a modified FSMS-DI with 49 indicators was obtained, which can be used as a tool to assess the performance of FSMS in food service establishments in view of their context. Among the modifications 5 indicators were removed from the FSMS-DI, 13 indicators were changed (of which 8 were modified only by changing the grid), and 1 indicator was added to the FSMS-DI.

1. Introduction

The sector of food service establishments (FSE) is one of the main sources of foodborne outbreaks in industrialised countries (WHO, 2007; Olsen et al., 2000; Hughes et al., 2007; López & Martín, 2004). This underpins that the food safety management systems (FSMS) applied in this sector still have room for improvement. As described in Chapter 1, the quality assurance (QA) standards that are translated into the company´s specific FSMS are principally developed for its application in food manufacturing industries and are less suitable for food service establishments (Mortlock et al., 1999; Rodgers, 2005a; Airey & Greaves, 2005). As a first step to improve FSMS of food service establishments, it is necessary to assess its actual performance.

In order to assess the performance of a FSMS, Luning and co-authors (2008, 2009a, sumbmitted 2009b, submitted 2009c) developed a FSMS-diagnostic instrument (FSMS-DI) that evaluates implementd FSMS independently of the QA-standard that has been used. This tool takes into account the context wherein the company operates since it is considered that the design and operation of a FSMS should be adapted to its context in order to be effective (Luning et al., submitted 2009b, submitted 2009c). The FSMS-DI enable a systematic assessment of the context characteristics and core control and assurance activities showing at what situation or level those characteristics and activities are acquainted, designed and operated (Luning et at., 2008, 2009a, submitted 2009b, submitted 2009c). Another characteristic of the FSMS-DI is that it takes into account technology dependent activities including facilities, equipment, tools and processes; and managerial activities such as procedures or information systems that refer to people requirements and behaviour because both activities affect the performance of the FSMS (Luning et al., 2008). The basic principle behind the FSMS-DI is that companies (establishments) operating in a more vulnerable (to safety problems), uncertain (due to lack of information), ambiguous (due to lack of insight in underlying mechanisms), and unpredictable situation, require a more advanced food safety management system to realise and assure product safety (Luning and Marcelis, 2006; Luning et al, submitted 2009b, submitted 2009c). Systems performing on a higher level (use of specific information, scientific knowledge, critical analysis, procedural methods, systematic activities, and independent positions) are more predictable, controllable and better able to achieve a desired safety outcome, because of less ambiguity, uncertainty and

vulnerability (Luning and Marcelis, 2006; Luning et al., 2008, 2009a, submitted 2009b, submitted 2009c).

The objective of this chapter is to evaluate the usefulness of the FSMS-DI for food service establishments by analysing the relevance for FSE of each indicator with support of literature. As a final result, a modified FSMS-DI is obtained which can be used as a tool to assess the performance of the FSMS in food service establishments.

The chapter starts with a description of the FSMS-DI, followed by a section that explains, through literature analysis, the usefulness of each indicator included in the FSMS-DI.

2. Food Safety Management System-Diagnostic Instrument (FSMS-DI)

The FSMS-DI consist of a list of indicators referring to a *companies´ context* that may influence the performance of a FSMS, and a list of indicators relating to *core control* and *assurance activities* of FSMS that have been found to influence food safety. Each context indicator has a grid with descriptions of three contextual situations (low-risk, medium-risk and high-risk), and each activity indicator has a grid with four levels of performance (low level, basic level, average level and advanced level).

Companies´context refers to the situations, which are a given fact or cannot be easily changed in a short term, but with which the company must execute its management system. It is assumed that a more risky context will put higher demands on the FSMS in order to obtain a certain safety level (Luning et al., submitted 2009b, submitted 2009c). Four major contextual factors have been identified i.e. product characteristics, process characteristics, organisational characteristics, and chain environment characteristics. The product characteristics refer to the intrinsic characteristics of raw material, food products and packaging concepts, whereas the production process characteristics refer to the properties of the process. Both characteristics create situations that make the food to be more or less susceptible to growth or survival of microorganisms (Luning et al., submitted 2009b, submitted 2009c).

The organisational characteristics refer to those aspects that direct people behaviour toward the achievement of safety goals in the company by making adequate decisions on FSMS activities. The chain environment characteristics refer to the position of the company in the food chain and its relationships with stakeholders such as customers, suppliers and legislation.

The FSMS-DI includes *core control activities* that are aimed at realising food safety by maintaining the product and process conditions under acceptable safety limits through the assessment of the performance of the technological and managerial processes and taking the necessary corrective actions (Luning et al., 2008). The indicators related to the core control activities are grouped in two main sections: design of the control activities and the operation of those measures. The design considers preventive measures, intervention processes and monitoring system. The operation takes into account the actual performance of control activities related to people and equipment.

The preventive measures are those activities that are aimed at avoiding the entry and/or growth of pathogens in the production system by reducing the chance of (cross) contamination. These measures improve the efficiency and effectiveness of the FSMS because they reduce the number of critical control points (Luning et al., 2008).

The intervention processes are those activities aimed at inactivating, eliminating or reducing pathogens to acceptable levels by physical, chemical or microbiological treatments. The physical methods are considered as intervention equipment, while the chemical and microbiological interventions are grouped as intervention methods (Luning et al., 2008). The monitoring system refers to those activities that provide information about the actual status of the product and process conditions and thus helps to apply corrective actions and improve the system (Luning et al., 2008).

The FSMS-DI also includes *core assurance activities* that are aimed at providing confidence to the stakeholders that the safety requirements are met by setting the requirements, evaluating the system performance and organising the necessary changes (Luning et al., 2009a). The indicators related to the assurance activities are subdivided in four core activities: setting of system requirements, validation, verification, and documentation and record-keeping system. The system requirements come from external needs given by the stakeholders, and from internal information given by the own control system. The FSMS must be able to translate or adapt those requirements into control and assurance activities (Luning et al., 2009a). The validation and verification activities are aimed at providing evidence and confidence to stakeholders that requirements are actually met by the system because they critically judge the FSMS performance and give information for necessary changes (Luning et al., 2009a). Documentation and record-keeping support the assurance activities because it makes the system transparent and enable stakeholders to certify the system and provide them evidence and confidence (Luning et al., 2009a).

3. Usefulness of the FSMS-DI for Food Service Establishments

In order to evaluate the usefulness of the FSMS-DI for food service establishments each indicator was analysed with literature references to check its relevancy for FSE. Thus, if the indicator was found to be not relevant then it was removed from the FSMS-DI, and if the indicator was found to be relevant then it was kept in the FSMS-DI. Moreover, some indicators were modified to make them more applicable for food service establishments and others were added to the FSMS-DI because were found to be relevant for FSE. The modified FSMS-DI list of indicators is shown in Figure 1 and the modified FSMS-DI grid for the assessment of indicators is shown in Table 1 for organisational context, in Table 2 for core control activities and in Table 3 for core assurance activities. All tables referring to the grid for assessment were based on the grids established by Luning & co-authors (2008, 2009a, submitted 2009b, submitted 2009c). It can be seen in Figure 1 that the *italic* indicators refer to those indicators that were removed from the former FSMS-DI because were found to be not relevant for FSE, whereas the **bold** indicators refer to those indicators that were modified or added to make them more applicable for FSE. Similarly, in Table 1, 2 and 3, the *italic* descriptions refer to those aspects that were removed because were considered as not relevant for FSE, wherease the **bold** descriptions refer to the aspects that were added to make the grid more applicable for FSE. The literature analysis showing why each indicator was relevant or not for FSE is explained as follows.

3.1 Contextual factors

Product characteristics

The indicators to describe product characteristics are “risk of raw material” and “risk of products” as shown in Figure 1.

Risk of raw material

Raw materials and product design (recipe and preparation method) affect the quality of the final product (Rodgers, 2005a). FSE deal with many types of raw material ranging from high risk products such as meat, fish, poultry, dairy products, fruits, and vegetables to less hazardous products like canned, frozen, pasteurized, vacuum packaged or modified atmosphere packaged items (Panisello et al., 2000; Worsfold,

2001; Griffith and Clayton, 2005; Dalton et al, 2004; Bolton & Maunsell, 2004; Montes, 2005). A high risk of raw materials demands the FSMS to have more control of incoming supplies, more effective intervention measures that actually reduce the microbial load, and more control of the storage conditions. The assortment of raw material and the different levels of microbiological contamination that can be found in this type of raw material make this indicator relevant for FSE.

Risk of products – Risk of meals:

The final product in FSE is the meal, thus the former indicator of "risk of product" was changed to "risk of meals". There are many types of meals with different degrees of susceptibility to growth or survival of pathogens. For instance, there are meals that are not handled but are served as bought such as desserts or packaged dairy products like yogurts; there are meals that are cooked and served where post contamination is not likely to happen; there are meals that are cooked but held at room temperature before consumption adding then another risk to the safety of the meal; and there are meals, such as fresh-type salads, that do not have any intervention step to inactivate the original microbial flora of the raw material and are likely to be contaminated during its preparation with the contact surfaces or hands (Griffith and Clayton, 2005; Bolton & Maunsell, 2004; Worsfold, 2001). In order to include the different types of meals, additional characteristics were included in the grid to facilitate the allocation of the FSE with respect to this indicator. Thus, the meals that are served as bought are considered as situation 1, the cooked and served meals as situation 2, and the fresh-type meals or hot-held meals as situation 3. If the FSE provide meals of the three different situations, then it should be allocated in situation 3 because is the most vulnerable situation. This indicator directly impacts the strictness of the FSMS. For example, if the customer asks for undercooked meat ("bleu" meat) then the control of raw material, preservation and preparation techniques for that kind of meal should be stricter (Montes et al., 2005).

Safety contribution of packaging concept:

In FSE, the package is used for preservation purposes of the food items that are prepared on advance to prevent recontamination, improve the storage space and minimise labour costs (Olsson et al., 2004). Due to the fact that package in FSE does not contribute to the safety of the final meal because the meals that are served to

consumers are not packaged or if that is the case (i.e. dairy packaged desserts such as yogourt) the package is not done by FSE, then this indicator was considered as not relevant for FSE and removed from the FSMS-DI.

Producton process characteristics:

The indicators referring to production process characteristics are “extent of intervention steps”, “extent of production process changes” and “rate of product/process design changes”, as shown in Figure 1.

Extent of intervention steps:

The intervention step available in FSE is the heat treatment that is done with various types of cooking equipment such as stoves, convection ovens, steam ovens, microwave ovens, fryers, grillers, tilting bratt pans, boiling pans, bain Marie devices (Bello, 1998; Anderson, Shuster, Hansen, Levy and Volk, 2004; Bolton & Maunsell, 2004; Griffith and Clayton, 2005; Montes et al., 2005; Rodgers, 2005a). In FSE if the meal preparation has a lethal step that reduces the microbial load to acceptable levels, such as cooked and served meals, then the FSMS turns to be more simple and easier to control. On the other hand, a meal preparation process that requires several steps and has no lethal step to achieve a safety level, like fresh-type meals, is more vulnerable to contamination, survival and growth of microorganisms. The former grid was changed with an additional description to facilitate the assessment of the extent of intervention steps in which the cooked and served meals have steps considered as situation 1, the cooked-stored and reheated meals as situation 2, and the fresh-type meals as situation 3.

Extent of production process changes – Extent of assortment of meal production process:

FSE handle a large assortment of raw materials and meals (Montes et al., 2005) that are prepared at the same time, using same facilities, utensils and surfaces that requires constant cleaning interventions. The less differentiated areas increase the chance of cross contamination (Sun and Ockerman, 2005). Therefore, the FSE have to deal with the traditional risks of cross-contamination and temperature abuse and other food safety risks given by the various steps in the process of preparation and the extension of shelf-life of the food items prepared on advance (Rodgers, 2005b). Furthermore, some

researchers have argued that the commercial pressure to prepare meals above the designed capacity of the establishments has been found to be more important for the employees than their knowledge of food hygiene (Powell et al., 1997; Jones et al., 2008). Taking into account these facts, this indicator replaced the former indicator "Extent of production process changes". Thus, situation 1 is described by low number of recipes allowing the use of equipment and surfaces for only one food type such as student halls of residence where a single day meal is prepared. Situation 2 is characterised by a medium number of meals that allows enough time to clean the equipment and surfaces after each change of food type. Situation 3 is defined by a high number of meals where time at rush hours is short to clean or adjust the equipment and surfaces for other food type.

Rate of product/process design changes – Rate of menu changes:

The indicator "rate of product/process design changes" was changed to "rate of menu changes" since the product in FSE is the menu. The rate of development of new meals is commonly rather high at FSE and those innovations are "by trial" with artistic and intuitive approaches in order to retain customer interest (Rodgers, 2007). Due to the higher rate of change of meals in FSE, the grid was changed with respect to the frequency of changes. Thus, situation 1 is present when the changes are done once a year, situation 2 is described when the changes are seasonal, and situation 3 is evident when the changes are done more times during each season.

Organisational characteristics:

The indicators related to organisational characteristics are "lack of technological staff", "degree of variability in workforce composition", "deficiency of operator competences", "lack of management commitment", "deficiency of employee involvement", "absence of formalisation" and "deficiency of information systems" as shown in Figure 1.

Lack of technological staff:

It has been demonstrated that the employment of experienced and technically qualified people is one of the more important factors to implement HACCP (Taylor, 2001). The small size of FSE makes a position of a food technologist or food hygienist cost

prohibited. This fact requires the managers to have the technical knowledge themselves or hire external assessment in specific aspects of the FSMS that needs this technological knowledge (Rodgers, 2005a). Furthermore, it has been shown that small companies do not have sufficient in-house expertise (Montes et al., 2005) and are wary of hiring consultants for guidance and rely on the visits of public health inspections (Taylor & Kane, 2005). The importance of technological knowledge to design a reliable FSMS and the aforementioned studies mentioning that this kind of knowledge is absent in small companies, which could be the case for FSE, make this indicator as relevant for FSE. The grid was changed by replacing industrial company for establishment.

Degree of variability of workforce composition:

It is common in FSE to have a relatively high turn-over of personnel or temporary staff, which may complicate the development of a regular training program and cause problems with poor handling practices, or would require stronger management to ensure that staff adhere to food safety controls (Worsfold, 2001; Jones & Angulo, 2006; Jones et al., 2008). More specifically, Jones and co-authors (2008) did a case-control study of management practices in catering businesses that were associated with a foodborne outbreak between 2002 and 2003 in England and Wales and established that outbreaks were more likely to occur in businesses employing casual staff and relief managers (larger businesses such as hotels) than at micro businesses employing full-time staff or operated with close supervision of the owner or manager working in the kitchen. These studies underpin the relevance of this indicator for FSE.

Deficiency in operator competences:

The operator competences include basically experience and knowledge which is related to the training programs. There are studies that have showed low level of knowledge and training in FSE (Taylor, 1996; Panisello & Quantick, 2001; Jones & Angulo, 2006). For example, Sneed and co-authors (2004) conducted an assessment of 3-hour observations of 40 assisted-living facilities from Iowa and found that food safety education should be a priority for managers and employees because operations with food safety certified personnel used a greater number of appropriate food safety practices than those without certified personnel. It has been shown that the knowledge is improved with training. For instance, Walker and co-authors (2003a) evaluated 444

food handlers of 104 independent food businesses located at the East Midlands region of the UK and found that the lack of training contributed to the lack of food hygiene knowledge. Panisello & Quantick (2001) also mentioned that training courses should be developed specifically for the level of technical expertise of the employees and their degree of responsibility; and when managers do not have appropriate training, they may think that as long as the product looks normal and there is no evidence of spoilage, the product is safe. Since they have had good results in using "common sense" practices during the past and were unaware of the risks involved with the handling of their raw material and processing operations, then they do not see the need of HACCP systems (Panisello & Quantick, 2001). The importance of knowledge and training for the proper execution of tasks in FSE and the actual lack of these requirements show the relevance of this indicator for FSE. The former grid was changed replacing the education level in agri-food to educational level in cuisine, and experience en food safety control to experience in food service establishments.

Lack of management commitment:

The managers of the establishment play an important role in the organisational structure since they determine the policies, goals, strategies, rules and values that all personnel must follow. If those items are not tailored toward the food safety then it will be difficult for the personnel to follow attitudes and procedures to accomplish food safety (Luning & Marcelis, 2009). Adequate resources such as money, time, manpower, monitoring equipment and training aids, must be facilitated to supervisory personnel in order to develop, monitor and verify an effective HACCP plan. For this, management should take a pro-active attitude to provide these resources (Panisello & Quantick, 2001). Similarly, Cenci-Goga and co-authors (2005) remarked that some essential management measures to implement HACCP are provision of continuing professional education and the availability of a proper working environment. Even though food safety is one of the most important aspects in food service operations, it usually receives the smallest amount of attention from management (Manask, 2002). The importance of management commitment to develop and operate a FSMS makes this indicator relevant for FSE. The grid was changed by replacing the requirement of having an official quality (safety) team in situation 2 and 3 for the presence of competent person in charge

of the quality and safety within the establishment in situation 2 and without the technical knowledge in situation 3.

Deficiency in employee involvement:

Personnel involvement is a factor that positively increases motivation and understanding of procedures done in the company (Luning & Marcelis, 2009). If personnel are involved in the development of the procedures, then they can give feedback of the functioning of the procedures since they have the experience and are daily applying those procedures in their tasks. Furthermore, the fact that their opinion and knowledge is considered at the company increases their motivation to perform the procedures, since they understand and believe them (Hancer & George, 2003). On the other hand, the lack of personnel involvement would require specific and continuous instructions, training and control of employees to assure that they follow up the procedures and perform their tasks as expected. Furthermore, it has been observed that the motivation of personnel involved with HACCP contributes to the implementation and maintenance of the system, especially if it requires continuous monitoring and documentation (Panisello & Quantick, 2001). Similarly, there are studies that remark that an effective implementation of HACCP requires employee involvement, encouragement of self-inspection procedures, and giving staff the possibility to suggest and implement further hygienic practices (Taylor & Kane, 2005; Cenci-Goga; 2005). Therefore, the employee involvement is relevant for FSE.

Absence of formalisation:

It is important to have procedures since they are aimed at directing people´s decision-making behaviour toward safety and are necessary for the compliance of a quality management system (Luning & Marcelis, 2009; Luning et al., 2009a). The large restaurant chains requires more formalisation through procedures because there are often multiple workers in multiple restaurants conducting similar activities; thus, they have to establish routine procedures such as checking temperatures with thermometers to standardize cooking practices and ensure consistency across restaurants (Green et al., 2005). Taking into account the influence of formalisation to direct personnel behaviour and standardized preparation practices, this indicator is relevant for FSE.

Deficiency in information systems:

In order to make decisions toward the same goal, companies must have an information system that provides reliable information at the right moment to operate and improve the performance of the organisation structure (Luning & Marcelis, 2009). Furthermore, a FSMS must have a reliable information system with data about the microbial population, the characteristics of the food prepared and the processing conditions (McMeekin et al., 2006). FSE, as a company, also needs available information to make appropriate decisions toward food safety. Therefore, this indicator is relevant for FSE.

Chain environment characteristics:

The indicators that refer to the chain environment characteristics are "safety contribution in chain position", "lack of power in supplier relationships", "lack of power in customer relationships" and "strictness of stakeholders requirements", as shown in Figure 1.

Safety contribution in chain position:

The FSE are the last part of the food chain and a large proportion of foodborne diseases have been attributed to this sector (Panisello et al., 2000; Martinez-Tome et al., 2000, Eves & Dervisi, 2005). These facts make the FSE to be in a critical position since they directly contribute to the reduction of hazards by being the link with the final customer. Therefore, this indicator is relevant for FSE.

Lack of power in supplier relationships:

Companies working jointly with their customers and suppliers may integrate activities along the supply chain and effectively supply products to customers (Hill & Scudder, 2002). The supplier tends to adapt to its customers needs in order to satisfy them. The main variables influencing long-term relationships with suppliers are the satisfaction and commitment, and these aspects can be affected by the size of the customer company. The antecedents of the level of satisfaction are the climate of trust, the collaboration and exchange of information. The larger or smaller size of the organisation may determine greater or lesser levels of power-dependency with respect to its suppliers (Polo & Cambra, 2007). The FSE can be able to influence the quality and handling practices of the foods before they enter the kitchen and ensure that the

supplies are obtained from high-quality suppliers (Jones & Angulo, 2006).The importance of the supplier relationship to have standardised supplies complying with the safety requirements outlines the relevancy of this indicator for FSE.

Lack of power in customer relationships:

Due to the nature of the FSE business, where there is no chance of power to influence the customer with respect to the use of the product, this indicator in not reliable for FSE. However, consumers should avoid consumption of high-risk foods, such as undercooked eggs or undercooked ground beef (Jones & Angulo, 2006). The only aspect that must be considered in the FSE is that the consumers cover the whole population, which includes vulnerable groups like children, elder and immune-comprised people (McCabe-Sellers & Beattie, 2004) and this fact requires a reliable FSMS.

Strictness of stakeholder requirements

The main stakeholder in FSE is the government and legislation requires that FSE must have a FSMS based on HACCP principles (Codex, 2003). The degree in which the government asks, through legislative requirements and inspections, to comply with certain safety rules directly impacts the complexity of the FSMS. The inspections are an important element of how regulatory government departments attempt to assure that consumers are provided with safe food (Griffith, 2005). It has been found that small companies have lack of understanding of legislation and basic food safety principles, and are sceptical of the relevance and importance of certain legal requirements, which may contribute to poor levels of compliance (Yapp & Fairman, 2006). There are other quality assurance standards that FSE apply in their systems to show stakeholders, specifically customers, that they work with high safety standards, such as ISO, UNE167000:2006, European Foundation for Quality Management (EFQM), Institute of Spanish Hospitality Quality (ICHE), Spanish Tourism Quality certified by the Institute for Spanish Tourism Quality (ICTE), Excellence of Services (Puig-Duran, 2006). The influence of the legislative requirements and the additional QA standards to the design of a FSMS shows the relevancy of this indicator for FSE. The grid was modified changing the former QA-standards of BRC, IFS with some specific voluntary QA-standards like ISO, EFQM, ICHE and ICTE.

3.2 Core Control Activities

Preventive measures design

The indicators that describe the preventive measures design are “sophistication of hygienic design of equipment and facilities”, “adequacy of cooling facilities”, “specificity of sanitation programs”, “extent of personnel hygiene requirements”, “specificity of raw material control” and “adequacy of product specific preventive measures” as shown in Figure 1.

Sophistication of hygienic design of equipment and facilities:

The equipment design affects food safety since the equipment layout is linked to sanitation, productivity and capital costs. The design of facilities is based on the principles of space efficiency, flexibility, product flow, food safety and ergonomics. For instance, the improved ways of temperature measurement or recording and equipment easiness for cleaning support HACCP and GMP (Rodgers, 2005a). An unhygienic design of facilities may result in deficiencies in employees behaviour or sanitation procedures (Montes et al., 2005). For example, inadequate ventilation could cause uncomfortable work conditions making the employee to behave unhygienically by drinking water or cleaning sweat during preparation tasks, increase ambient temperature and microbiological load in the air, facilitate condensation and accumulation of fumes from cooking areas; or hand-washing stations located in unavailable positions in the kitchen may interfere in appropriate hand washing (Montes et al., 2005). Moreover, inadequate layout of equipment could generate spaces difficult to clean (it is recommended to have at least 30 cm of separation between equipment and floor and 5 cm of separation between walls) or may facilitate cross contamination because there is no forward flow with returns and crossings among raw materials, ready-to-eat meals and trash (Montes et al., 2005). A well designed establishment with hygienically designed and reliable equipment will help in maintaining hygienic conditions, facilitate cleanliness and control pest infestations (Panisello & Quantick, 2001; Montes et al., 2005). Frequently, FSE are unhygienically designed and crowded with staff and machinery to satisfy occasional workloads and makes difficult to control basic sanitary standards resulting in an increased number of CCPs and CPs to prevent the risk of cross-contamination and recontamination of food (Panisello & Quantick, 2001).

Considering that the hygienic design has a link with the cleanliness of food contact surface and that the World Health Organisation and European Food Safety Authority have established contamination from dirty contact surfaces as a main cause of foodborne outbreaks highlight the importance to assess this aspect in FSE (WHO, 2007; EFSA, 2007). The aforementioned literature underpins the relevance of this indicator for FSE. The grid was changed by replacing food production for meal production.

Adequacy of cooling facilities:

The cooling facilities have been found to be an important measure to prevent contamination and growth of pathogens (Likar & Jevsnik, 2006; Walker, Pritchard & Forsythe, 2003b; Jackson, 2007). The cooling facilities is one of the main equipment used in FSE to prevent the growth of pathogens and maintain the quality of food (Bello, 1998; Montes, 2005), thus the performance of this indicator is relevant for the assessment of the performance of the FSMS in FSE.

Specificity of sanitation program:

The sanitation programs have been shown to be essential to prevent contamination and growth of pathogens (Thevenot, 2006). The sanitation program is a main issue to consider because inadequate cleaning and disinfection represents a risk factor for contamination because of the possible presence of pathogens that have low minimum infective dose such as *Escherichia coli* O157:H7 (Davidson et al. 1999) or *Listeria* spp (Gibbons, Adesiyun, Seepersadsingh, & Rahaman, 2006), and because is an effective means to reduce cross-contamination and the occurrence of foodborne diseases outbreaks (Cogan et al, 2002; Watchel et al, 2003; WHO, 2007; EFSA, 2007). The literature described above shows the relevance of this indicator for FSE.

Extent of personnel hygiene requirements:

The personnel hygiene has been considered as crucial to prevent contamination, growth of pathogens and occurrence of foodborne outbreaks (Martínez-Tomé, Vera & Murcia, 2000; Borch & Arinder, 2002; Aycicek, 2004; Lucca & Torres, 2005; WHO, 2007; EFSA, 2007). The requirements of personnel hygiene in order to limit the risk of contamination include personal cleanliness, restrincting the entrance of employees having illness, covering with water resistant bandages and gloves any infected cut or

wound, taking care when coughing or sneezing, prohibiting smoking or eating while preparing food; availability of hand-washing stations, pedal activated dustbins, protective clothing; and specific training or instructions (Martínez-Tomé et al., 2000; Aycicek, 2004; Baert et al., 2005; Montes et al., 2005; Smith et al., 2005). Research indicates that there is a positive association between knowledge and training and safe food handling practices (Campbell et al., 1998, Cotterchio et al., 1998). Legnani and co-authors (2004) evaluated mass catering establishments after a HACCP system was implemented and showed that the staff educational program introduced in the catering centres has certainly helped to increase the level of awareness and the sense of responsibility regarding food hygiene. Similarly, Green and co-authors (2005) detected that personnel with more intensive food handling responsibilities were more likely to wash their hands when needed. The fact that FSE deals with preparation techniques that have direct contact with personnel hands, makes the requirements on hand washing practices and personal care and health to become extremely high (Bidawid, Farber & Sattar, 2000; Clayton & Griffith, 2004; Smith, Kanas, McCoubrey & Belton, 2005). As shown, the personnel hygienic requirements influence personnel behaviour and the actual performance of the FSMS; therefore, it is a relevant indicator for FSE.

Specificity of raw material control:

Efforts should be made to start operations using raw materials and ingredients with less microbial load, especially with red meat, poultry, marine foods, vegetables and fruit due to its potential bacteriological hazards and its relation with foodborne outbreaks (WHO, 2007; EFSA, 2007), and because avoidable contamination of raw materials unnecessarily increases the severity of processing (Cenci-Goga et al., 2005). Among those efforts is the rejection of cracked eggs, slightly slimy meats, softened fishes, slightly musty cereal products, mouldy fruits, sauces showing early signs of fermentation, etc (Mossel, Jansen & Struijk, 1999; Montes, 2005). Big FSE companies such as fast food chains build their competitiveness on the standardization of raw materials (Rodgers, 2005a). Higher initial levels of pathogens require more sophisticated and reliable FSMS (Luning et al., 2008). The importance of the raw material control for the design and operation of the FSMS makes this indicator reliable for FSE.

Adequacy of product specific preventive measures – Specificity of meal preservation, Specificity of defrosting methods, Specificity of hot-holding methods:

The product specific preventive measures for FSE are meal preservation, defrosting methods and hot-holding methods. Therefore, the indicator "adequacy of product specific preventive measures" was changed to three indicators: "specificity of meal preservation", "specificity of defrosting methods" and "specificity of hot-holding methods".

The indicator "specificity of meal preservation" was found to be relevant for FSE because food service establishments commonly have high stock of raw materials, partly prepared meals and meal components (like sauces) in order to save time during preparation to comply with the need of serving many types of meals to large numbers of people simultaneously (Gilbert et al., 1996; Worsfold, 2001). This typical situation requires FSE to have reliable and safe preservation techniques since these preservation methods may add microbial risks to the meals and need to be controlled to prevent overgrowth of microorganisms.

There are various methods to preserve meals but one of the main methods is storage in refrigerated conditions which requires safe chilling methods, adequate cooling facilities that include storage rooms, refrigerated cabinets, refrigerated displayers (Bello, 1998); and proper storage conditions in the storage room.

Other methods used in FSE to preserve meals prepared on advance are package, freezing, sugar concentration, dehydratation, addition of chemicals to obtain salted items, pickles and marinades (Bello, 1998; Montes et al., 2005). The variety of packaging products for cooked meals includes unit-portion packs, vacuum barrier bags, trays for frozen and chilled meals, flexible pouches, "bag-in-a-box" products, and disposable heat-resistant bags for cooking and hot-holding (Brody, 2003). The freezing process must consider the adequacy of package, and speed/time of freezing (which depends on several factors such as cooling capacity, thermal conductivity of the food and package, dough and thickness of the food) (Bello, 1998). Salted food items are preserved by the addion of salt, which has the capacity to reduce water activity in the food; while pickles and marinades are preserved by the addition of vinegar, which reduces pH, and seasonings, which have antimicrobial capacity (Bello, 1998).

Taking into account that the aim of the preservation methods is to increase shelf-life, the method by which it is established is important in the development of the preservation technique. There are several indicators according to the type of food. For example, an indicator for fish is the odour, for poultry is the appearance and for meat is the colour (Rybka et al., 2001).

The indicator "specificity of defrosting methods" was considered relevant for FSE because unsafe defrosting facilitates the overgrowth of microorganisms or pathogens. Rapid chilling systems permit a safe defrosting method to prevent bacterial growth, and if costs are prohibitive, the defrosting should be done overnight in the refrigerated storage rooms portioning or slicing the food items in smaller portions (Bolton et al., 2008) and with with means to avoid contact with defrosting water (from the melting of ice crystals) such as screens (Montes et al., 2005).

The indicator "specificity of hot-holding methods" was found to be relevant for FSE because incorrect hot-holding temperature is the leading causative factor of the foodborne outbreaks of *Bacillus cereus* and *Clostridium perfringens* (McCabe-Sellers & Beattie, 2004). Furthermore, it has been found to be a contributory factor by 60% of foodborne outbreaks in the US (Olsen et al., 2001).

The degree in which these product specific preventive measures are designed in accordance with legislative or guidance documents and tested for its effectiveness determines the situation of the indicator. Thus, if the measures are designed based on experience the FSE must be allocated in level 1, if they are based on legislation or valid guidelines then the FSE is described as level 2, and if they are tested it is then considered as level 3.

Intervention process design

The indicators that describe the intervention process design are "adequacy of physical intervention equipment", "adequacy of packaging intervention equipment", "specicifity of maintenance & calibration program for equipment" and "effectiveness of intervention methods", as shown in Figure 1.

Adequacy of physical intervention equipment:

The adequacy of intervention equipment depends on the potential process capability and the maintenance and calibration program that suits the specific production circumstances (Luning & Marcelis, 2009; Srikaeo & Hourigan, 2002; Scott, 2005). Big sized FSE such as fast food chains build their competitiveness on the accuracy of cooking equipment (Rodgers, 2005a). The designers of food service equipment tend to improve aspects such as better temperature distribution and control, faster cooking, less energy and labour costs, safer operations, better sanitation, and flexibility. Examples of this kind of equipment are modern ovens that can prepare salmon fillets in 3 minutes, steam-powered cooking, steamers with vacuum pump, pressure fryers, induction heating, etc (Rodgers, 2007). Due to the fact that the FSE commonly use intervention equipment as the main process to reduce microbial load, this indicator is relevant for FSE.

Adequacy of packaging intervention equipment:

In FSE the package is not used as an intervention step but as a method to preserve meals prepared on advance. Therefore, this indicator was considered as not relevant for FSE.

Specificity of maintenance and calibration program for the intervention equipment:

The maintenance and calibration program for equipment is part of the pre-requisite programs that is needed for an adequate implementation of safety systems such as HACCP (Sun & Ockerman, 2005). A specific maintenance and calibration program is described by a design according to production circumstances using data from own breakdown analyses, with detailed instructions and well-documented (Khan & Haddara, 2004; Bertolini & Bevilacqua, 2006). Since the maintenance and calibration is essential for the adequate performance of the intervention equipment, this indicator is relevant for FSE.

Effectiveness of intervention methods:

Besides the heat treatment, another procedure to reduce microbial load is the washing of fresh-type meals like salads, which is a common procedure done at restaurants. Soriano and co-authors (2005) suggested that the dynamics of the washing processes and the effectiveness of the operations play the most important role in the reduction of the

contamination level. It was recommended that lettuce, onion, carrots and tomatoes used for salad preparation be washed prior to use in order to partially remove the microorganisms that are intrinsic in vegetables and eliminate any present organic material. This elimination would improve the subsequent disinfection with chlorine solution because the activity of chlorine will diminish if this disinfectant is combined with organic material (Soriano et al, 2005). Level 3 is described by a more specific and complete washing procedure, where the chemical agents and cleaning steps are tested for actual reduction of contamination to assure that the fresh raw material initial contamination is reduced to acceptable levels. The relevance of this indicator for FSE is evident due to the importance of the intervention methods, which is another procedure to reduce microbial load of fresh-type meals.

Monitoring system design

The indicators that describe the monitoring system design are “appropriateness of CCP analysis”, “appropriateness of standards & tolerances design”, “adequacy of analytical methods to assess pathogens”, “adequacy of measuring equipment to monitor process/product status”, “specificity of calibration program for measuring & analytical equipment”, “adequacy of sampling design (for microbial assessment) & measuring plan” and “extent of corrective actions”, as shown in Figure 1.

Appropriateness of CCP analysis:

Complete and accurate determination of CCPs is fundamental for the control of food safety hazards (Doménech, Escriche & Martorell, 2008).The appropriate allocation of CCP defines the reliability of the monitoring system (Panisello, Quantick & Knowles, 1999; Orris & Whitehead, 2000; Mortimore, 2001; Baert et al., 2005). It requires scientific evidence, allocation in a systematic way and tests for the specific production circumstances (Kvenberg & Schwalm, 2000; Baert et al., 2005; Escriche et al., 2006). In In general, the hazards may come from raw material, introduced during the process or changed during the process (growth or survival). The hazards that must be selected are those with high probability of incidence, severity and possibility of detection. The rest of hazards can be controlled with preventive measures (Montes et al., 2005). The most common CCPs in FSE operations are control of raw material, cooking, cooling,

reheating, and hot/cold holding (Sun & Ockerman, 2005). Due to the fact that the CCP analysis is essential to control hazards, this indicator is relevant for FSE.

Appropriateness of standards and tolerances design:

The limits must be monitored by measurement or observation, based upon factors such as temperature, time, physical dimensions, humidity, moisture level, water activity, pH, salt concentration, available chlorine, viscosity, etc. Furthermore, these limits must be scientifically and/or regulatory based (Doménech, Escriche & Martorell, 2008). The standards and tolerances/limits must be complete, specific, in alignment with legislative requirements, scientifically underpinned and tested for specific production situation (Mortimore, 2001; Baert et al., 2005; Bertolini, Rizzi & Bevilacqua, 2007). Some common limits and standards found in FSE are chilled storage < 4ºC, frozen storage < -18ºC, defrosting <4ºC and <7ºC if the items will be cooked, cooking 72ºC for 15 seconds, hot holding > 65ºC, chilling from 65ºC to 8ºC in less than 2 hours, cold holding <4ºC and <8ºC if it is to be consumed in 24 hours, reheating > 65ºC, disinfection solution for fresh-type meals of 70 ppm with a contact time of 5 minutes (Montes et al., 2005). This indicator is relevant for FSE because it assess the adequacy of the limits that the CCP must comply with.

Adequacy of analytical methods to assess pathogens:

The assessment of pathogens is a direct tool to monitor the effectiveness of the FSMS to control microbial hazards (Brown et al., 2000; Jacxsens et al., 2009). The adequacy is determined by sensitivity, specificity, repeatability, reproducibility and rapidity executed based on internationally acknowledged and accredited procedures (DeBoer & Beumer, 1999; Ellis & Goodacre, 2001; Feinberg & Laurentie, 2006; Maraz et al., 2006). The importance of the adequacy of the methods to evaluate the presence of pathogens in the meals indicates the relevancy of this indicator for FSE.

Adequacy of measuring equipment to monitor process/product status:

The effectiveness of the CCP depends on the accuracy and reliability of the monitoring equipment (Doménech, Escriche & Martorell, 2008). Its adequacy depends on the accuracy and responsiveness according to the production circumstances (Nott & Hall, 1999). The measuring equipment must be user-friendly and based on easy-to-record

parameters such as temperature or sensory characteristics. Consequently, managers should be aware of the limitations of their operations and realistically design monitoring procedures and schedules according to their operations (Panisello & Quantick, 2001). If the core temperature cannot be measured there are other sensorial parameters that can be used to monitor process status such as boiling (100ºC), coagulation of eggs (70ºC), or color and absence of exudative liquid in meats (70º) (Montes et al., 2005). The actual status of the process or the product within the operations is assessed by the measuring equipment, thus, this indicator is relevant for FSE.

Specificity of calibration program for measuring & analytical equipment - Specificity of calibration program for measuring equipment:

The equipment used to monitor a critical step due to its impact over final safety must be systematically calibrated and checked for accuracy in the set operating range and at intervals of enough frequency to provide assurance that the CCP is under control (FDA, 2006). Therefore, this indicator is relevant for FSE. The assessment of analytical equipment was removed from this indicator because it was considered that FSE, due to its contextual factors, do not have analytical equipment to measure microbiological safety parameters. The grid was changed by removing the descriptions referring to analytical equipment.

Adequacy of sampling design (for microbial assessment) and measuring plan:

Adequate sampling plans are those that are statistically underpinned and based on the specific production data in order to determine the right location, frequency, sample size and rejection criteria (Luning & Marcelis, 2009). If the sampling plan is not done correctly or statistically supported then the data obtained from it may not be representative of the real situation of the process. At the same time, the measurements done to the sample must be relevant to select criteria that can establish if the process is complying with safety requirements. The importance of the adequacy of sampling makes this indicator as relevant for FSE.

Extent of corrective actions:

When a deviation of the system is detected, appropriate corrective actions must be taken to re-establish control to assure that the potentially hazardous products do not reach the

consumer (Doménech, Escriche & Martorell, 2008). Therefore, structural analysis of possible causes of deviations is required. The importance of a description of corrective actions to re-establish control shows the relevance of this indicator for FSE.

Operation of core control activities

The indicators referring to the operation are “actual availability of procedures”, “actual compliance to procedures”, “actual hygienic performance of equipment and facilities”, “actual cooling capacity”, “actual process capability of physical intervention processes”, “actual process capability of packaging equipment”, “actual performance of measuring equipment” and “actual performance of analytical equipment”, as shown in Figure 1.

Actual availability of procedures:

The procedures are aimed at directing people’s behaviour since they guide what, how, when and why to do at the establishment to obtain certain safety goals (Luning & Marcelis, 2007, 2009; Luning et al., 2009a). Therefore, the procedures must be available at the right places, understandable for the people who use them, and accurate in order to exactly show all the activities, responsibilities and instructions that must be done. Due to the importance of the availability of procedures to direct personnel behaviour, this indicator is relevant for FSE.

Actual compliance to procedures:

The compliance to procedures depends on the ability and disposition of the people toward the safety tasks (Gerats, 1990), awareness and knowledge of the procedures (Gilling, Taylor, Kane & Taylor, 2001; Azanza & Zamora-Luna, 2005), and persistence of existing habits and attitudes (Robbins & McSwane, 1994; Panisello et al., 2001). There are studies that have found that even when FSE workers demonstrate good knowledge of food safety or have a positive attitude towards food safety, they do not always comply with safe preparation practices or improve in their food hygiene behaviour (Clayton et al., 2002; Howes et al., 1996; Taylor, 1996; Angelillo et al., 2000). Similarly, Sneed and co-authors (2004) demonstrated that the food-handling practices that needed improvements were appropriate hand washing; recording of food temperatures and storage rooms or sanitizer concentration; lack of knowledge of the correct minimum end-point cooking temperature, lack of checking the effectiveness of

sanitizing procedures; deficiencies in the cleaning and disinfection procedure because it did not include a disinfection step or because the detergent was mixed with the sanitizer; lack of proper labelling and dating of foods. Several surveys have shown that one in five food handlers does not routinely wash their hands or the cutting boards after cutting raw meat or chicken (Altekruse et al, 1999; Klontz et al, 1995). The need to evaluate the actual compliance to procedures and the availability of studies showing differences between knowledge and actual performance of personnel behaviour indicate the relevance of this indicator to assess the performance of the FSMS in FSE.

Actual hygienic performance of equipment and facilities:

The equipment may result in an important source of contamination if it is not well cleaned and disinfected (Evans et al., 2004). The microbial quality of surfaces has been identified as a useful indicator to assess the performance of the procedures of cleaning and disinfection (Legnani et al., 2004), and to assess the performance of a FSMS (Jacxsens, 2009). Therefore, the cleanliness must be checked on a regular basis to ascertain that contamination is controlled. Due to the importance of checking actual cleanliness of contact surfaces in FSE, this indicator is relevant for the assessment of performance of FSMS in FSE.

Actual cooling capacity:

As explained before, the cooling step is an important preventive measure to avoid overgrowth of microorganisms in FSE. Considering that the cooling performance depends on the cooling capacity of the devices used to maintain food items under safe chilling temperatures (Bello, 1998; Montes, 2005), it is important to assess the actual cooling capacity of those equipments/facilities. Futhermore, some authors have found that the actual cooling capacity is not measured in small sized FSE. For instance, Walter et al., 2003b found found lack of control of the adequacy of cooling and storage due to the presence of domestic refrigerators without temperature-check devices. Similarly, Bolton et al., 2008 observed that in many cases the temperature of the food items during refrigerated storage is never tested and the food temperatures are assumed to be the same as the displayed in the storage room. The importance of measuring the cooling capacity and the aforementioned studies underpinning that cooling capacity since it is not always checked and/or achieved demonstrate the relevance of this indicator.

Actual hot-holding capacity

The capacity of the facilities to maintain safe hot-holding temperatures and to measure the actual temperature is related with the compliance of keeping food items at safe temperatures before consumption. It has been reported that the hot-holding temperature is measured directly from the food (73,8%), relying on the equipment internal thermometer (14,9%), and monitoring the temperature of the water in the Bain Marie container (11,3%) (Bolton et al., 2008). The fact of being a factor to cause foodborne outbreaks and the existence of studies showing that the hot-holding capacity is not adequately measured underpin the relevance of this indicator for FSE. The grid for assessment is based on the grid for the assessment of the indicator "actual cooling capacity".

Actual process capability of physical intervention processes

A capable intervention process is characterised by stability and minor deviations (Luning & Marcelis, 2009). It is commonly found that the temperature during cooking processes is poorly monitored due to the absence of an accurate method to check temperatures (Walker et al., 2003b). Therefore, the cooking effectiveness is assessed by experience, visual inspection, or cooking time (Bolton et al., 2008). The importance of assessing the actual capability of the intervention processes and the actual inadequate measurement of this capability in FSE shows the relevance of this indicator for the modified FSMS-DI. The grid was changed by replacing production lines for meals and by removing the descriptions referring to use of control charts.

Actual process capability of packaging intervention:

Since packaging intervention equipment is not relevant for FSE, the actual process capability of the packaging intervention was also disregarded in the FSMS-DI modified for FSE.

Actual performance of measuring equipment

The measuring equipment in FSE may not be able to do on-line monitoring but discontinuous monitoring because equipment like refrigerators or cookers may not have temperature-check devices or may have not been calibrated (Panisello & Quantick, 2001). However, the measuring equipment must be stable under the different process

conditions in order to provide reliable information about the product or process status. Thus, it must be assessed in the FSMS-DI modified for FSE. The grid was changed by replacing production process for meal production.

Actual performance of analytical equipment:

Due to the fact that FSE do not have analytical equipment to assess its process, the actual performance of analytical equipment was considered as not relevant for the FSMS-DI modified for FSE.

3.3 Core Assurance Activities

Setting of system requirements

The indicators used to describe the setting of system requirements are “sophistication of translation of stakeholder requirements into own FSMS requirements”, and “extent of systematic use of feedback information to modify FSMS”, as shown in Figure 1.

Sophistication of translation of stakeholder requirements into own FSMS requirements:

The external requirements are given by the stakeholders that include the government, customers, etc. The government demands the implementation of Good Manufacturing Practices and HACCP principles (Codex, 2003), while customers such as retailers or multinationals require the compliance of specific standards such as ISO or EFQM. The importance of translating stakeholder requirements into FSMS requirements makes this indicator relevant for FSE.

Extent of systematic use of feedback information to modify FSMS:

As well as the external information is used to set the requirements of the FSMS, the feedback information of the control system is also used to modify and improve the system in order to overcome failures or adapt the system to recipe or process changes (Luning et at., 2009a). Therefore, the assessment of this indicator is necessary in FSE.

Validation:

The indicators related to validation are “sophistication of validation of preventive measures”, “sophistication of validation of intervention processes”, and “sophistication of validation of monitoring systems”, as shown in Figure 1.

Sophistication of validation of preventive measures & Sophistication of validation of intervention processes:

The validation activities check in advance the effectiveness of the designed control measures (Luning et al., 2009a). As described by Luning and co-authors (2009a) one of the main sources of information to validate activities is the use of scientific publications and regulatory documents that confirm the effectiveness of specific control measures (Scott, 2005; CAC, 2008; Jacxsens et al., 2009). Along with the availability of reliable information, the validation activities need microbial data to assess the actual effect of the control measure (Scott, 2005; CAC, 2008; Martins & Germano, 2008). The importance of validation activities with acknowledged scientific data and microbiological tests to assure that the control activities are able to ascertain food safety makes these indicators relevant for the FSMS-DI modified for FSE.

Sophistication of validation of monitoring system:

The CCP determination, the standards and limits, and the monitoring system itself must be validated (ILSI, 2004; Scott, 2005; CAC, 2008). The monitoring system, as well as the preventive measures and intervention processes, can be validated through the use of experimental trials, scientific literature and government regulations by independent experts (Sperber, 1998). As well as the validation of the preventive measures and intervention processes is relevant for FSE, the validation of the monitoring system is also important to consider for the assessment of performance of the FSMS in FSE.

Verification:

The indicators referring to verification are “extent of verification of people related performance” and “extent of verification of equipment and methods related performance”, as shown in Figure 1.

Extent of verification of people related performance & Extent of verification of equipment and methods related performance:

The verification activities check afterwards whether the control activities are operated as designed (Luning et al., 2009a). The verification needs valid and reliable information and performance data to judge if the system is achieving the requirements. Thus, it uses procedures, records, observations, performance data and microbial analysis to confirm the actual performance (Cornier et al., 2007; Kvenberg & Schwalm, 2000). Verification is commonly perceived in small and micro business as a burden because the manager is on site all the time and verifies the system by observation and visual confidence (Taylor, 2001). Due to the importance of the verification of actual people and equipment performance, and the common lack of verification activities in small sized FSE, these indicators are relevant for the FSMS-DI modified for FSE.

Documentation and record-keeping:

The indicators describing documentation and record-keeping system are "appropriateness of documentation system" and "appropriateness of record keeping system", as shown in Figure 1.

Appropriateness of documentation:

Documentation aims at keeping knowledge and information of the system by procedures, instructions, complaints, statistical analyses, etc (Luning et al., 2009a). Despite the fact that documentation is not a legal requirement, an appropriate documentation system reflects the commitment of the establishments' management to consistently apply the basic control measures identified in HACCP (Eves & Dervisi, 2005) and it helps to determine the source of contamination in case of a safety problem. The fact that small and micro businesses regard the documentation and record-keeping as time consuming requires the FSMS to have a documentation system in accordance to actual practice with the minimal disruption (Taylor, 2001). In addition, it has been seen that FSE actually do not perform the intervention processes with a documented system and rely the reduction of microbial load on visual checks and experience (Walker & Jones, 2002). Considering the importance of an appropriate documentation system and the common actual lack of use of documentation in FSE, makes this indicator relevant for FSE.

Appropriateness of record keeping system:

Record-keeping aims at collecting data through the use of specifications, process and product data, records of storage, etc (Luning et al., 2009a). In small sized FSE, the lack of use of procedures and record-keeping systems due to time-related issues has been observed (Rodgers, 2005a; Eves & Dervisi, 2005; Taylor, 2001; Panisello & Quantick, 2001). Therefore, a "user friendly" system is needed to assure that all the required information is collected (Panisello & Quantick, 2001). The importance of record-keeping and the appropriateness of the system to collect the information according to the organisational circumstances in the establishment make this indicator relevant for FSE.

The FSMS-DI modified for FSE is shown in Appendix 1.

Summarizing the modifications done to the FSMS-DI to make it more useful for FSE in view of the literature analysise, it can be said that 5 indicators were removed from the FSMS-DI, 13 indicators were modified (of which 8 were modified only by changing the grid), and 1 indicator was added to the FSMS-DI. These changes make a total of 49 indicators to assess actual performance of FSMS operated in FSE.

The next step is to use this FSMS-DI modified for FSE in a statistically significant sample of FSE in Spain (Burgos) in order to assess actual performance of FSMS implemented in FSE.

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Figure 1: FSMS-DI modified for food service establishments (adapted from Luning and co-authors, 2008, 2009a, submitted 2009b, submitted 2009c)

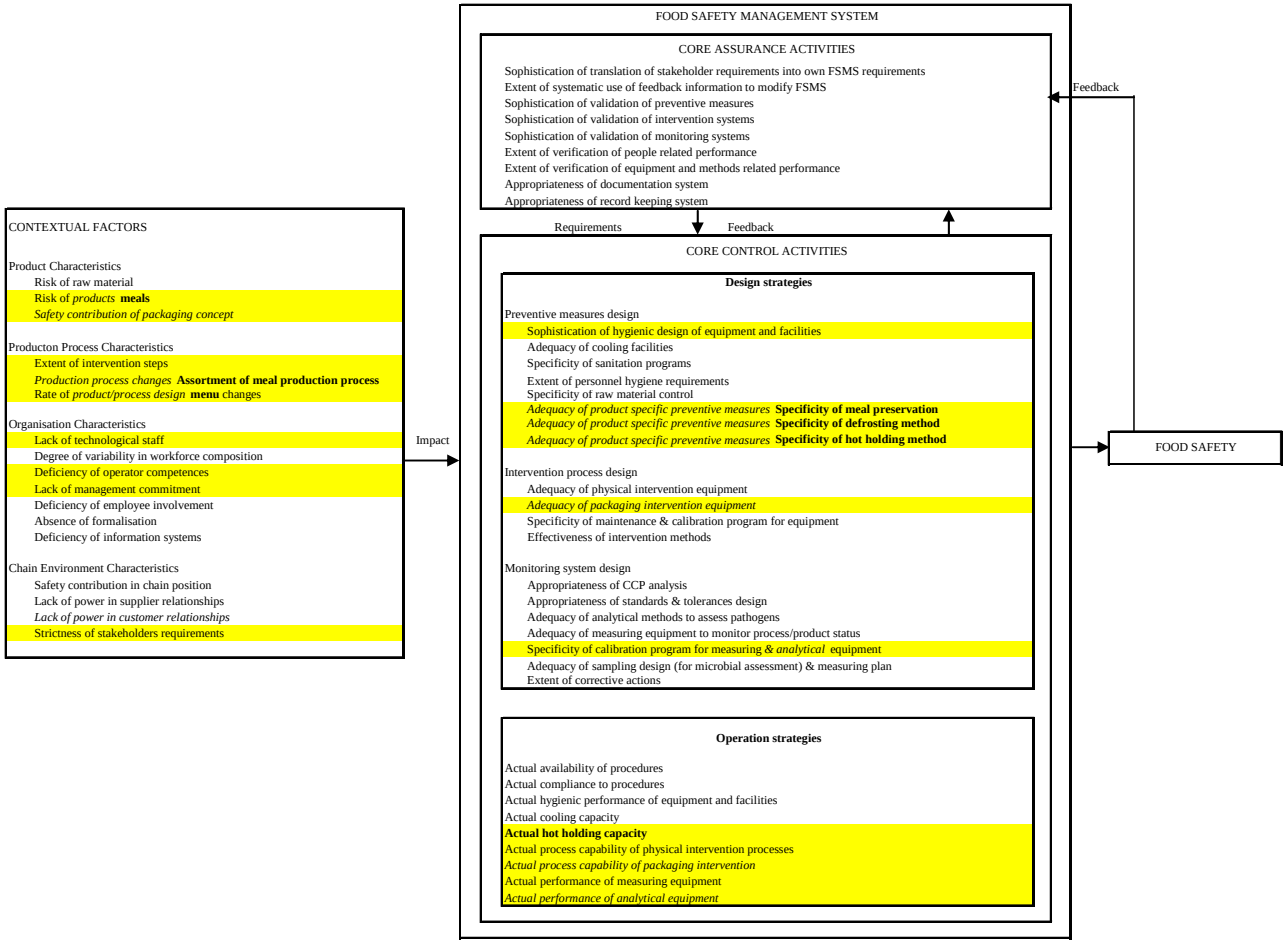

Table 1 Grid with assumption and situations of the contextual factors of the FSMS-DI modified for FSE (adapted from Luning & co-authors, submitted 2009b, submitted 2009c).

Indicator	**Assumption**	**Situation 1**	**Situation 2**	**Situation 3**
Product characteristics				
Risk of raw materials	Raw materials associated with pathogens and/or high initial microbial levels with potential impact on final safety and which require special storage conditions, increase chance on lower FS performance and put higher demands on the FSMS by requiring advanced control and assurance activities.	• Basic/major raw materials are <u>not</u> associated with high initial microbial levels and pathogens • Storage at (uncontrolled) room temperature conditions	• Minor raw materials/ingredients associated with high initial microbial levels and pathogens, which potentially can affect safety of final product. • Storage at lower than room temperature but no specific, strict control requirements	• Basic/major raw materials associated with high initial microbial levels and pathogens, which potentially can affect safety of final product • High requirements on storage conditions and its control
Risk of *products* **meals**	Meals which are susceptible to pathogen growth or toxin formation (due to the intrinsic product properties and or applied inactivation technique), increase chance on lower FS performance, and put higher demands on FSMS by requiring advanced control and assurance activities	• Low risk meals (microbiologically stable) (a_w < 0.6 or pH < 4.2 or intrinsic antimicrobial agents) • *and/or sterilised products* (inactivation complete flora, post contamination not likely). • **Served as bought, no handling before service**	• Medium risk meals (0.98 >a_w > 0.6, or 4.2< pH <6.5, no antimicrobials) • *and/or in-pack pasteurised, UHT (ultra high temperature), frozen* (post contamination not likely). • **Cooked/reheated–served meals**	• High risk meals (aw > 0.98, pH 6.5-7.5, or no antimicrobials), • and fresh or pasteurised products (inactivation of original flora and chance on post contamination). • **(fresh-type meals, hot-held meals)**
Production process characteristics				
Extent of intervention steps	Increasing number of critical process steps that are required to achieve the intervention (i.e. inactivation/reduction hazard) increase chance on lower FS performance and will put higher demands on FSMS by requiring advanced control and assurance activities	• Process with a lethal intervention resulting in full inactivation of pathogens and spores • **No further steps that may contaminate (cooked & served)**	• Process with restricted set of intervention steps resulting in inactivation of pathogens to acceptable level, but spores not inactivated • **Further steps may recontaminate and thus require control to prevent growth to unacceptable levels (cooked-chilled/frozen-reheated/served, hot-held)**	• Process with no inactivation steps or a (complex) combination of steps aimed at reducing pathogens to certain level (spores not inactivated, and pathogens not fully inactivated) • **Washed/assembled-served**
Production process changes **Extent of assortment of meal production process**	Higher number of recipes prepared on the same preparation shift, more cleaning and disinfection interventions, less differentiated preparation areas increase chance on cross contamination (resulting in lower FS performance), and put higher demands on FSMS by requiring advanced control and assurance activities	• *Core process is characterised by continuous flow processes* • *High degree of automation, restricted interference of people* • *Cleaning in place (fully automated)* • **The meal production process is characterised by low number of recipes to be prepared on the preparation shift allowing the use of the equipment and surfaces for only one type of food restraining chances of cross contamination** • **(hall of residence with a single day meal)**	• *Core process characterised by repetititve flow i.e. relatively large batches with minor equipment modifications between batches* • *Partly automated, still people interference* • *Cleaning intervention between batches necessary (partly/not automated)* • **The meal production process is characterised by medium number of recipes to be prepared on the preparation shift allowing enough time to clean the equipment, surfaces and utensils before changing to another type of food.** • **(restricted number of day menu meals or organisation of production to have enough time during service)**	• *Core process characterised by intermittent flow i.e. relatively small batches, with major modifications between batches (daily batches)* • *Low degree of automation, clear interference of people with physical system* • *Cleaning between batches very critical, not automated* • **The meal production process is characterised by a high number of recipes to be prepared on the preparation shift facilitating the conditions for cross contamination since there is not enough time to clean and adjust the equipment and surfaces for the other type of food.** • **(menu "a la carte" with more than 30 different items)**
Rate of *product/process design* **menu** changes	Higher rate of changes in menu design (i.e. product, process modifications), can negatively affect FS performance by operation according to 'old' habits, and put higher demands on FSMS by requiring advanced control and assurance activities	• Relatively stable *product* **menu** assortment. • *No product and/or packaging modifications and/or innovative product (line) in last 2-3 years* • **No menu modifications or changes every year.**	• Medium variable *product* **menu** assortment. • *Between 1-5 product and/or packaging modifications and/or innovative product (line) per 1-2 years* • **Menu modifications every season (3-4 months) or more than once in a year**	• Highly variable *product* **menu** assortment. • *More than 5 product and/or packaging modifications, and/or innovative product (line) per ½ -1 year* • **Menu modifications within seasons**

Table 1 (Continued 1) Grid with assumption and situations of the contextual factors of the FSMS-DI modified for FSE (adapted from Luning & co-authors, submitted 2009b, submitted 2009c).

Indicator	Assumption	Situation 1	Situation 2	Situation 3
Organisation characteristics				
Lack of technological staff	Establishments with restricted (no) technological staff, expertise, and laboratory facilities will be less able to take adequate underpinned decisions, which negatively affects FS, and put demands on FSMS by requiring advanced control and assurance activities (e.g. hiring right expertise, tailored procedures, motivation people, operator control)	• *Industrial company* **Establishment** with a significant QA department with • Own staff and experts in food safety areas (e.g. food microbiologists, food quality management expert, etc) • Own research lab for all microbial analyses, safety controls.	• *Company* **Establishment** which has a QA manager (and/or small department) • With restricted number of people with expertise in food safety; collaboration with external experts (e.g. University) • Research facilities for routine analyses, complex analyses at external labs.	• *Company* **Establishment** has one person responsible for QA • With no specific food safety expertise, expertise is hired from outside (e.g. HACCP consultant) • Microbial analyses, safety controls at external labs
Degree of variability of workforce composition	Variability in workforce composition due to part-time workers and high personnel turnover may result in loss of company specific experience, which can increase chance on poor execution of safety tasks, which negatively influences FS putting demands on FSMS by requiring advanced control and assurance activities (e.g. robust procedures, more operator control)	• Low turnover of employees (> 5 years) • Occasionally temporary operators	• Common turnover of employees in food industry (1-5 years) • Temporary operators at specific seasons	• High turnover of employees (< 1 year) • Temporary operators at whole year around
Deficiency in operator competences	Recruited operators with inadequate education level, lack of experience, and restricted training support, increase chance on poor execution safety tasks, which negatively affects FS putting demands on FSMS by requiring advanced control and assurance activities (e.g. robust procedures, understandable for specific worker, different languages, more operator control)	• High and specific requirements on competence level of operators: medium/ professional education level in *agri-food* **cuisine** • Broad experience in *food safety control* **food service establishments** (minimal 3 years) • Specific requirements on language skills • Specific FS and FSMS training on regular basis	• Minimal requirements on competence level of operators; low professional education level not necessarily in *agri-food* **cuisine** • Some experience in *food industry* **food service establishments** (minimal 1 year) • No specific requirements on language skills, ability to speak current language • Basic food safety training at start then ad-hoc follow up training	• No specific requirements on competence level of operators • No specific requirements on experience • No requirements on language skills. • Basic training (instructions) in food safety control at start but no follow up training
Lack of management commitment	Lack of management commitment on food safety control shifts priorities of employees/operators to other issues, which increases chance on poor operation (e.g. not following procedures adequately which negatively affects FS performance), and put higher demands on FSMS by requiring advanced control and assurance activities	• Company has detailed written vision statement on safety. • It has an official quality (safety) team • with formalised meetings and own budget	• Company has general written vision statement on safety. • *It has an official quality (safety) team* • **It has a competent person in charge of the quality and safety within the establishment.** • with regular meetings and restricted budget	• Company has no written vision statement on safety. • *It has no official quality (safety) team* • **It has a person in charge of quality and safety within the establishment but without the technical knowledge** • only meetings on safety control in case of recalls, problems, no specific budget.
Deficiency of employee involvement	Lack of employee involvement will result in less committed and motivated operators, which favours inappropriate operation, and put higher demands on FSMS by requiring advanced control and assurance activities (e.g. more instructions, training, operator control)	• Operators are explicitly involved in design and modifications of FSMS • They are expected to bring in their knowledge to improve systems	• Operators' opinions are considered in design and modifications of FSMS • They are stimulated to provide ideas/ suggestions for improvements	• Operators are only informed about modifications in FSMS by production or QA manager • They are not asked to provide ideas/suggestions for improvements
Absence of formalisation	Absence of establishment of activities in formal procedures and lack of formalised meetings increase chance on unexpected decision-making behaviour at safety tasks, and put higher demands on FSMS by requiring advanced control and assurance activities	• All activities are described in SOP´s (standard operating procedures) • formalised meetings for all different issues • Structured documentation of minutes or meetings available via central system	• Procedures and meetings are restricted to crucial processes typically related to the FSMS. • Regular meetings • Structured documentation of minutes of meetings available via QA department/QA person	• No (few) procedures, people are not used to work with it. • Working instructions are communicated via informal meetings or direct communication • No (structured) documentation of meetings
Deficiency in information systems	Lack of appropriate information systems affects availability of accurate information, which may favour inappropriate operation (due to lack of (correct) info at safety tasks), and put higher demands on FSMS by requiring advanced control and assurance activities (increased efforts in obtaining appropriate information at right time and place)	• Company has a specific Quality Information Management (QIM) to support decisions in control, assurance, design, and improvement of product safety and quality • Accessible for all people to support execution of food safety control activities (i.e. all have authority of use, user friendly, at right location)	• Company has production information system, from which some information sources are suitable to support decisions in product safety control • System is only accessible to authorised people	• Company has standard information system for bookkeeping (incoming and outgoing materials); information is not very accurate for food safety control decisions • System is only accessible to authorised people

Table 1 (Continued 2) Grid with assumption and situations of the contextual factors of the FSMS-DI modified for FSE (adapted from Luning & co-authors, submitted 2009b, submitted 2009c).

Indicator	Assumption	Situation 1	Situation 2	Situation 3
Chain environment characteristics				
Safety contribution in chain position	A critical chain position of a company with respect to reduction/inactivation of pathogen to acceptable level, has more potential impact on final safety at consumption, which puts higher demands on FSMS by requiring advanced control and assurance activities	• No contribution to final safety, any microbial contamination is reduced to acceptable level further in the chain.	• Contribution to final safety by prevention of pathogens but no significant reduction to acceptable level for final consumption	• Critical contribution to final safety by significant reduction of pathogens to acceptable level, and/or prevention of post contamination and/or growth of pathogens to maintain acceptable level
Lack of power in supplier relationships	Lack of power in supplier relationship means less influence of a company on their suppliers, which may result in more unpredictable safety levels of incoming materials, which puts higher demands on FSMS by requiring advanced control and assurance activities	• Company is explicitly involved in development of product specifications of major suppliers • and can influence their FSMS/QMS (e.g. via audits)	• Company can discuss about product specifications of major suppliers • but has no influence on their FSMS/QMS	• Company has no influence on product specifications nor the FSMS/QMS of major suppliers • only possibility to check specifications and/or measure raw materials
Strictness of stakeholders requirements	Strict and differing requirements on your FSMS set by *stakeholders* (government, *branch organisations, customers, retailers, etc)* put higher demands on FSMS by requiring advanced control and assurance	• General legislative requirements on food safety (PRP/HACCP according to Codex Alimentarius)	• Additional QA requirements (e.g. ISO, EFQM, ICHE, ICTE) but similar for major stakeholders.	• Additional (sometimes conflicting) QA requirements (e.g. ISO, EFQM, ICHE, ICTE) which are different for major stakeholders.

Table 2 Grid with assumption and levels of the core control activities of the FSMS-DI modified for FSE (adapted from Luning & co-authors, 2008).

Indicator	Assumption	Level 0	Level 1	Level 2	Level 3
Preventive measures design					
Sophistication of hygienic design of equipment and facilities	Advanced hygienic design of critical equipment and facilities decreases chance on (cross) contamination and enables effective cleaning, which will positively contribute to food safety	• Hygienic design of equipment and facilities not important/ not an issue	• Critical equipment not hygienically designed • Facilities meet basic requirements for *food* **meal** production	• Critical equipment purchased from suppliers of standard equipment designed in line with hygiene requirements • Facilities comply with specific hygiene requirements	• Integrated hygienic design of critical equipment and facilities (according to EHEDG or comparable design criteria) • Adapted and tested for companies' specific *food* **meal** production characteristics in collaboration with equipment and cleaning suppliers.
Adequacy of cooling facilities	Adequate cooling facilities better maintain strict temperature conditions to prevent growth of micro organisms and pathogens, which will positively contribute to food safety	• Cooling facilities not used in production	• Domestic/general cooling facilities • Principal cooling capacity not known nor testing product temperature	• Industrial cooling facilities • Information about principal cooling capacity from suppliers, no testing of product temperature for different circumstances	• Industrial cooling facilities specifically adapted for companies' specific food production circumstances • Capacity tested by temperature check of environment and products, for different circumstances
Specificity of sanitation program	Specific, full-steps and tailored sanitation programs with appropriate cleaning agents, supported with appropriate instructions better prevent contamination, which will positively contribute to food safety	• No specific sanitation programs in place	• Incomplete program not differentiated for specific equipment/facilities • Common cleaning agents not specific for production system. • Instructions derived from information on label or company experience	• Complete programme and differentiated for equipment and facilities • Cleaning agents (i.e. detergents & disinfectants) selected based on advices of suppliers. • Idem for instructions about use and frequency	• Complete programs, tailored for different equipment & facilities • Cleaning agents specifically modified and tested on effectiveness in the companies' specific food production system • Instructions on use and frequency based on test results
Extent of personnel hygiene requirements	Higher and more specific personal hygiene requirements and specific instructions reduce chance on contamination, which will positively contribute to food safety	• Personal hygiene requirements are not implemented	• Standard requirements for all employees on clothing (caps, gloves, jacks) • Idem personal care and health • Common washing facilities • No specific hygiene instructions	• Additional task-specific requirements on clothing (own clothing, specific storage conditions) • Idem for personal care and health. • Special hand washing facilities • Basic hygiene instructions	• High/ specific requirements, for all food operators, on clothing • Idem for personal care and health. • Tailored facilities to support personal hygiene. • Specific training and hygiene instructions
Specificity of raw material control	Systematic and adequate incoming raw material control will prevent (high and variable initial) acceptance of contaminated raw materials which will reduce chance on (cross) contamination of the production process which will positively contribute to food safety.	• No incoming raw material control	• Raw material control on food safety is ad hoc and is mainly based on historical experience with suppliers	• Raw material control on food safety is systematic and is based on guidelines, or legislative requirements, or guidance document for sector	• Raw material control on food safety is systematic using statistical underpinned acceptance sampling (i.e. sampling frequency, location, analysis, rejection criteria, etc) based on actual historical data of suppliers
Adecuacy of product specific preventive measures **Specificity of meal preservation**	Adequate meal preservation measures that specifically reduce (high initial) contamination will reduce chance of contamination of production process which will positively contribute to food safety.	• *No product specific measures used* • **No meal preservation**	• *Product specific preventive measure* **Meal preservation** is based on company knowledge/experience and or common knowledge • but not tested	• *Product specific preventive measure* **Meal preservation** is based on guideline, legislative requirement, guidance document, expert knowledge • but not tested.	• *Product specific preventive measure* **Meal preservation** is based on legislative requirement/guidance documents • and tested for specific food production circumstances
Specificity of defrosting methods	**Adequate defrosting methods that specifically reduce (high initial) contamination will reduce chance of contamination of production process which will positively contribute to food safety.**	• *No product specific measures used* • **No defrosting methods**	• *Product specific preventive measure* **Defrosting method** is based on company knowledge/experience and or common knowledge • but not tested	• *Product specific preventive measure* **Defrosting method** is based on guideline, legislative requirement, guidance document, expert knowledge • but not tested.	• *Product specific preventive measure* **Defrosting method** is based on legislative requirement/guidance documents • and tested for specific food production circumstances
Adequacy of hot holding methods	**Adequate hot holding facilities better maintain strict temperature conditions to prevent growth of micro organisms and pathogens, which will positively contribute to food safety**	• *No product specific measures used* • **No hot holding methods**	• *Product specific preventive measure* **Hot holding method** is based on company knowledge/experience and or common knowledge • but not tested	• *Product specific preventive measure* **Hot holding method** is based on guideline, legislative requirement, guidance document, expert knowledge • but not tested.	• *Product specific preventive measure* **Hot holding method** is based on legislative requirement/guidance documents • and tested for specific food production circumstances

Table 2 (Continued 1) Grid with assumption and levels of the core control activities of the FSMS-DI modified for FSE (adapted from Luning & co-authors, 2008).

Indicator	Assumption	Level 0	Level 1	Level 2	Level 3
Intervention processes design					
Adequacy of physical intervention equipment	Capable intervention equipment enables less unpredictable process variation and better compliance to standards, which will positively contribute to food safety	• No physical intervention equipment used	• General intervention equipment not product specific • Process equipment capability not known	• 'Best standard' intervention equipment available in practice, product specific • Process equipment capability described in specifications (provided by equipment suppliers). Equipment is principally capable to comply with standards and tolerances, but not tested for own production system	• Intervention equipment specifically modified for companies' specific food production circumstances • Process equipment capability is tested in company specific circumstances and information is well-documented
Specificity of maintenance and calibration program for intervention equipment	Structural and tailored programmes for maintenance with specific instructions about frequency and tasks will cause less unexpected safety problems due to unreliable equipment, which will positively contribute to food safety	• No maintenance applied	• Maintenance is basically initiated by problems, ad hoc • No (clear) instructions about frequency and maintenance tasks • Not well documented	• Maintenance program developed with support of, or by suppliers of equipment/tools • Specific instructions about frequency and maintenance tasks • Well documented (at location or at equipment suppliers)	• Maintenance program specifically designed for production process using data from regular inspections and breakdown analyses • Specific instructions on frequency maintenance tasks • Well documented (at company)
Effectiveness of intervention methods	Specific intervention methods reduce better contamination load of (raw) materials, which will positively contribute to food safety	• No chemical or biological intervention methods used	• Intervention methods are applied based on company knowledge, and experience • Potential reduction level not known	• Application of intervention method based on advices of specialised suppliers, but not tested for specific food production systems characteristics. • Potential reduction level known based on literature or expert knowledge	• Intervention method is modified for the companies' specific food production system characteristics. • Actual reduction level is known by testing in the real production system conditions and is well-documented

Table 2 (Continued 2) Grid with assumption and levels of the core control activities of the FSMS-DI modified for FSE (adapted from Luning & co-authors, 2008).

Indicator	Assumption	Level 0	Level 1	Level 2	Level 3
Monitoring system design					
Appropriateness of CCP analysis	A higher level of scientific evidence and a more systematic way to analyse hazards and associated risk together with actual testing of CCP and CPs will result in more reliable and accurate control points, which will positively contribute to food safety	• No analysis of CCPs and CPs executed (nor by company nor by external experts)	• Internal experience/knowledge used for hazard identification and risk evaluation, selection of hazards to be controlled based on internal discussions • No strict methodology used. • CCP/CP determination based on consensus and not tested in practice	• Hazard identification, risk analysis and allocation of CCP/CPs based on hygiene codes for sector or executed by external expertise (consultancy) who work • according to official Codex guidelines • CCP/CP determination by microbial product tests and/or historical data	• Hazard identification, risk analysis and allocation of CCP/CPs executed by using own knowledge/ experience, additional scientific literature and or expert knowledge • according to Codex guidelines • CCP/CP determination by microbial product tests and predictive modelling of hazad behaviour and/or challenge tests.
Appropriateness of standards and tolerances design	More complete specification of both standards and tolerances for both critical process and product parameters, supported by scientific based data will result in more accurate CCP's, which will positively contribute to food safety	• No written standards for product and process parameters	• Standards for critical product and process parameters are specified but tolerances not clearly specified • Assessments of product/process standards basically on historical data and company experience.	• Standards and tolerances for critical product and process parameters are clearly specified. • Standards and tolerances of product/process parameters derived from general hygiene codes and legal requirements.	• Standards and tolerances for critical product/process parameters are clearly specified. • Standards and tolerances of product/process parameters derived from legal requirements, hygiene codes, and literature, adapted for own food production system.
Adequacy of analytical methods to assess pathogens	Sensitive, specific, repeatable, reproducible and rapid methods to assess pathogens will result in more adequate determination of pathogens, which will positively contribute to food safety	• Pathogens are not analysed (not by company nor by external lab)	• Conventional culture-based methods used (i.e. plate counts, most probable number, presence -absence tests) • No (inter)nationally acknowledged procedures is followed	• Conventional culture-based methods used (i.e. plate counts, most probable number, presence - absence tests) or modified quicker methods • Internationally validated methods are used (not accredited)	• Conventional culture-based methods used (i.e. plate counts, most probable number, presence - absence tests) or modified quicker methods • Internationally validated and accredited methods are used
Adequacy of measuring equipment to monitor process/product status	Accurate and responsive equipment to monitor critical process and or product parameters will result in more adequate monitoring, which will positively contribute to food safety	• No measuring equipment	• No standardised measuring equipment (accuracy not tested) • Off-line/ at-line measurement, not automated, no information/data history available	• Standard available measuring equipment complying with ISO (other international recognised) norms (accepted accuracy). • On-line/ in line measurement (immediate response), often automated, information/data history available	• Specifically selected equipment and adapted to the companies' specific production process, and tested on accuracy. • On-line/ in-line measurement (immediate response), automated, information history immediately visual.
Specificity of calibration program for measuring & *analytical* equipment	Structural and tailored programmes for calibration/verification and testing of measuring equipment will cause less unreliable test data, which will positively contribute to food safety	• No calibration/verification program for measuring *nor analytical* equipment	• Calibration of measuring *and/or analytical* equipment on ad-hoc basis • Tasks and frequency not clear, and not (well) documented.	• Calibration outsourced at equipment suppliers *or at external laboratorios for analytical equipment* • Task and frequency based on international standards, not specific for food production system, documentation at equipment suppliers	• Calibration program specifically designed based on data from own food production system, according to international standards. • Tasks and frequency in- house documented
Adequacy of sampling design (for microbial assessment) and measuring plan	A statistical underpinned and tailored sampling design, measuring plan increases reliability of information on actual product/process status, which will positively contribute to food safety	• No sampling design nor a measuring plan in place	• Sampling design and measuring plans based on experience and in-house knowledge. No information about distribution of pathogens, samples are taken as spot-check procedure	• Sampling design and measuring plan based on common sampling plans for the specific sector as available in literature (e.g. EU guidelines, or ICMSF)	• Sampling design and measuring plan based on statistical analysis of pathogen distribution in own food production process
Extent of corrective actions	A complete and differentiated description of corrective actions linking severity of deviations to type of corrective actions will positively contribute to food safety	• No corrective actions have (yet) been described	• Corrective actions based on experience, and consensus within company. • Incomplete descriptions of process adjustments and handling of non-compliance products • No structural analysis of cause of deviation. Corrective measures not differentiated for different deviations.	• Corrective actions based on hygiene codes including process adjustment measures and handling non-compliance products • Complete descriptions but not adjusted for own process, product characteristics • Ad hoc analysis of cause of deviations, no differentiated measures.	• Corrective actions based on systematic causal analysis of own product/process deviations, • Complete descriptions including process adjustments and handling of non-compliance products • Structural analysis of cause of deviations, differentiated measures.

Table 2 (Continued 3) Grid with assumption and levels of the core control activities of the FSMS-DI modified for FSE (adapted from Luning & co-authors, 2008).

Indicator	Assumption	Level 0	Level 1	Level 2	Level 3
Operation of preventive measures, intervention processes and monitoring system					
Actual availability of procedures	Accurate and understandable procedures at the right place will better direct peoples' decision-making behaviour in control, which will positively contribute to food safety	• No procedures in place	• Procedures are sometimes/ partly available on location (often paper-based) • Difficult to understand by users • and are not kept up-to-date	• Procedures are available at location (often paper-based) • and well to understand for most users • but are kept up-to-date on ad-hoc basis	• Procedures very easily available (digital, on-line) at location, • and are designed for specific users • and updated at a regular basis
Actual compliance to procedures	Complete (all steps followed) and accurate (in right way) compliance to procedures due to full adherence will result in more appropriate decision-making behaviour in control, which will positively contribute to food safety	• No procedures • No idea about compliance to procedures of operators	• Majority of food handlers execute tasks according to own insights, because they are not aware of existence of procedures for certain tasks • Operators are controlled on compliance to procedures on ad-hoc basis	• Majority of operators are familiar with existence of procedures (but not always exact content); tasks are executed based on habits. • Operators are controlled on compliance to procedures on regular basis	• All operators are aware of existence and content of procedures and are consciously following procedures, safety tasks are internalised. • Self control of compliance to procedures
Actual hygienic performance of equipment and facilities	Stable hygienic performance of equipment and facilities, which can be well noticed will result in less (cross)contamination which will positively contribute to food safety	• Hygienic design is no issue • No information/ idea about hygienic performance	• Regularly unexpected and unexplainable contaminations due to inappropriate equipment or facilities. • Hygienic performance of equipment and facilities never tested.	• Sometimes unexpected and unexplainable contaminations due to inappropriate equipment or facilities • Hygienic performance of equipment and facilities tested on ad-hoc basis	• Stable hygienic performance of equipment and facilities • Hygienic performance tests are executed on regular basis according to EHEDG/ similar guidelines
Actual cooling capacity	Stable performance of cooling facilities, which can be well noticed will result in constant low temperatures with few variation, which will better prevent growth of pathogens and will positively contribute to food safety	• Cooling facilities not used • No cooling performance information known	• Regularly unstable performance with significant variations in facility temperature, • No automatic temperature devices and deviations not systematically analysed • No information about product temperature	• Sometimes unstable performance • Automatic temperature control but no systematic analysis of deviations • Ad hoc information about product temperature	• Stable performance of cooling facilities • Environmental temperature is automatically monitored and deviations are systematically analysed • Constant information about product temperatures
Actual hot holding capacity	**Stable performance of hot-holding facilities, which can be well noticed will result in constant high temperatures with few variation, which will better prevent growth of pathogens and will positively contribute to food safety**	• **Hot-holding facilities not used** • **No hot-holding performance information known**	• **Regularly unstable performance with significant variations in temperature,** • **No automatic temperature devices and deviations not systematically analysed** • **No information about product temperature**	• **Sometimes unstable performance** • **Automatic temperature control but no systematic analysis of deviations** • **Ad hoc information about product temperature**	• **Stable performance** • **Environmental temperature is automatically monitored and deviations are systematically analysed** • **Constant information about product temperatures**
Actual process capability of physical intervention processes	Stable intervention processes with minor differences between different production lines, and well noticeable capability performance will result in more products within specifications, which will positively contribute to food safety	• No intervention equipment in place • No performance information known	• Regularly unstable process with unexplainable deviations from mean values of process parameters; variation not constant over time • Variable differences in capabilities between different *production lines* **meals** • *No use of control charts*	• Sometimes unstable process, with unexplainable deviations of process parameters; variation constant over time • Significant but constant differences in capabilities between various *production lines* **meals** • *Control charts used but not systematically interpreted*	• Stable process, mean values and variation of process parameters according to specifications and constant over time • Minor deviations in mean values and variation between *production lines* **meals** • *Control charts used and systematically interpreted*
Actual performance of measuring equipment	Stable measuring equipment that is reliable under different product/process conditions provide more reliable information on product and process status, which will positively contribute to food safety	• No measuring equipment used • No information about measuring equipment performance	• Measuring equipment very sensitive to changes in *production process* **meal production** circumstances	• Measuring equipment sensitive for few specific well known *production process* **meal production** changes	• Measuring equipment very stable under all different *production process* **meal production** circumstances

Table 3 Grid with assumption and levels of the core assurance activities of the FSMS-DI modified for FSE (adapted from Luning & co-authors, 2009a).

Indicator	Assumption	Level 0	Level 1	Level 2	Level 3
Setting of system requirements					
Sophistication of translation of stakeholder requirements into own FSMS requirements	Systematic and precise translation of stakeholder requirements will result in suitable requirements on the FSMS, which will contribute to assurance of product safety	• Not (yet) any stakeholder requirement(s) translated	• Translation of external assurance activities initiated by food safety performance problems (reactive) as perceived by stakeholders and/or due to external directives, only necessary changes	• Translation of external assurance activities by actively acting on changes in external assurance and setting (new) requirements with support of external experts (e.g. consultants)	• Pro-active translation of external assurance requirements based on systematic analysis of possible changes in stakeholder requirements (e.g. new legislation, new branch demands) and evaluated on critical aspects of own food production system; well documented
Extemt of systematic use of feedback information to modify FSMS	Systematic use of valid feedback information from control system will result in appropriate system modifications, which will contribute to assurance of product safety	• FSMS has not (yet) ever been modified	• Ad hoc modification of FSCS initiated by problems from own food production system • Not documented	• Regular use of standard data from food production system (process/product data); modifications mainly focused on control activities in production system • Not systematically documented	• Systematic analysis of information from validation & verification reports, translations into concrete modifications in FSMS are established in clear procedures with assigned responsibilities • Well documented
Validation activities					
Sophistication of validation of preventive measures	A scientific evidence based, systematic, and independent validation of effectiveness of selected preventive measure will result in an effective FSMS, which will positively contribute to assurance of product safety	• Effectiveness of preventive measures have (yet) never been validated	• Effectiveness of preventive measures is validated based on historical knowledge only, judged by own people • On ad-hoc basis • Findings scarcely (not) described.	• Effectiveness of preventive measures is validated based on opinion of independent expert, using expert knowledge, regulatory documents and historical results • On regular basis and after system modifications • Findings described in reports	• Effectiveness of preventive measures is systematically validated, by independent experts, based upon specific scientific sources (like scientific data/literature on validation studies, predictive modelling), historical results, and own experimental trials; • On regular basis and after system modifications • Activities and results well documented
Sophistication of validation of intervention processes	A scientific evidence based, systematic, and independent validation of effectiveness of selected intervention strategies will result in a more effective FSMS, which will positively contribute to assurance of product safety	• Intervention systems have (yet) never been validated	• Effectiveness intervention systems validated based on historical knowledge only, judged by own people • On ad-hoc basis • Findings scarcely (not) described.	• Effectiveness of intervention systems validated based on opinion of independent expert, using expert knowledge, regulatory documents and historical results • On regular basis and after system modifications; • Findings described in reports	• Effectiveness of intervention systems validated by independent experts/ persons, based on specific scientific sources (like scientific data/literature on validation studies, predictive modelling), historical results, and own experimental trials • Regular basis and after system modifications, • Activities and results well documented
Sophistication of validation of monitoring system	A scientific evidence based, systematic, and independent validation of CCP determination and establishment of control circles will result in a more effective FSMS, which will positively contribute to assurance of product safety	• Effectiveness of monitoring systems have (yet) never been validated	• Validation based on historical and/or commonly available knowledge • Executed by own people on ad hoc basis • Findings (not) scarcely described	• Validation based on comparison with regulatory documents (like specific hygiene codes) • By external expert on regular basis • Findings described in expert report	• Validation based on scientific sources (reviews, historical data on hazards, reports on foodborne illnesses, data on survival or multiplication, studies on control mechanisms); • By independent expert on regular basis and after system modifications; • Activities and results well documented.

Table 3 (Continued 1) Grid with assumption and levels of the core assurance activities of the FSMS-DI modified for FSE (adapted from Luning & co-authors, 2009a).

Indicator	Assumption	Level 0	Level 1	Level 2	Level 3
Verification activities					
Extent of verification of people related performance	A more specific, systematic, and independent verification of procedure characteristics and compliance will result in a more reliable FSMS, which will positively contribute to assurance of product safety	• Procedures and compliance to procedures have (yet) never been verified	• Verification of procedures and compliance based on checking presence of procedures and records, • On ad-hoc basis • By own people who execute system • Not documented	• Verification of procedures and compliance based on analysing procedures (both content and presence) and records • On regular basis • By independent internal staff • Internal report	• Verification of procedures and compliance based on analysing procedures and records, and observations • With defined frequency and when system modifications • By independent external (official) expert • Activities and results well documented
Extent of verification of equipment and methods related performance	A more specific, systematic, and independent verification of equipment and methods performance will result in a more reliable FSMS, which positively contributes to the assurance of product safety	• Performance of equipment and methods have (yet) never be verified	• Verification of equipment/methods performance based on checking if product, process parameters are correctly set (e.g. of equipment, facilities, measuring, analysis methods) • On ad hoc basis • By people working in the system and provide the information • Not documented	• Verification of equipment/methods performance based on analysing records (e.g. control charts, records data loggers, etc.) and calibration activities, restricted testing of actual performance • On regular basis • By internal staff using information from production • Internal report	• Verification of equipment/methods performance based on analysing records, calibration activities, and confirmation of performance by actual (e.g. microbial) testing, • With defined frequency and after system modifications • By independent experts; • Activities and results well documented
Documentation and record-keeping system					
Appropriateness of documentation system	An integrated, kept-up-to-date and accessible documentation system will improve information (experience, scientific knowledge, legislative requirements) supply for FSMS, which will support validation and verification activities, which will positively contribute to the assurance of product safety	• No documentation of procedures, information, knowledge at all	• No structured documentation system ad hoc	• Structured documentation system, de-centrally organised and kept up to date, (partly) automated, available via specific persons; access to external sources not formalised (individual contacts)	• Structured documentation system, kept-up-to-date with assigned responsibilities, centrally organised, automated and on-line available for all, and with access to external sources of information (libraries, databases, etc).
Appropriateness of record-keeping system	A structured, integrated, and accessible record-keeping system will support validation and verification activities, which will positively contribute to assurance of product safety	• No record keeping of product nor process data at all	• Ad hoc registration of record keeping data.	• Full registration of critical product and process data in separated systems (not integrated), accessible via specific (authorised) persons.	• Full registration of critical product and process data, in central integrated system, on line available and accessible to all persons

CAPITULO 3

Evaluación del rendimiento del sistema de gestión de seguridad alimentaria (FSMS) de establecimientos de restauración – Análisis cuantitativo en España

Introducción

La necesidad de mejorar el sistema de gestión de seguridad alimentaria requiere comprender el rendimiento actual de los mismos en el sector de establecimientos de restauración (FSE). Dicha evaluación comúnmente se evalúa con auditorías en el que se verifica si los requerimientos del estándar de calidad se cumplen (Cornier et al., 2007; Wallace et al., 2005). Sin embargo, con el instrumento de diagnóstico se puede evaluar el rendimiento de los sistemas de gestión independientemente del estándar de calidad que use el establecimiento (Luning, et al., 2008; Luning et al., 2009a). La teoría detrás de éste instrumento de diagnóstico es que los establecimientos que operan en un contexto más vulnerable, incierto y ambiguo como el que puede tener el sector de restauración requiere un sistema de gestión más avanzado que pueda predecir y controlar la seguridad alimentaria (Luning and Marcelis, 2006; Luning et al, submitted 2009b, submitted 2009c).

El objetivo de éste estudio es analizar el rendimiento del sistema de gestión de seguridad alimentaria considerando el contexto en el que operan 50 establecimientos de restauración españoles mediante el uso del instrumento de diagnóstico desarrollado por Luning y co-autores y que fue modificado para establecimientos de restauración (Capítulo 2).

Metodología

La muestra de los 50 establecimientos de restauración seleccionada en Burgos incluyó 4 residencias de estudiantes con una capacidad máxima constante entre 75 y 197 estudiantes, 10 hoteles con diferentes tamaños y capacidad variando desde 150 hasta 1200 clientes por día durante los fines de semana o festivos, 2 restaurantes que pertenecían a una cadena de restaurantes que también trabajan en el resto de España, 2

restaurantes vegetarianos, 4 restaurantes de tapas, 8 restaurantes de menú del día incluyendo a 2 cafeterías para estudiantes, y 20 restaurantes con menú a la carta.

La evaluación del rendimiento del sistema de gestión de seguridad alimentaria se realizó con una entrevista cara a cara con el responsable del establecimiento (usualmente el dueño o el cocinero jefe) en la que mediante una serie de preguntas se asignó en una de las situaciones o niveles de la escala de los indicadores relacionados con el contexto y el propio sistema de gestión. Asimismo, se realizó análisis de los documentos para revisar su contenido y actualización, y se llevaron a cabo observaciones en la cocina para confirmar las respuestas.

El análisis de datos se enfocó en determinar las principales similitudes y diferencias entre los establecimientos de restauración. Para ello se utilizaron herramientas estadísticas de análisis de componentes principales y análisis de “clusters” jerárquico con el método de vecino más lejano y distancia Euclideana al cuadrado. De ésta manera se obtuvieron grupos homogéneos representados por gráficas de los componentes principales y dendogramas respectivamente. Los diferentes grupos obtenidos se analizarón en función de sus diferentes perfiles de acuerdo con los factores contextuales, y las principales actividades de control y aseguramiento.

Resultados y Discusión

Similitudes

Se encontró que todos los establecimientos de restauración trabajan con materia prima y productos que con llevan un riesgo microbiológico elevado y vulnerables a aumentar dicha contaminación. Asimismo, la extensión de los pasos de intervención fue asignada en situación más riesgosa y vulnerable porque todos preparan platos que no conllevan pasos de intervención letales que impliquen cocción (por ejemplo: ensaladas). Otra característica en la mayoría de establecimientos (29) es que se maneja un alto número de platos en un mismo espacio y con las mismas superficies de contacto requiriendo intervenciones de limpieza que muchas veces no se realizan en las horas pico de trabajo.

En relación al contexto organizativo se encontró que ninguno de los establecimientos poseía personal técnico ni laboratorios que asesoraran en el desarrollo y gestión del sistema aunque algunos de ellos contrataban a empresas y laboratorios externos para ese

fin. Asimismo, el sistema de información en los establecimientos se limitaba al almacenamiento de ciertos procedimientos, registros o albaranes de entrada de materia prima que son accesibles solamente a personal autorizado y todas las tareas a realizar se informan mediante comunicación oral o carteles pegados en la pared.

Las características del contexto externo demostraron que todos los establecimientos están posicionados en un eslabón crítico en la cadena alimentaria pues son el enlace directo con los consumidores y por lo tanto es esencial su actuación para lograr la seguridad alimentaria de los platos que consumirán los clientes. Por otro lado, los requerimientos externos que se exigen provienen simplemente de la legislación. Y las relaciones con los proveedores se asignaron en una situación 2 porque pueden establecer las especificaciones de la materia prima porque las relaciones son fuertes y de largo plazo y hay alta oferta de proveedores, pero no tienen el suficiente poder para influir en el sistema de gestión de seguridad alimentaria de los proveedores. Probablemente porque la mayoría de proveedores también son pequeñas y medianas empresas o simplemente comercios minoristas de alimentación, como carnicerías, pescaderías o fruterías.

Con respecto a las características del propio sistema de gestión, se encontró que todos los establecimientos tienen instalaciones de almacenamiento frigoríficas, por lo que se valoró con un nivel 2, porque son industriales y con capacidad conocida, pero no han sido probadas para las distintas condiciones de producción del establecimiento y se mide la temperatura ambiente, pero no la temperatura interna de los alimentos que se almacenan. Finalmente, ninguno de los establecimientos poseía programa de calibración de equipo, descripción de acciones correctivas, ni información acerca del rendimiento real del equipo de medida o del diseño higiénico de las instalaciones y equipos.

Diferencias

Los tratamientos estadísticos aplicados agruparon a los restaurantes en cuatro grupos diferentes. **El grupo 1** (7 establecimientos) incluyó 3 residencias para estudiantes, 2 hoteles, un restaurante de menú a la carta y 1 restaurante tipo “buffet” que pertenece a una cadena española. **El grupo 2** (4 establecimientos) incluyó 1 hotel, 1 restaurante de menú del día y las 2 cafeterías para estudiantes. **El grupo 3** (17 establecimientos) incluyó 6 hoteles, 6 restaurantes de menú a la carta, 2 restaurantes de menú del día, 1

residencia para estudiantes, 1 restaurante de tapas y 1 restaurante de menú a la carta que también es parte de una cadena española. Finalmente, el **grupo 4** (22 establecimientos) incluyó 1 hotel, 13 restaurantes de menú a la carta, 3 restaurantes de tapas, 3 restaurantes de menú del día y los 2 restaurantes vegetarianos. El dendograma y el análisis de componentes principales se muestran en las Figuras 1 y 2 del Capítulo 3.

Las gráficas de la figura 3 del Capítulo 3 muestran que para el grupo 1 las características de las organizaciones presentan un personal estable, empleados con conocimiento de cocina y más de 3 años de experiencia, y una gestión con compromiso hacia la seguridad alimentaria. Dichas características les permiten tomar decisiones apropiadas en el funcionamiento del sistema de gestión. En cambio en el grupo 2 el compromiso gerencial y la formalización (grado en el que las actividades se describen en manuales y procedimientos escritos) resultaron menores (situación 2). El grupo 3 resultó similar al grupo 2 con respecto al contexto organizativo pero con empleados con menor competencia y menos participación (situación 2). Finalmente el grupo 4 fue el grupo con menor compromiso gerencial y formalización.

Con respecto a las medidas de control se encontró que el grupo 1 tiene instalaciones y equipo diseñado y dispuesto higiénicamente, programas de limpieza y desinfección completos, requerimientos higiénicos específicos para el personal, instalaciones que apoyan las prácticas higiénicas del personal como estaciones de lavado de manos completas y cubos de basura accionados con pedal, instrucciones específicas de comportamiento higiénico, equipo con capacidad conocida y probada para las distintas condiciones de producción, autocontrol de puntos críticos desarrollados con asesoría de compañías expertas y validadas con análisis microbiológicos. La única actividad que resultó con menor nivel en éste grupo fueron los métodos de conservación que están basados en experiencia y no han sido validados microbiológicamente. Los otros grupos mostraron mejor rendimiento en las actividades de control. Específicamente, el grupo 2 presentó bajo nivel de diseño higiénico de instalaciones y equipos en general con capacidad desconocida, pero dado que contrata a empresas externas para recibir asesoría en el diseño del sistema de gestión y en validar los métodos aplicados, resultó con alto rendimiento en actividades relacionadas con los métodos de intervención, diseño de estándares y muestreo, y métodos analíticos para evaluar microorganismos. Por el contrario, el grupo 3 incluye a establecimientos con diseño higiénico de instalaciones y

equipo más sofisticado porque son empresas con mayor presupuesto para ello pero debido a que no tienen asesoramiento ni validación de sus métodos con análisis microbiológicos resultaron con bajo rendimiento en las actividades que resultaron altas en el grupo 2. Finalmente el grupo 4 demostró bajo rendimiento en todas las actividades de control ya que utilizan experiencia y equipo general para diseñar y operar el sistema de gestión de seguridad alimentaria.

En general se encontró que las actividades que se realizan en menor medida son, como lo describen otros estudios: la falta de monitoreo o medida de los puntos de control y por lo tanto ausencia de información acerca del rendimiento real del sistema (Walker, Pritchard & Forsythe, 2003; Worsfold, 2001; Taylor, 2008; Eves & Dervisi, 2005); falta de procedimientos y mantenimiento de registros (Rodgers, 2005; Taylor, 2001; Eves & Dervisi, 2005); procesos establecidos por experiencia y sin validación con análisis microbiológicos (Taylor & Kane, 2005; Taylor, 2008); y falta de verificación para confirmar que los requerimientos han sido alcanzados (Taylor & Kane, 2005; Taylor, 2008). Éstos resultados junto con el hecho de que los establecimientos de restauración tienen que trabajar en un contexto vulnerable e incierto aumentan la posibilidad de que ocurran problemas de seguridad alimentaria.

En éste estudio se analizó solamente el nivel en el que se diseñan y operan las actividades de control y aseguramiento de los sistemas de gestión de seguridad alimentaria en base a la situación contextual en el que deben trabajar los establecimientos de restauración. Sin embargo, es necesario hacer éste análisis junto con una evaluación del rendimiento microbiológico real para verificar si el sistema de gestión de seguridad alimentaria implementado asegura la calidad higiénica de los platos que se preparan. Este análisis combinado se realiza en el siguiente capítulo (Capítulo 4).

CHAPTER 3

Assessment of Food Safety Management System performance of Food Service Establishments – A quantitative analysis in Spain

Abstract

As a first step to improve the microbiological performance of Food Safety Management Systems (FSMS) operated in the sector of Food Service Establishments (FSE) it is necessary to assess actual performance of FSMS in view of the context wherein FSE must execute their tasks. For this purpose a modified FSMS-Diagnostic Instrument (FSMS-DI) developed by Luning and co-authors (2008, 2009a, submitted 2009b, submitted 2009c) was used to analyse the riskiness of contextual factors in relation to the advancedness of core control and assurance activities. This tool was done in 50 typical FSE in Burgos, Spain. The results were classified through statistical tools of hierarchical cluster analysis and principal component analysis. The assessment showed that the FSE work within a high-risk context situation requiring advanced control and assurance activities. It also differentiated four clusters of FSE that showed different organisational situations and different levels of performance of core control and assurance activities. The main conclusions were that FSE with low-risk organisational situation typified by high workforce quality, supportive organisational structures and specific information system (to support decisions in FSMS) revealed higher levels of control and assurance activities; and that FSE require improvements in monitoring and measuring activities, in documentation and recording, and in validation and verification activities to obtain a more predictable and controllable FSMS that may assure food safety in their meals.

1. Introduction

Food service establishments (FSE) have been found as an important source of foodborne outbreaks with percentages of occurrence of 29% in industrialised countries (WHO, 2007), 54% in England and Wales (Hughes, 2007), and 23% in Castilla y León, Spain (López y Martín, 2004). These facts demonstrate that, even though the food safety management systems (FSMS) of FSE must comply with the legislation (853/2004 EC Regulation) that requires them to have a FSMS based on the HACCP principles, its performance have resulted in meals with uncertain food safety.

The need to improve FSMS requires insight in the actual performance of current FSMS operated in FSE. Although various studies have been done to understand the reasons of insufficient performance of FSMS in FSE, it has not yet been systematically analysed in view of their typical contextual factors. Thus, the objective of this study is to assess the performance of FSMS in light of the contextual factors wherein these systems operate in a range of 50 Spanish FSE. The FSMS-DI developed by Luning and co-authors (2008, 2009a, submitted 2009b, submitted 2009c) that was modified for FSE (Chapter 2) was used to systematically assess core control and assurance activities, together with the particular contextual factors.

As a starting point, literature analysis from Chaper 1 showed that FSE have to operate in a rather vulnerable, ambiguous, and uncertain context. They commonly prepare many meals (containing risky ingredients like, fresh meat, fish, chicken, eggs, sliced vegetables, etc). Moreover, they have to manage a high assortment of meals that must be prepared partly in advance, often in same areas, with pressure of time, and the number of clients is usually not known in advance (Chapter 1; Sun and Ockerman, 2005; Worsfold, 2001). They are responsible for final reduction of microbiological load to acceptable levels before consumption, which put demands on their FSMS as well. Also the typical organisational characteristics of FSE (often small establishments, restricted hygiene knowledge, no formalisation, lack of commitment) may contribute to vulnerability, ambiguity and uncertainty.

Literature about actual functioning of FSMS in SME's (which is a common organisation size for FSE) have shown typical deficiencies, such as lack of monitoring activities, especially if those require analytical measurements and recording (Walker,

Pritchard & Forsythe, 2003; Worsfold, 2001; Taylor, 2008; Eves & Dervisi, 2005). In such situations the actual performance of the control activities is unknown. It has also been found that small companies, as the majority of FSE, commonly do not use written procedures or instructions to guide people's decision making (Rodgers, 2005; Taylor, 2001; Taylor, 2008; Eves & Dervisi, 2005). Similarly, lack of validation activities is expected since this typical assurance activity requires expertise and scientific support, which is commonly not available in FSE (Taylor & Kane, 2005; Taylor, 2008, Luning et al, 2009a). Finally, verification of people, equipment and methods performance is expected to be absent in FSE, because the managers in small companies and micro business are on site all times and have visual confidence that the system is running according to plan, so they (usually) perceive verification activities as useless double checking exercise (Taylor, 2001; Taylor & Kane, 2005; Taylor, 2008).

The structure of the study consists of a methodology section describing how the performance of the FSMS was assessed, and a section of results and discussion that identifies, through similarities and differences, the typical contextual factors and the core control and assurance activities done in the sample of 50 Spanish FSE.

2. Materials and Methods

Selection of the Food Service Establishments

Fifty FSE from the location of Burgos, Spain were selected for the study. The sample consisted of 4 halls of residence for students with a constant maximum capacity between 75 to 197 students during the whole year; 10 hotels with different size and capacity varying from 150 to 1200 customers that are commonly full during the weekends; 2 "brand" restaurants that belong to a chain that works in other locations of Spain; 2 vegetarian restaurants that prepare different menus each day; 4 restaurants specialised in the preparation of "tapas"; 8 restaurants that offer a "day menu" including 2 that are student cafeterias; and 20 restaurants that have "menu a la carte". All the restaurants (except the ones that belong to a chain) are micro enterprises with less than 10 employees working in the kitchen and where the owner is actively executing tasks in the establishment as a waiter or cook.

Assessment of contextual factors and core control and assurance activities

The Food Safety Management System - Diagnostic Instrument (FSMS-DI) (Luning et al., 2008, 2009a, submitted 2009b, submitted 2009c) modified for FSE (Chapter 2) was used to assess contextual factors and core control and assurance activities addressed in the FSMS of the 50 FSE. The main changes to the FSMS-DI in order to adapt it for FSE were explained in Chapter 2.

Table 1 shows the criteria behind the grids to assess contextual situations and to assess control and assurance activity levels, which is adapted from Luning and co-authors (submitted 2009c). In chapter 2 the complete grids are shown.

Face-to-face interviews were conducted with the person in charge of the FSMS, in most of cases the owner or the chief cook, with a set of questions describing the different situations for each contextual factor and levels for each core control and assurance activity. Each FSE was allocated into the corresponding situation or level according to the answers. Furthermore, document analyses and observations in the kitchen facilities were done to support the assigned situations and levels.

Data analyses

Data analyses were focused on determining main similarities and differences between contextual situations and core control and assurance activities in the FSE. The hierarchical cluster analyses were applied using SPSS (15.0 version for Windows) with the furthest neighbour method and the squared Euclidean distance. It was done to identify homogenous clusters of cases based on contextual situations and levels of core control and assurances activities. The outcome of the hierarchical cluster analysis is represented graphically as a dendrogram using a specific distance used to describe the dissimilarities (Moros et al., 2009). The larger the horizontal distance, the more dissimilar are the FSE. Thus, a large distance outlines fewer clusters which are more variable and dissimilar, while a short distance displays more clusters which are more similar between each other. The selected distance to differentiate the clusters was between 10 and 15 units.

Moreover, principal component analyses were conducted using Statgraphics Plus 5.1, which calculates linear combinations between variables that explain most variance in the data. As a result, data can be reduced to a set of new variables called principal components (Andrea et al., 2009). The loadings of principal components define the direction of greatest variability and score values represent the projection of each object onto the principal components. The first principal component is the linear combination of original variables which explains the greatest variability. The second principal component explains the second greatest amount of variability (Huan-Feng et al., 2006). The plots of component weights of each principal component show the FSE that are more similar or different from each other, and the scatterplots display the factors that cause the separation between the FSE. Principal component analysis gives thus further insight in why the FSE were separated.

Spider-web graphs were made for the qualitative analysis of contextual factors and core control and assurance activities for each cluster obtained. The spider-web graphs were constructed with the mean values of the contextual factors, core control activities and core assurance activities. Only those contextual factors and control and assurance activities that showed most variation between the FSE were used. The mean values were calculated by making an average (adding separate indicator scores of each FSE divided by the total number of FSE that conform each cluster). Due to the qualitative

character of the grids, mean scores as such have no meaning (e.g. a mean level of 2.5 has no meaning). Thus, mean scores were transformed to an assigned level/situation score as previously described (Luning et al., submitted 2009b, submitted 2009c) as follows:

If mean score of a set of indicators to analyse core control/assurance activities is between 0-0.2, then assigned score 0.

if mean ‘level’ score between 0.3-1.2, then assigned score 1

if mean ‘level’ score between 1.3-1.7, then assigned score 1-2

if mean ‘level’ score between1.8-2.2, then assigned score 2

if mean ‘level’ score between 2.3-2.7, then assigned score 2-3

if mean ‘level’ score between 2.8-3.0, then assigned score 3

Similarly, if mean ‘situation’ score of major contextual factor is between 1-1.2 then assigned situation 1

if mean ‘situation’ score between 1.3-1.7, then assigned score 1-2

if mean ‘situation’ score between 1.8-2.2 then assigned score 2

if mean ‘situation’ score between 2.3-2.7 then assigned score 2-3

if mean ‘situation’ score between 2.8-3.0 then assigned score 3

The assigned scores can be only used to obtain an overall indication of the FSMS and its contextual situation, however, one need to use in addition the separate results for detailed analysis (Luning et al., submitted 2009b, submitted 2009c).

3. Results and Discussion

The objective of the study was to get insight in the current performance of FSMS and the typical contextual situation wherein these systems operate, in a range of 50 Spanish FSE. It was expected that variation in FSMS in food service establishments mainly relate to differences in organisational characteristics. Furthermore, it was assumed that major weaknesses in the currently implemented FSMS are lack of monitoring, validation and verification activities, poor documentation and record keeping, and lack of insight in actual performance of employees, equipment and methods (Taylor, 2001; Worsfold, 2001; Walker, Pritchard & Forsythe, 2003; Rodgers, 2005; Eves & Dervisi, 2005; Taylor & Kane, 2005; Taylor, 2008; Luning et al, 2009a).

The results of the assessment of the contextual factors, the core control activities and the core assurance activities of the 50 FSE are shown in Appendix 2.

Similarities between FSE

First, the major similarities between the FSE were analysed. Table 2 shows the number of FSE that received a same score for certain contextual situations and Table 3 shows the number of FSE with same scores for certain core control and assurance levels. For detailed descriptions of contextual situations (1, 2 and 3) and levels (0, 1, 2, and 3) of control and assurance one is referred to Chapter 2.

Table 2 shows that for all the FSE the indicators to assess the contextual factor ‘product characteristics’ were positioned in situation 3. Situation 3 is associated with highly risky and highly vulnerable (Table 1). FSE were allocated in this situation due the facts that they typically work with risky raw materials, like fresh meat, poultry, fish, dairy products, vegetables and fruits, and that they prepare risky meals containing fresh vegetables, fruits or fresh cheese, and meals that have dairy sauces or eggs. These results have been mentioned by other authors to be a critical factor in FSMS performance in the catering sector (Panisello & Quantick, 2001; Worsfold, 2001; Dalton et al, 2004; Bolton & Maunsell, 2004; Griffith and Clayton, 2005).

With respect to the process characteristics, 49 FSE received a score 3 for the indicator ‘extent of intervention steps’ (highly risky, vulnerable). They received this score because all deal with fresh-type meals that do not undergo a lethal step to inactivate the

original microbial flora of the raw material and are likely to be contaminated with the contact surfaces and hands (Griffith and Clayton, 2005; Bolton & Maunsell, 2004; Worsfold, 2001). Only one FSE that does not prepare this type of meals was allocated in situation 2. With respect to the 'rate of menu changes' the majority of the FSE (36) were allocated in situation 2 (i.e. potentially risky, vulnerable). This is due to the fact that the changes of menu are done every season. Another common aspect to mention is that for various FSE (29) the 'assortment of meal production process' was allocated in situation 3, because they prepare a high number of different meals on same contact surfaces, requiring cleaning interventions that are not always performed at rush hours due to lack of time (i.e. highly risky, vulnerable situation). These findings are in alignment with various studies showing that FSE handle a high assortment of meals and preparation processes, which makes them vulnerable to food safety problems (Sun and Ockerman, 2005; Worsfold, 2001; Jones et al., 2008).

The organisation characteristics that resulted similar between the FSE were the technological staff and information systems which were allocated in situation 3. These situations are characterised by the absence of specific food safety expertise that is sometimes hired from outside, microbiological analyses done at external laboratories; and standard bookkeeping information system accessible only through authorised people and request of tasks through posters posted on walls. Some studies have outlined that the presence of a food technologist or hygienist is cost prohibited in small size companies such as the FSE and sometimes the hiring of consultants for guidance is not done because they rely only on the recommendations given by the visits of public health inspections (Rodgers, 2005; Taylor & Kane, 2005). It was seen that the employees in the majority of FSE have more than 3 years of experience and have established the preparation process by the knowledge acquired from their own experience, and since they have not had safety problems perceived by customers yet, they continue to work in that way. This may be a factor that explains the lack of technical support.

With respect to chain environment characteristics, all FSE have been positioned in situation 3, for the indicator 'safety contribution in chain position', because they critically contribute to the reduction and prevention of post contamination before consumption due to the nature of the business. Furthermore, all the FSE were allocated in situation 1 with respect to 'strictness of stakeholders' requirements' owing to the fact

that they only have to deal with governmental requirements, i.e. implementation of pre-requisite programs and HACCP principles (Codex, 2003; Airey & Greaves, 2005; FSA, 2006; Jones et al., 2008) and not with other stakeholders' requirements. Also the situation with respect to supplier relationships is quite similar. The majority of FSE (46) is allocated in situation 2, because they have the possibility to establish specifications in collaboration with their supplies, since there is a high offer of suppliers and the relationships are usually strong and long-term. However, FSE, commonly do not have influence on the FSMS of their suppliers via auditing, or other types of inspections (which is typical for situation 1) maybe due to the fact that their suppliers are also small and medium enterprises.

As described before, various product, process and chain environment characteristics are rather similar between the 50 FSE and are typically at situation 2-3 (risky, vulnerable, uncertain and ambiguous), which would demand advanced FSMS performing at higher levels to be able to control microbiological performance.

Besides similarities in contextual situations, also similarities in the levels of core control and assurance activities have been found (Table 3). Obviously all FSE scored a level 2 for the 'adequacy of cooling facilities' and 'actual cooling capacity', which corresponds with the presence of industrial cooling facilities with capacity known from suppliers but not tested for own production circumstances, and automatic control of temperature but ad-hoc measurement of product temperature. This result demonstrates an improvement of the presence of adequate cooling facilities to prevent safety problems in comparison with other assessment where 60% of the cooling facilities of 102 UK establishments were domestic type with poor temperature control (Walker et al., 2003). It was also observed by other author that in many cases the temperature of the food items during refrigerated storage is never tested and the food temperatures are assumed to be the same as the displayed in the storage room (Bolton et al., 2008). Furthermore, all the FSE scored level 0 with respect to the following indicators 'specificity of calibration program for measuring equipment', 'extent of corrective actions' (about monitoring design), and 'actual performance of measuring equipment' (about actual operation). They received this score because of the absence of these activities in their FSMS, and the lack of information about actual performance of control activities since the equipment like refrigerators or cookers did not have temperature-check devices or were

not calibrated. Similarly, the majority of FSE (45) did not have any information or insight in the actual hygienic performance of its equipment and facilities (level 0). These results comply with other studies that have found that especially small companies/establishments do not have monitoring systems and commonly have poor insight in their actual performance due to the lack of measurements (Panisello & Quantick, 2001; Worsfold, 2001; Walker, Pritchard & Forsythe, 2003; Taylor, 2008; Eves & Dervisi, 2005).

With respect to the core assurance activities, Table 3 shows that there are no evident similarities between the FSE.

Differences between FSE

Hierarchical cluster analysis (Figure 1) and principal component analysis (Figure 2) were done to get insight in typical differences between the FSE for the control and assurance activity levels and contextual situations of the FSE.

This distance of dissimilarity in the dendrogram (10 units) resulted in four clusters (Figure 1) which coincided with the separation obtained with the principal component analysis (Figure 2). The number of FSE (elements) in the dendogram ranged from 4 to 22 per cluster. Cluster 1 (7 FSE) included 3 student halls of residence, 2 big hotels, 1 "menu a la carte" restaurant that is more than 40 years old and one of the most expensive in the city of Burgos, and 1 buffet restaurant that is part of a Spanish chain of restaurants that prepare most of the meals in a central catering establishment located in other Spanish city, which distributes the prepared meals as pasteurized, packaged and frozen meals to the member restaurants of the chain. Cluster 2 (4 FSE) consisted of 1 hotel, 1 "day menu" restaurant, and 2 student cafeterias. Cluster 3 (17 FSE) included 6 hotels, 6 "menu a la carte" restaurants, 2 "day menu" restaurants, 1 student hall of residence, 1 "tapas" restaurant and 1 "menu a la carte" restaurant that is also part of another Spanish chain of restaurants in which the meals are prepared with same kind of suppliers and following standardized preparation processes. Cluster 4 (22 FSE) consisted of 1 hotel, 13 "menu a la carte" restaurants, 3 "tapas" restaurants, 3 "day menu" restaurants, and 2 "vegetarian" restaurants.

The principal component analysis (Figure 2) revealed that component 1 and 2 represent respectively 62.3 % and 12.7 % of variance in the whole data set. The scatterplot shows

that the variation in the data set on the first component (right and left side of the diagram) can be explained by differences of organisational characteristics, such as absence of formalisation and lack of management commitment. The variation on the second component (top and bottom of the diagram) can be explained by differences of sophistication of validation and appropriateness of record-keeping (typical assurance activities), and appropriateness of CCP analysis (part of monitoring design).

Figure 3 exhibits spider-web graphs to get insight in organisation characteristics, design control activities, operation of control activities and assurance activities that differed between the four clusters (when similar for all, not presented).

Organisation characteristics

The spider-web graph of Cluster 1, showed that for the organisational characteristics of 'variability of workforce composition', 'operators competence', 'management commitment' and 'formalisation' have an assigned score of 1 or 1-2, except for 'extent of involvement' (2-3). These FSE are typified by low turnover, employees with cuisine knowledge and more than 3 years of experience, organisation with a statement related to safety and written procedures and meetings to guide personnel decision-making. Such administrative conditions enable people in taking appropriate and consistent decisions when functioning in the FSMS.

On the other hand, in Cluster 2 the characteristics of 'management commitment' and 'formalisation' were scored at 2 because the vision on safety is general and the procedures and meetings are restricted to critical measures of the FSMS. The spider-web graph of Cluster 3 resulted rather similar to Cluster 2 but with differences in the characteristics of 'operators competence' and 'extent of involvement' that were allocated in situation 2 which is described by minimal requirements on the competence of the operators and basic training at start, and by employees whose opinion is stimulated and taken into account for the design of the FSMS. It was also found in other studies that personnel from FSE have low level of knowledge and training (Panisello & Quantick, 2001; Walker et al., 2003; Sneed et al., 2004; Jones & Angulo, 2006). Finally, Cluster 4 showed that the characteristics of 'management commitment' and 'formalisation' were scored at situation 3 because there was no vision on safety, the

meetings were done only after recalls or problems, and there were no procedures or documentation and thus the instructions were given through informal communication.

For all the clusters the 'variability of workforce composition' was allocated in situation 1-2, which corresponds with a rather stable workforce composition. This situation is different from other studies that mentioned a high turnover in employees as a typical characteristic in the catering sector (Worsfold, 2001; Jones & Angulo, 2006; Jones et al., 2008). It should be mentioned that for this indicator, waiters were not taken into account for the assessment.

The food service establishments in cluster 1, which are mainly typified by 1, 1-2 situations, have organisational characteristics that would lead to less unpredictable decision-making behaviour (Luning and Marcelis, 2007, 2009). Accurate and predictable decision-making will create less uncertain and vulnerable situations, which will put less demand on the FSMS (Luning et al, submitted 2009b, submitted 2009c).

The next part of the qualitative analysis is to look into detail to the control and assurance activity levels as addressed in the FSMS for the different clusters.

Design of control activities

Figure 3 shows for Cluster 1 that the activities of 'hygienic design of equipment and facilities', 'sanitation program', 'personnel hygienic requirements', 'hot-holding facilities', 'intervention equipment', 'intervention methods', and 'CCP analysis' received assigned scores of 3 and 2-3. These levels are characterised by hygienic, adapted and tested equipment and facilities, complete sanitation program with cleaning agents tested and selected by suppliers, specific requirements on clothing, personal care and health, tailored facilities to support personnel hygiene such as complete hand-washing stations or pedal-pulled dustbins, specific training instructions related to hygiene, industrial and adapted hot-holding facilities, intervention equipment with known capability, adapted and tested, validated intervention methods like cleaning and disinfection of raw materials used for fresh-type meals, and CCP analysis done by expert knowledge and based upon Codex guidelines and microbiological tests. The rest of the activities in Cluster 1 were assessed at level 2, except the 'meal preservation methods' that was allocated at level 1 because the methods were based on experience and not tested.

Figure 3 displays evident differences between Cluster 1, which had a sophisticated design of control activities, and the other three Clusters where the majority of activities were allocated at basic levels (1, 1-2). For instance, Cluster 2 was scored in level 1 for various activities except the one related to 'intervention methods' that was scored at level 3; and the activities of 'standards and tolerances design', 'analytical methods to assess pathogens', and 'sampling design and measuring plan' that were scored at level 2 because the standards and sampling plan were based on general codes or legislative requirements, and the analytical methods done by the external laboratories were internationally validated but not accredited. These results were obtained because the FSE of this cluster hire external companies to help them to design its FSMS and also to perform microbiological analyses.

On the contrary, the FSE of Cluster 3 do not hire external experts and do not carry out microbial analyses but presented a score of 2-3 in the activities of 'hygienic design of equipment and facilities' and 'intervention equipment' because they have more investments in the design and layout of the kitchen. This Cluster scored 2 in the activities of 'extent of personnel hygiene requirements' and 'measuring equipment to monitor process/product status' since there were requirements on clothing, personnel health and care, hand-washing facilities and basic hygiene instructions, and the measuring equipment was standard with immediate response, but had low scores (1, 1-2) for the rest of activities.

Finally Cluster 4 showed levels 1, 1-2 or absence of activity in all the measures. Thus, the FSE from this cluster have designed their FSMS with lack of scientific evidence, use of own experience and common equipment making the activities variable and unpredictable.

The equipment and facilities of the FSE from Cluster 2 and 4 matches up with other studies that have found it to be un-hygienically designed, crowded with staff and machinery to satisfy occasional workloads, and not complying with the needs of sanitation and production characteristics (Panisello & Quantick, 2001; Rodgers, 2005).

Operation of control activities

Figure 3 points out an advanced performance of the operation of control activities in Cluster 1 in comparison with the other Clusters. Cluster 1 presented assigned scores of

2-3 and 3 in the activities of ‘actual compliance to procedures’ and ‘actual process capability of intervention processes’ because the FSE of this cluster follow the procedures and know the actual intervention capability of their ovens which have measuring devices that indicate the core temperature and time of heating. It was scored at level 2 for the rest of activities (‘actual availability of procedures’, ‘actual hygienic performance of equipment and facilities’, and ‘actual hot holding capacity’) because the procedures are available and understandable but kept up-to-date on ad-hoc basis, have knowledge of the actual hygienic performance of its equipment and facilities due to the microbial analyses done on ad-hoc basis in its contact surfaces, and have knowledge of the actual capability of the hot-holding facilities since they measure on ad-hoc basis the temperature of the food items that are hot-held.

In Cluster 2 the activities of ‘actual availability of procedures’ and ‘actual compliance to procedures’ had an assigned score of 2 because, even though the procedures are available, employees keep executing tasks according to their old habits and require constant control. This fact was also observed by other authors that distinguished a gap between food safety knowledge and the actual preparation practices (Howes et al., 1996; Taylor, 1996; Angelillo et al., 2000; Clayton et al., 2002; Sneed et al., 2004). The rest of the activities were scored at levels 0 and 1 because the FSE of this Cluster have no information about the hygienic performance of its equipment and facilities, its hot-holding facilities do not have automatic temperature check devices and no data about the core temperature of the items that are hot-held, and have unstable intervention processes due to lack of measuring devices (except the hotel and the “menu a la carte” restaurant).

Cluster 3 presented scores of 2 and 3 in the activities of ‘actual availability of procedures’, ‘actual compliance to procedures’ and ‘actual process capability of intervention processes’ but low-basic level (0, 1) in the activities of ‘actual hygienic performance of equipment and facilities’ and ‘actual hot holding capacity’. The score of 3 in ‘actual process capability of intervention processes’ was expected in this cluster because, as shown in the section of design of control activities, the FSE are characterised by the presence of sophisticated intervention equipment that has measuring devices that may help to maintain the process within acceptable limits.

Cluster 4 was scored at low and basic level (0, 1) in all the operation activities, demonstrating that the food service establishments of this Cluster have no information about the actual operation of their FSMS, do not work with procedures and their equipment and methods are unstable.

The 'actual process capability of intervention processes' of the FSE from Cluster 2 and 4 comply with other studies that have found that the temperature during cooking processes is poorly monitored due to the absence of an accurate method to check temperatures and thus, the cooking effectiveness is assessed by experience, visual inspection, or cooking time without linking temperature values with the role of cooking to control microbiological hazards (Walker et al., 2003; Bolton et al., 2008).

Assurance activities

Also the levels of assurance activities were rather different between the clusters (Fig 3). Figure 3 shows that Cluster 1 had assigned scores of 2-3 and 3 in the activities of 'systematic use of feedback information to modify FSMS', 'validation of preventive measures', 'validation of intervention processes', 'verification of people related performance', and 'verification of equipment and methods related performance'. The FSE from this Cluster are thus described by systematic analysis of information from validation and verification reports and from the production system, which is then used to modify procedures; validation of preventive measures and intervention processes through microbial analysed done by independent external experts; verification of people performance by observation and analysis of records and procedures; and verification of equipment and methods performance through microbiological tests and analysis of records. The activities of 'translation of stakeholder requirements into own FSMS requirements', 'validation of monitoring system', 'documentation' and 'record-keeping system' have an assigned score of 2 because the FSE from this Cluster are actively aware of stakeholders changes and search for new equipment or customers needs with the help of external experts, the validation of the monitoring system is done with legislative requirements but not based on scientific sources, and the documentation and record-keeping system are structured and available via specific persons but not automated, integrated and without access to external sources of information.

Cluster 2 had assigned scores of 3 in the activities of 'validation of preventive

measures', 'validation of intervention processes', and 'verification of equipment and methods related performance' because the FSE of this Cluster carry out microbial analyses of their meals and contact surfaces but have a score of 1 in the activities of 'validation of monitoring system' and 'record-keeping system' because some FSE of the Cluster do not have a CCP analysis and the registration of the records is done in ad-hoc basis.

Cluster 3 presented scores of 1-2, 1 and 0 in all the activities, except in 'documentation' (level 2). Similarly, Cluster 4 has scores of 1 and 0 in all the assurance activities. Thus, the FSE of Clusters 3 and 4 do not use external information or data from the FSCS but are problem driven to modify and improve the system, execute activities that are not validated and are based only by experience, do not verify the actual performance of the employees, equipment and methods, and do not use documentation and registration of records. With respect to the verification activities, the FSE from Cluster 3 and 4 have similar results as found in other study that established that the verification is commonly perceived in small and micro business as a burden because the manager is on site all the time and verifies the system by observation and visual confidence (Taylor, 2001). Indeed, the owner of these micro-sized FSE was working as waiter or cook within the establishment. On the other hand, Jones and co-authors (2008) found that a more closely supervised kitchen is less likely to have safety problems due to the vested interest in the business. The documentation and record-keeping system of Clusters 2, 3 and 4 comply with other studies that have found that small and micro sized FSE regard the documentation and record-keeping as time consuming and rely the reduction of microbiological load on visual checks and experience (Panisello & Quantick, 2001; Taylor, 2001; Walker et al., 2003; Eves & Dervisi, 2005; Rodgers, 2005).

These results along with the ones related to the control activities confirm what has been found in other studies, which are lack of measurement and thus unknown actual performance (Walker, Pritchard & Forsythe, 2003; Worsfold, 2001; Taylor, 2008; Eves & Dervisi, 2005), lack of procedures and record-systems (Rodgers, 2005; Taylor, 2001; Eves & Dervisi, 2005), processes established by experience and not validated with microbial analyses to assure its effectiveness to control hazards (Taylor & Kane, 2005; Taylor, 2008), and no verification activities to confirm that specified requirements have been met (Taylor & Kane, 2005; Taylor, 2008).

FSMS were core control and assurance activities are executed at advanced levels result in more predictable food safety outcomes due to less ambiguity (because better scientifically underpinned, well-tested in own practical situation, stable people and equipment performance), and less uncertainty (due to accurate, precise information) (Luning and Marcelis, 2006, Luning et al, 2008, 2009a). On the other hand, if the FSMS are performed at low or basic levels combined with vulnerable, ambiguous, and uncertain contextual situation may facilitate the occurrence of unexpected and unpredictable food safety problems.

4. Conclusions

The quantitative diagnosis in 50 FSE showed that the FSMS have to operate in rather risky contextual situations (risky products and processes, vulnerable chain position), that demands FSMS to perform at advanced levels to be able to serve safe meals all the time. The analyses showed four clusters of FSE that indeed differed in their organisational characteristics and levels of performance of control and assurance activities. The clusters ranged from FSE with organisational characteristics that support appropriate and consistent decision making in FSMS, and with rather advanced FSMS (level 2-3 in cluster 1), to FSE with less supporting conditions and low FSMS activity levels (cluster 4). Based upon the results it is expected that FSE that have similar profiles as cluster 1, have a lower risk on unexpected and unpredictable safety problems than the other 3 clusters, because they are better organised and have FSMS performing at an advanced level. On the other hand, the FSE from cluster 4 need more control and assessment from external stakeholders such as governmental public health inspections to help them in improving the activities that were not well performed. However, for all FSE there is still room for improvement in activities such as calibration, development of corrective actions, assessment of actual performance of measuring equipment and actual hygienic performance of equipment and facilities, and design of the meal preservation methods.

The FSMS-DI modified for FSE has been found useful for the identification of weak points in the FSMS in view of the contextual situation wherein FSE have to operate. However, a limitation in this study was that in most of the cases the owner of the establishment was the interviewee, which may result in an over-scored assessment.

In order to get insight in the actual microbiological performance of the FSMS one needs in addition a systematic microbial assessment, as also proposed by Jacxsens and co-authors (2009). Therefore, in the next chapter (Chapter 4) the assessment of FSMS performance in light of the context situation will be done in combination with an assessment of the final microbiological safety of meals with the objective of checking the actual microbiological performance of the activities addressed in the FSMS.

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Table 1: Mutual characteristics of different situations and levels (adapted from Luning et al., submitted 2009c)

Contextual factors	**Situation 1**	**Situation 2**	**Situation 3**
Product characteristics (PROD CHAR) Process characteristics (PROC CHAR)	- Not risky (in terms of initial contamination, growth conditions for pathogens, survival of pathogens) - Not vulnerable (for cross contamination, unexpected problems)	- Potentially risky, potentially vulnerable	- Highly risk, highly vulnerable
Organisational characteristics (ORG CHAR)	- High workforce quality (related to safety expertise, stability, and competences) - Supportive organisational structures (in terms of safety commitment, involvement in FSMS activities, established rules and procedures) - Specific information system (to support decisions in FSMS)	- Constrained workforce quality - Restricted organisational structures - Restricted information system	- Low workforce quality - Lack of organisational structures - Lack of information system to support FSMS decisions
Chain environment characteristics (CHAIN CHAR)	- Not vulnerable (for safety problems at final consumption) - Low dependency (in terms of ability to affect suppliers and customers)	Potentially vulnerable, restricted dependency	Highly vulnerable, highly dependent
Core control activities*	**Level 1**	**Level 2**	**Level 3**
Design preventive measures (PREV MEAS) Design intervention processes (INT MEAS) Design monitoring system (MON SYS)	- Process equipment (standard, general, capability unknown) - Methods (based on experience, general knowledge) - Programs (on ad-hoc basis, incomplete, problem driven, no specific instructions, common materials) - Measuring equipment /methods (not standardised, not internationally acknowledged)	- Process equipment (best available in practice, supplier support and expertise used, potentially capable) - Methods (based on sector , governmental guidelines, expert knowledge) - Programs (complete, structured,, supplier expertise (selection, use materials) - Measuring equipment /methods (standardised, internationally acknowledged)	- Process equipment (tailored/modified for specific circumstances, capability tested in practice) - Methods (scientifically supported, and tested under practical circumstances) - Programs (complete, structured,, tailored, tested for own specific circumstances (specific materials, instructions) - Measuring equipment /methods (standardised, internationally acknowledged, accredited)
Actual operation (OPER)	- People related (unawareness of procedures, execute task by own insights, unavailable procedures/ instructions, ad hoc control of people) - Equipment related (regularly unexpected problems, regularly unstable process, very sensitive for minor changes)	- People related (familiar with procedures, execution tasks based on habits, procedures available on location, regular people control) - Equipment related (sometimes unexpected problems, unstable process, sensitive for known circumstances)	- People related (full awareness, procedures internalised, self control - Equipment related (stable (tested) performance, robust, not sensitive for changes)
Core assurance activities	**Level 1**	**Level 2**	**Level 3**
Defining system requirements (SYS REQ)	- Initiated by stakeholder problems (reactive), ad hoc/restricted modifications based on problems - No documentation	- actively acting on stakeholder requirements, regular modifications, use restricted feedback information/data - No systematic documentation	- pro-actively acting on stakeholder requirements, systematic analysis, use verification and validation feedback data/info - Complete documentation
Validation (VAL) Verification (VER)	- Use historical experience/data, no independent judgement - Only checking presence of procedures/records, parameter settings (no data analysis) - Scarcely reported, documented	- Use expert knowledge/regulatory documents, (internal) expert judgement - Additional analysis procedures, records, etc - Regular reporting (expert/internal reports	- Use specific scientific sources, own test/trials, judgement by external experts - Additional analysis, and actual performance measuring - Comprehensive reporting/documentation
Documentation and record-keeping (DOC REC)	- Not structured, ad-hoc, no access external sources	- Structured, kept up to date, de-centrally organised, access via authorised persons, restricted external sources	- Structured, kept-up-to date, centrally organised, available for all, access external information sources

* For all control and assurance activities, also a level 0 is included. Level 0 is associated with absence, not possible, not applied, not relevant, unknown

Table 2. Contextual factors: number of FSE within each situation

Contextual factors	Indicator	Situation 1	Situation 2	Situation 3
Product characteristics	Risk of raw material	0	0	50
	Risk of meals	0	0	50
Process characteristics	Extent of intervention steps	0	1	49
	Assortment of meal production process	5	16	29
	Rate of menu changes	8	36	6
Organisation characteristics	Lack of technological staff	0	0	50
	Degree of variability in workforce composition	25	18	7
	Deficiency of operator competences	20	24	6
	Lack of maganement commitment	5	15	30
	Deficiency of employee involvement	5	33	12
	Absence of formalisation	5	21	24
	Deficiency of information systems	0	0	50
Chain environment characteristics	Safety contribution in chain position	0	0	50
	Lack of power in supplier relationships	4	46	0
	Strictness of stakeholders requirements	50	0	0

Table 3. FSMS performance: number of FSE within each level

	Indicator	Level 0	Level 1	Level 2	Level 3
Core control activities					
Preventive measures design	Sophistication of hygienic design of equipment and facilities	0	21	9	20
	Adequacy of cooling facilities	0	0	50	0
	Specificity of sanitation programs	0	28	19	3
	Extent of personnel hygiene requirements	0	23	14	13
	Specificity of raw material control	0	36	14	0
	Specificity of meal preservation	14	19	14	3
	Specificity of defrosting methods	6	8	35	1
	Specificity of hot holding methods	16	13	17	4
Intervention process design	Adequacy of physical intervention equipment	0	16	8	26
	Specificity of maintenance and calibration program for equipment	0	21	29	0
	Effectiveness of intervention methods	22	15	1	12
Monitoring system design	Appropriateness of CCP analysis	34	0	11	5
	Appropriateness of standards and tolerances design	0	24	26	0
	Adequacy of analytical methods to assess pathogen levels	38	0	12	0
	Adequacy of measuring equipment to monitor process/product status	13	1	36	0
	Specificity of calibration program for measuring equipment	50	0	0	0
	Adequacy of sampling design (for microbial assessment) and measuring plan	0	36	14	0
	Extent of corrective actions	50	0	0	0
Operation of preventive measures, intervention process and monitoring systems	Actual availability of procedures	19	0	31	0
	Actual compliance to procedures	19	2	25	4
	Actual hygienic performance of equipment and facilities	45	0	1	4
	Actual cooling capacity	0	0	50	0
	Actual hot-holding capacity	16	31	0	3
	Actual process capability of intervention processes	13	0	1	36
	Actual performance of measuring equipment	50	0	0	0
Core Assurance activities					
Setting of system requirements	Sophistication of translation of stakeholder requirements into own FSMS requirements	0	25	24	1
	Extent of systematic use of feedback information to modify system	0	26	21	3
Validation activities	Sophistication of validation of preventive measures	38	0	0	12
	Sophistication of validation of intervention systems	38	0	0	12
	Sophistication of validation of monitoring systems	34	0	16	0
Verification activities	Extent of verification of people related performance	27	0	16	7
	Extent of verification of equipment and methods related performance	0	25	14	11
Documentation and record-keeping	Appropriateness of documentation system	0	25	25	0
	Appropriateness of record keeping system	25	8	17	0

Figure 1. Dendrogram

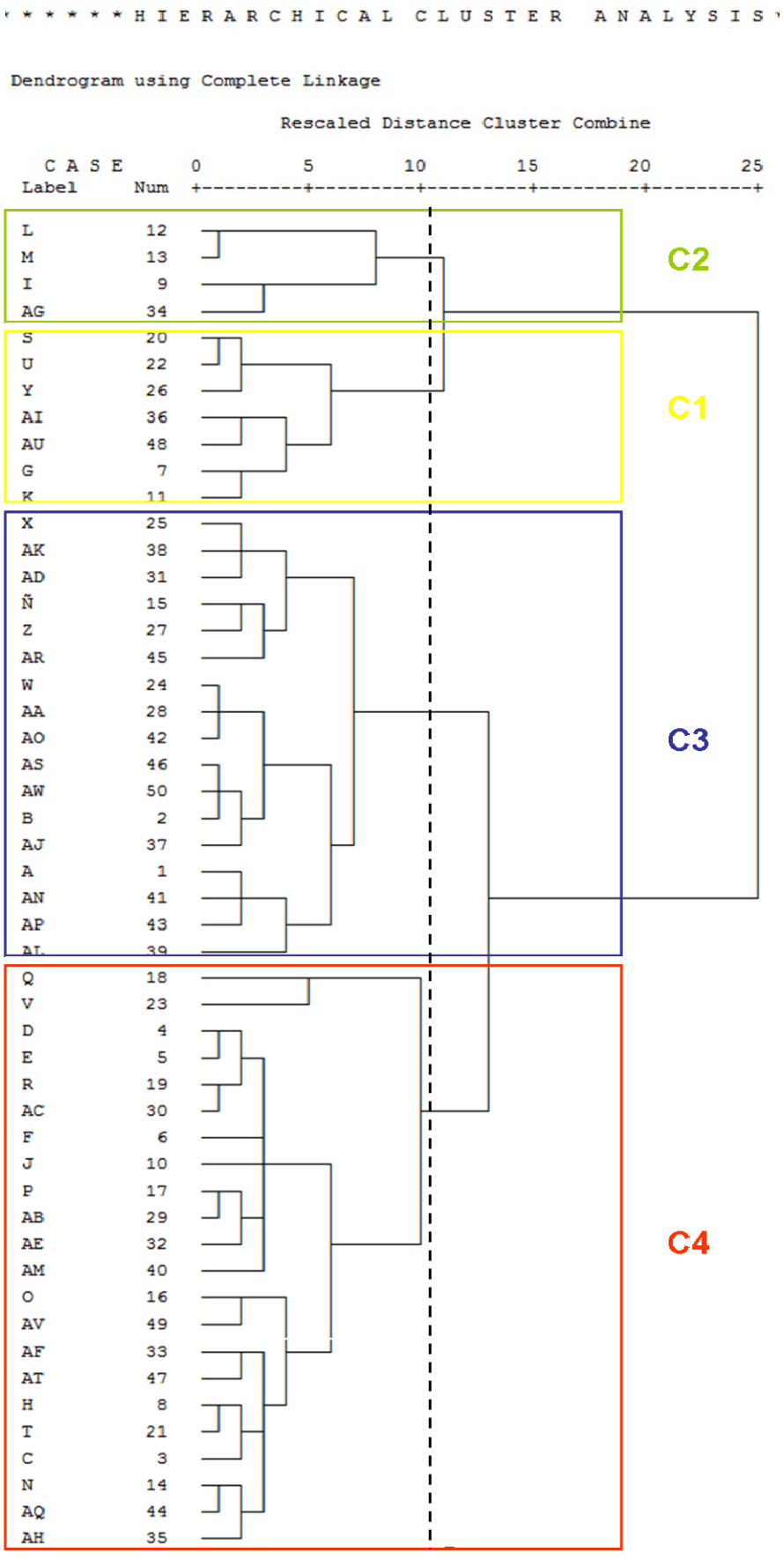


Figure 2. Principal component analysis

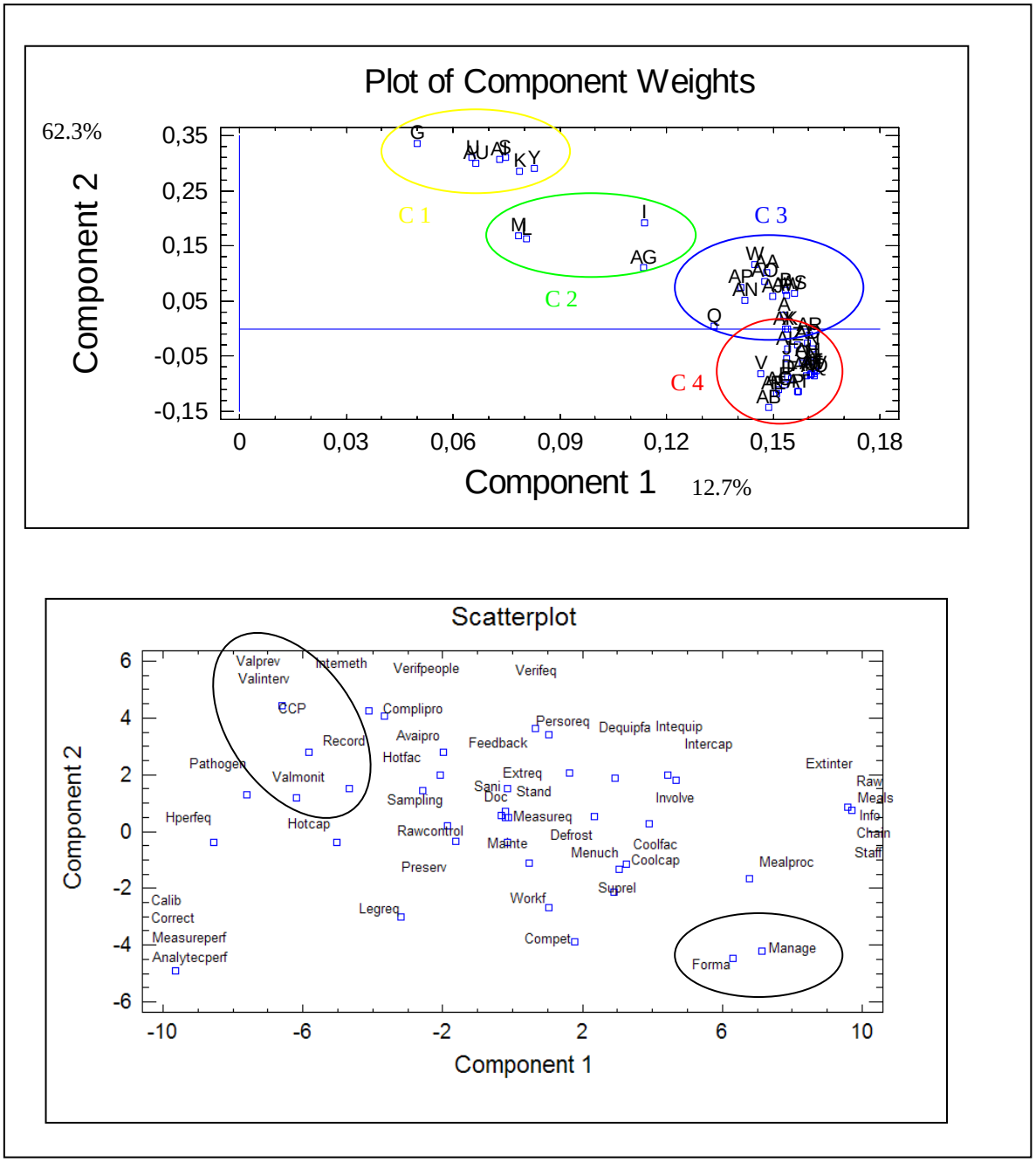
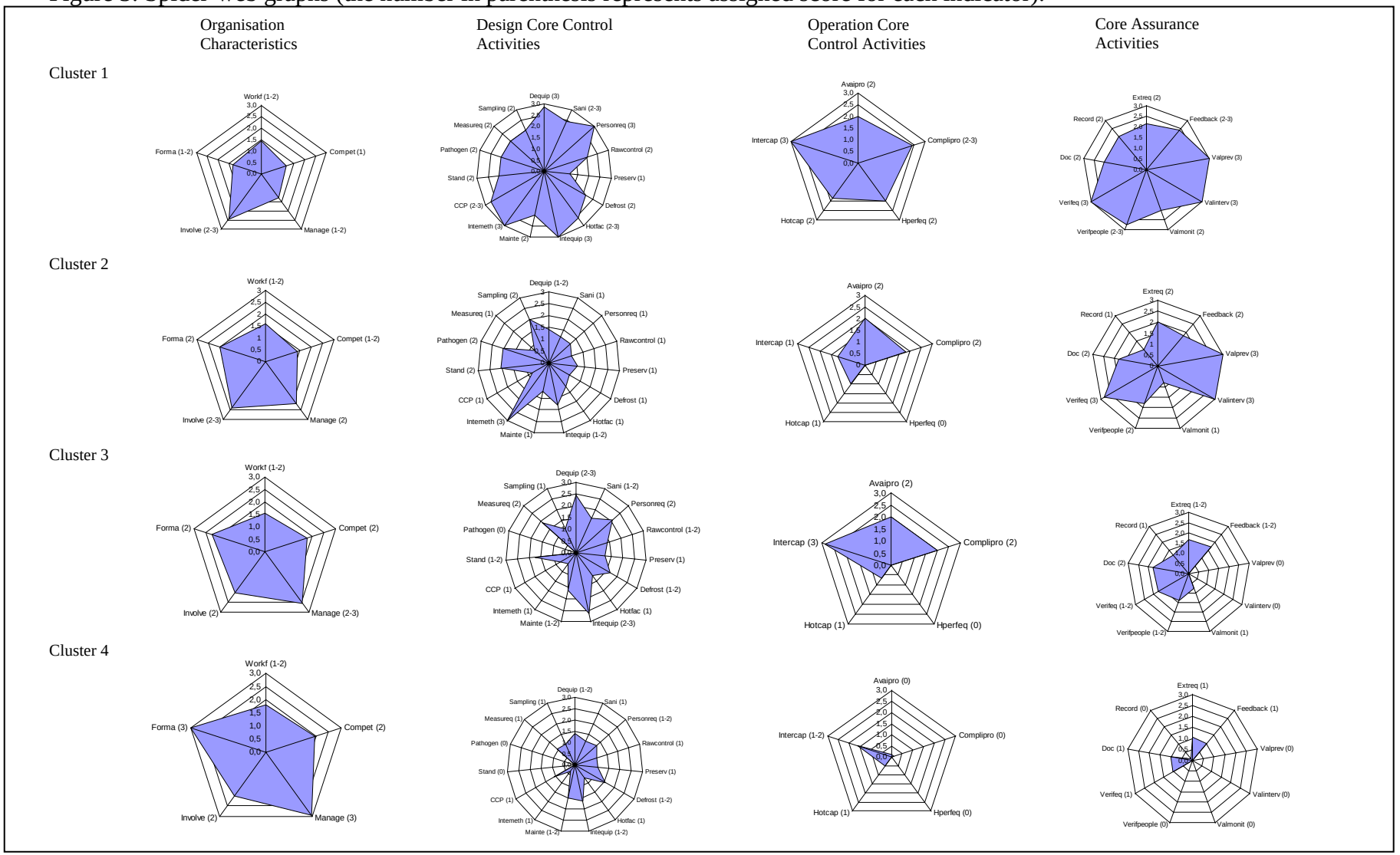


Figure 3: Spider-web graphs (the number in parenthesis represents assigned score for each indicator).



CAPITULO 4

Evaluación del rendimiento del sistema de gestión de la seguridad alimentaria de un FSE mediante el empleo combinado del FSMS-DI y análisis microbiológico

Introducción

En el capítulo 3 se demostró que el instrumento de diagnóstico para evaluar el rendimiento de los sistemas de gestión de seguridad alimentaria es útil para detectar los puntos que se pueden mejorar para asegurar la calidad microbiológica de los alimentos, que se preparan considerando el contexto en el que debe operar el sistema. Sin embargo, el rendimiento real microbiológico del sistema requiere realizar análisis microbiológicos. Por lo tanto, con el objetivo de analizar sistemáticamente el rendimiento microbiológico del sistema se utilizó la herramienta "Esquema de evaluación microbiológica" (MAS, Microbiological Assessment Scheme). Dicha herramienta se adaptó para la situación del sector de restauración debido a la diversidad de platos, materia prima y condiciones en la cocina que hacen difícil la aplicación de la herramienta original en la que se evalúa toda la línea de producción desde materia prima hasta producto final. Por consiguiente, en la modificación de la herramienta se evaluaron solamente los platos finales de los cuatro tipos de preparación que pueden conllevar una mayor contaminación microbiológica.

El objetivo en éste estudio es describir los puntos débiles que puede tener un sistema de gestión de seguridad alimentaria en base los resultados del instrumento de diagnóstico y la herramienta de esquema de evaluación microbiológica y así generar posibles intervenciones que puedan mejorar el sistema.

Materiales y métodos

El instrumento de diagnóstico y el esquema de evaluación microbiológica (modificados para la situación del sector de restauración) fueron aplicados a 10 establecimientos de restauración (FSE) que incluyeron 1 residencia para estudiantes, 4 hoteles y 5 restaurantes localizados en Burgos. Las modificaciones del esquema de evaluación microbiológica (MAS) fueron principalmente, el tipo de muestra que se tomó dado que

solamente se muestrearon los platos finales. Los cuatro tipos de preparación que se tomaron en cuenta para el muestreo fueron aquellos que por revisión literaria han estado mayormente implicados en brotes de enfermedades transmitidas por alimentos. Por lo tanto se muestrearon. a) platos que no llevan un paso de intervención con cocción como son las ensaladas frescas; b) platos que se cocinan, se almacenan en condiciones de refrigeración y finalmente se sirven fríos; c) platos que se cocinan, almacenan en condiciones de refrigeración y se recalientan antes de servir; y d) platos que se mantienen en caliente antes de servirse.

Los parámetros microbiológicos que se analizaron en los platos fueron *Listeria monocytogenes* como indicador de seguridad, *Escherichia coli* y *Enterobacteriaceae* como indicadores de higiene, *Staphylococcus aureus* como indicativo de la higiene del personal, y bacterias totales aeróbicas como indicador global del rendimiento del sistema. El criterio que se utilizó para determinar si el plato cumplía con los niveles máximos de contaminación fue la legislación española RD 3484/2000 BOE 121/2001. El rendimiento real microbiológico se estableció como + si solo algunas muestras excedían el límite para el indicador de rendimiento global del sistema, +/- si varias muestras excedían el límite para el indicador de rendimiento global del sistema y una o más los indicadores de higiene, y – si una o mas muestras excedían el límite del indicador de seguridad.

Resultados y Discusión

De acuerdo a los resultados del instrumento de diagnóstico se determinó que los establecimientos de restauración analizados operan en un contexto ambiguo, incierto y vulnerable por lo que se esperaba que las actividades de control y aseguramiento se ejecutaran a niveles altos para lograr la seguridad alimentaria de los platos, sin embargo no fue así puesto que frecuentemente se encontraron actividades llevadas a cabo a niveles bajos o básicos.

Estos resultados concordaron con los resultados del esquema de evaluación microbiológica que mostró que 4 establecimientos tenían *Listeria monocytogenes* en platos servidos sin ninguna intervención y platos cocinados-servidos fríos, 9 establecimientos sobrepasaron los límites de *Enterobacteriaceae*, y 10 establecimientos excedieron los límites de bacterias aeróbicas totales.

Al analizar ambos resultados de los dos instrumentos, se pudo comprobar que la residencia para restaurantes resultó con mejor rendimiento microbiológico (solamente dos muestras con bacterias aeróbicas totales sobre los límites) debido a que es el establecimiento con actividades de control y aseguramiento diseñados y operados a niveles promedio y avanzado (entre 2 y 3). Por otro lado, los restaurantes que presentaron menor rendimiento microbiológico (incluso dos de ellos mostraron presencia de *Listeria monocytogenes*) deben mejorar con respecto a las actividades de control y aseguramiento relacionados con el diseño de las instalaciones y el equipo, el control de materia prima, métodos de limpieza y desinfección, información acerca del rendimiento de equipo, validación de los métodos de preparación, y verificación del comportamiento del personal.

Debido a que se encontró que el método de limpieza y desinfección y las actividades relacionadas con el comportamiento del personal fueron unos de los puntos del sistema de gestión de seguridad alimentaria operados a niveles bajos o básicos, el siguiente capítulo se concentra en el análisis de las prácticas higiénicas del personal y del rendimiento microbiológico de las superficies de contacto.

CHAPTER 4

Combined assessment of Food Safety Management System and microbial performance of Food Service Establishments – A semi quantitative study in Spain

Abstract

Food Service establishments (FSE) need improvements in their food safety management systems (FSMS) due to their implication in foodborne outbreaks. The objective of this study was to get insight in weak points in implemented FSMS in FSE in view of their contextual situation and microbiological performance of critical final meals, and to derive possible interventions for improvement. Ten FSE were analysed using a modified Food Safety Management System - Diagnostic Instrument (FSMS-DI) and a modified Microbial Assessment Scheme (MAS). Assessment of contextual situations, core control and assurance activities clearly showed that all FSE operate in a rather vulnerable, ambiguous, and uncertain contextual situation, whereas various important control activities were not addressed or executed at low or basic levels, thus creating conditions for microbiological (safety) problems; although considerable differences between the FSE were observed. Microbiological results indeed showed that in 4 establishments *Listeria monocytogenes* was identified in fresh-type and cooked-served-cold meals. *Escherichia coli* and *Staphylococcus aureus* were not detected in any of the meal samples. However, all FSE had one or more meal type samples with exceeding limits for *Enterobacteriaceae* and total aerobic count. Interpretation of combined data revealed weak points in FSMS of the different FSE. Major intervention suggestions related to improvement of incoming materials, enhancement of sanitation performance, increasing insight in actual time-temperature conditions, improvement of prevention of undesired growth, and people related suggestions like enhancement of employee involvement, increase of management commitment, improvement of competences, and development of suitable procedures to support people's decision-making behaviour at critical safety control activities. Results of the combined assessment may help the FSE to set priorities on those measures to be taken first, which with relatively small investments may result in considerable improvement.

1. Introduction

The number of foodborne outbreaks coming from Food Service Establishments (FSE) in industrialised countries has increased the efforts to improve food safety performance in the last decade (Olsen et al., 2003; Effler et al., 2001; Codex Alimentarius Commission, 2003). Nowadays, there are various quality assurance standards and guidelines that can be used to develop a company specific Food Safety Management System (FSMS), such as Good Hygienic Practices, Hazard Analysis Critical Control Points principles, BRC standard, SQF standard, and ISO 22000 standard (Jacxsens et al., 2009a; Luning and Marcelis, 2009). Some studies have indicated positive safety performance effects due to implementation of HACCP principles in a food safety management system of catering establishments (e.g. Soriano et al, 2002; Cenci-Goga et al, 2005; Kokkinakis, et al, 2007). However, in a review study it has been stressed that there visually appears to be still a tremendous need for better FSMS than is currently in place in the food service area, especially in small and medium size establishments (Sun and Ockerman, 2005). To illustrate, a surveillance study revealed various shortcomings regarding equipment, incorrect procedures, tools and work surfaces with unacceptable contamination in 10% of samples, and also unacceptable contamination in food samples (Legnani et al, 2004). It has been discussed that a straightforward implementation of HACCP principles in FSE is not so easy due to the distinct differences with manufacturing industries (Seward, 2000; Chapter 1). In fact, food safety management systems in the food service sector have to operate under rather vulnerable conditions. For example, FSE commonly work with ingredients and products that are sensitive to contamination and growth of spoilage bacteria and pathogens, and initial quality of incoming supplies is often not known. Moreover, there is a lot of people interference with the food products, and they commonly have to operate in restricted areas increasing the risk of contamination (Martinez-Tome, et al, 2000; Rooney et al, 2004; Todd et al, 2007; Howells et al, 2008). In addition, people with insufficient hygiene knowledge and lack of awareness of consequences of inadequate hygienic handling on food safety also contribute to a situation that is more susceptible to food safety problems (Lynch et al, 2003; Bolton et al, 2008).

Luning and co-authors (2009a) discussed that the performance of a company specific FSMS not only depends on the level at which core control and assurance activities are

designed and executed but can be also affected by the contextual situation wherein the company operates. Therefore, they proposed to analyse a FSMS within its contextual situation to get a broader insight in possible causes of safety problems. Recently, two tools have been developed that can support in analysing and assessing the performance of a company specific FSMS independent of the QA standards and guidelines that have been implemented. The first tool is a 'Food Safety Management System - Diagnostic Instrument' (FSMS-DI) that is explained in Chapter 2. The second tool is a 'Microbiological Assessment Scheme' (MAS) that enables a systematic analysis of the actual microbiological performance of an implemented FSMS. Based on a MAS assessment, microbial safety level profiles can be derived, indicating which microorganisms and to what extent they contribute to microbiological safety for a specific food processing company (Jacxsens et al., 2009a).

The combined use of above tools give insight in weak and strong points in the FSMS in view of the contextual situation, and provide indications on how to go to perform the FSMS at advanced levels, and/or reduce the impact of the context (Luning et al., submitted 2009c). Various authors have emphasised that any investment to improve the FSMS performance requires money, efforts, and time which can especially be a burden for small and medium enterprises (Maldonado, et al, 2005; Bata et al, 2006; Semos and Kontogeorgos, 2007). The results of the systematic combined assessment may support establishments in the food service sector in taking strategic decisions on improvement in the FSMS and/or their contextual situation.

Chapter 3 already demonstrated that there are considerable differences between organisational characteristics of food service establishments and how they have designed and executed their food safety management system but the actual microbiological performance of the implemented systems was not assessed.

The objective of this study is to get insight in weak points in implemented food safety management systems of food service establishment (FSE) in view of the contextual situation wherein they have to operate and the microbiological performance of some of their critical final meals, and to generate possible interventions to improve the FSMS. Ten Spanish FSE (in the area of Burgos) that differed in their organisational characteristics and who wanted to participate were selected to get a set of typical Spanish FSMS. The FSMS-DI and MAS tools were used, which were both slightly

modified to make them applicable for the analysis of FSMS in the typical food service establishment environment.

2. Materials and Methods

2.1 Characteristics of Food Service Establishments (FSE)

In total 10 FSE wanted to participate to do a combined assessment of their food safety management system performance. Table 1 shows the characteristics of the 10 FSE, consisting of 1 hall of residence (RH), 4 hotels (H1 -H4) and 5 restaurants (R1-R5), ranging in management organisation, number of meals, maximum capacity, number of employees, and analysed meals.

2.2 Assessment of Food Safety Management Systems

Principle Food Safety Management System –Diagnostic- Instrument (FSMS-DI)

The basic principle behind the FSMS-DI is that companies (or establishments) that operate in a more vulnerable, uncertain, and ambiguous situation (due to e.g. highly risky product and processes, less supporting organisational conditions, highly vulnerable, depend chain position) require an advanced FSMS (i.e. based on precise information, scientifically underpinned, critically analysed, procedure-based, systematic, and independent) to be able to realise and ensure safety of their products (Luning et al, submitted 2009b, submitted 2009c). The typical characteristics of contextual situations (low-risk 1, moderate-risk 2, high-risk 3) and the levels of performance of core control and assurance activities (low level 0, basic level 1, average level 2, advanced level 3) are briefly summarised in Table 1 of Chapter 3 (adapted from Luning et al, submitted 2009c). The FSMS-DI has been slightly modified for assessment of FSE and for detailed descriptions of indicators and grids the reader is referred to chapter 2.

Actual FSMS diagnosis

The food safety management system of each FSE was diagnosed with the modified FSMS-DI by having an in-depth interview with the person in charge of the FSMS, in most of the cases the owner or the chief cook. They had to answer a set of questions in order to assess the levels of control and assurance activities, and to assess the situations of the contextual factors. The interview took approximately one hour. Then, the facilities of the kitchen were on-site checked, and the available documentation was analysed with respect to its content, completeness and up-dating.

Data analysis

The food safety management system diagnosis results in a list of scores for the separate indicators for control and assurance activities, and for contextual factors (see Table 2). As done in Chapter 3, mean values were calculated and transformed to *assigned scores* to obtain an overall impression of *levels* of core control and assurance activities, and *situations* of major contextual factors. The mean values were calculated by doing and average of the indicators that represent each group of characteristics/measures. For example, to assess organisational characteristics, in total seven indicators are used (i.e. 'lack of technological staff', 'variability in workforce composition', 'insufficiency in operator competences', 'lack of management commitment', 'deficiency of employee involvement', 'absence of formalisation', and 'insufficiency supporting information systems'). So the mean value is the sum of the score of each individual indicator divided by the total number of indicators. The transformation to assigned scores was done in the same way as described in Chapter 3.

2.3 Assessment of Microbiological Performance

Principle Microbial Assessment Scheme (MAS)

The MAS tool supports in a systematic analysis of microbiological counts in order to assess the current microbiological performance of an implemented FSMS. The MAS is a procedure that supports in the identification of critical sampling locations, the selection of microbiological parameters, the assessment of sampling frequency, the selection of sampling and analysis method, and data processing and interpretation. Based on the MAS assessment, microbiological safety level profiles can be derived, indicating which microorganisms and to what extent they contribute to food safety for a specific food processing company. The basic principle behind the tool is that low numbers of microorganisms and small variations in microbiological counts indicate an effective FSMS (Jacxsens et al., 2009b).

Actual MAS analysis

The different steps of MAS were adapted because the situation in FSE is significantly different from food manufacturing industries (Chapter 1). This study was primarily focused on product samples and not (yet) on environmental and people samples as prescribed in MAS. The modified steps are described below.

Critical sampling locations

A critical sampling location is defined as a location that could lead to unacceptable safety problems due to growth or survival of microorganisms and thus need to be sampled to provide information about the performance of the control measures (Jacxsens et al., 2009b). Final meals that are more likely to be contaminated were selected as critical sampling locations, and the differentiation in four preparation lines according to Bolton and Maunsell (2004) was used to select the meals for sampling, i.e. Meal consisting of fresh raw materials that are assembled and served; coded as '**Fresh type (FT)**' meals. It is important to sample this type of meals since there are studies that have demonstrated that fresh-type meals such as salads are known to serve as vehicles of foodborne pathogens and toxins (Soriano, Prieto, Moltó & Mañes, 2005; Bracket, 1999; Viswanathan & Kaur, 2001; Martínez-Tomé et al., 2000).

Meal that is cooked and stored at chilled or frozen conditions, and finally served cold; coded as '**cooked-served cold (CS)**'meals. In such types of meals, any cross contamination after the cooking step will not be reduced and/or may even increase to unacceptable levels if it is not well stored at safe temperatures (Legnani et al., 2004).

Meal that is cooked, stored at chilled or frozen conditions, reheated and served hot; coded as '**cooked stored reheated (CSR)**' meals. In such types of meals, insufficient reheating step may not reduce pathogens to acceptable levels (Rooney et al., 2004; Cardinale et al., 2005; Todd et al., 2007).

Meal that is hot held before consumption; coded as '**hot held served hot (HH)**' meals. Hot holding is known to be rather vulnerable to (cross) contamination or growth of microorganisms in case of insufficient cleaning or inadequate temperature maintenance (Ochiai et al, 2005). The actual products that were analysed are listed in Table 1.

Selected microbiological parameters

According to MAS, microbiological parameters should be selected to indicate respectively safety, hygiene, and overall performance (Jacxsens et al, 2009b). In this study, *Listeria monocytogenes* was selected to give an indication about safety, because it is a pathogen that is commonly spread in FSE (Legnani et al., 2004). *Escherichia coli* and *Enterobacteriaceae* were selected because they are common indicators for hygiene (Anonymous, 2005), and are also widely used to measure effectiveness of sanitation programmes (Buchanan, 2000).

Staphylococcus aureus was selected because it can provide an indication of personnel hygiene and hand practices (Aarnisalo et al., 2006). Finally, total aerobic (mesophilic) count was selected because it is indicator for overall performance of a critical sampling location (ICMSF, 2002; Mossel et al., 1995).

Sampling frequency

Similar to the MAS protocol, samples were taken at three different days, to get some insight in the range of variation in microbiological counts. Sampling of meals required the cooks to prepare the food as if they have to prepare it for a customer, stored in sterile plastic bags, and transported in a refrigerated box to the laboratory for analysis.

Sampling and analysis method

All microbiological parameters were sampled and analysed following ISO standards, as it is recommended in the MAS protocol. *Listeria monogytogenes* was sampled and analysed according to ISO 11290-2:1998 and confirmed with Polymerase Chain Reaction (PCR) analysis using SureFood® PREP Listeria kit for DNA sample extraction, and SureFood® Pathogen Listeria PLUS R kit for detection, with internal amplification control following instructions of the manufacturer (CONGEN, Berlin, Germany), and using the iCycler iQ™ Thermal Cycler machine (Bio-Rad Laboratories, California, USA). *Escherichia coli* was sampled and analysed according to ISO 16649-1:2001, *Enterobactericeae* according to ISO 21528-2:2004, *Staphylococcus aureus* according to ISO 6888-1:1999 and confirmed with coagulation of rabbit plasma. Total aerobic mesophilic plate count was sampled and analysed according to ISO 4833:2003.

Results expressed as colony forming units (CFU) were converted into CFU per gram of sample, and were transformed by logarithm of 10 to normalise data (Larson et al., 2003).

Data processing and interpretation

Data was interpreted using European Regulation on microbiological criteria for foodstuffs (Anonymous, 2005) as prescribed in the MAS protocol. In this study, the Spanish regulation RD 3484/2000 BOE 121/2001 was used to select the legal limits. It establishes that the meals that are not heat-treated or have ingredients that were not heat-treated must have <5 log CFU/g for total aerobic count, <3 log CFU/g for *Enterobacteriaceae*, <1 log CFU/g for *Escherichia coli* and *Staphylococcus aureus*, and absence of *Listeria monocytogenes* in 25 g

of sample. Similarly, the meals that are heat-treated must have <4 log CFU/g for total aerobic count, <1 log CFU/g for *Enterobacteriaceae*, absence of *Escherichia coli* / g, <1 log CFU/g for *Staphylococcus aureus* and absence of *Listeria monocytogenes* in 25 g of sample. Therefore, the meals categorised as Fresh-type meals were assessed under the limits for meals that are not heat treated, while the rest of the meals that were sampled were assessed under the limits for meals that are heat treated (except in the case of the hall of residence RH where the cooked-served cold meals had ingredients that were not heat treated such as lettuce).

The MAS tool also describes how 'microbiological safety level profiles' could be made to indicate performance of the FSMS. However, in this study these 'rules' were not applied due to differences in type of sampling locations. Therefore, the qualitative indication of FSMS performance was provided in terms of + (only few samples exceeding limit for overall performance indicator), +/- (various samples with exceeding limits for overall performance indicator, and for one or more hygiene indicators), and – (when one or more samples with exceeding limits for safety indicator).

3. Results and discussion

3.1 FSMS Diagnosis

Assessment contextual situation

Table 3 shows the assigned overall scores for the major contextual factors. Scores of separate indicators are listed in Table 2, whereas Table 1 of Chapter 3 provides brief descriptions of typical aspects associated with the different contextual situations (from Luning et al., submitted 2009c). For detailed grids the reader is referred to Chapter 2.

Obviously, all food service establishment (FSE) received an assigned score 3 for the contextual factor 'product characteristics', whereas for 'process characteristics' it ranged between 2 and 2-3. Situation 3 is typically associated with *highly* risky (with respect to initial concentrations, growth conditions, and survival of bacteria/pathogens) and *highly* vulnerable towards (cross) contamination and unexpected safety problems, whereas situation 2 is linked to *potentially* risky and vulnerable (Table 1 of Chapter 3). The analysed FSE typically worked with 'high risk' raw materials like meat, poultry, fish, dairy products, vegetables and fruits, and 'high risk' meals like fresh salads, and meals containing duck liver cake, fresh cheese, or dairy sauces. Moreover, their processes are characterised by various meal preparations without inactivation steps, using same areas, equipment and workplaces for different types of food preparations, and regular manual product handling by the cooks. Only the student hall of residence (RH) has a meal preparation process at situation 1 (Table 2), because it has a low number of meals that are prepared using equipment and surfaces for only one type of food. The findings of this study are in alignment with other studies that underpinned that catering, restaurants, hotels and other FSE types typically work with 'high risks' food products and meal preparation processes with much people interference, and restricted working circumstances (Kassa, 2001; Bemrah, et al, 2003; Rosset et al, 2004).

The contextual factor 'organisational characteristics' received assigned scores 2 (RH, R1, R2, R3), 2-3 (H1-H4, R4), and 3 (R5). Typical aspects described as situation 3 are low workforce quality, lack of organisational structures, and lack of information systems, whereas 2 is linked to constrained and restricted circumstances (Table 1 of Chapter 3). Such organisational situations may facilitate less appropriate decision-making on food safety management issues (Luning and Marcelis, 2007, 2009), and may cause uncertainty and ambiguity due to lack of information and lack of insight (Luning and Marcelis, 2006; Luning et al, 2009a). More in

detail (Table 2), as expected for all FSE, 'technological staff' was assessed in situation 3 (no own food safety expertise, no laboratory), but some hired external expertise (H3) and have systematic support from external laboratories (RH, H1, R1, R2). Lack of technological expertise and support has been mentioned by various authors as a problem for small and medium enterprises (Taylor, 2001; Taylor and Kane, 2005; Celaya et al., 2007). The indicator 'variability in workforce composition' was typically allocated in situation 1 and 2 due to the (rather) stable composition of employees at the FSE , which is in contrast with other studies that mentioned high turnover rate of employees as a characteristic of the catering sector (Worsfold, 2001; Jones & Angulo, 2006; Jones et al., 2008). The FSE obtained for 'insufficiency of operator competences' scores 1 and 2, because they put specific requirements on experience and specific skills, and some (RH, R1, R2, and R3) of the FSE even provide regularly safety training (situation 1). The importance of food safety training has been emphasised by many authors (Lynch et al, 2003; Sun and Ockerman, 2005; Egan et al, 2007; Santos et al, 2008). However, it has also been discussed that training should be dedicated to the specific circumstances and be repeated to really enhance food safety knowledge and awareness, and change hygienic behaviour (Worsfold & Worsfold, 2005; Bolton et al, 2007; Seaman & Eves, 2008). Obviously, the scores for 'lack of management commitment' varied between 2 and 3 for all FSE, which means that they do have no detailed written vision statement on safety, and no official quality team/manager with a specific budget. Crucial for situation 3 is that management only reacts in case of food safety problems. Appropriate management commitment has been found to be essential for the development and maintenance of FSMS (Celaya et al, 2007).

Scores for the indicator 'deficiency of employee involvement' ranged between 2 and 3 (except for R4 because only one person is in charge of the restaurant), corresponding with operators not being or (partly) involved in design and improvement of the FSMS. Crucial for situation 3 is that they are only informed afterwards in case of changes. For 'absence of formalisation' most FSE scored a 2, which corresponds with a situation with some procedures and rules but these are usually restricted to preparation tasks and cleaning. Situation 3 (H4, R4, R5) refers to absence of written procedures and lack of formal meetings. Often in small firms one can see the authority concept, where formalisation is very restricted because a strong leader is making decisions, granting subordinates to make decisions "like he should do it" (Luning and Marcelis, 2009). As expected, all FSE scored 3 for 'insufficiency of information system', because they only have a kind of bookkeeping system of incoming

materials and the tasks to be done are requested orally or through posters pasted on the walls, and no access to other information sources to support decision-making in food safety management issues.

The contextual factor 'chain environment characteristics' achieved an assigned score 2 for all FSE, due to the fact that they all operate at a very vulnerable position in the food chain (situation 3). Although, they have to some extent influence on their suppliers because they can set specifications on the supplies but cannot persuade on their FSMS (situation 2) due to the fact that majority of suppliers are small sized companies, and they just have to comply with basic stakeholder QA requirements, which are legislative requirements (situation 1) (Codex, 2003; Jones et al., 2008).

Above assessment results indicate that FSE have to operate in a rather ambiguous, uncertain, and vulnerable contextual situation (Luning et al, 2009a). So, it is expected that core control and assurance activities should be executed at advanced levels to be effective in realising food safety of the meals.

Assessment of core control and assurance activities

The FSMS assessment is divided in the analysis of core *control* activities (i.e. design of respectively preventive measures, intervention processes and monitoring system, actual operation of control activities) and core *assurance* activities (setting system requirements, validation, verification and documentation and registration), because both activities have a different function (Luning and Marcelis, 2007, 2009). Table 3 shows the assigned overall scores for the core control and assurance activities, whereas scores of separate indicators are listed in Table 2. Table 1 of Chapter 3 provides brief descriptions of typical aspects associated with the different levels at which activities are executed, and detailed grids are described in Chapter 2.

With respect to the *core control activities*, it is noticeable that the majority of the FSE mainly received assigned scores 1 and 1-2 for respectively design of preventive measures, monitoring system design, and actual operation, only design of intervention processes received an assigned score 2-3 for some FSE. Typical aspects of control activities at level 1 are use of standard/general equipment, methods based on experience, programs ad-hoc, incomplete, equipment/methods not standardised, execute tasks by own insights, ad hoc people control, regularly unexpected problems (Table 1 of Chapter 3). The overall picture of assurance

activities is more diverse and reveals that some FSE have average-advanced levels 2, and 2-3, whereas others have typical low or basic levels 0 and 1. Assurance activities at level 2 are characterised by use of expert knowledge, additional analyses, restricted use of feedback information, regular reporting, and structured. Crucial for level 3 is comprehensive documentation, actual testing and judgement by independent experts.

Looking more in detail to the individual indicators (Table 2) for *design of preventive measures* shows that all FSE scored level 2 for 'adequacy of cooling facilities', because they use 'industrial' storage facilities and cooling capacity is known from suppliers but is not tailored and tested for their specific circumstances (Table 1 of Chapter 3). Some studies observed poor cooling facilities typically in SME's (Walker et al, 2003), but it seems rather well established in the food service establishments in this study. However, with respect to the typical hygiene measures, the majority of FSE scored level 1 for 'specificity of sanitation program' due to having incomplete cleaning programs, common cleaning agents, and use of agents and cleaning frequency are based on own experience. Only the food service establishments RH and H2 scored 2, because they designed their sanitation program with expertise support of specific cleaning suppliers. Also other studies showed that cleaning and disinfection was not well established in restaurants, catering and other types of FSE (e.g. Walker and Jones, 2002; Sheth et al, 2005; Phillips et al, 2006; Todd et al, 2007). For the 'extent of personal hygiene requirements' half of the FSE (H3, H4, R1, R2, R3) scored level 1, due to the fact that they have standard requirements for all employees on clothing, personal care and health, they use common washing facilities (same as for washing vegetables, no soap, no paper), and they provided no specific hygiene instructions. Only, the food service establishments RH and H2 scored level 3 because they have tailored hand washing facilities, and high personal hygiene requirements. Lack of strict personal hygiene requirements has been found to be a potential cause of outbreaks in restaurants (Hedberg et al, 2006; Todd et al, 2007). Moreover, lack of appropriate hand washing facilities has been mentioned as a perceived barrier for appropriate food safety practices in the food service sector (Howells et al, 2008). Also for the 'sophistication of hygienic design of equipment and facilities' half of the FSE (H4, R1, R2, R3 and R5) scored level 1, because they do not use hygienically designed equipment and just have facilities complying with basic hygienic requirements. Only the establishments RH, H1 and H2 received the high score 3, which means that hygienic design of facilities and equipment is integrated and actual hygiene performance has been tested for the specific circumstances. Similarly, an analysis on records of restaurant

inspections (ca 400) by Phillips and co-authors (2006) indicated significant differences in hygienic practices and hygienic facilities between restaurants.

With respect to the various specific preventive measures like ‘adequacy of meal preservation’, ‘adequacy of defrosting method’ and ‘adequacy of hot holding methods’ the scores ranged between 1 and 2, with an exception for FSE (RH) (score 2 for defrosting and 3 for hot holding). Level 1 corresponds with aspects like standard equipment, unknown process capability, and methods based on experience, general knowledge, which implicates that the design of these measures is less advanced and induces a higher risk of safety problems. Level 2 corresponds with best available equipment, supplier expertise/support, known capability, and methods based on sector/governmental guidelines or expert knowledge. Crucial for level 3 is that equipment and methods have been tailored and tested for the specific circumstances. Interestingly, the study of Phillips and co-authors (2006) revealed recurrent violations on, amongst others, food holding temperature. Another study showed that ca 22% of interviewed head chefs (n=200) did not report safe practices in defrosting (Bolton et al, 2008).

Another obvious finding is that all FSE scored level 1 (except RH score 2) for the ‘adequacy of their raw material control’, because it is based on experience by just checking expiration date, package status and visual characteristics. The initial safety level of supplied (raw) materials is extremely important in FSE, because often no additional treatments are applied, and cross contamination can easily occur during preparation of meals (Rosset et al, 2004; Rooney et al, 2004).

The indicators to assess *design of intervention processes* revealed that half of the FSE (RH, H1, R1, and R2) scored level 3 for ‘adequacy of intervention method’, and three FSE (RH, H1 and H2) scored level 3 for ‘adequacy of intervention equipment’ (Table 2). Level 3 is associated with aspects like capability tested in practice, and methods scientifically supported and tested. However, four FSE (R1, R2, R3 and R4) scored level 1 for ‘adequacy of intervention equipment’ (capacity unknown, common equipment), which induces a high risk on inadequate reduction of micro-organisms, which might result in safety and/or spoilage problems. Inadequate (re)heating of foods in food service establishment has been associated with increasing risk of pathogen contamination (Rooney et al, 2004; Cardinale et al, 2005; Tod et al, 2007).

Analysing the *design of monitoring systems* shows that 6 out of the 10 FSE have not assigned critical control points (level 0), and that only four (RH, H3, R1, R2) did assess CCP's with support of external experts that worked according to official guidelines (level 2). Obviously, most FSE clearly specified both standards and tolerances (mainly for temperature conditions) using general hygiene codes and legal requirements (level 2), except H4, R4, and R5 (level 1, not clearly specified/ based on experience). However, none of the FSE has defined any corrective actions (i.e. what to do in case product or process parameters exceed tolerances), all scored level 0, which is in alignment with other studies reporting weaknesses in corrective actions (Motarjemi and Käferstein, 1999; Legnani, et al, 2004)

The measuring aspects of the monitoring system design shows that 4 of the FSE (RH, H1, R1, and R2) scored 2 for both 'adequacy of analytical methods for pathogens' and 'specificity of sampling plans' due to the fact that their sampling design and measuring plan is based on official guidelines, and their samples for pathogen analysis are sent to an external laboratory using internationally acknowledged methods (but not accredited). The other FSE (H2, H3, H4, R3, R4 and R5) have no scientifically underpinned sampling design (level 1, i.e. ad-hoc, based on in-house experience) and or have not yet send any samples for pathogen analysis (level 0). Interestingly, 'adequacy of measuring equipment' (mainly temperature measuring devices) scored level 2 (RH, H1, H2, H3, H4, R5), which means use of standardised equipment or level 0 (R1, R2, R3, R4), which means absent, no measuring equipment. None of the FSE had a calibration program for measuring equipment. Lack of temperature checking devices for foods and storage facilities have been also reported in several studies in the catering sector (Martinez et al, 2000; Legnani et al, 204; Hertzman and Barrash, 2007; Howells, et al, 2008).

Not only the design but also actual operation of control activities determines the performance of a FSMS (Mortimore, 2001; Luning et al, 2008). Apparently, with respect to procedures, only three FSE (H4, R4, R5) had no procedures available in place, the other FSE have procedures which are easy to understand for most users but are kept up-to-date on ad-hoc basis (level 2). With respect to 'actual compliance to procedures', only RH received score 3, which means that all operators are aware of existence and content of procedures and are consciously following procedures, and safety tasks are internalised. Two FSE (H3, R3) scored 1 because tasks are executed according to own insights, and employees are not aware of existence of procedures for certain tasks. The other FSE with procedures (H1, H2, R1, and

R2) scored level 2 because the majority of employees are familiar with existence of procedures, but not always with the exact content and they are controlled on regular basis. Lack of correct and written procedures (e.g. with respect to cleaning practices, temperature control, etc) and poor compliance have been found in various studies, especially when people have to operate under high work pressure (Walker and Jones, 2002; Sneed et al, 2004; Rooney et al, 2004; Legnani et al, 2004; Sheth et al, 2005; Todd et al, 2007; Hertzman and Barrash, 2007; Strohbehn, 2008; Santos et al, 2008), which is rather common in the food service sector. Such situations may result in inadequate and unpredictable decision-making behaviour in food safety control activities (Luning and Marcelis, 2007, Luning et al, 2008), which potentially increases the risk on food safety problems.

Another evident finding is that, except RH, none of the FSE, have insight in the actual hygiene performance of their equipment and facilities (level 0). Also actual 'hot holding capacity' scored low (level 1) for most FSE, which corresponds with regularly unstable performance with significant variations, which increases the risk of safety problems. For example, Rosset and co-authors (2004) observed in a study of school catering, the coincidence of extended storage duration (due to weekends) and temperature abuse, which could lead to a significant microbial development (predicted based on modelling). Bolton and co-authors (2007) found that *Salmonella* survived in foods stored at typical catering refrigeration temperatures and significantly increased under conditions of thermal abuse. However, 'actual cooling capacity' received score 2 for all FSE, which means that it is just sometimes unstable.

With respect to the *assurance activities*, it is noticeable that 6 out of 10 FSE (RH, H1, H3, R1, R2 and R3) actively act on changes in external assurance and setting (new) requirements with support of external experts (e.g. consultants) (level 2), most of the FSE also use data from their product and process controls to change the system (level 2). However, four FSE (H2, H4, R4 and R5) mainly react on food safety performance problems as perceived by stakeholders and or due to external directives (level 1). Bolton and co-authors (2008) reported in Ireland that 78% of head chefs and catering managers were unaware of current food safety legislation including their specific responsibilities. This may complicate appropriate setting of own FSMS requirements.

Another remarkable observation is that four of the FSE (RH, H1, R1, R2) scored high on validation activities for preventive and intervention measures (level 3), which means that

effectiveness of these safety control measures have been objectively (independently) tested in advance, and that it has been well documented. It should be noticed that the FSE (R1 and R2) showed high scores because they are managed by the same central management of the hall of residence RH, which is the FSE most concerned about safety in this study. But on the other hand, the other FSE (H2, H3, H4, R3, R4, R5) did not validate any of their control measures (level 0), which reveals a large difference between the establishments. Interestingly for 'extent of verification of people activities' 6 FSE scored minimally level 2 (RH, H1, H2, H3, R1, R2), which means that records are analysed on regular basis but no systematic observations of people, the others received score 0 (no verification of people related performance). All FSE apply to a certain extent verification activities related to equipment performance (i.e. minimally level 1), but also here the FSE RH, H1, H2, H3, R1, and R2 scored higher than the others (R3, R4, R5, and H4) on this aspect. In small companies and micro business where the manager is on site all times and has visual confidence that the system is running according to plan, they (often) perceive verification activities as useless double checking exercise (Taylor, 2001).

Last but not least, half of the FSE (RH, H1, H2, H3, R1, and R2), scored level 2 for 'appropriateness of documentation system', which means a structured documentation system (others scored 1 which corresponds with ad hoc documentation). However, only three (RH, H1, H2) of them also scored level 2 for 'appropriateness of record-keeping', whereas the majority scored level 0 (no records) or level 1 (ad hoc registration). Appropriate documentation and record-keeping has been mentioned by several authors to be a point of concern in food safety management systems in SME and FSE (Walker and Jones, 2002; Vela and Fernández, 2003; Walker, Pritchard, and Forsythe, 2003; Taylor and Kane, 2005; Sneed et al, 2004).

3.2 Microbiological Assessment

The FSMS diagnosis revealed that all 10 food service establishments operate in a rather vulnerable, ambiguous, and uncertain contextual situation (situation 2-3), whereas assigned scores for major control and assurance activities showed mainly values of 2 and lower. Based upon this assessment we might expect that most FSE have a considerable chance on unexpected and unpredictable microbiological (safety) problems. The microbiological results (Table 4) show that in four of the ten FSE (H1, H4, R3, R5) *Listeria monocytogenes* was detected in both fresh-type (FT) and cooked-served-cold (CS) meals. Lianou and Sofos

(2007) reviewed the incidence and transmission of *Listeria monocytogenes* through ready to eat products in various types of FSE and indicated as major sources of contamination the environment, food handlers, and incoming raw ingredients, or processed products that have become contaminated after the lethality treatment at the manufacturing facility. Typical ingredients and products that have been sources of outbreaks of listeriosis were dairy (based) products, fresh and processed pork (Oliver et al, 2005; Thevenot et al, 2006). The contaminated products in this study were salads (FT meals), truffle cheese, and duck liver cake (cooked-served-cold meal types). *Listeria monocytogenes* can survive and grow over a wide range of environmental conditions, which allows the pathogen to overcome food preservation and safety barriers (Thevenot, et al, 2006; Gandhi and Chikindas, 2007). In this study, the vegetables that were used for the salads were washed and disinfected with a solution containing chloride compounds to remove micro-organisms that are intrinsic to the vegetables. However, the effectiveness of disinfection of vegetables for fresh salad preparation with chlorine is affected by the dynamics of the washing process prior to the disinfection step (Soriano, et al, 2005).

Results of the hygiene indicators revealed that *Staphylococcus aureus* counts were below legal limit in all meal types for all FSE, which is an indication that personnel hygiene and hand practices seem sufficient (Aarnisalo et al, 2006). In another study in FSE, the incidence of *Staphylococcus aureus* was reported in raw beef (7.5%), raw pork (17.5%), raw poultry (2.5%), and raw lettuce (2.5%), whereas the incidence in the ready to eat products ranged between 0-5% (Soriano et al, 2000). In a study comparing effect of gloves and bare hands it appeared that 8 out of 171 plain four tortillas collected from fast food restaurants were contaminated with *Staphylococcus aureus*, with no difference between samples handled with and without gloves (Lynch et al, 2005)

Escherichia coli and *Enterobacteriaceae* can provide an indication of (faecal) hygiene problems (Anonymous, 2005; Jacxsens et al, 2009b), and their presence indicates a substantially increased risk of presence of pathogens (Frank et al, 1990). In this study, *Escherichia coli* counts were below legal limit in all meal types for all FSE, but *Enterobacteriaceae* counts exceeded the limit in one or more meal types in all food service establishments (except RH). Too high counts were found in 8 out of 27 ‘fresh type’, in 12 out of 30 ‘cooked-served cold’, and in 2 out of 15 ‘cooked stored reheated’ meal types (Table 4). Similar high counts have been reported in other catering/restaurants studies for salads,

omelette, and cheese (Martinez-Tomé et al., 2000; Soriano et al., 2000). High initial levels in raw materials and ingredients, insufficient low temperature and/or too long storage, unsatisfactory reheating, and inadequate cleaning may be causes of growth or survival of *Enterobacteriaceae* (Soriano et al., 2000; Kassa et al., 2001; Friedhoff et al., 2005).

Last but not least, in all food service establishments, total aerobic counts exceeded limits, more specifically, in 16 samples out of the 27 'fresh type', 19 samples out of the 30 'cooked-served cold', 6 samples out of the 15 'cooked stored reheated', and 4 samples out of the 9 'hot held served hot' meal types. This parameter gives an indication of the overall microbiological performance at critical sampling locations (Mossel et al., 1995; ICMSF, 2002; Jacxsens et al, 2009b), which indicates that in this study the overall microbiological performance is rather unsatisfactory (in ca 50% of all samples). Exceeding limits for total aerobic counts have been noticed in other studies in the food service establishment sector in products, on contact services, and hands (Cenci-Goga et al, 2005; Guida et al, 2006; Suppin et al, 2007; Kokkinakis and Fragkiadakis, 2007; Lues and Van Tonder, 2007). Typical causes for too high total aerobic counts are cross contamination via contaminated contact surfaces and tools (like cutting boards, preparation areas, slicing machines, knives) or via hands (Meredith et al., 2001; Gorman et al., 2002; Beumer and Kusumaningrum, 2005; Gibbons et al., 2006). Undesirable growth may also occur due to inadequate time-temperature conditions (like insufficient cooling facilities, keeping products at room temperature, too long storage of products, too low hot hold temperature) (e.g. Johnson, 1999; Unicomb et al., 2003; Bolton et al, 2007).

The variation of data (difference between the set of three samples taken per meal type) shown in Table 4 was considered as low since only 4 of the 27 sets of triplicate samples had a difference higher than 3 log units for *Enterobacteriaceae* and 3 of the 27 sets for Total aerobic count. It is also noticeable that the variation for total aerobic count was only evident in H4. This kind of variation may be due to unstable process in the FSE among the days of sampling or limitations of the sampling and analysis method.

Overall it can be concluded that the food service establishment RH revealed the best microbiological results. The hotels H2, H3 and restaurants R1, R2 and R4 seem to have mainly problems with too high counts of respectively *Enterobacteriaceae* (hygiene indicator) and total aerobic counts (overall microbiological performance indicator). However, hotels H1, H4 and restaurants R3, R5 in addition also seem to have a *Listeria monocytogenes* problem,

which can be due to an incidental contamination or more structural contamination from the environment (Thevenot et al, 2006; Lianou and Sofos, 2007).

3.3 Evaluation of weak points in current FSMS

The basic line of interpreting the combined data to assess weak points in a FSMS is as follows. All FSE operate in a rather vulnerable contextual situation (situation 2-3, 3) and average-advanced levels (2 and 3) of activities in the FSMS are expected to be effective. If the obtained microbiological results are perceived as unsatisfactory, the first step is to critically look to those (combinations of) control activities that have a link with the microbiological performance and which have low scores (starting with the 0 and 1 levels), and to those contextual factors being assessed at situation 3 that may create vulnerability, uncertainty and ambiguity in the context wherein the control activities must be executed. This gives a first idea about possible control activities that might be strengthened, which may be combined with interventions in context factors to lower the vulnerability, ambiguity and or uncertainty of the contextual situation. The analysis of assurance activities with low scores, gives insight in possibilities to improve the validation and verification of applied control activities, which will increase the reliability of the FSMS (Luning et al., submitted 2009c).

Overall it can be said that, all 10 FSE in this study have to operate in a rather vulnerable, uncertain, and ambiguous contextual situation (2 and 3), this in combination with core control and assurance activities often being assessed at levels 0, 1, and 2, makes the FSE susceptible to microbiological (food safety) problems, which is supported by the microbiological data found in this study. Meal samples exceeding the limits have been found for *Listeria monocytogenes* (in 4 FSE), for *Enterobacteriaceae* (in 9 FSE), and too high total aerobic counts were found in all 10 FSE. The presence of *Listeria monocytogenes* in some of the FSE and the relatively large number of samples exceeding limits for *Enterobacteriaceae* and total aerobic count (although they do not directly point out safety problems), indicate that there is room for improvement in the implemented FSMS. Some of the FSE will be discussed in more detail to illustrate how the combined assessment provides insight in possible points of attention and/or needs for improvement.

Obviously the residence hotel (RH) has a rather good microbiological performance (only too high total aerobic counts in 2 samples), which seems in alignment with the fact that they received of all FSE most often scores 2 and 3 for core control and assurance activities.

Moreover, their meal production process is organised in such a way that it is less vulnerable (situation 1) as compared to the others (situation 2 and 3). This FSE has to prepare only 5 meals per day for a set number of customers (approximately 150 students) who are served at an established hour. This in combination with an average-advanced design of respectively preventive measures (e.g. hygienically designed equipment (level 3), adequate cooling facilities (level 2), complete sanitation program based on expert support (level 2), strict personal hygienic requirements (level 3), adequate defrosting (2) and hot holding capacity (3), intervention processes, and various monitoring activities that are at level 2 may support this FSE to have good microbiological performance. However attention to calibration of equipment and corrective actions should be paid. Also for actual operation they received scores 2 and 3 for equipment related issues, except hot holding facilities seem sometimes variable, which might be a point for improvement. So overall their equipment and facilities seem to support a rather good food safety performance. Looking to people related aspects reveals that they have a stable workforce composition (situation 1), put strict requirements on competence levels of their employees (situation 1). Only management commitment (situation 2) and employee involvement (situation 3) could create conditions for less appropriate decision-making in food safety control. Although compliance to procedures scored high (3), and they verify people performance by analysis of records (but no actual observations) (2). Due to their contacts with external labs they also have technological support.

Another example, hotel H1 (having a large maximum meal capacity and a broad meal assortment) had a 'Cooked-Served-cold' sample type (cheese with truffles) with *Listeria monocytogenes* counts, but only a few samples exceeding limits for *Enterobactereacea* and total aerobic counts, as compared to the other FSE. *Listeria monocytogenes* contamination can be prevented by adequate raw material control, hygienic designed equipment and facilities, adequate cooling and cooking, systematic monitoring of temperature, effective sanitation programs, and compliance to critical procedures (like for cleaning, temperature control, etc) by competent people (Thevenot et al, 2006; Lianou and Sofos, 2007). The FSMS-DI data reveal that they received often score 2 for various control and assurance activities, corresponding with support by expertise, according to guidelines, best available equipment in practice, etc (Table 2), which principally provides a solid basis for a FSMS. To illustrate, they have advanced hygienically designed equipment, intervention equipment and methods (3) cooling and hot holding facilities with basically known capacity but not tailored for circumstances (2), and meal preservation and defrosting methods based on

guidelines/expertise (2), adequate measuring equipment and analyses executed by established labs (2). However, their sanitation program is based on common cleaning materials, instructions and use are based on experience rather than (external) expertise (1), their raw material control is restricted to visual inspection of incoming materials (1) (which is very common in FSE), they have no insight in actual hygiene performance (0) and their hot-holing capacity is regularly unstable (1). Moreover, they have not assigned CCPs and corrective actions. For this FSE it might be interesting to pay attention to their sanitation program (e.g. find support from specialised cleaning suppliers, testing of actual hygiene performance, develop clear cleaning instructions or procedures, verify regularly), check the stability of hot holding equipment by regular monitoring of temperature and care about maintenance, but also carefully look to their incoming materials (e.g. discuss stricter specifications with suppliers, sampling of incoming materials by external lab, adequate storage). Furthermore, they may consider the assignment of a few CCP with clear corrective actions (e.g. in collaboration with experts in HACCP & catering situations) to support their current system and focus control measures on those activities/locations that are really critical.

The set of restaurants R1, R2, R3, R4, and R5 was taken as another example to interpret combined assessment data. *Listeria monocytogenes* was found in fresh type and cooked-served meals in respectively R3 and R5 (salad with lettuce, tomato and olives in R3 and duck liver cake in R5), which can be assigned to, amongst others, poor sanitation program and practice, (in combination with) inadequate hygienic design of equipment and facilities, and contaminated raw materials. Similar measures are relevant for them as discussed for H1. Furthermore, it is obvious that all restaurants have too high counts for *Enterobactereaceae* and total aerobic counts in their cooked-served meals (except R2 for *Enterobacteriaceae*), for R3 also in their cooked-stored reheated meals, for R4 in their hot-hold meals for total aerobic counts; and also for R1, R2, R3 and R5 in their fresh type meals. These too high counts can be due to cross contamination (e.g. due to too high initial counts in raw materials, insufficient washing of fresh produce, ineffective cleaning program, inadequate cleaning practices, poor equipment design) and in combination with poor time-temperature conditions growth may be even stimulated (e.g. due to too long storage, too high storage temperature, inadequate cooking/reheating, inadequate defrosting, too low hot hold temperature, etc). Focusing first on contamination sources, it is evident, that all restaurants have a simple incoming material control mainly based on visual inspection and no bacteriological analyses, which means that they are heavily dependent on initial microbiological quality of raw materials as provided by

their suppliers. This fact may be due to lack of understanding of the importance of control of supplies or because the suppliers are actually small sized companies with no advanced FSMS. Although, they all seem to have influence on setting specifications (situation 2), they have no influence on the actual FSMS performance of their suppliers. This in combination with the high risk of the raw materials (situation 3) creates a rather vulnerable situation with respect to contamination of raw materials. Another source of cross contamination is via contaminated equipment (slicing machines, knives, etc), food contact surfaces (cutting boards, preparation areas), due to inadequate hygienic design and/or in combination with poor sanitation program and practices (Cools et al, 2005; Watchel et al, 2003; DeVere & Purchase, 2007; Grassi et al., 2008; Sheen & Hwang, 2008) . All restaurants have equipment that is not specifically hygienically designed and facilities just comply with basic hygiene requirements (level 1) except R5 (level 2). Moreover, their sanitation program is at level 1 (common materials, no supplier support with respect to cleaning agents, etc). Above, situation in the implemented FSMS increases the risk of contaminated (raw) materials and meals. Points of attention are therefore supply of raw materials (like check and discuss existing specifications with suppliers, selection of new certified suppliers, analysis of incoming materials by external laboratories), cleaning and disinfection (like, search for specialised cleaning agent suppliers for catering, testing cleaning & disinfection and hygienic design performance with laboratory/expert support, instruct people on (new) cleaning practices, and consider hygienic design aspects when buying new equipment (supported by supplier expert knowledge). These suggestions are in line with some presented in other studies about FSE (Seward, 2000; Martinez et al, 2000; Griffith & Clayton, 2005; Rodgers, 2005; Hertzman and Barrash, 2007; Kivi et al., 2007).

Looking to ‘time-temperature control’ related measures reveals following. All restaurants do have potentially capable cooling facilities (level 2), with specified standards and tolerances based on guidelines (level 2) (except R4 and R5), which principally can create adequate conditions for cooling and prevention of undesired growth, but no corrective actions have been specified (level 0). Moreover, they all have common hot-holding equipment with unknown capability (level 1) (except R5 with level 2), which seems regularly unstable (level 1), and also actual cooling capacity seems sometimes not stable due to known causes (2). Furthermore, all restaurants (except R5) appear to have no specific measuring equipment and/or devices (1) nor any calibration program for equipment (0). Moreover, at R3, R4, and R5 verification of equipment performance is restricted to just checking of equipment setting

(1), without registration of records (0), and in these restaurants no feedback information is used to improve the system (0). However, R1 and R2 do have a kind of simple registration of records (1), verification includes besides checking of parameters also a certain extent of analysing the records (2), and they use this feedback data to modify their system (2). Summarising the technological (equipment) related control measures reveals that all restaurants have principally capable cooling facilities (strong point). However, there are still various time-temperature related control measures that are at low levels or even absent, and therefore may create conditions for undesired growth and/or lack of insight in these conditions. As also discussed by other authors, the restaurants should pay attention to actual monitoring of time and temperature conditions at critical locations (R4 and R5 also have assigned no CCP's) using adequate measuring equipment (e.g. supplier supported also with respect to maintenance), verify on regular basis using simple records and registration and use feedback information to improve system (Martinze et al, 2004; Sneed et al, 2004; Rodgers, 2005). Also attention could be paid to the capability of actual hot hold equipment (e.g. by regular temperature measurement, discussion with equipment suppliers, critical selection in case of new equipment, testing actual capability by expert/external laboratory).

Some other interesting points for attention can be concluded when looking more specifically to people related aspects. It is noticeable that R5 has various control measures at higher levels (2) as compared to the other restaurants (0 and 1), like for sophistication of hygienic design, (2), personal hygiene requirements (2), defrosting method (2), adequacy intervention equipment (2) (although not validated level 0), extent of equipment maintenance program (2), and adequacy of measuring equipment (2). However, they have no procedures available (0), (so also no compliance to procedures 0), they do not verify people related performance (0). In addition, analysing organisational characteristics shows that, 'degree of variability in workforce composition' was assessed in situation 2, and 'insufficiency of operator competences' in situation 3, in contrast to the other restaurants (for both aspects situation1). Moreover, also 'lack of management commitment', 'deficiency of employee involvement', and 'absence of formalisation' were assessed at situation 3. This in combination with the fact that they have various cooks (7 cooks with 4 per shift, 1 cleaning person, owner is waiter, Table 1), indicates that attention could be paid to the people working in the restaurant, such as enhancing hygiene and safety related competences (e.g. by dedicated training), involvement of cooks in design and operation of safety control activities, striving for a sustainable workforce, development of suitable procedures at critical locations and activities (in

collaboration with cooks and hygiene/HACCP experts in FSE), showing management commitment (e.g. by creating time for control measures), but also verification of actual people performance. Some similar suggestions for improvement have been mentioned in other studies in catering, like improvement of knowledge and practices of food safety and sanitation (e.g. Soriano et al, 2002; Legnani et al, 2004; Cenci-Goga et al, 2005; Hertman and Barrash, 2007), and development of adequate (standard) operating procedures (Sneed et al, 2004; Cardinale et al, 2005; Cenci-Goga et al, 2005).

4. Conclusions

The objective of this study was to get insight in weak points in implemented food safety management systems of food service establishment (FSE) in view of the contextual situation wherein they have to operate and the microbiological performance of their more critical meals. The combined assessment was useful to derive points of attention for the specific food service establishments as basis for possible interventions to improve their FSMS. Major suggestions related to improvement of incoming materials, enhancement of sanitation performance, increasing insight in actual time-temperature conditions, improvement of prevention of undesired growth, and suggestions related to typical managerial issues like enhancement of employee involvement and management commitment, improvement of competences, and development of suitable procedures to support peoples decision-making behaviour at critical safety control activities. The combined assessment can serve as a basis for discussions about strategic discussions on interventions in the food safety management system (improvements in control and assurance activities) as well as interventions in the contextual situation (like organisational and chain environment characteristics). This may help them to set priorities on those measures to be taken first, which with relatively small investments may result in considerable improvement.

Due to the fact that cross contamination form contact surfaces and/or employees were considered as probable causes of low microbiological performance, the next Chapter (Chapter 5) will focus on actual hygienic practices and actual sanitation performance.

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Table 1: Characteristics of the Food Service establishments

FSE	Type of FSE	Organisation	Production characteristics				Meals that were sampled
			No. Meals	Maximum capacity	No. Employees in the kitchen		
					Cooks	Cleaning personnel	
RH	Hall of residence	Central management	5 / day	150	2	2	Lettuce, Russian salad, country salad, chickpea salad
H1	Hotel	Chain	7/day for “day meal”, 30 “a la carte”, 50 for groups	400 during summer, 200 rest of the year	4	2	Lettuce, cheese with truffle, beef meat filled with onion & pepper, meat sauce
H2	Hotel	Chain	27 “a la carte”, 80 for groups	200	4	3	Lettuce, vinaigrette vegetables, Catalan soup
H3	Hotel	Owner is waiter	59 “a la carte”, 30 for groups	300	3	2	Lettuce, dairy desserts, beef stew, fish soup, vegetable stew
H4	Hotel	Owner is chief cook	29 “a la carte”, 27 for groups	400	5	2	Lettuce, dairy desserts
R1	Student cafeteria	Central management (same as RH)	6 / day	100	2		Mixture of fish, ham & mayonnaise
R2	Student cafeteria		6 /day	70	1	1	Mixture of fish, ham & mayonnaise
R3	Day menu" Restaurant	Owner is waiter	5/ day	70	2		Salad with lettuce, tomato & olives, fresh cheese, pork tail, small cuttlefish, beans
R4	"Day menu" Restaurant	Owner is the cook	9 / day, 5 "tapas"	30	1		Lettuce, lamb stew, hake fish with sauce, veal stew
R5	"Menu a la carte" Restaurant	Owner is waiter	30 "a la carte"	60	7	1	Cabbage salad, duck liver cake, pepper filled with monkfish sauce

Table 2: Context and Food Safety Management System performance

	RH	H1	H2	H3	H4	R1	R2	R3	R4	R5
Contextual Factors										
Product Characteristics										
Risk of raw material	3	3	3	3	3	3	3	3	3	3
Risk of meals	3	3	3	3	3	3	3	3	3	3
Assigned Sub Score	3	3	3	3	3	3	3	3	3	3
Production process characteristics										
Extent of intervention steps	3	3	3	3	3	3	3	3	3	3
Extent of assortment of meal production process	1	3	3	3	3	2	2	2	2	3
Rate of menu changes	2	2	2	2	1	2	1	2	2	2
Assigned Sub Score	2	2-3	2-3	2-3	2-3	2-3	2	2-3	2-3	2-3
Organisation characteristics										
Lack of technological staff	3	3	3	3	3	3	3	3	3	3
Degree of variability in workforce composition	1	2	2	2	2	1	1	1	1	2
Deficiency of operator competences	1	2	2	2	2	1	1	1	2	3
Lack of maganement commitment	2	2	2	3	3	2	2	2	3	3
Deficiency of employee involvement	3	2	2	2	3	3	3	2	1	3
Absence of formalisation	2	2	2	2	3	2	2	2	3	3
Deficiency of information systems	3	3	3	3	3	3	3	3	3	3
Assigned Sub Score	2	2	2-3	2-3	2-3	2	2	1-2	2-3	3
Chain environment characteristics										
Safety contribution in chain position	3	3	3	3	3	3	3	3	3	3
Lack of power in supplier relationships	2	2	2	2	2	2	2	2	2	2
Strictness of stakeholder requirements	1	1	1	1	1	1	1	1	1	1
Assigend Sub Score	2	2	2	2	2	2	2	2	2	2
Assigned Contextual Factors Score	**2**	**2-3**	**2-3**	**2-3**	**2-3**	**2**	**2**	**2**	**2-3**	**2-3**
Core Control Activities										
Preventive measures design										
Sophistication of hygienic design of equipment and facilities	3	3	3	2	1	1	1	1	1	2
Adequacy of cooling facilities	2	2	2	2	2	2	2	2	2	2
Specificity of sanitation programs	2	1	2	1	1	1	1	1	1	1
Extent of personnel hygiene requirements	3	2	3	1	1	1	1	1	2	2
Specificity of raw material control	2	1	1	1	1	1	1	1	1	1
Specificity of meal preservation	0	2	2	1	1	0	0	1	0	1
Specificity of defrosting methods	2	2	2	1	1	0	0	1	2	2
Specificity of hot holding methods	3	2	2	0	2	1	1	1	1	2
Assigned Sub Score	2	2	2	1	1-2	1	1	1	1-2	1-2
Intervention process design										
Adequacy of physical intervention equipment	3	3	3	2	2	1	1	1	1	2
Specificity of maintenance and calibration program for equipment	2	1	2	2	1	1	1	1	2	2
Effectiveness of intervention methods	3	3	2	1	0	3	3	1	0	1
Assigned Sub Score	2-3	2-3	2-3	1-2	1	1-2	1-2	1	1	1-2
Monitoring system design										
Appropriateness of CCP analysis	2	0	0	2	0	2	2	0	0	0
Appropriateness of standards and tolerances design	2	2	2	2	1	2	2	1	1	1
Adequacy of analytical methods to assess pathogen levels	2	2	0	0	0	2	2	0	0	0
Adequacy of measuring equipment to monitor process/product status	2	2	2	2	2	0	0	0	0	2
Specificity of calibration program for measuring and analytical equipment	0	0	0	0	0	0	0	0	0	0
Adequacy of sampling design (for microbial assessment) and measuring plan	2	2	1	1	1	2	2	1	1	1
Extent of corrective actions	0	0	0	0	0	0	0	0	0	0
Assigned Sub Score	1-2	1	1	1	1	1	1	1	1	1
Operation of preventive measures, intervention process and monitoring systems										
Actual availability of procedures	2	2	2	2	0	2	2	2	0	0
Actual compliance to procedures	3	2	2	1	0	2	2	1	0	0
Actual hygienic performance of equipment and facilities	3	0	0	0	0	0	0	0	0	0
Actual cooling capacity	2	2	2	2	2	2	2	2	2	2
Actual hot-holding capacity	1	1	1	0	1	1	1	1	1	1
Actual process capability of intervention processes	3	3	3	3	3	0	0	0	0	3
Actual performance of measuring equipment	0	0	0	0	0	0	0	0	0	0
Actual performance of analytical equipment	0	0	0	0	0	0	0	0	0	0
Assigend Sub Score	2	1-2	1-2	1	1	1	1	1	1	1
Assigned Core Control Activities Score	**2**	**1-2**	**1-2**	**1**	**1**	**1**	**1**	**1**	**1**	**1**
Core Assurance Activities										
Setting of system requirements										
Sophistication of translation of stakeholder requirements into own FSMS requirements	2	2	1	2	1	2	2	2	1	1
Extent of systematic use of feedback information to modify system	2	2	2	2	1	2	2	1	1	1
Assigned Sub Score	2	2	1-2	2	1	2	2	1-2	1	1
Validation activities										
Sophistication of validation of preventive measures	3	3	0	0	0	3	3	0	0	0
Sophistication of validation of intervention systems	3	3	0	0	0	3	3	0	0	0
Sophistication of validation of monitoring systems	2	0	0	2	0	2	2	0	0	0
Assigned Sub Score	2-3	2	0	1	0	2-3	2-3	0	0	0
Verification activities										
Extent of verification of people related performance	2	3	2	2	0	2	2	0	0	0
Extent of verification of equipment and methods related performance	2	3	2	2	1	2	2	1	1	1
Assigned Sub Score	2	3	2	2	1	2	2	1	1	1
Documentation and record-keeping										
Appropriateness of documentation	2	2	2	2	1	2	2	1	1	1
Appropriateness of record keeping system	2	2	2	1	0	1	1	0	0	0
Assigned Sub Score	2	2	2	1-2	1	1-2	1-2	1	1	1
Assigned Core Assurance Activities Score	**2-3**	**2**	**1**	**1-2**	**1**	**2**	**2**	**1-2**	**1**	**1**
Assigned Overal Score of FSMS	**2**	**1-2**	**1-2**	**1**	**1**	**1-2**	**1-2**	**1**	**1**	**1**

Table 3: Overall assigned scores for contextual factors, core control and core assurance activities

FSE	Contextual factors				Core control activities				Core assurance activities				FS** PERF
	PROD* CHAR	PROC CHAR	ORG CHAR	CHAIN CHAR	PREV MEAS	INT MEAS	MON SYS	OPER	SYS REQ	VAL	VER	DOC REC	
RH	3	2	2	2	2	2-3	1-2	2	2	2-3	2	2	+
H1	3	2-3	2-3	2	2	2-3	1	1-2	2	2	3	2	-
H2	3	2-3	2-3	2	2	2-3	1	1-2	1-2	0	2	2	+/-
H3	3	2-3	2-3	2	1	1-2	1	1	2	1	2	1-2	+/-
H4	3	2-3	2-3	2	1-2	1	1	1	1	0	1	1	-
R1	3	2-3	2	2	1	1-2	1	1	2	2-3	2	1-2	+/-
R2	3	2	2	2	1	1-2	1	1	2	2-3	2	2	+/-
R3	3	2-3	2	2	1	1	1	1	1-2	0	1	1	-
R4	3	2-3	2-3	2	1-2	1	1	1	1	0	1	1	-
R5	3	2-3	3	2	1-2	1-2	1	1	1	0	1	1	-

*Full names in Table 2; ** FS PERF is a qualitative indication of the food safety performance based on the microbiological results as shown in Table 4

Table 4: Total number of samples with too high counts for different microbiological parameters

FSE	Meal [1] types	Pathogen indicator *Listeria monocytogenes*		Hygiene indicators *Enterobacteriaceae*		*Escherichia coli*		*Staphylococcus aureus*		Overall indicator Total aerobic count		Limit[%]	FS PERF
RH	FT[2]	A*	(0/3)	<1	(0/3)	<1	(0/3)	<2	(0/3)	3.2-3.3	(0/3)	NHT	+
	CS[3]	A	(0/3)	<1	(0/3)	<1	(0/3)	<2	(0/3)	**2.7-4.8**	**(2/3)**	NHT	
H2	FT[2]	A	(0/3)	**2.7-3.9**	**(1/3)**	<1	(0/3)	<2	(0/3)	**4.3-7.0**	**(2/3)**	NHT	+/-
	CS[4]	A	(0/3)	<1	(0/3)	<1	(0/3)	<2	(0/3)	<1	(0/3)	HT	
	CSR[5]	A	(0/3)	<1	(0/3)	<1	(0/3)	<2	(0/3)	1.6-2.0	(0/3)	HT	
H3	FT[2]	A	(0/3)	**<1-3.6**	**(1/3)**	<1	(0/3)	<2	(0/3)	**5.6-6.6**	**(3/3)**	NHT	+/-
	CS[6]	A	(0/3)	<1	(0/3)	<1	(0/3)	<2	(0/3)	**4.5-4.9**	**(3/3)**	HT	
	CSR[7]	A	(0/3)	**<1-5.2**	**(1/3)**	<1	(0/3)	<2	(0/3)	**5.0-6.3**	**(3/3)**	HT	
R1	FT[2]	A	(0/3)	<1-2.6	(0/3)	<1	(0/3)	<2	(0/3)	**3.8-5.5**	**(1/3)**	NHT	+/-
	CS[8]	A	(0/3)	**3.8-4.0**	**(3/3)**	<1	(0/3)	<2	(0/3)	**4.5-6.0**	**(3/3)**	HT	
R2	FT[2]	A	(0/3)	<1-1.8	(0/3)	<1	(0/3)	<2	(0/3)	**3.4-6.2**	**(2/3)**	NHT	+/-
	CS[8]	A	(0/3)	<1	(0/3)	<1	(0/3)	<2	(0/3)	**4.0-5.3**	**(3/3)**	HT	
R4	CS[9]	A	(0/3)	**1.5-4.4**	**(3/3)**	<1	(0/3)	<2	(0/3)	**5.2-6.0**	**(3/3)**	HT	+/-
	HH[10]	A	(0/3)	<1	(0/3)	<1	(0/3)	<2	(0/3)	**4.2-6.4**	**(3/3)**	HT	
H1	FT[2]	A	(0/3)	<1-2.6	(0/3)	<1	(0/3)	<2	(0/3)	**5.0-6.0**	**(2/3)**	NHT	-
	CS[11]	**P+**	**(3/3)**	**<1-1.9**	**(1/3)**	<1	(0/3)	<2	(0/3)	2.4-3.3	(0/3)	HT	
	CSR[12]	A	(0/3)	<1	(0/3)	<1	(0/3)	<2	(0/3)	<1- 1.6	(0/3)	HT	
	HH[13]	A	(0/3)	<1	(0/3)	<1	(0/3)	<2	(0/3)	<1- 3.7	(0/3)	HT	
H4	FT[2]	**A-P**	**(1/3)**	**3.5-4.6**	**(3/3)**	<1	(0/3)	<2	(0/3)	**<1- 6.2**	**(1/3)**	NHT	-
	CS[6]	A	(0/3)	**<1- 5.0**	**(1/3)**	<1	(0/3)	<2	(0/3)	**<1- 6.1**	**(1/3)**	HT	
	HH[14]	A	(0/3)	<1	(0/3)	<1	(0/3)	<2	(0/3)	**<1-5.3**	**(1/3)**	HT	
R3	FT[15]	**A-P**	**(2/3)**	<1-2.4	(0/3)	<1	(0/3)	<2	(0/3)	**5.0-6.3**	**(2/3)**	NHT	-
	CS[16]	A	(0/3)	**3.3-4.3**	**(3/3)**	<1	(0/3)	<2	(0/3)	**6.2-7.1**	**(3/3)**	HT	
	CSR[17]	A	(0/3)	**<1-4.1**	**(1/3)**	<1	(0/3)	<2	(0/3)	**4.9-5.1**	**(3/3)**	HT	
R5	FT[18]	A	(0/3)	**3.0-3.4**	**(3/3)**	<1	(0/3)	<2	(0/3)	**6.1-6.2**	**(3/3)**	NHT	-
	CS[19]	**A-P**	**(1/3)**	**<1-1.5**	**(1/3)**	<1	(0/3)	<2	(0/3)	**3.7-5.3**	**(1/3)**	HT	
	CSR[20]	A	(0/3)	<1	(0/3)	<1	(0/3)	<2	(0/3)	1.3-3.0	(0/3)	HT	
Total	FT	**A-P**	**(3/27)**	**<1-4.6**	**(8/27)**	<1	(0/27)	<2	(0/27)	**<1-7.0**	**(16/27)**		
	CS	**A-P**	**(4/30)**	**<1-5.0**	**(12/30)**	<1	(0/30)	<2	(0/30)	**<1-7.1**	**(19/30)**		
	CSR	A	(0/15)	**<1-5.2**	**(2/15)**	<1	(0/15)	<2	(0/15)	**<1-6.3**	**(6/15)**		
	HH	A	(0/9)	<1	(0/9)	<1	(0/9)	<2	(0/9)	**<1-6.4**	**(4/9)**		

[1] Not all meal types were prepared in all FSE.
FT=fresh type, CS=cooked-served cold, CSR= cooked stored reheated, HH=hold held served hot.

[2]Lettuce, [3]Russian salad, country salad, chickpea salad, [4]Vinaigrette vegetables, [5]Catalan soup, [6]Dairy desserts, [7]Beef stew, fish soup, vegetables stew, [8]Mixture of fish, ham & mayonnaise, [9]Potato omelette [10]Lamb stew, hake fish with sauce, veal stew, [11]Cheese with truffle, [12]Beef meat filled with onion & peppers, [13]Meat sauce, [14]American sauce, [15]Salad with lettuce, tomato & olives, [16]Fresh cheese, [17]Pork tail, small cuttlefish, beans, [18]Cabbage salad, [19]Duck liver cake, [20]Pepper filled with monkfish sauce

A*= absent in 25g; P+= present in 25 g.

Limit[%] = According to Spanish legislation RD 3484/2000 BOE 121/2001 where NHT = Limits for meals that are not heat-treated; HT = Limits for meals that are heat-treated

CAPITULO 5

Evaluación de prácticas higiénicas y su influencia en el rendimiento microbiológico en superficies de contacto en establecimientos de restauración

Introducción

Los resultados del Capítulo 4 demostraron que las actividades realizadas a niveles más bajos o básicos y que pueden tener mayor relación con el bajo rendimiento microbiológico de los platos son el programa de limpieza y desinfección y las prácticas del personal.

Enfocándose en la contaminación debida a superficies de contacto sucias y a las prácticas higiénicas del personal, los objetivos de éste estudio fueron evaluar las prácticas reales del personal y el rendimiento microbiológico de las superficies de contacto y manos, y chequear la efectividad de limpieza y desinfección en 10 establecimientos de restauración.

Se asume como hipótesis general que el grado de contaminación microbiana de un establecimiento de restauración, es el resultado de una organización que apoye a los empleados a comportarse higiénicamente y por lo tanto a preparar los platos en superficies de contacto y con las manos limpias.

Materiales y métodos

El análisis del rendimiento microbiológico de las superficies de contacto y de las manos se aplicó a los mismos 10 establecimientos de restauración, en los que se evaluó el rendimiento de sus sistemas de gestión de seguridad alimentaria y el rendimiento microbiológico de sus platos (Capítulo 4).

Dado que el comportamiento del personal depende, en gran medida, del apoyo que reciba por parte de la organización (establecimiento) (Luning et al., 2002; Cenci-Goga, 2005) se evaluó: la competencia del personal (descrito por el conocimiento y experiencia), disponibilidad de tiempo para preparar los platos, grado de diferenciación

de tareas del personal de cocina, circunstancias de preparación, procedimiento de limpieza y desinfección y estado de los puntos de lavado de manos. La evaluación del apoyo de la organización se realizó mediante observación del trabajo de los operarios en cocina durante 3 días consecutivos y realizando preguntas al personal.

Las prácticas de personal que se observaron durante 6 horas por 3 días consecutivos fueron: lavado de manos, uso correcto de utensilios al manejar alimentos listos para consumir, uso de utensilios al cambiar de tipo de alimentos y uso de trapo de cocina. Estas prácticas se han encontrado en otros estudios como influyentes sobre la seguridad alimentaria de los platos (FDA, 2001; Meredith, Lewis & Haslum, 2001; Beumer & Kusumaningrum, 2005; Smith et al., 2005). Para establecer el grado en el que el empleado cumplía las prácticas seleccionadas se apuntó el número de veces que lo hacía correctamente, que lo hacía incorrectamente o que no lo hacía. Si lo realizaba, por lo menos el 80% del tiempo de determinada manera, se consideraba ese patrón de comportamiento, como característico para ese empleado.

Las superficies de contacto que se analizaron fueron aquellas en las que otros estudios han identificado como superficies críticas para contaminación cruzada. Por lo tanto se muestrearon las tablas de cortar (Cools et al, 2005; Watchel et al, 2003; Welker et al, 1997), las cortadoras (Grassi et al., 2008; Sheen & Hwang, 2008; Vorst, Todd & Ryser, 2006) y las manos (Bidawid, Farber & Sattar, 2000; Gorman, Bloomfield & Adley, 2002; Aarnisalo et al., 2006). El parámetro seleccionado para evaluar el rendimiento microbiológico global fue el recuento total de bacterias aeróbicas porque indica el rendimiento global del sistema (ICMSF, 2002; Mossel et al., 1995). El muestreo se realizó durante 3 días consecutivos tomando muestras de las superficies antes de iniciar el trabajo, antes de procesos de limpieza y desinfección y después de la limpieza y desinfección. El valor que se consideró como límite superior para considerar a una superficie limpia fue 2 log UFC/cm^2 según recomendaciones encontradas en la legislación española y otros estudios relacionados (Mossel et al., 1999, Griffith et al., 2000; Moragas & De Pablo, 2008).

Resultados y Discusión

Se encontró que la mayoría de los empleados en los establecimientos de restauración analizados poseían suficiente competencia dado que todos han recibido cursos acerca de

manipulación de alimentos y tenían más de 15 años de experiencia. También se observó que los establecimientos que trabajaban con presión de tiempo fueron los hoteles y uno de los restaurantes de menú a la carta mientras que el resto de establecimientos no tenían esa presión de tiempo debido a que preparaban los platos con antelación durante la mañana antes del servicio. Asimismo, los establecimientos con diferenciación de tareas en las que cada empleado es encargado de un tipo de alimento fueron los hoteles. En el resto de establecimientos se compartían las tareas o era una sola persona la encargada de toda la cocina.

Con respecto a las prácticas reales del personal (Tabla 3 del Capítulo 5) se encontró que solamente la residencia para estudiantes cumplió correctamente con las prácticas observadas; 4 FSE (1 hotel, las dos cafeterías de estudiantes y 1 restaurante) realizaron correctamente por lo menos dos prácticas higiénicas, mientras que el resto de FSE no realizaron las prácticas higiénicas o las realizaron incorrectamente. El lavado de manos resultó incorrecto o poco frecuente en aquellos establecimientos con presión de tiempo, con distinción de tareas (cada empleado era encargado de un solo tipo de alimento), y en los que las estaciones de lavado de manos eran incompletas (falta de jabón, papel desechable o posición inaccesible dentro de la cocina).

Los resultados microbiológicos (Tabla 4, 5 y 6 del Capítulo 5) demostraron que las condiciones de preparación de las tablas de cortar (una sola tabla para todo tipo de alimentos que se limpia después de cada uso o varias tablas distinguidas por colores que se usan para un solo tipo de alimentos) no influyen sobre el rendimiento microbiológico de las tablas, dado que se encontraron resultados similares. Esto es un ejemplo de flexibilidad para los establecimientos de restauración ya que pueden utilizar una sola tabla si se limpia después de cada uso o varias tablas destinadas para cada tipo de alimento. También se observó que las tablas de cortar que se limpian con lavavajillas mostraron mejores resultados microbiológicos que las que se lavaban a mano.

La efectividad de limpieza de las superficies de contacto fue suficiente porque los resultados de las muestras tomadas después de limpieza resultaron menores al límite establecido. Sin embargo, existieron algunas excepciones debido a diferentes causas como incumplimiento del proceso de limpieza (uso de otro desinfectante o ausencia de uso, secado con trapo sucio), o proceso incorrecto de limpieza (sin uso de desinfectante o en algunos establecimientos sin uso de detergente). Por lo tanto, se recomienda

establecer, validar y verificar que el proceso de limpieza con apoyo de proveedores de agentes de limpieza para las diferentes condiciones de preparación en el establecimiento. Asimismo, se recomienda escribir dicho procedimiento y asegurarse que el personal siempre lo sigue.

Con respecto a las manos, los días en los que se encontraron resultados por encima de los límites en las manos después de limpiar, fueron debidos al uso de trapos, generalmente sucios, para secarse las manos o falta de uso de jabón. Y la ausencia de éstos pasos fue debido a su vez, porque las estaciones de lavado de manos no tenían papel desechable para secarse ni jabón. Por tanto, se demostró la importancia del apoyo organizativo del establecimiento para que el personal pueda cumplir con las buenas prácticas higiénicas.

CHAPTER 5

Analysis of hygienic practices and microbiological performance of contact surfaces in Food Service Establishments

Abstract

There are several studies indicating that one of the main sources of food safety problems in foodservice establishments is the cross contamination from food contact surfaces, equipment and employees. The objective of this study is to investigate the effect of actual hygienic practices on the microbiological performance of cutting boards, slicers and hands in ten Spanish foodservice establishments. The results showed that the foodservice establishments with a supportive organisation which provided the means to clean hands and surfaces, displayed better compliance to hygienic practices and revealed a better microbiological performance. It was also found that other factors such as time pressure, availability of procedures, and own safety concern influence the compliance to hygienic practices and actual cleaning procedures.

1. Introduction

Food service establishments (FSE) such as restaurants, hotels, bars, and cafeterias are considered an important source of foodborne outbreaks as studied in various European countries (Effler et al, 2001; Olsen et al., 2000; Hughes et al., 2007). There are several studies that have discussed that the main causes of microbial contamination typically occurring in foodservice establishments are contaminated supplies, dirty food contact surfaces, poor personnel hygiene practices, inappropriate storage temperatures, and insufficient cooking (Käferstein, 2003; Griffith & Clayton, 2005; WHO, 2007; EFSA, 2007; Jones et al., 2008).

More in detail, various studies have demonstrated that the main sources of cross contamination during processing come from food contact surfaces, equipment and employees (Gill et al., 2001; McEnvoy et al., 2004; Tsalo et al., 2007; Aarnisalo et al., 2006; Bagge-Ravn et al., 2003; Cools et al., 2005; Fuster-Valls et al., 2008). Equipment and surfaces can be source of direct contamination when they have not been effectively cleaned or remained wet between cleaning and use (Evans et al., 2004). Food handlers have a major role in the prevention of foodborne diseases since they may cross-contaminate raw and ready-to-eat food, and be asymptomatic carriers of food poisoning microorganisms (Walker et al., 2003).

As described in Chapter 4, the food safety management system performance and the microbiological performance of various meals were assessed in 10 food service establishments. It showed that major weak points to improve are sanitation performance, employee involvement, management commitment, compliance to procedures, employee's competences, and development of suitable procedures.

Taking into account the results from Chapter 4 (deficiency of the sanitation program with respect to design of facilities and equipment, weakness of employee hygienic requirements and their actual performance) and the aforementioned studies underpinning the effect of cleanliness of contact surfaces and employee behaviour over microbiological performance, the objectives of this study are to investigate the effect of actual hygienic practices on the microbiological performance of food contact surfaces and hands, and to study the effectiveness of applied cleaning procedure in ten Spanish foodservice establishments that were assessed in the previous study (Chapter 4).

In order to get insight in the possible mechanism behind actual employee behaviour and its consequences for microbiological performance a research model was developed based on literature.

The hypothesis of the study is that cross contamination by hands and food contact surfaces can be reduced if there are adequate procedures, hygienically designed facilities, and actual compliance to hygienic practices such as hand-washing and compliance to cleaning and disinfection procedures.

2. Research model

The research model was developed based on literature and is shown in Figure 1. It consists of three elements: i.e. (I) supportive administrative and technological conditions that may affect actual hygienic practices, (II) hygienic practices that were selected based on its impact over cross contamination and microbiological performance, and (III) microbiological parameters that were chosen as indicators of the microbiological performance of contact surfaces. Each element is discussed as follows.

2.1 Supportive conditions

Luning and Marcelis (2009), based on the study by Gerats (1990), pointed out that personnel behaviour toward quality issues, such as safety, depends on disposition and ability of the employee to behave in a certain direction. Disposition depends on aspects like personal quality standard, quality knowledge, observed standards of colleagues and boss, and observed opportunities to really demonstrate quality behaviour. Ability depends on issues like competence, facilities and means, availability of time, and support of colleagues, supervisor and company.

Furthermore, Luning and Marcelis (2006, 2007) established that food quality is a function of food behaviour and human behaviour (FQ = f(FB, HB)). Food behaviour depends on the technological conditions (process, storage conditions, equipment, facilities, measurement) that control the intrinsic variation of the food and make the product to have desired properties. Similarly, human behaviour depends on the managerial conditions (organisational relationships, available information, procedures, communication systems, training programs) that control decision-making of people who have individual characteristics and make different and unpredictable decisions.

Similarly, Cenci-Goga and co-authors (2005) demonstrated that some essential management measures to implement HACCP principles into an own Food Safety Management System are provision of continuing professional education, encouragement of self-inspection procedures, giving staff the possibility to suggest and implement further hygienic practices, and the availability of a proper working environment.

According to the aforementioned studies, the research model proposes that actual hygienic practices depend on the supportive conditions that management provides to

direct employees decision-making toward hygienic practices. Based on the techno-managerial approach (Luning and Marcelis, 2006, 2007) these supportive conditions were divided into administrative conditions that support employees in taking decisions with less unpredictable behaviour, and technological conditions that enable people to take appropriate decisions and execute tasks properly (e.g. tailored equipment and facilities).

Supportive administrative conditions

The items selected for the evaluation of the supportive administrative conditions in the research model were competence (knowledge and experience), availability of procedures, availability of time, and degree of differentiation of tasks.

Knowledge and experience, which are considered as competence aspects in this study, were selected to analyse the supportive administrative conditions because there are several authors that found a positive relation between knowledge and training and safe food handling practices (Campbell et al., 1998, Cotterchio et al., 1998). More specifically, a study where mass catering establishments were evaluated after HACCP principles were implemented showed that the staff educational program introduced in the catering centres certainly helped to increase the level of awareness and the sense of responsibility regarding food hygiene (Legnani et al., 2004).

The availability of procedures was considered as supportive administrative conditions because procedures influence human dynamics (variability in decisions) by setting the rules and steps that employees must follow to comply with hygienic practices (Luning and Marcelis, 2009).

The availability of time and the degree of differentiation of tasks (that refers to the way in which the tasks are organised in order to reduce cross contamination) were considered as supportive administrative conditions because FSE are a fast-moving environment where time is always limited and people prioritise tasks according to their own perception of importance (Panisello & Quantick, 2001). The pressure to prepare meals in a short period of time, often above the designed capacity of the establishments, may influence negatively the attitude toward safe practices, creating an evident gap between knowledge and practices (Howes et al, 1996; Taylor, 1996; Angelillo et al, 2000; Wordsfold, 2001; Clayton et al, 2002; Jones et al., 2008). Furthermore, if the

degree of differentiation of tasks is high (each employee is in charge of a certain food type) then the possibility of cross contamination is reduced (Montes et al., 2005).

Supportive technological conditions

The items selected for the analysis of the supportive technological conditions in the research model were preparation circumstances, adequacy of cleaning and disinfection (C&D) procedure and adequacy of hand-washing station.

The preparation circumstances refer to the characteristics of preparation (or production process) in the establishment. Due to the fact that the production process in the kitchen is complex restraining the chance to analyse all of its processes, in this research model, the preparation circumstances were focused on the cutting boards and the slicers because these surfaces are major sources of cross contamination as it will be explained in the section of the research model referring to the microbiological performance. Therefore, the preparation circumstances of the cutting boards distinguished if it was multi-purposed (the same kind of cutting board is used for the different types of food) or if it was single-purposed (specific cutting board, commonly coloured, is used for a determined food type, eg. red coloured cutting board for meat, blue coloured for fish, etc). While the preparation circumstances of the slicer refer to the type of food that is handled on it and the frequency of use (if it is used during the whole shift or only a few times during the shift).

The cleaning and disinfection procedure is important to consider because inadequate cleaning and disinfection of food contact surfaces represents a risk factor for cross contamination because of the possible presence of pathogens that have low minimum infective dose such as *Escherichia coli* O157:H7 (Davidson et al. 1999) or *Listeria* spp (Gibbons, Adesiyun, Seepersadsingh, & Rahaman, 2006), and because is an effective means to reduce cross contamination and the occurrence of foodborne outbreaks (Cogan et al, 2002; Watchel et al, 2003). The aspects used to describe the adequacy of the cleaning and disinfection procedure were the means (done by a dishwasher or by hand), if chemical agents were selected according to suppliers' advice or were common agents bought in the market, the completeness of the procedure and its frequency (Luning et al., 2008).

The adequacy of the hand-washing station was considered as another aspect of the supportive technological conditions because it has been outlined that one of the factors that affects actual hand-washing practices is the presence of appropriate means and facilities such as soap and disposable paper, which should be supplied by management (Clayton & Griffith, 2004; Pragle et al., 2007; Howells, 2008). Therefore, it was checked if the hand-washing station was pedal or elbow activated, if soap and disposable paper were available and if the position within the kitchen was easily accessible for all employees.

2.2 Actual hygienic practices

In order to analyse if employees actually performed hygienic practices, four hygienic practices were chosen: “hand-washing”, “use of clean utensils to handle ready-to-eat (RTE) food”, “use of clean utensils after changing food type”, and “use of dishcloth” (which must be used only to clean leaks or hold hot surfaces and not to dry hands or clean/dry surfaces). These hygienic practices were considered because they have been emphasised in various studies to influence food safety and to critically avoid cross contamination and thus reduce possibility of a foodborne outbreak (FDA, 2001; Rue & Graf, 2003; Montes et al., 2005; Smith et al., 2005). For instance, FDA recommends foodservice workers to adopt four food preparation practices to prevent foodborne illness, which include: hand-washing; applying measures to avoid cross contamination like use of gloves, spatulas or dispensing equipment to handle ready-to-eat foods; checking cooking temperatures of foods to ascertain they reach appropriate temperatures; and restricting workers from food manipulation when they are ill with vomiting or diarrhoea (FDA, 2001). Similarly, Smith and co-authors (2005) discussed that food handler hygiene, hand washing, and use of clean equipment must be controlled in order to limit the risk of contamination.

Beumer & Kusumaningrum (2005) found that the main vectors of bacterial contamination in the kitchen are the hand towels and cleaning clothes. Dishcloths contain up to 10^8 bacteria, and may transfer bacteria to hands or clean surfaces in sufficient numbers to cause infection if food is in contact with that surface (Rusin, Orosz-Coughlin & Gerba, 1998). Similarly, Meredith, Lewis & Haslum (2001) reported that dishcloths are an important source of contamination transferring pathogens to work surfaces and fingers. The damp conditions, which prevail in dishcloths between

preparations of meals, may result in cloths that are contaminated during the preparation of one meal and then acting as a source of contamination during the preparation of the next. If the dishcloths are used to dry cleaned hands they can re-contaminate them. Therefore, they recommended the use of fresh cloths at each meal preparation and to use single use disposable towels to dry hands (Meredith, Lewis & Haslum, 2001).

2.3 Microbiological performance

Along with the analysis of employees hygienic behaviour, it is also important to evaluate actual microbiological performance of end products, raw material and contact surfaces in order to check the effectiveness of a food safety management system and to appraise performance of critical control points, good hygienic practices and standard operating procedures (Brown et al., 2000; Cornier et al., 2007; Jacxsens et al., 2009). The microbial quality of surfaces has been identified as a useful indicator for control of the critical points related to the procedures of cleaning and disinfection (Legnani et al., 2004). Furthermore, the microbial analysis of food contact surfaces may indicate the actual status of the hygienic design of equipment and facilities and actual specificity of the sanitation program; while the microbial analysis of hands will indicate the actual performance of personnel hygienic practices (Jacxsens et al., 2009).

The selection of the contact surfaces to analyse the microbiological performance was based on other studies that have highlighted contamination on them. Thus, the cutting board was selected because it has been shown that when cutting boards become contaminated, pathogens can survive and multiply on the surfaces, and are readily transferred to other surfaces in sufficient numbers to represent an infection hazard (Cools et al, 2005; Watchel et al, 2003; Welker et al, 1997). Furthermore, the cutting board is one of the top five sites most contaminated with heterotrophic bacteria in the kitchen and may facilitate transmission of foodborne pathogens by cross-contamination (DeVere & Purchase, 2007) due to the fact that it is a moist environment and is frequently touched (Rusin, Orosz-Coughlin & Gerba, 1998).

In the same way, slicers have been found to be critical surfaces that may retain bacteria and pathogens such as *Listeria monocytogenes* and to be sources of cross contamination (Grassi et al., 2008; Sheen & Hwang, 2008; Vorst, Todd & Ryser, 2006).

Finally, hands is also considered as a critical source of cross contamination according to other studies that have found contamination with *Campylobacter* and *Staphylococcus aureus* microorganisms coming from hands (Bidawid, Farber & Sattar, 2000; Gorman, Bloomfield & Adley, 2002; Aarnisalo et al., 2006). Hands can contaminate food through residential flora of the skin e.g. micrococci, staphylococci, propionic bacteria and corynebacteria; and the transient flora such as faecal pathogens like *Escherichia coli* and *Salmonella* (Aarnisalo et al., 2006) or viruses such as the Hepatitis A virus (Bidawid, Farber & Sattar, 2000) when they have contact with the environment.

3. Materials and Methods

3.1 Selection of Food Service Establishments (FSE)

The selection of the FSE was based on Chapter 4 that compared contextual situation, core control and assurance activities, and microbiological performance of final meals of ten FSE located in Burgos, Spain. The results showed opportunities for improvement in various activities of the food safety management systems including control of raw material, sanitation programs, layout and design of equipment and facilities, and measures related to employees' hygienic behaviour such as management commitment and development of suitable procedures. These 10 FSE were also used for this study. The sample of FSE included one "student hall of residence" (RH), four hotels (H1, H2, H3, H4), two student cafeterias (R1, R2), two "day menu" restaurants (R3, R4) and one "menu a la carte" restaurant (R5).

3.2 Analysis of supportive conditions

The method to describe the supportive conditions of the FSE was done through a consecutive 3-day observation and by face-to-face interviews. The aspects of availability of time and degree of differentiation of tasks (administrative conditions), and adequacy of the hand-washing station (technological condition) were analysed by observation. The aspects of knowledge and experience and availability of procedures (administrative conditions), and preparation circumstances and adequacy of cleaning and disinfection procedure (technological conditions) were analysed by face-to-face interviews with each employee.

3.3 Analysis of actual hygienic practices

The analysis was done by checking during 6 hours for 3 consecutive days the compliance of the selected hygienic practices writing down the times that each employee performed the hygienic practice correctly and the times and description of any non-compliance to hygienic practices with the aim of showing a pattern of behaviour for each employee. In this study, 3 patterns of behaviour were chosen: *not* done, done *wrongly or incompletely*, and done *correctly and completely*.

The *not* done was defined when the hygienic practice was actually not done in the case of the hygienic practice "hand-washing" or if it was always done wrong in the 6-hours shift for the rest of the hygienic practices.

The description of a hygienic practice done *wrong or incomplete* in the "hand-washing" was distinguished when soap was not used or when hands were not dried with disposable paper but with a dishcloth used for other activities. In the case of the hygienic practice of "use of clean utensils to handle RTE food" or "after changing food type", the *wrong/incomplete* was described by the use of utensils that were not properly cleaned because were only scrubbed with a dishcloth. With respect to the hygienic practice of "use of dishcloth", the *wrong/incomplete* situation was represented when the dishcloth was also used to dry hands or clean utensils such as knives.

The done *correctly/completely* description for "hand-washing" was given when the hands were cleaned with soap and dried with disposable paper every time they were contaminated, after changing food type or before handling RTE food. The hygienic practices of "use of clean utensils after changing food type" or "before handling RTE-foods" were considered as done *correctly/completely* when the utensils were actually cleaned and disinfected before using them. And the hygienic practice of "use of dishcloth" was defined as done *correctly/completely* when it was used only to hold hot surfaces or clean leaks (not used to dry hands or clean utensils/contact surfaces).

After the 3-days observation each employee was allocated in one of the three patterns of behaviour depending on the times that the behaviour was observed. If the majority of time, at least 80% of the time, the employee executed the hygienic practice properly, then his behaviour was evaluated as *correct/complete*. If the pattern showed a behaviour done in a wrong way, at least 80% of the time, then the employee´ behaviour was evaluated as *wrong/incomplete*, and if the employee did not perform the hygienic practice, at least during 80% of the time, then it was assumed that the hygienic practice was *not* done.

3.4 Analysis of microbiological performance

Selection of sampling locations

As shown in the research model the locations selected for sampling were the cutting boards, slicers and hands because are contact surfaces that may facilitate cross contamination (Cools et al., 2005: Watchel et al., 2003; DeVere & Purchase, 2007; Grassi et al., 2008; Sheen & Hwang, 2008; Vorst, Todd & Ryser, 2006; Bidawid, Farber & Sattar, 2000; Gorman, Bloomfield & Adley, 2002; Aarnisalo et al., 2006).

Selection of microbial parameter

The enumeration of total aerobic mesophilic plate count gives insight of the overall performance of the sampling locations (ICMSF, 2002; Mossel et al., 1995). Therefore, this microbial parameter was selected for the microbiological analysis in this study.

Sampling method

Sampling was done during the same 3 consecutive days of observation of hygienic practices and it included samples taken before starting to work, before any important cleaning procedure and after cleaning. Those samples were chosen in order to check three different points. First, the samples “after cleaning” and “before starting” were compared in order to see if there was environmental contamination during the night or if the cleaning procedure was done the same way during the night shift. Then, the samples “before starting” and “before cleaning” were compared to determine the degree of contamination that is handled in the contact surface. And finally, the samples “before cleaning” and “after cleaning” were compared to check the effectiveness of the cleaning procedure.

The sampling procedure was done according to the ISO standards. Therefore, ISO 18593:2004 was used to sample surfaces, including hands. It specifies horizontal methods using contact plates or swabs (ISO, 2004). In this analysis, the swab technique was done using sterile cotton Rediswab ™ sampling swabs (Biotrace International, Bridgend, UK) moistened in tubes containing 4 ml of Letheen broth which was used as a neutralising buffer, and disposable sterile plastic templates to outline a known area of 100 cm^2 inside which the swabbing took place. The swabbing was done with a pencil eraser-type pressure with horizontal, vertical and diagonal ways over the surface

(Larson et al., 2003). After taking the sample, the tubes were transported in a refrigerated box to the laboratory and immediately analysed.

Method of analysis

For the enumeration of the total aerobic bacteria count, the samples were diluted 10 fold up to 10^{-2} in which one millilitre of the bacterial suspension contained in the 4 ml Letheen tubes was pipetted on a Petri dish and approximately 15 ml of plate count agar (Oxoid, Basingstoke, UK) was added. The contents were thoroughly mixed and then the plates were incubated at 30ºC during 72 hours. After the incubation period, all the colonies that grew on the plate were considered for the enumeration. Data processing was performed after the values were transformed by logarithm of 10 in order to normalize data (Larson, et al, 2003). Therefore, the data was expressed as log CFU/cm^2.

Data interpretation

There are several studies underpinning the target values of cleanliness. For instance, values <2,5 logCFU/cm^2 have been suggested to define a surface as clean and have been found to be attainable for a range of surfaces (Mossel et al., 1999, Griffith et al., 2000). The references found in Spanish legislation related to microbiological limits of food contact surfaces are limited to mesophilic aerobic bacteria. The value of 2 log CFU/cm^2 was considered as the upper limit of cleanliness, values higher than 2 indicate that the surface is dirty and must be cleaned again (Moragas & De Pablo, 2008). Therefore, in this analysis the results of the food contact surfaces that are expected to be clean (before starting and after cleaning procedures) that were higher than 2 logCFU/cm^2 were considered as above limits of cleanliness.

4. Results

4.1 Supportive conditions

Table 1 and 2 show the supportive conditions (administrative and technological conditions). Table 1 describes competence level (experience and knowledge), availability of procedures, availability of time and degree or differentiation of tasks. Table 2 shows the technological conditions of preparation circumstances (multipurposed or singlepurposed for cutting board, and type of food and frequency of use for slicer), the adequacy of the C&D procedure (means of cleaning, if chemical agents are from suppliers advice, completeness, and frequency), and the adequacy of the hand-washing station (pedal/elbow activated, availability of soap and disposable paper and position in the kitchen).

Table 1 shows that the majority of FSE, 8 out of 10, have a team with cooks that have received courses about hygienic handling of food. The other two (H4 and R5) have one cook with no education background related to cuisine or hygienic behaviour. It also points out that the FSE with cuisine technicians are the hotels and restaurant R5. Furthermore, the range of experience is from 3 months (H2 and R5) up to 43 years (H1), but the majority of FSE have cooks with more than 15 years of experience.

According to the 3-day observation, the FSE that work within a time-pressure environment during rush hours are the hotels and restaurant R5. The rest of the FSE indicated to have no direct time pressure because they prepare the meals in advance before the time of service due to the nature of their business (hall of residence, cafeterias, and “day menu” restaurants). Finally, the hotels were the food service establishments that had one cook in charge of a food type during the preparation shift (eg. one cook to prepare meat, another cook to prepare fish, and other cook to prepare desserts and salads). The rest of the FSE have no differentiation of tasks (RH, R1, R5) or have a single person in charge of the preparation since there is only one cook in the kitchen (R2, R3, R4) and thus prepare various food types at the same time.

According to Table 2, the Food Service Establishments H2, H3, H4, and R5 have single-purposed cutting boards, distinguished by colours, to use for a specific food type, that are cleaned at the end of the shift. The rest of the FSE have multi-purposed cutting

boards used for all the food types, that are cleaned after each use to avoid cross contamination, except in R3 where is cleaned at the end of the shift.

In the majority of FSE, the slicer was used to cut different types of food including ham, cheese, vegetables and cooked meat, except in H4, R1, R3 and R5 where the slicer is used only to slice ham and cheese. Furthermore, the slicer was used during the whole shift in H2, H3 and R5. The rest of FSE used it only a few times during the shift.

Table 2 also shows that the cutting boards are cleaned in a dishwasher, except in H1 and H4 where they are scrubbed by hand and are not disinfected. The only FSE that have selected the chemical agents upon the supplier's advice are RH and H2. The other FSE use common agents and have established the cleaning and disinfection procedure by experience. The slicers are cleaned by hand in all the FSE with different procedures. Some FSE (RH, H2, R1, R2) use a mixture of detergent and disinfectant (containing chloride compounds). H3 and H4 do not use disinfectant. In H1 it is cleaned only with hot water without the use of chemicals. In R3 it is cleaned only by scrubbing with a wet dishcloth. The only FSE where the cleaning and disinfection of slicer is complete, using chloride compounds or alcohol to disinfect, is R5. Only RH and H1 cleaned the slicer after each use, while the rest of FSE did it until the end of the shift.

With respect to the hand-washing stations, Table 2 shows that only RH, H2, R1 and R4 have complete hand-washing stations, which are described by the availability of soap and disposable paper to dry, and are situated in an accessible position where all employees can reach them. The only restraint in R1 and R4 is that the stations were not pedal/elbow activated. In R3 and R5 the soap is difficult to find, while in H3 and H4 the soap is even missing. The Food Service Establishments H1, H3, R2 and R3 do not have disposable paper, and in H4 and R5 the disposable paper is difficult to find. The position of the hand-washing station within the kitchen is accessible in all the FSE, except in H1 and H4 that have only one station in the kitchen making it difficult for some employees to reach the station to wash their hands.

4.2 Actual hygienic practices

Table 3 summarizes the number of employees allocated in each of the patterns of behaviour (*not* done, done *wrongly/incompletely*, or done *correctly/completely*) for the four selected hygienic practices ("hand washing", "use of clean utensils to handle ready-

to-eat food", "use of clean utensils after changing food type" and "dishcloth is used only to clean leaks or hold hot surfaces").

Table 3 indicates that the only FSE that performs the four hygienic practices *correctly/completely* is RH. Then, the Food Service Establishments H2, R1, R2 and R4 that have cooks executing at least two hygienic practices *correctly/completely*, while the rest of the FSE did *not* performed the hygienic practices or did them in a *wrong/incomplete* way.

It was also observed that the pattern of behaviour at the time of executing the selected hygienic practices in each kitchen is the same between all the employees for the majority of FSE, except in H2, H3, H4, and R5 where some employees behave differently from the others. In the case of H2, the chief cook showed a better compliance to hygienic practices. In H3 the better compliance was done by the cook in charge of the preparation of salads and desserts. In H4 the better compliance was done by the chief cook-owner and other cook, who was responsible for the preparation of salads and desserts and had also worked as cleaning employees. In R5 the better compliance was done by the cuisine technician students.

4.3 Microbiological performance

Table 4 summarize the preparation circumstances, the C&D procedure done during the time of sampling and the microbiological results expressed as log CFU/cm^2 of the cutting boards. The results above cleanliness limit (2 log CFU/cm^2) are highlighted with **bold**. In the same way, Table 5 shows the microbiological results of the slicers. And Table 6 shows the status of the hand-washing station, the C&D procedure done to wash their hands at the time of sampling and the microbiological results of hands.

Cutting boards

Table 4 shows that FSE with better microbiological performance were H3, R2 and R5 because the samples supposed to be clean (samples before starting and samples after cleaning) were within cleanliness limits.

The rest of FSE showed total aerobic counts above cleanliness limit at least one day of sampling. For instance, the higher contamination in RH corresponded to the sample taken after cleaning where raw pork rib was handled. In the case of H1 and H4, the

samples with higher bacterial counts were the ones that were cleaned by hand (not dishwasher). In R3, the samples with bacterial counts above cleanliness limits were dried with a dirty dishcloth. In R4, the samples with contamination over limits were the ones taken from a wooden type cutting board that was not cleaned with a dishwasher.

The results also outlines that the contamination of the samples taken before cleaning reached values around 3 log CFU/cm^2 and up to 4.7 log CFU/cm^2, indicating that the contact surfaces may attain high levels of contamination that can contaminate food if it is not properly cleaned with a certain frequency, becoming then a potential risk to cause cross contamination.

Slicers

Table 5 shows that FSE with better microbiological performance were RH, H1, H4, R1 and R2 because the total aerobic counts were within cleanliness limits in the surfaces that are expected to be clean (before starting or after cleaning).

The rest of FSE had results above established limit at least one day. The slicers with higher bacterial counts were those from the FSE that had a more frequent use of it because they used the slicer during the whole shift (H2, H3 and R5). In R3 the higher contamination was probably due to the C&D procedure (only scrubbing with a wet dishcloth).

It was also observed that there were samples where disinfectant was not always used (R2 and R5), and samples that were disinfected with alcohol instead of chloride compounds (R5). These results show lack of compliance to C&D procedures.

Hands

The results of Table 6 show that the cleaning procedure is effective in those FSE that used soap and disposable paper to dry their hands (RH, H2, H3, H4, R1, R4 and R5).

In the case of H4, the cleaning procedure of hands was done correctly and completely at the time of sampling. However, during the analysis of the hygienic practices it was observed that the majority of employees did not wash their hands during the shift (Table 3).

It can be seen that there were samples where hands were dried with a dishcloth (H1, H3, R2, R3 and R5) and where soap was not used (R2).

5. Discussion

As stated in the hypothesis, cross contamination by hands and food contact surfaces can be reduced if there are adequate procedures, hygienically designed facilities, and actual compliance to hygienic practices such as hand-washing and compliance to cleaning and disinfection procedures. According to the research model, microbiological performance depends on the actual hygienic practices (including hand-washing and use of clean utensils), whereas the actual hygienic practices depend on the supportive administrative and technological conditions. The first part of this section discusses the effect of actual hygienic practices to microbiological performance of cutting boards, slicers and hands, while the second part discusses the effect of the supportive administrative and technological conditions to actual hygienic practices.

5.1 Effect of actual hygienic practices to microbiological performance

Data revealed that if employees used soap and disposable paper to dry their hands the bacterial counts were below limit (as seen in all FSE that did a complete hand-washing during sampling, Table 6). On the other hand, if the employees dried their hands with dishcloths (H1, R2, R3) or did not use soap (R3), the bacterial counts were above limit (Table 6). These findings are in alignment with other studies that found an increase of contamination if soap is not used (Clayton & Griffith, 2004) or if dried with dishcloths (Rusin, Orosz-Coughlin & Gerba, 1998; Meredith, Lewis & Haslum, 2001; Beumer & Kusumaningrum, 2005; Pragle et al., 2007). However, the microbiological performance of hands in H3 and R5 were within cleanliness limits even though during some days they dried their hands with a dishcloth. These results can be explained by the limitations of the sampling method or because the dishcloths were not dirty enough to transfer contamination to hands during the days of sampling.

Moreover, in case the C&D procedure was done incorrectly (eg no use of dishwasher or no use of disinfectant, and dried with a dishcloth) the contact surfaces (cutting boards and slicers) resulted with bacterial counts above limit. For example, the cutting boards of H1, H4 and R4 (cleaned by hand) (R4 with wooden materials) presented higher contamination than the ones cleaned by dishwasher. These results comply with other studies that have demonstrated that the dishwasher is an effective means of disinfection (Ebner et al., 2000; Cliver, 2006; Sharma et al., 2009). Additionally, various authors

have discussed that wooden type cutting boards are more difficult to clean in comparison to plastic type cutting boards because of the physical structure of wood, which can absorb moisture and retain bacteria (Carpentier, 1997; Boucher, Chamberlain & Adams, 1998; Welker et al, 1997; Deza, Araujo & Garrido, 2007).

In case of slicers, it they were disinfected with chemicals containing chlorine compounds, the bacterial count was within cleanliness limits (RH, R1, R5). Various authors have found that rinsing with water and domestic chemical cleaners does not ensure total elimination of bacteria (Cogan et al, 2002; Watchel et al, 2003), and antimicrobial agents are necessary to achieve complete hygiene of surfaces (Schonwalder et al., 2002; Taylor, Rogers & Holah, 1999). More specifically, various studies demonstrated that the use of chlorine-containing compounds is effective to reduce bacteria and pathogens such as *Escherichia coli* to acceptable limits requiring short to moderate contact time (Kim, Hung & Brackett, 2000; Williams, Avery, Killham & Jones, 2005). Data also showed that some FSE resulted with bacterial counts below cleanliness limit even though they did not disinfected the surface (H1, H4, R2) while other FSE had bacterial counts above limit although they disinfected the surface (H2). These results can be explained by the limitations of the sampling method or because the effectiveness of the C&D procedure has to do with other aspects such as frequency of use or type of food (Rodriguez et al., 2003). Indeed, H2 used the slicer during the whole shift while the other (H1, H4, R2) used it only a few times during the shift.

There were some results out of the expected results (more contamination before starting than after cleaning or less contamination before cleaning than after cleaning) that can be explained by an ineffective C & D procedure or by the limitations of the sampling method. Among the limitations of the swab technique, some studies remark problems associated with the recovery of microorganisms, particularly from a dry surface (Davidson et al., 1999; Moore et al., 2001) The accurate detection and enumeration of microbial contamination using the traditional swabbing technique relies initially upon the ability of the swab to remove the microorganisms from the surface, followed by their effective release from the swab bud and their subsequent recovery (Moore & Griffith, 2002). Furthermore, the degree of microbial adhesion and survival on a surface is influenced by many factors, such as material geometry, porosity, roughness,

composition, hydrophobicity, temperature and moisture (Williams, Avery, Killham & Jones, 2005).

5.2 Effect of supportive administrative and technological conditions to actual hygienic practices

Data showed that not providing the means to execute hygienic practices may increase the chance for employees to behave un-hygienically because the FSE that did not have a complete hand-washing station (lack of soap and/or disposable paper, unaccesible position) showed *wrong/incomplete* compliance to hand-washing (H1, H4, R2 and R5) or did *not* wash their hands during the 3-days observation (H3 and R3). These results comply with other authors that have found the lack of adequate facilities as a barrier to correct hand-washing (Pragle, 2007; Howells, 2008). However, it was also seen that providing adequate hand-washing facilities is not a guarantee for complete compliance to hygienic practices because the FSE with complete hand-washing stations demonstrated both *correct/complete* (RH and R4) and *wrong/incomplete* (H2 and R1) compliance to actual hand-washing. It is worth to mention that RH (as described in Chapter 4) is a FSE concerned about safety with employees that are conscious to comply with procedures, whereas R4 is a FSE where the person in charge of the preparation of meals is the owner of the establishment so is more interested in executing tasks properly. The *wrong/incomplete* behaviour toward hand-washing in the other FSE (H2 and R1) although they had complete hand-washing stations might be explained by other factors such as time pressure, lack of technical knowledge concerning the risks of not washing hands properly or because they did not feel to wash their hands by working with the same type of food (eg one employee for meat, other for fish, other for salads and desserts). The effect of time pressure as a restrain to actual hand-washing was also observed by other authors (Angelillo et al., 2000; Worsfold, 2001; Clayton et al., 2002; Pragle et al., 2007; Jones et al., 2008;). Furthermore, Green and co-authors (2005) found that employees with more intensive food handling responsibilities were more likely to wash their hands when needed. They explained this fact because employees were more concerned about food safety or whether they were simply being more likely to get food on their hands and in response washed their hands more frequently.

Data showed that although employees had many years of experience (H1, H3, H4, R3, R5) they do not always comply with hygienic practices. Such results have also been

found by other authors that observed that even when foodservice workers demonstrate good knowledge of food safety or have a positive attitude towards food safety, they do not always comply with safe preparation practices or improve in their food hygiene behaviour (Clayton et al., 2002; Howes et al., 1996; Taylor, 1996; Angelillo et al., 2000; Sneed et al., 2004).

6. Conclusions

As it was assumed, the microbial performance of contact surfaces and hands seems to be affected by the actual hygienic practices, which were also affected by the supportive conditions in the establishment. It was demonstrated that the FSE with supportive conditions with the necessary means to clean hands or surfaces (soap, disposable paper, available position, adequate cleaning and disinfection procedure) showed better compliance to hygienic practices and resulted with better microbial performance of the cutting boards, slicers and hands (RH, H2, and R1). On the other hand, the FSE with time pressure, employees without technical knowledge, no availability of the means to clean hands and surfaces, no adequate cleaning and disinfection procedures and unhygienic facilities demonstrated low compliance to hygienic practices, specially those related to hand-washing and correct use of dishcloth, and thus resulted with higher microbiological contamination of contact surfaces and hands (H1, H3, H4, R3 and R5). In order to improve employees behaviour, which would be reflected in a better microbial performance, the FSE management must provide the necessary means and organisation to support important hygienic practices, such as availability of complete hand-washing stations, availability of means for appropriate cleaning (presence of dishwasher, disinfectants, disposable paper), training to increase the concern of safety among the employees, organisation of the tasks to reduce the time pressure, written procedures to direct people decision-making (specially those related to cleaning procedures, which must describe an effective process and frequency in accordance to the different food types and the preparation circumstances of the FSE (type of surface, if the contact surface is used during the whole shift for only one type of food or for different types of food, or if it is used only a few times in the shift).

The similarities of results between the FSE that use multi-purposed or single-purposed cutting boards shows that both types of preparation may have the same microbiological performance. Therefore, a kitchen may have a single-purposed cutting board for only one type of food that is cleaned until the end of the shift, or it may have a multi-purposed cutting board that is cleaned after each use or after changing a food type. This is an example of flexibility, which is a proposed requirement for QA-standards/guidelines tailored for FSE (Chapter 1).

This study can be used as a starting point for other studies aimed at analysing the effect of hygienic practices to microbiological performance, and understanding why employees of FSE do not always comply with hygienic practices.

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Figure 1. Research model

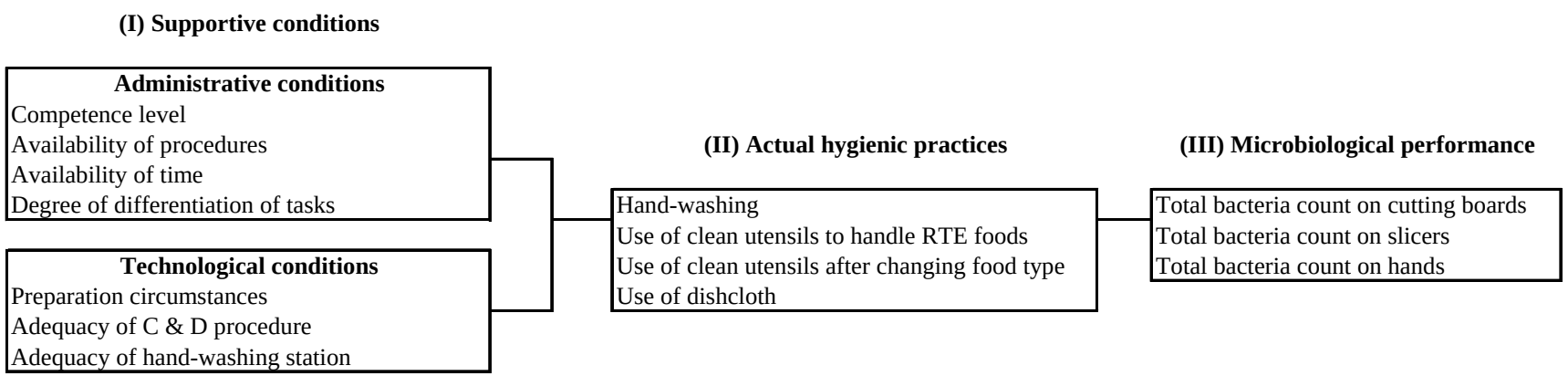

Table 1. Administrative conditions

FSE	Competence level			Availability of procedures	Availability of time	Degree of differentiation of tasks
	Job Position	Experience	Knowledge			
RH	Chief cook	4 years	Courses of hygienic handling, "tapas", miniature foods, vaccum package	Written C&D procedure	No time pressure	No differentiation of tasks
	Cook	5 years	Courses of hygienic handling			
H1	Chief cook	3 years	Courses of hygienic handling	No written procedures	Time pressure during rush hours	Each cook is in charge of a food type
	Cook	38 years	Courses of hygienic handling			
	Cook	2 years	Cuisine technician, courses of hygienic handling			
	Cook	43 years	Courses of hygienic handling			
H2	Chief cook	8 years	Cuisine technician, courses of hygienic handling	Written C&D procedure	Time pressure during rush hours	Each cook is in charge of a food type
	Cook	9 years	Architect and courses of hygienic handling			
	Cook	6 months	Cuisine technician, courses of hygienic handling			
	Cook	3 months	Cuisine technician, courses of hygienic handling			
H3	Chief cook	20 years	Cuisine technician	No written procedures	Time pressure during rush hours	Each cook is in charge of a food type
	Cook	25 years	Courses of hygienic handling			
	Cook	20 years	Cuisine technician			
H4	Owner-chief cook	25 years	Cuisine technician, courses of hygienic handling	No written procedures	Time pressure during rush hours	Each cook is in charge of a food type
	Cook	3 years	Courses of hygienic handling			
	Cook	14 years	Cuisine technician, courses of hygienic handling			
	Cook	30 years	Courses of hygienic handling			
	Cook	1 year	Not related to cuisine			
R1	Cook	17 years	Courses of hygienic handling	No written procedures	No time pressure	No differentiation of tasks
	Cook	25 years	Courses of hygienic handling			
R2	Cook	16 years	Courses of hygienic handling, freezing techniques, cooking	No written procedures	No time pressure	A single person is in charge of preparation
R3	Chief cook	15 years	Courses of hygienic handling	No written procedures	No time pressure	A single person is in charge of preparation
R4	Owner-chief cook	2 years	Quality technician,courses of hygienic handling	No written procedures	No time pressure	A single person is in charge of preparation
R5	Chief cook	35 years	Courses of hygienic handling	No written procedures	Time pressure during rush hours	No differentiation of tasks
	Cook (practices)	3 months	Cuisine technician			
	Cook (practices)	3 months	Cuisine technician			
	Cook	17 years	Courses of hygienic handling			
	Cook	7 years	Cuisine technician			
	Cook	10 years	Courses of HACCP and hygienic handling			
	Cook	2 years	Not related to cuisine			

Table 2. Technological conditions

FSE	Cutting boards		Slicer		Adequacy of hand-washing station
	Preparation circumstances	Adequacy of C & D procedure	Preparation circumstances	Adequacy of C & D procedure	
RH	Multipurposed	Dishwashing	For all food type	Handwashing	Pedal activated
		Agents from suppliers	Used few times / shift	Agents from suppliers	With soap
		Complete		Mixture of soap & disinfectant	Disposable paper
		After each use		After each use	Available position
H1	Multipurposed	Handwashing	For all food type	Handwashing	No pedal/elbow activated
		Common agents	Used few times / shift	No agents	With soap
		No disinfection		Only water	No disposable paper
		After each use		After each use	Only one in the kitchen
H2	Single purposed	Dishwashing	For all food type	Handwashing	Pedal activated
		Agents from suppliers	Used during whole shift	Agents from suppliers	With soap
		Complete		Mixture of soap & disinfectant	Disposable paper
		At the end of the shift		At the end of the shift	Available position
H3	Single purposed	Dishwashing	For all food type	Handwashing	No pedal/elbow activated
		Agents from suppliers	Used during whole shift	Common agents	No soap
		Complete		No disinfection	No disposable paper
		At the end of the shift		At the end of the shift	Available position
H4	Single purposed	Handwashing	For ham and cheese	Handwashing	No pedal/elbow activated
		Common agents	Used few times / shift	Common agents	No soap
		No disinfection		No disinfection	Difficult to find disposable paper
		At the end of the shift		At the end of the shift	Only one in the kitchen
R1	Multipurposed	Dishwashing	For ham and cheese	Handwashing	No pedal/elbow activated
		Agents from suppliers	Used few times / shift	Common agents	With soap
		Complete		Mixture of soap & disinfectant	Disposable paper
		After each use		At the end of the shift	Available position
R2	Multipurposed	Dishwashing	For all food type	Handwashing	No pedal/elbow activated
		Agents from suppliers	Used few times / shift	Common agents	With soap
		Complete		Mixture of soap & disinfectant	No disposable paper
		After each use		At the end of the shift	Available position
R3	Multipurposed	Dishwashing	For ham and cheese	Handwashing	No pedal/elbow activated
		Agents from suppliers	Used few times / shift	No agents	Soap difficult to find
		Complete		Only scrubbing	No disposable paper
		At the end of the shift		At the end of the shift	Available position
R4	Multipurposed	Dishwashing	No use of slicer		No pedal/elbow activated
		Agents from suppliers			With soap
		Complete			Disposable paper
		After each use			Available position
R5	Single purposed	Dishwashing	For ham and cheese	Handwashing	No pedal/elbow activated
		Agents from suppliers	Used during whole shift	Common agents	Soap difficult to find
		Complete		Complete	Difficult to find disposable paper
		At the end of the shift		At the end of the shift	Available position

Table 3. Actual hygienic practices

FSE	N*	Core activity	Number of employees		
			Not done	Wrong/Incomplete	Correct/Complete
RH	2	Hand washing			2
		Use of clean utensils to handle RTE food			2
		Use of clean utensils after changing food type			2
		Dish cloth is used only to clean leaks or hold hot surfaces			2
H1	4	Hand washing		4	
		Use of clean utensils to handle RTE food	4		
		Use of clean utensils after changing food type		4	
		Dish cloth is used only to clean leaks or hold hot surfaces	4		
H2	4	Hand washing		3	1
		Use of clean utensils to handle RTE food		3	1
		Use of clean utensils after changing food type			4
		Dish cloth is used only to clean leaks or hold hot surfaces		4	
H3	3	Hand washing	3		
		Use of clean utensils to handle RTE food	3		
		Use of clean utensils after changing food type	2	1	
		Dish cloth is used only to clean leaks or hold hot surfaces	3		
H4	5	Hand washing	3	2	
		Use of clean utensils to handle RTE food	5		
		Use of clean utensils after changing food type	3	2	
		Dish cloth is used only to clean leaks or hold hot surfaces	5		
R1	2	Hand washing		2	
		Use of clean utensils to handle RTE food			2
		Use of clean utensils after changing food type			2
		Dish cloth is used only to clean leaks or hold hot surfaces			2
R2	1	Hand washing		1	
		Use of clean utensils to handle RTE food			1
		Use of clean utensils after changing food type			1
		Dish cloth is used only to clean leaks or hold hot surfaces	1		
R3	1	Hand washing	1		
		Use of clean utensils to handle RTE food		1	
		Use of clean utensils after changing food type	1		
		Dish cloth is used only to clean leaks or hold hot surfaces	1		
R4	1	Hand washing			1
		Use of clean utensils to handle RTE food			1
		Use of clean utensils after changing food type			1
		Dish cloth is used only to clean leaks or hold hot surfaces		1	
R5	7	Hand washing		7	
		Use of clean utensils to handle RTE food	7		
		Use of clean utensils after changing food type	4	3	
		Dish cloth is used only to clean leaks or hold hot surfaces	7		

Notes:
*: Total number of employees

Table 4. Microbiological performance of cutting boards

FSE	Preparation circumstances	C&D procedure during sampling	Microbiological results (log CFU/cm2)								
			Before starting			Before cleaning			After cleaning		
			Day 1	Day 2	Day 3	Day 1	Day 2	Day 3	Day 1	Day 2	Day 3
RH	Multipurposed	Dishwasher After each use	<1	<1	<1	4.50	2.88	<1	**3.39**	<1	<1
H1	Multipurposed	Hand-washed After each use	1.71	1.53	<1	3.71	3.54	1.56	**3.24**	**2.26**	<1
H2	For meat	Dishwasher Until end of shift	<1	<1	**4.43**	3.28	4.71	4.08	<1	<1	<1
H3	For salads & desserts	Dishwasher Until end of shift	<1	<1	1.88	<1	<1	3.65	<1	<1	1.05
H4	For salads & desserts	Hand-washed Until end of shift	**2.58**	**3.87**	<1	2.67	3.18	2.91	**2.12**	1.33	1.15
R1	Multipurposed	Dishwasher After each use	1.07	1.99	**2.82**	2.69	1.51	2.75	1.73	<1	1.13
R2	Multipurposed	Dishwasher After each use	<1	<1	<1	1.85	4.11	2.63	<1	1.72	<1
R3	Multipurposed	Dishwasher/dried with dishcloth Until end of shift	**4.03**	1.01	1.78	3.81	3.21	1.92	**3.51**	1.87	**2.77**
R4	Multipurposed Day 1 & 2: wooden type	Day 1 & 2: hand-washed Day 3: dishwasher After each use	**2.01**	**2.24**	1.16	4.15	2.96	3.91	**3.39**	**3.45**	<1
R5	For salads & desserts	Dishwasher Until end of shift	<1	1.97	<1	2.78	3.59	1.90	<1	<1	<1

Table 5. Microbiological performance of slicers

FSE	Preparation circumstances	C&D procedure during sampling	Microbiological results (log CFU/cm2)								
			Before starting			Before cleaning			After cleaning		
			Day 1	Day 2	Day 3	Day 1	Day 2	Day 3	Day 1	Day 2	Day 3
RH	All type food Used few times/shift	Mixture of soap & disinfectant After each use	<1	<1	<1	<1	<1	<1	<1	<1	<1
H1	All type food Used few times/shift	Only water After each use	<1	<1	<1	3.34	1.09	4.05	<1	<1	<1
H2	All type food Used during whole shift	Mixture of soap & disinfectant Until end of shift	**2.02**	1.35	**2.11**	2.05	2.27	2.63	<1	<1	<1
H3	All type food Used during whole shift	No disinfectant Until end of shift	**2.85**	**2.02**	**3.75**	2.53	2.62	2.93	<1	<1	1,29
H4	For ham & cheese Used few times/shift	No disinfectant Until end of shift	<1	<1	<1	<1	<1	1.25	<1	<1	<1
R1	For ham & cheese Used few times/shift	Mixture of soap & disinfectant Until end of shift	<1	1.01	<1	2.28	3.65	3.24	<1	1.42	1.27
R2	All type food Used few times/shift	Mixture of soap & disinfectant Day 1 & 2: no use of disinfectant Until end of shift	<1	<1	<1	<1	2.33	3.99	1.80	1.34	1,82
R3	For ham & cheese Used few times/shift	Scrubbing with wet dishcloth Until end of shift	**2.36**	1.08	<1	2.28	1.83	2.90	1.98	1.87	**2.39**
R5	For ham & cheese Used during whole shift	Complete Day 1: disinfected with chloride compounds Day 2: disinfected with alcohol Day 3: no use of disinfectant Until end of shift	**3.10**	**3.12**	<1	2.09	<1	1.65	<1	1.03	1.39

Table 6. Microbiological performance of hands

FSE	Hand-washing station	C&D procedure during sampling	Microbiological results (log CFU/cm2)					
			Before cleaning			After cleaning		
			Day 1	Day 2	Day 3	Day 1	Day 2	Day 3
RH	Complete	Complete	2.91	3.16	<1	<1	1.16	<1
H1	No disposable paper Not available position	Dried with dishcloth	3.63	<1	2.88	**2.23**	1.16	**2.18**
H2	Complete	Complete	<1	<1	<1	<1	<1	<1
H3	No disposable paper No soap	Day 1: Complete Day 2 & 3: dried with dishcloth	2.11	3.45	4.64	<1	1.78	1.15
H4	Disposable paper difficult to find No soap Not available position	Complete	<1	3.76	2.41	<1	1.16	1.55
R1	Complete No pedal/elbow activated	Complete	1.07	1.88	2.36	<1	<1	<1
R2	No disposable paper	Day 1: Complete Day 2: Dried with dishcloth Day 3: No use of soap	1.52	3.39	3.86	<1	1.82	**2.18**
R3	No disposable paper Soap difficult to find	Day 1: Complete Day 2 & 3: dried with dishcloth	3.19	1.94	3.98	<1	1.53	**3.51**
R4	Complete No pedal/elbow activated	Complete	3.24	2.79	4.41	<1	<1	1.72
R5	Disposable paper difficult to find Soap difficult to find	Day 1 & 2: complete Day 3: Dried with dishcloth	1.86	3.43	1.02	<1	2.00	1.86

CAPITULO 6

Recomendaciones para mejorar el rendimiento de los sistemas de gestión de seguridad alimentaria en establecimientos de restauración

De acuerdo a los resultados descritos anteriormente, las recomendaciones para mejorar el rendimiento de los sistemas de gestión de seguridad alimentaria incluyen mejoras en el diseño higiénico del equipo e instalaciones, en el programa de limpieza y desinfección, en el rendimiento de los empleados, en el control de la materia prima, en los procesos de conservación, descongelado y mantenimiento en caliente, en los procesos de intervención (los cuales conllevan cocción), en el sistema de monitoreo y en las actividades de aseguramiento (establecimiento de requerimientos externos, uso de información de los reportes de validación y verificación, validación, verificación y documentación). Todas las recomendaciones sugeridas requieren del compromiso gerencial, porque si la administración del establecimiento no está dispuesta a invertir los recursos necesarios (incluyendo dinero y tiempo) no hay posibilidad de mejorar el sistema de gestión de seguridad alimentaria.

Las recomendaciones sugeridas implican cinco acciones principales: inversión monetaria, programas de formación, asesoramiento externo que incluya análisis microbiológico, tareas de documentación, y planificación de actividades. La inversión monetaria es necesaria para mejorar la capacidad y las características del equipo e instalaciones, para proporcionar las instalaciones adecuadas que apoyen las buenas prácticas higiénicas (como estaciones de lavado de manos completas, basureros accionados por pedal, ropa adecuada y disponibilidad de utensilios limpios), y para contratar servicios externos que asesoren en el diseño del sistema y en su validación y verificación.

Las actividades que requieren programas de formación debido a su directa relación con el comportamiento del personal son los programas de limpieza y desinfección, el control de materia prima, los métodos de intervención, las técnicas de conservación, los métodos de descongelado, los programas de mantenimiento de equipo, y el sistema de mantenimiento de registros. Dichos programas de formación deben desarrollarse en base a las competencias del personal implicado y con la participación de los empleados

para que las medidas desarrolladas sean más simples de aplicar, y deben realizarse con suficiente frecuencia para que el personal siempre cumpla con los procedimientos y prácticas establecidas. Como la mayoría de establecimientos son pequeños, se sugiere la posibilidad que dichos cursos se den a través de la Asociación de Empresarios de la Hostelería.

El asesoramiento externo, los análisis microbiológicos y la documentación son necesarios para validar y verificar las actividades que requieran conocimiento técnico o estén relacionadas con la prevención o reducción de contaminación microbiológica para que el sistema sea fiable. Entre dichas actividades se encuentran el programa de limpieza y desinfección, el control de materia prima, las técnicas de conservación, los métodos de descongelado, el programa de mantenimiento de equipo, los métodos de intervención, el análisis de peligros y puntos de control críticos (APPCC), el establecimiento de estándares, el programa de calibración, el diseño de muestreo, las acciones correctivas, el rendimiento higiénico de equipo e instalaciones, la implementación de requerimientos externos, la documentación y el mantenimiento de registros.

La planificación de tareas es necesaria para disminuir el efecto negativo de la presión de tiempo durante la preparación. Por ejemplo, la entrada de materia prima y la preparación de alimentos con antelación se pueden realizar a horas que no sean las mismas para el servicio a clientes y así dejar tiempo suficiente para realizar la preparación higiénicamente (lavando manos y superficies de contacto al cambiar de tipo de alimento).

Los aspectos importantes que se deben considerar a la hora de diseñar el sistema de gestión de seguridad alimentaria son que todas las actividades deben estar validadas, verificadas, documentadas y basadas científicamente para hacer que el sistema sea fiable; que debe desarrollarse de acuerdo al contexto del establecimiento para hacerlo flexible; y que debe formularse de manera que corresponda con la competencia de los empleados para que su operación sea simple. Por ejemplo, si el establecimiento debe preparar platos sin cocción como ensaladas, entonces el método de intervención usado para lavar y desinfectar la materia prima debe chequearse con respecto a su efectividad para reducir la carga microbiana, o si el establecimiento debe preparar alimentos con antelación entonces las técnicas de conservación deben desarrollarse en base a datos y

guías científicas y probadas para evaluar si los platos son microbiológicamente seguros durante la vida útil que se le asigne y en las condiciones de almacenamiento óptimas. Del mismo modo, la flexibilidad puede aplicarse por ejemplo con el uso de tablas de cortar. De manera que un establecimiento puede tener varias tablas de cortar diferenciadas por color para cada tipo de alimento o una sola tabla que se limpia después de cada uso. Otro ejemplo de flexibilidad es el incremento de frecuencia de procedimientos de limpieza de equipos si éstos no están diseñados higiénicamente. Con respecto a la simplicidad, el uso de análisis sensoriales, si éstos están debidamente validados, en lugar de la medición de la temperatura interna de cada plato, simplifica la operación de las actividades de intervención. Asimismo, los procedimientos se pueden escribir en concordancia con la competencia de los empleados para que se facilite su comprensión y subsiguiente cumplimiento.

CHAPTER 6

Recommendations to improve the performance of Food Safety Management Systems of Food Service Establishments

1. Introduction

In view of the results obtained in the study, the main weak points of the FSMS implemented in food service establishments are described as follows:

The context wherein FSE must implement their FSMS is vulnerable, ambiguous and uncertain and may facilitate cross contamination from contact surfaces, raw material and employees if the core control and assurance activities are performed at low or basic levels.

The weak points found in the FSMS (due to low or basic performance) were the following: deficiencies in the hygienic design of equipment and facilities; incomplete sanitation programs; use of processes (including preservation, defrosting, intervention, hot-holding, reheating) established by experience or in some cases by expert knowledge but not validated with reliable tests; deficient control of raw material; lack of calibration procedures; lack of corrective actions; no information about the actual performance of the intervention equipment, the hot holding facilities, the measuring equipment and the hygienic performance of equipment and facilities; lack of setting of external requirements; lack of validation and verification activities; and deficiencies of documentation and record-keeping.

The process to set recommendations for improvement is to suggest some measures to strengthen those core control activities that were performed at low or basic levels in view of the vulnerability, uncertainty and ambiguity of the contextual situation, and other measures to increase the level of performance of core assurance activities to make the FSMS more reliable. All the recommendations require management commitment because, unless management is willing to invest resources (including money and time), there is no chance to improve the FSMS.

2. Recommendations to improve the performance of Food Safety Management Systems of Food Service Establishments

2.1 Recommendations to strengthen core control activities

Preventive measures

Hygienic design of equipment and facilities

Results from Chapter 3 showed that 21 of 50 FSE had deficiencies in the hygienic design of their equipment and facilities starting with the fact that the kitchens were undersized and not designed in accordance with the actual or potential capacity of the establishment creating conditions for cross contamination due to crossings and returns between raw material, semi-elaborated food, ready-to-eat food and trash. Other un-hygienic features observed were lack of maintenance, spaces where external contamination (pests, dust, etc) may enter into the kitchen, few space between walls and floor or equipment difficult to clean that may interfere with the cleaning and disinfection procedure.

The first step to design a hygienic kitchen is to know the capacity in which the establishment will work. For example, if the establishment offers a wide assortment of meals in the menu and it includes cooked and fresh-type meals, then the kitchen and storage rooms must have a different space for each type of food and preparation process to avoid cross contamination. Furthermore, there are guidelines and legislation that establishes the requirements of design and layout of equipment and facilities in food service establishments such as EC 852/2004 that could be used as a minimum starting point. The selection of equipment and facilities could be based according to suppliers because they may have an updated knowledge of new equipment with better features.

After the kitchen is designed, the easiness of cleaning and hygienic performance must be tested with reliable tests such as microbiological analyses to assure that the design is in accordance with the capacity and activities that are actually done in the kitchen. Another important aspect to consider after designing the kitchen is the maintenance program that should be planned in collaboration with suppliers and taking into account the microbiological performance results in order to determine a valid frequency of inspection to assess the hygienic performance. Considering that the maintenance of

equipment depends on how employees use them, another recommendation is to train people on how to use each equipment and to inform if they find characteristics that may show deficiencies of an adequate performance. For example, employees could be trained to have adequate criteria on when a cutting board should be replaced (due to excessive indentations where bacteria and soil may accumulate).

Sanitation program

The sanitation program has a direct link with the hygienic level of equipment and facilities because if these are not hygienically designed then the sanitation program must be stricter (more frequency or more specific and potent cleaning agents) to counteract these hygiene deficiencies and assure its cleanliness. The similarities of microbiological results of single-purposed cutting boards that are cleaned after changing food type and multi-purposed cutting boards cleaned until the end of the shift (Chapter 5) showed the effect of the relationship between hygienic design and sanitation program.

The design of the sanitation program should answer the questions of what to clean, how to clean, when to clean and who cleans. The what to clean and how to clean may be answered with the support of specialised cleaning suppliers because they have updated knowledge about new cleaning agents and about the conditions that each cleaning agent requires to be effective. The frequency of cleaning and disinfection depends on frequency of use, type of food, status of equipment, type of contamination, verification records and analyses (Rodríguez et al., 2003). The results of Chapter 5 also showed that the effectiveness of the cleaning and disinfection procedure depends on the preparation circumstances (type of surface, if the contact surface is used during the whole shift for only one type of food or for different types of food, or if it is used only a few times in the shift), so it is recommended to design a sanitation program according to those specific circumstances. The performance of the sanitation program for each equipment and facility should also be tested with reliable microbiological analyses to critically specify the frequency of cleaning and to assure that the cleaning and disinfection procedure is effective to reduce the microbial load that the establishment commonly handles. The question of who cleans requires the development of clear written cleaning instructions or procedures that can be used to instruct and guide the employees through each step of the cleaning process.

In order to facilitate the cleaning tasks, color-coding could be of use to distinguish between food contact and non-food contact chemicals or to differentiate between utensils used to clean contact surfaces that handle only ready-to-eat food, utensils used to clean contact surfaces that handle potentially hazardous food, and utensils used to clean non-food areas such as drains. These recommendations were also stated by other authors (Doucette, 1999; Hernández, 2000)

The results of Chapter 5 highlighted the importance of a disinfection step in the cleaning and disinfection procedure because the bacterial counts were below limits if the cutting boards and slicers were disinfected with hot water (>80ºC) from the dishwasher or by solutions containing chloride compounds. In the case of surfaces that must be continuously cleaned (for example cutting boards), the cleaning and disinfection procedure can be done by scrubbing with paper or one-use dishcloth and a detergent-disinfectant solution, then spraying water and drying with paper or one-use dishcloth as stated by Montes and co-authors (2005).

It is worth to mention that the sanitation program is a vital activity of the FSMS that requires the involvement of all employees who work in the kitchen because everyone should be aware of the importance of using only clean utensils and surfaces when they handle food, especially with ready-to-eat foods. It was seen in Chapter 5, that there are FSE where employees do not use clean utensils when they change food type or when they handle ready-to-eat food because they did not clean it or because they only cleaned it with a wet dishcloth or rinsing with water. These results demonstrate that the sanitation program not only depends on the person specifically in charge of cleaning tasks but on the cooks who use the utensils, equipment and facilities. Hernández (2000) suggested that motivating and rewarding employees is important because their enthusiasm and involvement will make them part of the process and result in greater efficiency and cleanliness.

Employees´ performance

Results of previous chapters highlighted that employees of some FSE did not have procedures or did not comply with them, behaving then un-hygienically. It has been described that employees´ performance is the result of an appropriate decision-making, which also depends on various factors such as knowledge, observed standards of

colleagues and boss, facilities and means, availability of time, support of colleagues, supervisor and company, accountability, involvement, motivation etc. (Gerats, 1990; Montes et al., 2005; Pragle, et al., 2007; Luning & Marcelis, 2009). The organisation characteristics of a company/establishment (organisational relationships, available information, procedures, communication systems, training programs) are the way in which all of these individual factors can be controlled in order to make homogenous and predictable decisions toward food safety (Luning & Marcelis, 2006, 2007). Therefore, it is proposed that employees´ performance can improve if the organisation characteristics support adequate and homogenous decision-making (Luning et al., submitted 2009b, submitted 2009c).

As a first step to direct employees´ behaviour, management should develop suitable procedures involving the people who will execute the tasks described in those procedures because various studies have found that employee´ involvement helps the performance of tasks (Hancer & George, 2003; Taylor & Kane, 2005; Cenci-Goga; 2005). Another important aspect to consider at the time of writing down procedures is to do it in accordance to the competence of employees because that facilitates its comprehension and further compliance.

Writing down procedures is not enough to control employees´ decisions unless these are consciously understood and adhered by management and employees on a daily basis. This requires training, which should be tailored to the specific knowledge of employees and actual conditions of the establishment. For instance, Bush and co-authors (2009) demonstrated if the owner/manager of the establishment attended a previous workshop with other owners/managers of small restaurants to have a demonstration of how to train their employees with simple and easy-to-use material increased the compliance to hygienic practices. Similarly, Montes and co-authors (2005) described that an effective training program should transmit the right knowledge, motivation and values. Some recommendations to achieve this objective are to use practical examples to facilitate comprehension and to explain the impact of their actions to the safety of the meals because then employees could perceive the importance of their behaviour to the health of the customers. Furthermore, Swanger & Rutherford (2004) suggested some basic tips to increase effectiveness of training programs that included: participation of employees to make it more interactive, relevancy of the topics to what employees actually do, incentives and rewards to encourage employees to do what is right, assessment of

employee knowledge of food safety and sanitation, leading by example to provide the model for what is expected, and holding meetings to remind about food safety and sanitation.

Cohen & co-authors (2001) found that the implementation of a training program focusing on sanitation significantly improved microbiological food quality. It has also been outlined that training and certification of managers, and appropriate training of food workers are important to assure that safe food handling practices are consistently followed (Jones & Angulo, 2006). Some aspects that need to be considered in a training program are to maintain food under safe temperatures to avoid overgrowth of microorganisms and maintain contact surfaces clean and dry. Another recommendation toward training topics is to show, with visual examples of microbiological tests done in the same kitchen, the effect of the not performing hygienic practices correctly.

An important step to control employees´ performance is to verify actual people performance through observation and immediate correction until old habits are changed for the new ones. One practical way to do this is through the chief cook who must have the ability to continuously train good handling practices until all the employees show that they have internalised a safe behaviour.

The goal of training programs is to have a team with self-commitment to behave hygienically. During the interviews done when the modified FSMS-DI was applied, several interviewees explained that a first filter to have a team committed to food safety is to hire people who have previous experience in other companies/establishments with renowned standards and hygiene and who have personal hygiene (clean clothes, well kept, etc) as described by Swanger & Rutherford (2004). But then, the training program was done on ad-hoc basis or not done, so it is recommended to start a training program to deal with the deficiencies of knowledge that the new hired person have, to deal with the un-hygienic behaviour observed during verification of employees performance, and after changes in the FSMS (new recipes, new equipment, new stakeholders´ requirements).

Besides training, the knowledge of good hygienic practices can be strengthened with visual posters reminding core hygienic practices such as hand-washing (Montes et al., 2005). Swanger & Rutherford (2004) also recommended printing a handout or including

it in the employees' manual that defines the policies and procedures regarding to food safety and sanitation.

Motivation depends on many aspects such as way of management, policy of incentives or bonus for employees, possibility of professional development, and work environment. In other words, management should provide all the means to achieve a positive psychological predisposition to behave hygienically (Montes et al., 2005). Results from Chapter 5 also showed that providing the means increases the compliance to hygienic practices.

The information systems must show all the required data to help on the right decision-making. Some simple measures to guide employees are for example posters pasted on the walls or available position showing the time-temperature conditions for each type of meal or the concentration of the solution used to disinfect fresh produce.

Due to the influence of time pressure toward actual hygienic practices (Howes et al, 1996; Taylor, 1996; Angelillo et al, 2000; Wordsfold, 2001; Clayton et al, 2002; Jones et al., 2008), it is recommended to organise and plan tasks in accordance to the actual capacity and operation of the establishment. For instance, the reception of raw materials and the preparation in advance can be done during hours that are not spent for service. This also requires planning the cleaning activities adequately with the aim of giving cooks clean utensils and surfaces during the service hours.

Control of raw material

Results from Chapter 3 and 4 showed that majority of FSE are not able to influence on the FSMS of their suppliers (due to various reasons like the fact that their suppliers are also small sized companies). This requires having stricter control of incoming raw materials to assure that their processes are able to reduce initial microbiological load. However, Chapter 3 and 4 also described that the control of raw material is actually performed at basic levels because majority of FSE check their raw material on ad-hoc basis through sensorial analyses established by experience. The lack of knowledge of actual microbial load in their supplies and the real effectiveness of their processes to reduce this initial load could result in safety problems. And indeed, some FSE showed low microbiological performance of some of their meals (specially fresh-type meals) (Chapter 4). Therefore, it is recommended to discuss stricter specifications with

suppliers or at least check that the supplier has a sanitary authorisation for the establishment and is registered in the General Sanitary Food Register and ask for a document accrediting that the refrigerated transport has been examined; to sample incoming materials by external laboratories; and to store them adequately (correct temperature, covered, adequate position) to avoid cross contamination or overgrowth of microorganisms and pathogens.

Considering the importance of checking raw material before it enters the kitchen, it is recommended to have a trained person in charge of the control of raw material or to write down a procedure and train all the employees who will check the compliance to specifications, which should be developed in collaboration with suppliers. This procedure must include what to check, how to check and what to do in case of non-compliance. Some aspects that need to be checked are condition, label, sanitary record, temperature, cleanliness of transport and delivery employees. The criteria to accept or reject an incoming material depends on each establishment but in general the aspects that may lead to reject a raw material are alteration or deficiencies of food safety or package such as dirty or broken eggs, soiled brown dry or rusted vegetables and fruits, fish and seafood with signs of un-freshness (matt aspect, brown guts, loosed flakes, sunken eyes, whitened pupils, flaccid consistency), slimy meat with superficial contamination, oxidized convex or bruised cans, vacuum packaged food with broken package, moldy food, frozen food with white areas, big ice crystals or defrosted, food with nearby expiration dates, food with temperatures above limits.

Some ways to simplify control is to organise suppliers to deliver raw material at hours when the kitchen activities are not overcrowded, increase frequency of control of new suppliers and reduce frequency on those suppliers that have demonstrated good results, focus on those raw materials that are potentially hazardous that will not have an intervention step (sushi, undercooked meat, fresh salads), and write down a check, temperature and name of the person who received the incoming material at the back of the delivery note.

Meal preservation, Defrosting, Hot holding

Results from previous chapters showed deficiencies in the specific preventive measures of meal preservation, defrosting and hot holding. For instance the majority of FSE have designed their meal preservation methods on experience without doing microbiological tests to assure that the chilling process, storage conditions, time of storage and reheating process are effective to maintain safety of the meals that are prepared on advance. This has more impact over meals that are preserved and served without any further intervention step. Moreover the actual capacity of the hot holding facilities was unknown because almost none of the FSE measured core temperatures or calibrated the measuring devices, even some FSE hot held their meals in the same pot where it was prepared. And some FSE defrosted food at room temperature creating conditions for overgrowth of microorganisms or pathogens.

There are various guidelines that recommend some limits to perform meal preservation techniques, defrosting and hot holding at safe conditions that could be used as a basis to establish own limits and process parameters. For instance, chilling process can be done with blast chillers, adding ice as a final ingredient, placing hot containers in ice baths and stirring, separating into smaller portions (food must go from 60ºC to 21ºC in 2 hours maximum and from 60ºC to 5ºC in 6 hours); storage conditions should consider position of raw foods below ready-to-eat foods leaving space between containers to allow air to circulate, cover, identification with expiration date, and systems “First In First Out (FIFO); frozen items must be kept at -18ºC and some foods cannot be frozen (hard boiled eggs, fat meat, sauces with starch, mayonnaise); if defrosting is done overnight it should be done at maximum temperature of 7ºC if the defrosted food will be cooked or maximum 4ºC if it will not be cooked, use of microwave oven or submersion under cool (<21ºC) running water; hot holding at temperatures higher than 63ºC with Bain Marie containers. However each FSE has its own context characteristics so the next step is to test with reliable tests such as microbiological analyses to check that the limits and parameters they use to perform these activities are actually safe.

Other important aspect to consider is that the equipment and facilities used to execute these activities should be adequately maintained, and that the measuring devices to check the compliance to process parameters should be adequately calibrated.

Intervention process

The intervention process in FSE include processes where heat is applied with certain time and temperature combinations using several intervention equipment such as ovens, stoves, microwave ovens, fryers, grillers, pans, bain Marie devices; and processes where the raw material is only cleaned, cut and served (fresh-type salads). Results from previous chapters showed that the intervention processes requiring intervention equipment in some FSE was established by experience and using sensorial parameters to check its effectiveness (change of colour or texture) and not measuring core temperature of food. Since the initial microbial load of raw material is not checked, then the actual effectiveness of these processes is unknown. In the case of intervention methods that do not require intervention equipment (cleaning of fresh produce), results also showed that these processes were established by experience, sometimes following some limits according to guidelines or suppliers, but not tested to check actual effectiveness to reduce initial microbial load. Furthermore, results of Chapter 4 showed that majority of fresh-type meals were above legislation limits underpinning the risk of performing this activity at low or basic level.

A first step to improve the intervention processes done with intervention equipment is to measure actual core temperature of meals to check if they reach safe temperatures (72ºC for 15 seconds or 65ºC for reheating). Some equipment has measuring devices (ovens), while other equipment (stoves, fryers, grillers, pans) would require the use of an external thermometer. In either case, the oven measuring devices or the thermometers should be adequately calibrated. This calibration can be done by immersing the thermometer and a control thermometer in hot and cold water to check that both are at approximate temperatures of 100ºC and 0ºC respectively. A further step would require executing microbiological tests to assure that the process is effective to reduce initial microbial load to safe limits. Since these processes require equipment, it is also necessary to include this equipment in the maintenance program.

The improvement of the intervention processes done without intervention equipment (cleaning of fresh produce) require as a starting point the use of limits or parameters given by legislation or guidelines. For example, rinse under running potable cold water, or soak, rinse with cold potable water, dry and store in a different container, use of a chloride solution with a concentration of 70 ppm. As for the intervention processes

requiring intervention equipment, these processes also require microbiological tests to assure that initial microbial load is actually reduced.

Monitoring system

Results from Chapter 3 and 4 showed that the monitoring system is the activity where most of FSE performed at low or basic levels. For instance, 34 of 50 FSE did not have CCP and none performed calibration activities and have not described corrective actions. The low performance of these activities may be explained by the contextual situation of the FSE because the product and process characteristics may hinder monitoring activities that are time consuming or because the organisation is not supportive to perform monitoring activities (lack of technological staff, lack of management commitment, and deficiency of operator competence). Other limitation for an advanced performance of monitoring activities is the use of less sophisticated equipment that do not have measuring devices assigning the control of parameters to visual inspection.

The improvement of the monitoring system requires the assignment of CCP with simple limits and clear corrective actions in collaboration with experts in HACCP & catering situations and involving employees who will execute the monitoring activities. This should be done based on HACCP principles and according to specific product and process characteristics. Critical limits can be sensory evaluated (if adequately validated) or replaced by good hygienic practices and pre-requisite programs. The monitoring of the CCP should be recorded every day by the chief cook.

2.2 Recommendations to improve core assurance activities

The application of the FSMS-DI to the sample of 50 FSE (Chapter 3) showed that majority of them perform core assurance activities at low or basic levels (specially the ones related to validation, verification and documentation activities). This data is also the result of the context situation (less supportive organisation). On first instance, it is necessary to increase the management commitment and change the organisation characteristics by hiring external experts to have scientific and independent advice to design a more predictable and controllable FSMS and to verify it, by doing microbiological tests (on own or external laboratory), measuring core temperatures and using scientific information to validate the preventive and intervention activities, by

writing down procedures, tasks and records to formalise the organisation and facilitate the process of decision-making and verification activities, by doing tailored training programs, and by acquiring a proactive attitude to accomplish stakeholders requirements and change the FSMS according to validation and verification activities.

3. Conclusion

In summary, FSE indeed face difficulties with the implementation of their FSMS. Therefore, it is necessary to detect the core control and assurance activities that are performed at low or basic levels in view of their specific contextual situations.

The application of the modified FSMS-DI, the microbiological tests done on final meals, contact surfaces, and the observation of some hygienic practices enabled the identification of weak points of the food safety management systems in view of the context wherein food service establishments must implement them. Some proposed recommendations to strengthen those core control and assurance activities performed at low or basic levels included measures to improve the design of equipment and facilities, the sanitation program, the employees´ performance, the control of raw material, the specific preventive measures (meal preservation, defrosting, hot holding), intervention process, monitoring system, setting of system requirements, validation, verification and documentation.

This study can be a starting point to focus on those core control and assurance activities in light of the typical context of FSE with tools to improve its performance. For example, the microbial assessment scheme developed by Jacxsens and co-authors (2009) can be applied in more susceptible preparation lines (e.g. fresh-type meals) to detect the conditions for a low microbiological performance and then direct improvement suggestions on the weak points.

A further research would require the implementation of the recommendations described above and check if the microbiological performance improves, and create guidelines with reliable measures to assure that the activities addressed in the FSMS are able to control microbiological contamination, flexible to adapt them to the specific technological context of the FSE, and simple to apply them according to the specific managerial context of the FSE.

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CONCLUSIONES GENERALES

1. Los datos estadísticos siguen mostrando al sector de la restauración como uno de los eslabones más vulnerables a la hora de mantener la seguridad alimentaria. Este hecho se debe en gran medida a las dificultades prácticas en la aplicación de los sistemas de autocontrol de manera efectiva. Se propone que para aumentar la efectividad de los mismos estos tienen que basarse en los principios de fiabilidad, flexibilidad y simplicidad.

2. Se ha modificado el instrumento de diagnóstico FSMS-DI al sector de la restauración para obtener una herramienta capaz de evaluar el funcionamiento real de los sistemas de gestión de la seguridad alimentaria (FSMS) en los establecimientos de restauración, independientemente de los estándares o guías de calidad empleados y considerando el contexto en el que debe operar éste sector.

3. La aplicación del FSMS-DI modificado para el sector de la restauración se ha mostrado como una herramienta eficaz para evaluar el funcionamiento real de los diferentes FSMS en los establecimientos de restauración, permitiendo discriminar entre diferentes “clusters”, lo que permite actuar de manera selectiva en los diferentes establecimientos en función de las deficiencias encontradas en cada uno de ellos. Esta herramienta puede ser empleada tanto por los propios restauradores, como por empresas de consultaría o por los propios servicios de inspección de alimentos, para conocer el funcionamiento real de los sistemas de autocontrol empleados.

4. La validez del FSMS-DI modificado como herramienta de evaluación de los sistemas de gestión de la seguridad alimentaria se ve corroborada con la evaluación del nivel de contaminación microbiológica en diferentes platos elaborados en los distintos establecimientos de restauración estudiados.

5. El uso combinado del FSMS-DI modificado, el análisis microbiológico en determinadas superficies de contacto, así como la observación del comportamiento del personal de cocina, permiten elaborar soluciones a medida para mejorar la seguridad alimentaria en los restaurantes analizados.

6. En función de los resultados obtenidos en este estudio se proponen una serie de medidas concretas para mejorar la seguridad alimentaria de los establecimientos de restauración.

GENERAL CONCLUSIONS

1. Surveillance data shows that the sector of food service establishments is the most vulnerable part of the food chain to assure food safety. This fact is mainly explained by the practical difficulties of application of current quality-assurance standards/guidelines at the time of implementing a food safety management system. It is proposed that food safety management systems (FSMS) of food service establishments should be reliable, flexible and simple to improve their performance.

2. The Food Safety Management System-Diagnostic Instrument (FSMS-DI) was modified for food service establishments to obtain a tool to assess actual performance of FSMS independently of the QA standard/guideline used to design the FSMS and considering the context wherein FSE must implement it.

3. The application of the modified FSMS-DI showed that it is a useful tool to assess actual performance of FSMS of FSE and to distinguish clusters of FSE that require different strategies of improvement in view of their weak points and context. This tool can be used by food service establishments, consultancy companies and public health inspectors to get insight of actual performance of FSMS.

4. The usefulness of the modified FSMS-DI was supported by microbiological analyses of meals because actual microbiological performance was in accordance with the results obtained from the application of the modified FSMS-DI.

5. The application of the modified FSMS-DI along with microbiological analyses of meals and contact surfaces, and observation of actual hygienic practices enabled the suggestion of tailored recommendations to improve food safety in the analysed food service establishments.

6. The results obtained with the study allowed the proposal of several recommendations to improve food safety in food service establishments.

APPENDIX

1. Food Safety Management System-Diagnostic Instrument (FSMS-DI) modified for Food Service Establishments (FSE) adapted from Luning & co-authors (2008, 2009a, submitted 2009b, submitted 2009c).

A. Assessment of product characteristics

1 In which situation would you place the **risk of your raw materials** in your establishment?

Situation **……**
Comments
……
……
……

Assumption: Raw materials associated with pathogens and/or high initial microbial levels with potential impact on final safety and which require special storage conditions, increase chance on lower FS performance and put higher demands on the FSMS by requiring advanced control and assurance activities.		
Situation 1	**Situation 2**	**Situation 3**
• Basic/major raw materials are <u>not</u> associated with high initial microbial levels and pathogens • Storage at (uncontrolled) room temperature conditions	• Minor raw materials/ingredients associated with high initial microbial levels and pathogens, which potentially can affect safety of final product. • Storage at lower than room temperature but no specific, strict control requirements	• Basic/major raw materials associated with high initial microbial levels and pathogens, which potentially can affect safety of final product • High requirements on storage conditions and its control

Supporting information to differentiate situation 2 and 3

- When your raw materials are associated with high initial microbial levels and or pathogens, and when they should be stored below room temperature, then it is level 2 or 3.
- Crucial for level 3 is that high requirements on storage are crucial for prevention of undesired growth of micro-organism (including pathogens).
- Examples of raw materials with different risks:
  Situation 1 products: flour, UHT and sterilized products
  Situation 2: fruits and vegetables
  Situation 3: raw meat, herbs and pasteurized milk

2 In which situation would you place the **risk of the meals** in your establishment?

Situation **……**
Comments **……**
……

Assumption: Meals which are susceptible to pathogen growth or toxin formation (due to the intrinsic product properties and or applied inactivation technique), increase chance on lower FS performance, and put higher demands on FSMS by requiring advanced control and assurance activities		
Situation 1	**Situation 2**	**Situation 3**
• Low risk meals (microbiologically stable) (a_w < 0.6 or pH < 4.2 or intrinsic antimicrobial agents) • inactivation complete flora, post contamination not likely. • Served as bought, no handling before service	• Medium risk meals (0.98 >a_w > 0.6, or 4.2< pH <6.5, no antimicrobials) • post contamination not likely. • (cooked/reheated–served meals)	• High risk meals (aw > 0.98, pH 6.5-7.5, or no antimicrobials), • and fresh (no inactivation of original flora and chance on post contamination). • (fresh-type meals, hot-held meals)

Supporting information to differentiate situation 2 and 3

- When your final products (groups) have a water activity a_w > 0.6 and or a pH>4.2, and or intrinsic antimicrobials, then it is situation 2 or 3.
- Crucial for situation 3 is that your final products have a very high water activity (a_w > 0.98) and or a pH>6.5, and or are sensitive to post contamination (not in-pack pasteurised)
- Examples of final products with different risk levels:
  Situation 1: dried products, canned food, sweets
  Situation 2: cheese, cooked meat, fermented sauces
  Situation 3; fresh meat, milk, fruit, RTE

B. Assessment of production process characteristics

3 In which situation would you place the **extent of intervention steps** in your establishment?

Situation **……**
Comments **……..**
……

Assumption: Increasing number of critical process steps that are required to achieve the intervention (i.e. inactivation/reduction hazard) increase chance on lower FS performance and will put higher demands on FSMS by requiring advanced control and assurance activities		
Situation 1	**Situation 2**	**Situation 3**
• Process with *one* lethal step and a few critical control points • No further steps that may contaminate (cooked & served)	• Process with *several* steps to *inactivate* pathogens to acceptable level (spores not inactivated) • Further steps may recontaminate and thus require control to prevent growth to unacceptable levels (cooked-chilled/frozen-reheated/served, hot-held)	• Process where *combination* of steps reduce or minimise pathogens to certain level (spores not inactivated, pathogens not fully inactivated) • (washed/assembled-served)

Supporting information to differentiate situation 2 and 3

- When your production is characterised by more critical process steps necessary to reduce pathogens whereby spores are not inactivated, then situation 2 or 3.
- Crucial for situation 3, is that each individual critical process step does not fully inactivate pathogens.

4 In which situation would you place **the meal production process** in your establishment?

Situation **……**
Comments **……..**
……

Assumption: Higher number of recipes prepared on the same preparation shift, more cleaning and disinfection interventions, less differentiated preparation areas increase chance on cross contamination (resulting in lower FS performance), and put higher demands on FSMS by requiring advanced control and assurance activities		
Situation 1	**Situation 2**	**Situation 3**
The meal production process is characterised by low number of recipes to be prepared on the preparation shift allowing the use of the equipment and surfaces for only one type of food restraining chances of cross contamination (hall of residence with a single day meal)	The meal production process is characterised by medium number of recipes to be prepared on the preparation shift allowing enough time to clean the equipment, surfaces and utensils before changing to another type of food. (restricted number of day menu meals or organisation of production to have enough time during service)	The meal production process is characterised by a high number of recipes to be prepared on the preparation shift facilitating the conditions for cross contamination since there is not enough time to clean and adjust the equipment and surfaces for the other type of food. (menu “a la carte” with more than 30 different items)

Supporting information to differentiate situation 2 and 3

- When you have to prepare different food types in the same surface or equipment, then situation 2 or 3.
- Crucial for situation 3 is menu “a la carte” with more than 30 different items that makes employees to have few time (especially at rush hours) to clean between food type.

5 In which situation would you place **rate of menu changes** of your establishment?

Situation **……**
Comments **……..**
……

Assumption: Higher rate of changes in menu design (i.e. product, process modifications), can negatively affect FS performance by operation according to 'old' habits, and put higher demands on FSMS by requiring advanced control and assurance activities		
Situation 1	**Situation 2**	**Situation 3**
• Relatively stable menu assortment. • No menu modifications or changes every year.	• Medium variable menu assortment. • Menu modifications every season (3-4 months) or more than once in a year	• Highly variable menu assortment. • Menu modifications within seasons

Supporting information to differentiate situation 2 and 3

- When no product or process modifications or changes more than once in a year, then it is situation 2 or 3.
- Crucial for situation 3 is changes within seasons.

C. Assessment of organisation characteristics

6 In which situation would you place your company with regards to **technological staff**?

Situation ……
Comments ……..
……

Assumptions: Establishments with restricted (no) technological staff, expertise, and laboratory facilities will be less able to take adequate decisions in FSMS, which may negatively affects FS, thereby putting demands on FSMS by requiring advanced control and assurance activities (e.g. hiring right expertise, tailored procedures, motivation people, operator control)		
Situation 1	**Situation 2**	**Situation 3**
• Establishmet with a significant QA department with • own staff and experts in food safety areas (e.g. food microbiologists, food quality management expert, etc) • Own research lab for all microbial analyses, safety controls.	• Establishment which has a QA team (or small department) • with restricted number of people with expertise in food safety; collaboration with external experts (e.g. University) • Research facilities for routine analyses, complex analyses at external labs.	• Establishment with only one (or no distinct) QA manager which has more than only QA tasks, • no specific food safety expertise, expertise is hired from outside (e.g. HACCP consultant) • Microbial analyses, safety controls at external labs

Criteria

- When there is no QA department with own staff and experts and an own research lab for all microbial analyses and safety controls, then it is situation 2 or 3.
- Crucial for situation 3 is that there is only one person responsible for food safety, while this is not his/her main task.

7 In which situation would you place the **variability of workforce composition** in your establishment?

Situation ……
Comments ……..
……

Assumption: Variability in workforce composition due to part-time workers and high personnel turnover may result in loss of company specific experience, which can increase chance on poor execution of safety tasks, which negatively influences FS putting demands on FSMS by requiring advanced control and assurance activities (e.g. robust procedures, more operator control)		
Situation 1	**Situation 2**	**Situation 3**
• Low turnover of employees (> 5 years) • Occasionally temporary operators	• Common turnover of employees in food industry (1-5 years) • Temporary operators at specific seasons	• High turnover of employees (< 1 year) • Temporary operators at whole year around

Supporting information to differentiate situation 2 and 3

- When employees typically leave your company within 5 years or when structurally temporary operators are hired, then situation 2 or 3.
- Crucial for situation 3 is a rather high turnover of employees (< 1 year) and temporary operators at whole year around.

8 In which situation would you place **operator competences** in your establishment?

Situation ……
Comments ……..
……

Assumptions Recruited operators with inadequate education level, lack of experience, and restricted training support, increase chance on poor execution safety tasks, which negatively affects FS putting demands on FSMS by requiring advanced control and assurance activities (e.g. robust procedures, understandable for specific worker, different languages, more operator control)		
Situation 1	**Situation 2**	**Situation 3**
• High and specific requirements on competence level of operators: medium/ professional education level in cuisine • Broad experience in food service establishments (minimal 3 years) • Specific requirements on language skills • Specific FS and FSMS training on regular basis	• Minimal requirements on competence level of operators; low professional education level not necessarily in cuisine • Some experience in food service establishments (minimal 1 year) • No specific requirements on language skills, ability to speak current language • Basic food safety training at start then ad-hoc follow up training	• No specific requirements on competence level of operators • No specific requirements on experience • No requirements on language skills. • Basic training (instructions) in food safety control at start but no follow up training

Supporting information to differentiate situation 2 and 3

- When people in your production typically have a low level of education, and or less than 1 year experience in cuisine, and when restricted training then situation 2 or 3.
- Crucial for situation 3 is *not any requirements* on basic education level or experience and only a basic training (or instructions) in food safety control *without any follow up*.

9 In which situation would you place **management commitment** in your establishment?

Situation ……
Comments ……..
……

Assumption: Lack of management commitment on food safety control shifts priorities of employees/operators to other issues, which increases chance on poor operation (e.g. not following procedures adequately which negatively affects FS performance), and put higher demands on FSMS by requiring advanced control and assurance activities		
Situation 1	**Situation 2**	**Situation 3**
• Company has detailed written vision statement on safety. • It has an official quality (safety) team • with formalised meetings and own budget	• Company has general written vision statement on safety. • It has a competent person in charge of the quality and safety within the establishment. • with regular meetings and restricted budget	• Company has no written vision statement on safety. • It has no official quality (safety) team or person in charge of quality and safety within the establishment • only meetings on safety control in case of recalls, problems, no specific budget.

Supporting information to differentiate situation 2 and 3

- When no detailed written vision statement on safety and or no official quality team with its own budget, then situation 2 or 3.
- Crucial for situation 3 is that management only reacts in case of recalls and comparable safety problems.

10 In which situation would you place the **employee involvement** in your establishment?

Situation **……**
Comments **……..**
……

Assumption: Lack of employee involvement will result in less committed and motivated operators, which favours inappropriate operation, and put higher demands on FSMS by requiring advanced control and assurance activities (e.g. more instructions, training, operator control)		
Situation 1	**Situation 2**	**Situation 3**
• Operators are explicitly involved in design and modifications of FSMS • They are expected to bring in their knowledge to improve systems	• Operators' opinions are considered in design and modifications of FSMS • They are stimulated to provide ideas/ suggestions for improvements	• Operators are only informed about modifications in FSMS by QA manager • They are not asked to provide ideas/suggestions for improvements

Supporting information to differentiate situation 2 and 3

- When operators are not fully involved in design and improvement of the FSMS, then situation 2 or 3.
- Crucial for situation 3 is that operators are only informed afterwards about changes in the FSMS.

11 In which situation would you place **formalisation** in your establishment?

Situation ……
Comments ……..
……

Assumption: Absence of establishment of activities in formal procedures and lack of formalised meetings increase chance on unexpected decision-making behaviour at safety tasks, and put higher demands on FSMS by requiring advanced control and assurance activities		
Situation 1	**Situation 2**	**Situation 3**
• A high level of formalisation is typified by: all activities are described in SOP's/procedures • formalised meetings for all different issues • Well documented minutes of meetings	• Procedures and meetings are restricted to crucial processes typically related to the FSMS. • Regular meetings • No structured documentation of minutes of meetings	• No (few) procedures (people are not used to work with it. • Working instructions are communicated via informal meetings or contacts • No documentation

Supporting information to differentiate situation 2 and 3

- When not all activities are provided with formal procedures and well organised formal meetings, then situation 2 or 3.
- Crucial for situation 3 is that basically all contacts on food safety decisions are informal and not documented

12 In which situation would you place **information systems** in your establishment?

Situation **……**
Comments **……..**
……

Assumption: Lack of appropriate information systems affects availability of accurate information, which may favour inappropriate operation (due to lack of (correct) info at safety tasks), and put higher demands on FSMS by requiring advanced control and assurance activities (increased efforts in obtaining appropriate information at right time and place)		
Situation 1	**Situation 2**	**Situation 3**
• Company has a specific Quality Information Management (QIM) • that is accessible (i.e. all have authority of use, user friendly, at right location) for all people to support execution of food safety control activities	• Company has production information system not specific for QA purposes, from which some information sources are suitable for food safety control decisions • system is only accessible to authorised people	• Company has standard information system for bookkeeping (incoming and outgoing materials); information is not very accurate for food safety control decisions • system is only accessible to authorised people

Supporting information to differentiate situation 2 and 3

- When there is no specific well accessible quality information system, then situation 2 or 3.
- Crucial for situation 3 is that there is even no production information system that is useful for food safety purposes.

D. Assessment of chain environment characteristics

13 In which situation would you place the **safety contribution in chain position** in your establishment?

Situation **……**
Comments **……..**
……

Assumption: A critical chain position of a company with respect to reduction/inactivation of pathogen to acceptable level, has more potential impact on final safety at consumption, which puts higher demands on FSMS by requiring advanced control and assurance activities		
Situation 1	**Situation 2**	**Situation 3**
Company does not contribute to final safety, any microbial contamination is reduced to acceptable level further in the chain.	Company contributes to prevention of growth of pathogens but no significant reduction to acceptable level for final consumption	Company contributes critically to reduction and or prevention of post contamination and or growth of pathogens to acceptable level

Supporting information to differentiate situation 2 and 3

- When your company is (due to its position in the chain) expected to contribute to the prevention or reduction of pathogens in end-products for consumption, then situation 2 or 3
- Crucial for situation 3 is that the company *critically* reduces and or prevents contamination and or growth of pathogens

14 In which situation would you place the **supplier relationships** in your establishment?

Situation **……**
Comments **……..**
……

Assumption: Lack of power in supplier relationship means less influence of a company on their suppliers, which may result in more unpredictable safety levels of incoming materials, which puts higher demands on FSMS by requiring advanced control and assurance activities		
Situation 1	**Situation 2**	**Situation 3**
• Company is explicitly involved in development of product specifications of major suppliers (of major critical materials) • and can influence FSMS/QMS (e.g. via audits) of major suppliers	• Company can discuss about product specifications of major suppliers • but has no influence on the FSMS/QMS of major suppliers	• Company has no influence on product specifications nor the FSMS/QMS of major suppliers • only check specs and or measure supplies

Supporting information to differentiate situation 2 and 3

- When your company is not able to put specific requirements on quality systems of major suppliers, then situation 2 or 3.
- Crucial for situation 3 is that you can also *not* set specific requirements on the supplies of major suppliers.

15 In which situation would do you place the **requirements of stakeholders** in your establishment?

Situation **……**
Comments **……..**
……

Assumption: Strict and differing requirements on your FSMS set by stakeholders (government, branch organisations, customers, retailers, etc) put higher demands on FSMS by requiring advanced control and assurance		
Situation 1	**Situation 2**	**Situation 3**
General legislative requirements on food safety (PRP/HACCP according to Codex Alimentarius)	Additional QA requirements (e.g. ISO, EFQM, ICHE, ICTE) but similar for major stakeholders.	Additional (sometimes conflicting) QA requirements (e.g. ISO, EFQM, ICHE, ICTE) which are different for major stakeholders.

Supporting information to differentiate situation 2 and 3

- When the company has to meet additional QA requirements from stakeholders, then it is situation 2 or 3.
- Crucial for situation 3 is that different stakeholders as different (sometimes conflicting) requirements.

II. Assessment of core <u>control</u> activities

E. Assessment of preventive measures design

16 At which level would you place the **hygienic design of equipment and facilities*** in your establishment?

Level ……
Comments ……..
……

Assumption: Advanced hygienic design of critical equipment and facilities decreases chance on (cross) contamination and enables effective cleaning, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
Hygienic design of equipment and facilities not important/ not an issue	• Critical equipment and facilities not hygienically designed • Facilities meet basic requirements for meal production	• Critical equipment purchased from suppliers of standard equipment designed in line with hygiene requirements • Facilities comply with specific hygiene requirements	• Integrated hygienic design of critical equipment and facilities (according to EHEDG or comparable design criteria) • Adapted and tested for companies' specific meal production characteristics in collaboration with equipment and cleaning suppliers.

* **facilities** are buildings and buildings connected installations

Supporting information to differentiate levels 2 and 3

- When critical equipment and facilities comply with EHEDG or comparable hygienic design criteria then level 2 or 3
- Crucial for level 3 is that hygienic design is adapted <u>and</u> tested for your production circumstances

17 At which level would you place the **cooling facilities** in your establishment?

Level ……
Comments ……..
……

Assumption: adequate cooling facilities better maintain strict temperature conditions to prevent growth of micro organisms and pathogens, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
Cooling facilities not used in production	• domestic/general cooling facilities • principal cooling capacity not known, no testing product temperature	• industrial cooling facilities • information about principal cooling capacity from suppliers, no testing of product temperature for different circumstances	• industrial cooling facilities specifically adapted for companies' specific food production circumstances • capacity tested by temperature check of environment and products, for different circumstances

Supporting information to differentiate levels 2 and 3

- When capacity of cooling facilities known then at level 2 or 3
- Crucial for 3 is that cooling facilities are adapted(modified) and tested for your production circumstances, and actual product temperature checked for different circumstances

18 At which level would you place the **sanitation programs** in your establishment?

Level ……
Comments ……..
……

Assumption: Specific, full-steps and tailored sanitation programs with appropriate cleaning agents, supported with appropriate instructions better prevent contamination, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
No specific sanitation programs in place	• incomplete program not differentiated for specific equipment/facilities • common cleaning agents not specific for production system. • instructions derived from information on label or company experience	• complete programme and differentiated for equipment and facilities • cleaning agents (i.e. detergents & disinfectants) selected based on advices of suppliers. • idem for instructions about use and frequency	• complete programs, tailored for different equipment & facilities • cleaning agents specifically modified and tested for companies' specific food production system • instructions on use and frequency based on test results

Supporting information to differentiate levels 2 and 3

- When complete (full-steps) sanitation program(s) then level 2 or 3
- Crucial for level 3 is that sanitation agents and their use are tested for your specific production circumstances

19 At which level would you place the **personnel hygiene requirements** in your establishment?

Level ……
Comments ……..
……

Assumption: Higher and more specific personal hygiene requirements and specific instructions reduce chance on contamination, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
Personal hygiene requirements are not implemented	• Standard requirements for all employees on clothing (caps, gloves, jacks) • Idem personal care and health • Common washing facilities • No specific hygiene instructions	• Additional task-specific requirements on clothing (own clothing, specific storage conditions) • Idem for personal care and health. • Special hand washing facilities • Basic hygiene instructions	• High/ specific requirements, for all food operators, on clothing • Idem for personal care and health. • Tailored facilities to support personal hygiene. • Specific training and hygiene instructions

Supporting information to differentiate levels 2 and 3

- When specific personal hygiene requirements (clothes, personal care, health), and facilities and instructions then 2 or 3
- Crucial for 3 is that specific (high) personal hygiene requirements are *for all* employees and that facilities and instructions are *tailored* (i.e. specific/special) for your production circumstances

20 At which level would you place the **raw material control** in your establishment?

Level ……
Comments ……..
……

Assumption: Systematic and adequate incoming raw material control will prevent (high and variable initial) acceptance of contaminated raw materials which will reduce chance on (cross) contamination of the production process which will positively contribute to food safety.			
Level 0 No incoming raw material control	Level 1 • raw material control is ad hoc • based on historical experience with suppliers	Level 2 • raw material control is systematic • based on guidelines, or legislative requirements, or guidance document for sector, or expert knowledge, but not on actual data of suppliers	Level 3 • raw material control is systematic • based on statistical underpinned acceptance sampling (i.e. sampling frequency, location, analysis, rejection criteria, etc) based on actual historical data of suppliers

Supporting information to differentiate levels

- When raw materials are systematically controlled then situation 2 or 3
- Crucial for situation 3 is that acceptance sampling is based on statistical analysis of actual historical data of suppliers

21 At which level would you place the **meal preservation** in your establishment?

Level ……
Comments ……..
……

Assumption: Adequate meal preservation measures that specifically reduce (high initial) contamination will reduce chance of contamination of production process which will positively contribute to food safety.			
Level 0	Level 1	Level 2	Level 3
No meal preservation	• meal preservation is based on company knowledge/experience and or common knowledge • but not tested	• meal preservation is based on guideline, legislative requirement, guidance document, expert knowledge • but not tested.	• meal preservation is based on legislative requirement/guidance documents • and tested for specific food production circumstances

Supporting information to differentiate levels 2 and 3

- When effect of product specific preventive measure is supported with expert knowledge/scientific information then level 2 or 3
- Crucial for situation 3 is that the product specific measure is tested for your production circumstances (it is known to what extent the measure reduced cross contamination, high initial loads, etc).

22 At which level would you place the **defrosting methods** in your establishment?

Level ……
Comments ……..
……

Assumption: Adequate defrosting methods that specifically reduce (high initial) contamination will reduce chance of contamination of production process which will positively contribute to food safety.			
Level 0	Level 1	Level 2	Level 3
No defrosting methods	• defrosting method is based on company knowledge/experience and or common knowledge • but not tested	• defrosting method is based on guideline, legislative requirement, guidance document, expert knowledge • but not tested.	• defrosting method is based on legislative requirement/guidance documents • and tested for specific food production circumstances

Supporting information to differentiate levels 2 and 3

- When effect of product specific preventive measure is supported with expert knowledge/scientific information then level 2 or 3
- Crucial for situation 3 is that the product specific measure is tested for your production circumstances (it is known to what extent the measure reduced cross contamination, high initial loads, etc).

23 At which level would you place the **hot holding methods** in your establishment?

Level ……
Comments ……..
……

Assumption: adequate hot holding methods better maintain strict temperature conditions to prevent growth of micro organisms and pathogens, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
Hot holding not executed in production	• hot holding method is based on company knowledge/experience and or common knowledge • but not tested	• hot holding method is based on guideline, legislative requirement, guidance document, expert knowledge • but not tested.	• hot holding method is based on legislative requirement/guidance documents • and tested for specific food production circumstances

Supporting information to differentiate levels 2 and 3

- When capability of hot holding facilities known then at level 2 or 3
- Crucial for 3 is that hot holding facilities are adapted(modified) and actual product temperature checked for different circumstances

F. Assessment of intervention processes design

24 At which level would you place the **intervention equipment** in your establishment?

Level ……
Comments ……..
……

Assumption: Capable intervention equipment enables less unpredictable process variation and better compliance to standards, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
No intervention equipment used	• Standard intervention equipment process • capability not known, information about process capability in equipment specifications	• 'Best standard' intervention equipment available in practice • capability described in equipment specifications (provided by equipment suppliers). Equipment is principally capable to comply with standards and tolerances, not tested for own production system	• Intervention equipment specifically modified for companies' specific food production circumstances and • process capability is tested and information is well-documented

Supporting information to differentiate levels

- When process capability of intervention equipment known then situation 2 or 3
- Crucial for 3 is that intervention equipment is specifically designed (modified) and tested for your production circumstances

25 At which level would you place the **maintenance and calibration program for the intervention equipment** in your establishment?

Level ……
Comments ……..
……

Assumption: Structural and tailored programmes for maintenance with specific instructions about frequency and tasks will cause less unexpected safety problems due to unreliable equipment, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
No maintenance applied	• maintenance is basically initiated by problems, ad hoc • no (clear) instructions about frequency and maintenance tasks • not well documented	• maintenance program developed with support of, or by suppliers of equipment/tools • specific instructions about frequency and maintenance tasks • well documented (at location or at equipment suppliers)	• maintenance program specifically designed for production process using data from regular inspections and breakdown analyses • specific instructions on frequency maintenance tasks • well documented (at company)

Supporting information to differentiate levels 2 and 3

- When structural maintenance program for equipment available then level 2 or 3
- Crucial for 3 is that the maintenance program is specifically designed for your production process (based on actual process data and analysis).

26 At which level would you place the **intervention methods** done in your establishment?

Level ……
Comments ……..
……

Assumption: Specific intervention methods reduce better contamination load of (raw) materials, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
No intervention methods used	• intervention methods are applied based on company knowledge, and experience • potential reduction level not known	• application of intervention method based on advices of specialised suppliers, but not tested for specific food production systems characteristics. • potential reduction level known based on literature or expert knowledge	• intervention method is modified companies' specific food production system characteristics. • reduction level is known by testing with experiments and is well-documented

Supporting information to differentiate levels 2 and 3

- When effect of the specific intervention method is supported with expert knowledge, scientific information then situation 2 or 3.
- Crucial for situation 3 is that the intervention method is tested for your production circumstances (it is known to what extent the measure reduced cross contamination, high initial loads, etc).

G Assessment of monitoring system design

27 At which level would you place the **analysis of CCP/CPs** in your establishment?

Level ……
Comments ……..
……

Assumption: A higher level of scientific evidence and a more systematic way to analyse hazards and associated risk together with actual testing of CCP and CPs will result in more reliable and accurate control points, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
No analysis of CCPs and CPs executed (nor by company nor by external experts)	• Internal experience/knowledge used for hazard identification and risk evaluation, selection of hazards to be controlled based on internal discussions • no strict methodology used. • CCP/CP determination based on consensus and not tested in practice	• Hazard identification, risk analysis and allocation of CCP/CPs based on hygiene codes for sector or executed by external expertise (consultancy) who work • according to official Codex guidelines. CCP/CP determination	• Hazard identification, risk analysis and allocation of CCP/CPs executed by using own knowledge/ experience, additional scientific literature and or expert knowledge • according to Codex guidelines • CCP/CP determination by microbial product tests

Supporting information to differentiate levels

- When your CCP/CP analysis is executed in a systematic way and based on expert knowledge, scientific information then level 2 or 3
- Crucial for level 3 is that CCP/CPs are *tested* for your actual production circumstances

28 At which level would you place the **standards and tolerances design** in your establishment?

Level ……
Comments ……..
……

Assumption: More complete specification of both standards and tolerances for both critical process and product parameters, supported by scientific based data will result in more accurate CCP's, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
No written standards for product and process parameters	• Standards for critical product and process parameters are specified but tolerances not clearly specified • Assessments of product/process standards basically on historical data and company experience.	• Standards and tolerances for critical product and process parameters are clearly specified. • Standards and tolerances of product/process parameters derived from general hygiene codes and legal requirements.	• Standards and tolerances for critical product/process parameters are clearly specified. • Standards and tolerances of product/process parameters derived from legal requirements, hygiene codes, and literature, adapted for own food production system.

Supporting information to differentiate levels 2 and 3

- When standards and tolerances are clearly specified and minimally based upon (available) legislative requirements then level 2 and 3
- Crucial for 3 is that standards and tolerance are scientifically underpinned and adapted for your production circumstances.

29 At which level would you place the **analytical methods to assess pathogens** in your establishment?

Level ……
Comments ……..
……

Assumption: sensitive, specific, repeatable, reproducible and rapid methods to assess pathogens will result in more adequate determination of pathogens, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
Pathogens are **not** analysed (not by company nor by external lab)	• conventional culture-based methods used (i.e. plate counts, most probable number, presence -absence tests) • no (inter)nationally acknowledged procedures is followed	• conventional culture-based methods used (i.e. plate counts, most probable number, presence -absence tests) or modified quicker methods • internationally validated methods are used (not accredited)	• conventional culture-based methods used (i.e. plate counts, most probable number, presence -absence tests) or modified quicker methods • internationally validated and accredited methods are used

Supporting information to differentiate levels 2 and 3

- When internationally validated methods are used for pathogen testing then level 2 o3
- Crucial for level 3 is that the method is also accredited

30 At which level would you place the **measuring equipment to monitor process/ product status** in your establishment?

Level ……
Comments ……..
……

Assumption: accurate and responsive equipment to monitor critical process and or product parameters will result in more adequate monitoring, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
No measuring equipment	• no standardised measuring equipment (accuracy not tested) • off-line/ at-line measurement, not automated, no information/data history available	• standard available measuring equipment complying with ISO (other international recognised) norms (accepted accuracy). • on-line/ in line measurement (immediate response), often automated, information/data history available	• specifically selected equipment and adapted to the companies' specific production process, and tested on accuracy. • on-line/ in-line measurement (immediate response), automated, information history immediately visual.

Supporting information to differentiate levels 2 and 3

- When internationally acknowledged (in line) measuring equipment recording history information then level 2 or 3
- Crucial for 3 is that the measuring equipment is adapted and tested on accuracy for your production circumstances.

31 At which level would you place the **calibration program for measuring equipment** in your establishment?

Level ……
Comments ……..
……

Assumption: structural and tailored programmes for calibration/verification and testing of measuring and analytical equipment will cause less unreliable test data, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
No calibration/verification program for measuring equipment	• calibration of measuring equipment on ad-hoc basis • tasks and frequency not clear, and not (well) documented.	• calibration outsourced at equipment suppliers • task and frequency based on international standards, not specific for food production system, documentation at equipment suppliers	• calibration program specifically designed based on data from own food production system, according to international standards. • tasks and frequency in- house documented

Supporting information to differentiate levels 2 and 3

- When structural calibration/verification program (for measuring equipment) according to international standards available then level 2 or 3
- Crucial for 3 is that the calibration/verification program is specifically designed (or adapted) for your production process (based on actual process data and analysis).

32 At which level would 35. you place the **sampling design (for microbial assessment) and measuring plan** in your establishment?

Level **……**
Comments **……..**
……

Assumption: a statistical underpinned and tailored sampling design, measuring plan increases reliability of information on actual product/process status, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
No sampling design nor a measuring plan in place	• Sampling design and measuring plans based on experience and in-house knowledge. No information about distribution of pathogens, samples are taken as spot-check procedure	• Sampling design and measuring plan based on common sampling plans for the specific sector as available in literature (e.g. EU guidelines, or ICMS for foods)	• Sampling design and measuring plan based on statistical analysis of pathogen distribution in own food production process

Supporting information to differentiate levels

- When sampling design and measuring plans are based on acknowledged guidelines/scientific information then level 2 or 3
- Crucial for level 3 is that sampling design and measuring plans are adapted based on statistical analysis of pathogen distribution in your production

33 At which level would you place the **corrective actions** in your establishment?

Level ……
Comments ……..
……

Assumption: a complete and differentiated description of corrective actions linking severity of deviations to type of corrective actions will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
No corrective actions have (yet) been described	• corrective actions based on experience, and consensus within company. • incomplete descriptions of process adjustments and handling of non-compliance products • no structural analysis of cause of deviation. Corrective measures not differentiated for different deviations.	• corrective actions based on hygiene codes including process adjustment measures and handling non-compliance products • complete descriptions but not adjusted for own process, product characteristics • ad hoc analysis of cause of deviations, no differentiated measures.	• corrective actions based on systematic causal analysis of own product/process deviations, • complete descriptions including process adjustments and handling of non-compliance products • structural analysis of cause of deviations, differentiated measures.

Supporting information to differentiate levels 2 and 3

- When complete description of corrective actions (minimally based on hygiene codes) then level 2 or 3
- Crucial for 3 is the structural analysis of causes of product/process deviations and differentiated corrective actions specific for your production.

H. Assessment of operation of preventive measures, intervention processes and monitoring systems

34 At which level would you place the **actual availability of procedures*** in your establishment?

Level **……**
Comments **……..**
……

Assumption: accurate and understandable procedures at the right place will better direct peoples' decision-making behaviour in control, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
No procedures in place	• procedures are sometimes/ partly available on location (often paper-based) • and or difficult to understand by users • and are not kept up-to-date	• Procedures are available at location (often paper-based) • and well to understand for most users • but are kept up-to-date on ad-hoc basis	• Procedures very easily available (digital, on-line) at location, • and are designed for specific users • and updated at a regular basis

* Procedures for core control activities like, cleaning, personal hygiene, maintenance & calibration intervention equipment, calibration measuring and analytical equipment, CCP procedures.

Supporting information to differentiate levels 2 and 3

- When procedures available at appropriate locations then level 2 or 3
- Crucial for level 3 is that procedures are specifically designed for the users and kept systematically up to date.

35 At which level would you place the **actual compliance to procedures** in your establishment?

Level ……
Comments ……..
……

Assumption: complete (all steps followed) and accurate (in right way) compliance to procedures due to full adherence will result in more appropriate decision-making behaviour in control, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
• no procedures • no idea about compliance to procedures of operators	• majority of food handlers execute tasks according to own insights, because they are not aware of existence of procedures for certain tasks • operators are controlled on compliance to procedures on ad-hoc basis	• majority of operators are familiar with existence of procedures (but not always exact content); tasks are executed based on habits. • operators are controlled on compliance to procedures on regular basis	• all operators are aware of existence and content of procedures and are consciously following procedures, safety tasks are internalised. • self control of compliance to procedures

Supporting information to differentiate levels

- When majority of employees are familiar with existence of procedures for core control activities then level 2 or 3
- Crucial for level 3 is that safety tasks are internalised (i.e. employees know well content of procedures) and they control themselves (not by chief/QA)

36 At which level would you place the **actual hygienic performance of equipment and facilities** in your establishment?

Level **……**
Comments **……..**
……

Assumption: stable hygienic performance of equipment and facilities, which can be well noticed will result in less (cross)contamination which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
• Hygienic design is no issue • No information/ idea about hygienic performance	• regularly unexpected and unexplainable contaminations due to inappropriate equipment or facilities. • hygienic performance of equipment and facilities never tested.	• sometimes unexpected and unexplainable contaminations due to inappropriate equipment or facilities • hygienic performance of equipment and facilities tested on ad-hoc basis	• stable hygienic performance of equipment and facilities • hygienic performance tests are executed on regular basis according to EHEDG/ similar guidelines

Supporting information to differentiate levels 2 and 3

- When stable hygienic performance of equipment and facilities with only few contamination problems then level 2 and 3
- Crucial for level 3 is that actual hygiene performance is systematically/regularly tested according to acknowledged guidelines/criteria (like described by EHEDG).

37 At which level would you place the **actual cooling capacity** in your establishment?

Level ……
Comments ……..
……

Assumption: stable performance of cooling facilities, which can be well noticed will result in constant low temperatures with few variation, which will better prevent growth of pathogens and will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
• cooling facilities not used • no cooling performance information known	• Regularly unstable performance with significant variations in facility temperature, • no automatic temperature devices and deviations not systematically analysed • no information about product temperature	• Sometimes unstable performance • automatic temperature control but no systematic analysis of deviations • ad hoc information about product temperature	• Stable performance of cooling facilities • environmental temperature is automatically monitored and deviations are systematically analysed • constant information about product temperatures

Supporting information to differentiate levels 2 and 3

- When stable cooling capacity with no or sometimes unexpected deviations based on information from (automatic) environmental temperature control then level 2 or 3
- Crucial for level 3 is that actual cooling capacity is also stable based on regular analysis of *actual product temperature* under your production circumstances

38 At which level would you place the **actual hot-holding capacity** in your establishment?

Level ……
Comments ……..
……

Assumption: stable performance of hot-holding facilities, which can be well noticed will result in constant high temperatures with few variation, which will better prevent growth of pathogens and will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
• Hot-holding facilities not used • no hot-holding performance information known	• Regularly unstable performance with significant variations in temperature, • no automatic temperature devices and deviations not systematically analysed • no information about product temperature	• Sometimes unstable performance • automatic temperature control but no systematic analysis of deviations • ad hoc information about product temperature	• Stable performance of cooling facilities • environmental temperature is automatically monitored and deviations are systematically analysed • constant information about product temperatures

Supporting information to differentiate levels 2 and 3

- When stable hot-holding capacity with no or sometimes unexpected deviations based on information from (automatic) environmental temperature control then level 2 or 3
- Crucial for level 3 is that actual hot-holding capacity is also stable based on regular analysis of *actual product temperature* under your production circumstances

39 At which level would you place the **actual process capability of intervention processes** in your establishment?

Level **……**
Comments **……..**
……

Assumption: stable intervention processes with minor differences between different production lines, and well noticeable capability performance will result in more products within specifications, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
• no intervention equipment in place • no performance information known	• regularly unstable process with unexplainable deviations from mean values of process parameters; variation not constant over time • variable differences in capabilities between different meals	• sometimes unstable process, with unexplainable deviations of process parameters; variation constant over time • significant but constant differences in capabilities between various meals	• stable process, mean values and variation of process parameters according to specs and constant over time • minor deviations in mean values and variation between meals

Supporting information to differentiate levels 2 and 3

- When stable (constant variation around mean) intervention equipment with no or sometimes unexpected deviations for individual meals (based on information from actual process data) then level 2 or 3
- Crucial for level 3 is that also *between* similar meals minor deviations.

40 At which level would you place the **actual performance of measuring equipment** in your establishment?

Level **……**
Comments **……..**
……

Assumption: stable measuring equipment that is reliable under different product/process conditions provide more reliable information on product and process status, which will positively contribute to food safety			
Level 0	Level 1	Level 2	Level 3
• no measuring equipment used • no information about measuring equipment performance	• measuring equipment very sensitive to changes in meal production circumstances	• measuring equipment sensitive for few specific well known meal production changes	• measuring equipment very stable under all different meal production circumstances

Supporting information to differentiate levels 2 and 3

- When measuring equipment not very sensitive towards changes in production systems then level 2 or 3
- Crucial for 3 is that measuring equipment is stable under all different circumstances.

III. Assessment of core assurance activities

I. Assessment of setting of system requirements

41 At which level would you place the **translation of stakeholder requirements into own FSMS requirements** in your establishment?

Level **……**
Comments **……..**
……

Assumption: Systematic and precise translation of stakeholder requirements will result in suitable requirements on the FSMS, which will contribute to assurance of product safety			
Level 0	Level 1	Level 2	Level 3
not (yet) any stakeholder requirement(s) translated	• translation of external assurance activities initiated by food safety performance problems *(reactive)* as perceived by stakeholders and or due to external directives, only necessary changes	• translation of external assurance activities by *actively* acting on changes in external assurance and setting (new) requirements with support of external experts (e.g. consultants)	• *pro-active* translation of external assurance requirements based on systematic analysis of possible changes in stakeholder requirements (e.g. new legislation, new branch demands) and evaluated on critical aspects of *own* food production system; well documented

Supporting information to differentiate levels 2 and 3

- When external assurance requirements *systematically* translated into (new) requirements on own food safety control systems then level 2 or 3
- Crucial for 3 is that assurance requirements are evaluated on *your critical* production circumstances and translation activities *well-documented*

42 At which level would you place the **systematic use of feedback information to modify FSMS** in your establishment?

Level ……
Comments ……..
……

Assumption: Systematic use of valid feedback information from core control activities will result in appropriate system modifications, which will contribute to assurance of product safety			
Level 0	Level 1	Level 2	Level 3
• FSMS has not (yet) ever been modified	• ad hoc modification of core control activities initiated by problems from own food production system • not documented	• regular use of standard data from food production system (process/product data); modifications mainly focused on control activities <u>in</u> production system • not systematically documented	• systematic analysis of information from validation & verification reports, translations into concrete modifications in FSMS are established in clear procedures with assigned responsibilities • well documented

Supporting information to differentiate levels

- When *systematically* information is used from food production system to modify food safety control system, then level 2 or 3
- Crucial for 3 is the use of verification and validation information established in procedures and all is *well-documented*

J. Assessment of validation activities

43 At which level would you place the **validation of preventive measures** in your establishment?

Level ……
Comments ……..
……

Assumption: A *scientific evidence based*, *systematic*, and *independent* validation of effectiveness of selected preventive measure will result in an effective FSMS, which will positively contribute to assurance of product safety			
Level 0	Level 1	Level 2	Level 3
• Effectiveness of preventive measures have (yet) never been validated	• Effectiveness of preventive measures is validated based on historical knowledge only judged by own people	• Effectiveness of preventive measures is validated based on opinion of independent expert, using expert knowledge, regulatory documents and historical results	• Effectiveness of preventive measures is systematically validated, by independent experts, based upon specific scientific sources (like scientific data/literature on validation studies, predictive modelling), historical results, and own experimental trials;
	• on ad-hoc basis	• on regular basis and after system modifications	• on regular basis and after system modifications
	• findings scarcely (not) described.	• findings described in reports	• activities and results well documented

Supporting information to differentiate levels 2 and 3

- When preventive measures independently (not by own people) validated based on expert knowledge and or scientific sources on a regular basis, then level 2 or 3
- Crucial for level 3 is that actual effectiveness is *tested* with experimental trials and validation activities are established in procedures and *well documented*

44 At which level would you place the **validation of intervention processes** in your establishment?

Level ……
Comments ……..
……

Assumption: A *scientific evidence based, systematic,* and *independent* validation of effectiveness of selected intervention strategies will result in a more effective FSMS, which will positively contribute to assurance of product safety			
Level 0	Level 1	Level 2	Level 3
• Intervention systems have (yet) never been validated	• Effectiveness intervention systems validated based on historical knowledge only judged by own people • on ad-hoc basis • findings scarcely (not) described.	• Effectiveness of intervention systems validated based on opinion of independent expert, using expert knowledge, regulatory documents and historical results • on regular basis and after system modifications; • findings described in reports	• Effectiveness of intervention systems validated by independent experts/ persons, based on specific scientific sources (like scientific data/literature on validation studies, predictive modelling), historical results, and own experimental trials • regular basis and after system modifications, • activities and results well documented

Supporting information to differentiate levels 2 and 3

- When intervention systems are independently (not by own people) validated based on expert knowledge and or scientific sources on a regular basis, then level 2 or 3
- Crucial for level 3 is that actual effectiveness is *tested* with experimental trials and validation activities are established in procedures and *well documented*

45 At which level would you place the **validation of monitoring systems** in your establishment?

Level ……
Comments ……..
……

Assumption: A *scientific evidence based, systematic,* and *independent* validation of CCP determination and establishment of control circles will result in a more effective FSMS, which will positively contribute to assurance of product safety			
Level 0	Level 1	Level 2	Level 3
• Effectiveness of monitoring systems have (yet) never been validated	• validation based on historical and/or commonly available knowledge	• validation based on comparison with regulatory documents (like specific hygiene codes)	• validation based on scientific sources (reviews, historical data on hazards, reports on foodborne illnesses, data on survival or multiplication, studies on control mechanisms);
	• executed by own people on ad hoc basis	• by external expert on regular basis	• by independent expert on regular basis and after system modifications;
	• findings (not) scarcely described	• findings described in expert report	• activities and results well documented.

Supporting information to differentiate levels 2 and 3

- When monitoring systems at CCP's are independently (not by own people) validated based on expert knowledge and or scientific sources on a regular basis, then level 2 or 3
- Crucial for level 3 is that actual effectiveness is *tested* with experimental trials and Crucial for 3 is that the actual performance is *confirmed* by real observations, and validation activities are established in procedures and *well documented*

K. Assessment of verification activities

46 At which level would you place the **verification of people related performance** in your establishment?

Level ……
Comments ……..
……

Assumption: A more *specific*, *systematic*, and *independent* verification of procedure characteristics and compliance will result in a more reliable FSMS, which will positively contribute to assurance of product safety			
Level 0	Level 1	Level 2	Level 3
• procedures and compliance to procedures have (yet) never been verified	• verification of procedures and compliance based on *checking presence* of procedures and records, • on ad-hoc basis • by own people who execute system • not documented	• verification of procedures and compliance based on *analysing* procedures (both content and presence) and records • on regular basis • by independent internal staff • internal report	• verification of procedures and compliance based on *analysing* procedures and records, and *observations* • with defined frequency and when system modifications • by independent external (official) expert • activities and results well documented

Supporting information to differentiate levels 2 and 3

- When verification of performance of people related activities is based on independent *analysis* of procedures, records, etc on a *regular basis*, then level 2 or 3
- Crucial for 3 is that the actual performance is *confirmed* by real observations, and verification activities are established in procedures and *well documented*

47 At which level would you place the **verification of equipment and methods related performance** in your establishment?

Level **……**
Comments **……..**
……

Assumption: A more *specific*, *systematic*, and *independent* verification of equipment and methods performance will result in a more reliable FSMS, which positively contributes to the assurance of product safety			
Level 0	Level 1	Level 2	Level 3
performance of equipment and methods have (yet) never be verified	• verification of equipment/methods performance based on checking if product, process parameters are correctly set (e.g. of equipment, facilities, measuring, analysis methods) • on ad hoc basis • by own people who execute system • not documented	• verification of equipment/methods performance based on analysing records (e.g. control charts, records data loggers, etc.) and calibration activities, restricted testing of actual performance • on regular basis • by internal staff • internal report	• verification of of equipment/methods performance based on *analysing* records, calibration activities, and confirmation of performance by actual (e.g. microbial) *testing*, • with defined frequency and after system modifications • by independent experts; • activities and results well documented

Supporting information to differentiate levels 2 and 3

- When verification of equipment and methods performance is based on independent analyses of records, data, calibration activities, etc on *regular basis*, then level 2 or 3
- Crucial for 3 is that the actual performance is *confirmed* by testing (e.g. microbial tests) and or real measuring, and verification activities are established in procedures and *well documented*

L. Assessment of documentation and record-keeping systems

48 At which level would you place **documentation** in your establishment?

Level **……**
Comments **……..**
……

Assumption: An integrated, kept-up-to-date and accessible documentation system will improve information (experience, scientific knowledge, legislative requirements) supply for FSMS, which will support validation and verification activities, which will positively contribute to the assurance of product safety			
Level 0	Level 1	Level 2	Level 3
• no documentation of procedures, information, knowledge at all	• no structured documentation system ad hoc	• structured documentation system, de-centrally organised and kept up to date, (partly) automated, available via specific persons; access to external sources not formalised (individual contacts)	• Structured documentation system, kept-up-to-date with assigned responsibilities, centrally organised, automated and on-line available for all, and with access to external sources of information (libraries, databases, etc).

Supporting information to differentiate levels 2 and 3

- When structured documentation system that is kept-up-to date is available then level 2 or 3
- Crucial for level 3 is that it is a central and integrated documentation system, which is on line available and for all accessible, and has links to external sources of information (like libraries, data banks, etc)

49 At which level would you place the **record keeping system** in your establishment?

Level **……**
Comments**……..**
……

Assumption: A structured, integrated, and accessible record-keeping system will support validation and verification activities, which will positively contribute to assurance of product safety			
Level 0	Level 1	Level 2	Level 3
• no record keeping of product nor process data at all	• ad hoc registration of record keeping data.	• full registration of critical product and process data in separated systems (not integrated), accessible via specific (authorised) persons.	• full registration of critical product and process data, in central integrated system, on line available and accessible to all persons

Supporting information to differentiate levels

- When full registration of critical data then level 2 or 3
- Crucial for level 3 is that it is a central and integrated system, which is on line available and for all accessible

2. Individual scores of contextual factors, core control and assurance activities of the 50 FSE

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	Ñ	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA	AB	AC	AD	AE	AF	AG	AH	AI	AJ	AK	AL	AM	AN	AO	AP	AQ	AR	AS	AT	AU	AV	AW
Contextual Factors																																																		
Product Characteristics																																																		
Risk of raw material	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Risk of meals	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Production Process Characteristics																																																		
Extent of intervention steps	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Assortment of meal production process	3	3	3	3	2	3	1	3	3	2	1	2	2	3	3	2	3	3	2	3	3	3	3	3	2	3	2	3	2	2	2	2	3	2	3	1	3	1	3	2	2	3	3	3	2	3	3	1	3	3
Rate of menu changes	2	2	1	2	2	1	2	2	2	2	2	2	1	2	2	3	2	1	2	2	2	2	2	1	2	3	2	1	2	2	2	2	3	2	2	2	2	1	2	3	3	2	2	2	2	3	2	1	2	2	2
Organisation Characteristics																																																		
Lack of technological staff	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Degree of variability in workforce composition	2	2	2	1	1	1	1	2	2	1	1	1	1	1	1	1	2	2	2	2	2	2	3	1	1	1	2	2	3	1	1	3	3	3	2	1	1	1	3	1	2	2	2	1	1	1	3	2	1	1
Deficiency of operator competences	2	2	2	1	2	1	1	3	2	1	1	1	1	1	2	2	1	2	3	1	2	1	2	1	2	1	2	1	3	2	1	2	1	2	1	1	1	2	3	2	2	2	2	2	2	3	2	3	1	
Lack of maganement commitment	3	2	3	3	3	3	1	3	2	2	2	2	2	3	3	3	3	3	3	1	3	1	3	2	3	2	3	2	3	3	3	3	3	3	3	1	2	3	3	3	2	2	2	2	3	2	3	1	3	3
Deficiency of employee involvement	2	2	3	2	1	2	3	3	2	2	3	3	3	1	2	1	2	3	3	3	2	2	2	2	2	2	2	3	2	3	2	2	3	2	2	2	2	1	2	1	2	2	2	2	2	2	2	2	2	2
Absence of formalisation	2	2	3	3	3	3	1	3	2	2	2	2	2	3	3	3	3	2	3	1	3	1	3	2	2	2	3	2	3	3	3	3	3	3	2	3	1	2	3	2	3	2	2	2	2	3	2	2	3	2
Deficiency of information systems	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Chain Environment Characteristics																																																		
Safety contribution in chain position	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Lack of power in supplier relationships	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	2	2	2	2	1	2	2
Strictness of stakeholders requirements	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Core Control Activities																																																		
Preventive Measures Design																																																		
Sophistication of hygienic design of equipment and facilities	2	3	1	2	1	1	3	2	3	1	3	1	1	2	1	3	1	1	1	3	2	3	1	3	3	2	2	3	1	1	3	1	1	1	1	3	3	3	1	1	2	3	3	1	2	3	1	3	3	3
Adequacy of cooling facilities	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Specificity of sanitation programs	1	2	1	1	1	1	3	1	1	1	2	1	1	1	1	2	1	1	1	3	2	3	1	2	2	2	1	2	1	1	2	1	1	2	1	2	2	2	1	1	1	2	2	1	1	2	2	2	2	2
Extent of personnel hygiene requirements	1	3	1	2	2	1	3	2	2	1	3	1	1	1	2	2	1	1	1	3	2	3	1	3	2	3	1	3	1	1	2	1	1	1	2	3	3	2	1	1	2	1	3	2	1	1	2	1	3	1
Specificity of raw material control	1	1	1	1	1	1	2	1	1	1	2	1	1	1	1	1	1	1	1	2	1	2	1	2	1	2	1	2	1	1	1	1	1	1	1	2	1	1	1	1	2	2	2	1	1	2	1	2	1	2
Specificity of meal preservation	1	2	1	1	0	0	0	1	2	1	0	0	0	2	1	2	1	1	1	3	2	3	0	2	2	2	2	0	2	1	2	2	0	1	3	1	0	2	0	1	0	0	1	1	2	1	1	1	0	1	2
Specificity of defrosting methods	1	2	1	2	2	0	2	2	2	1	2	0	0	2	1	2	2	2	1	2	2	2	0	2	2	2	2	0	2	2	2	2	0	2	2	2	2	2	1	2	1	2	2	2	2	2	3	1	2	
Specificity of hot holding methods	0	2	2	2	1	0	3	2	2	1	3	1	1	1	2	0	0	1	1	2	2	2	0	2	2	2	1	2	0	0	0	0	0	1	1	3	0	2	0	1	0	2	0	1	1	2	0	3	0	2
Intervention Process Design																																																		
Adequacy of physical intervention equipment	2	3	2	1	1	1	3	2	3	1	3	1	1	3	3	3	1	1	1	3	3	3	1	3	3	3	3	3	1	1	3	1	3	3	2	3	3	3	2	1	1	3	2	2	3	3	1	3	2	3
Specificity of maintenance and calibration program for equipment	2	2	1	2	2	1	2	2	1	1	2	1	1	2	1	1	1	1	1	2	2	2	2	1	2	2	1	2	1	2	2	1	1	2	2	2	2	2	2	1	1	1	2	2	1	2	1	2	2	2
Effectiveness of intervention methods	1	2	0	0	0	0	3	1	3	0	3	3	3	1	0	0	0	1	1	3	0	3	1	1	1	3	0	1	0	1	0	0	0	3	1	3	0	1	0	1	0	0	0	0	0	1	0	3	0	1
Monitoring System Design																																																	
Appropriateness of CCP analysis	2	0	0	0	0	0	3	0	0	0	2	2	2	0	0	0	0	2	0	3	0	3	0	2	0	3	0	2	0	0	0	0	0	0	0	2	0	0	0	0	0	2	2	2	0	0	0	3	0	0
Appropriateness of standards and tolerances design	2	2	1	1	1	1	2	1	2	1	2	2	2	1	2	1	1	2	1	2	1	2	1	2	1	2	2	2	1	1	1	1	1	2	2	2	2	1	2	1	2	2	2	1	2	1	1	2	1	1
Adequacy of analytical methods to assess pathogen levels	0	0	0	0	0	0	2	0	2	0	2	2	2	0	0	0	0	0	0	2	0	2	0	0	0	2	0	0	0	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	0	0	0	2	0	0
Adequacy of measuring equipment to monitor process/product status	2	2	2	0	0	0	2	2	2	0	2	0	0	2	2	2	0	0	0	2	2	2	0	2	2	2	2	2	0	0	2	0	2	2	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2
Specificity of calibration program for measuring equipment	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Adequacy of sampling design (for microbial assessment) and measuring plan	1	1	1	1	1	1	2	1	2	1	2	2	2	1	1	1	1	1	1	2	1	2	1	1	1	2	1	1	1	1	1	1	1	2	1	1	1	1	1	1	2	2	1	1	1	1	1	2	1	1
Extent of corrective actions	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Operation of Preventive Measures, Intervention Process and Monitoring System																																																	
Actual availability of procedures	2	2	0	0	0	0	2	0	2	2	2	2	2	0	2	0	0	2	0	2	0	2	2	2	2	2	2	2	0	0	2	0	0	2	0	0	2	2	2	2	0	2	2	2	0	2	2	0	2	2
Actual compliance to procedures	1	2	0	0	0	0	3	0	2	1	3	2	2	0	2	0	0	2	0	2	0	2	2	2	3	2	2	2	0	0	2	0	0	2	0	3	2	2	2	0	2	2	2	0	2	2	0	2	0	2
Actual hygienic performance of equipment and facilities	0	0	0	0	0	0	3	0	0	0	3	0	0	0	0	0	0	0	0	2	0	3	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Actual cooling capacity	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Actual hot-holding capacity	0	1	1	1	1	0	3	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	0	1	1	1	1	1	0	0	0	0	0	1	1	3	0	1	0	1	1	1	1	0	1	0	1	1	0	1
Actual process capability of intervention processes	3	3	3	0	0	0	3	3	3	0	3	0	0	3	3	3	0	0	0	3	3	3	0	3	3	3	3	3	0	0	3	0	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	3	3
Actual performance of measuring equipment	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Core Assurance Activities																																																	
Setting of System Requirements																																																	
Translation of stakeholder requirements into own FSMS requirements	2	1	1	1	1	1	2	1	2	2	2	2	2	1	2	1	1	2	1	2	1	2	1	2	1	2	2	2	1	1	1	1	1	2	2	2	2	1	2	2	1	1	3	1	1					
Systematic use of feedback information to modify system	2	2	1	1	1	1	3	1	2	1	2	2	2	1	1	1	1	1	2	1	3	1	3	1	2	1	2	1	2	1	1	1	1	1	2	1	2	2	1	2	1	2	2	2	1	2	2	1	2	2
Validation																																																	
Validation of preventive measures	0	0	0	0	0	0	0	3	0	3	0	3	3	3	0	0	0	0	0	0	0	3	0	3	0	0	0	3	0	0	0	0	0	0	0	3	0	3	0	0	0	0	0	0	0	0	0	3	0	0
Validation of intervention systems	0	0	0	0	0	0	0	3	0	3	0	3	3	3	0	0	0	0	0	0	0	3	0	3	0	0	0	3	0	0	0	0	0	0	0	3	0	3	0	0	0	0	0	0	0	0	0	3	0	0
Validation of monitoring systems	2	0	0	0	0	0	0	2	0	0	0	0	2	2	2	0	0	0	0	0	2	0	2	0	2	0	2	0	2	0	0	0	0	0	0	0	0	2	0	0	0	0	0	2	2	2	0	0	0	0
Verification																																																	
Verification of people related performance	2	2	0	0	0	0	3	0	3	0	2	2	2	0	0	0	0	2	0	3	0	3	0	2	0	3	0	2	0	0	0	0	0	2	0	2	2	0	2	0	2	2	3	0	0	2	0	3	0	2
Verification of equipment and methods related performance	2	2	1	1	1	1	3	1	3	1	2	2	2	1	1	1	1	1	2	1	3	1	3	1	2	1	3	1	2	1	1	1	1	1	3	1	3	2	1	2	1	2	2	2	1	2	2	1	3	1	2
Documentation and Record Keeping																																																	
Documentation	2	2	1	1	1	1	2	1	2	1	2	2	2	1	1	1	1	1	2	1	2	1	2	1	2	1	2	2	2	1	1	1	1	1	2	1	2	2	1	2	1	2	2	2	1	2	2	1	2	1	2
Record keeping system	1	2	0	0	0	0	2	0	2	0	2	1	1	0	0	0	0	1	0	2	0	2	0	2	0	2	0	2	0	0	0	0	0	1	2	2	2	0	1	0	1	2	2	0	1	2	0	2	0	2