

# OPTIONS méditerranéennes

SERIES A: Mediterranean Seminars  
2015 – Number 111

## Food Safety Challenges for Mediterranean Products

Edited by:

V. Sanchis, E. Liébana, I. Romagosa, A. López-Francos

The global food and feed trade is increasing steadily, the food chain is becoming more concentrated and health crises caused by food-borne outbreaks create human suffering, social alarm and lead to vast losses for the industry. The same trends are being felt in the Mediterranean basin and scientific exchanges and cooperation must be enhanced between its countries, that share borders and experience a rise in food safety concerns.

SAMEFOOD (Safe Mediterranean Food Network, [www.iamz.ciheam.org/samefood](http://www.iamz.ciheam.org/samefood)) is an open networking initiative, promoted since 2013 by the Mediterranean Agronomic Institute of Zaragoza of the International Centre of Advanced Mediterranean Agronomic Studies (IAMZ-CIHEAM) with the objectives of strengthening scientific cooperation for food safety and enhancing a scientifically-based approach in food safety risk assessment and communication in the Mediterranean Basin countries.

The “kick-off” scientific activity of SAMEFOOD was the International Workshop “Food Safety Challenges for Mediterranean Products”, that was held in Zaragoza (Spain) on 10-11 June 2014, organized by IAMZ-CIHEAM with the participation of the European Food Safety Authority.

This volume of Options Méditerranéennes publishes the proceedings of the Workshop, and contains 13 full articles on the invited presentations as well as 10 Country Profiles that summarize the institutional and governing map of food safety risk management in Albania, France, Greece, Lebanon, Malta, Morocco, Portugal, Spain, Tunisia and Turkey.



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Editors: V. Sanchis, E. Liébana, I. Romagosa, A. López-Francos

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## Workshop Papers



# Foreword

Food safety is a major global concern for consumers, industry and governments, in a world where foodborne illnesses are responsible of huge losses and damages in human terms and of enormous economic costs. Food and feed trade is increasing steadily, food chain is concentrating, and the irruption of food-borne outbreaks causes health crisis and create social alarm and vast losses for the industry. Risk analysis based on scientific evidence has proven to be a useful tool for addressing food safety challenges. The Mediterranean basin is experiencing the same trends and there is a need for enhancing scientific exchanges and cooperation between its countries, that share borders and food safety concerns but that are at different stages in the process of integrating scientific risk analysis in their policies and in the practices of the food industries.

SAMEFOOD (Safe Mediterranean Food Network, [www.iamz.ciheam.org/samefood](http://www.iamz.ciheam.org/samefood)) is an open networking initiative promoted since 2013 by the Mediterranean Agronomic Institute of Zaragoza of the International Centre of Advanced Mediterranean Agronomic Studies (IAMZ-CIHEAM) with the following general objectives: (i) to strengthen scientific cooperation for food safety in the Mediterranean Basin, focusing especially on North-South and South-South cooperation; and (ii) to promote a scientifically-based approach in food safety risk assessment and communication in the Mediterranean countries.

The "kick-off" scientific activity of SAMEFOOD was the Workshop "Food Safety Challenges for Mediterranean Products", that was held in Zaragoza (Spain) on 10-11 June 2014, intending: (i) to launch the Network at a large scale, identifying and attracting the interest of potential members of the Network in the Mediterranean basin countries, and establishing the constitutional framework and a working programme for the following years; and (ii) to make the first exchange of experiences and knowledge within the framework of the Network, on topics of common interest for the Mediterranean countries on food safety and risk assessment.

The Workshop was organized by the Mediterranean Agronomic Institute of Zaragoza (IAMZ) of the International Centre of Advanced Mediterranean Agronomic Studies (CIHEAM) with the participation of the European Food safety Authority. A total of 42 persons from 11 countries (Albania, France, Greece, Italy, Lebanon, Malta, Morocco, Portugal, Spain, Tunisia and Turkey) and 4 international organisations (EFSA, IAEA, OIE and IAMZ-CIHEAM) attended the Workshop. The participants were mainly scientists from universities and research centres involved in food safety risk assessment, and also officials from national food safety authorities / departments and international organisations involved in food safety.

This volume of *Options Méditerranéennes* publishes the proceedings of the Workshop, and contains 13 full articles on the invited presentations of the Workshop as well as 10 "Country profiles" that summarize the institutional and governing map of food safety risk management in Albania, France, Greece, Lebanon, Malta, Morocco, Portugal, Spain, Tunisia and Turkey. The profiles were prepared by the Network Focal points in the corresponding countries, following a common scheme proposed by Dr Gorgias Garofalakis (EFET, Greece).

We kindly acknowledge the Scientific Committee of the Workshop, EFSA, AECOSAN and CIHEAM for their support and collaboration, the authors and the panel of reviewers (L. Chekir, G. Garofalakis, E. Liébana, A. Ricci, A. Valero and A. Zinedine) who have made the publication of this volume possible and the attendees for their presence and their valuable feedback during the working sessions of the Workshop.

Vicente Sanchis  
University of Lleida (Spain)  
Scientific Coordinator of SAMEFOOD

Javier Sierra  
Director  
IAMZ-CIHEAM

# **SAMEFOOD**

## **A Mediterranean Network on Food Safety**

**A. López-Francos<sup>1</sup> and V. Sanchis<sup>2</sup>**

<sup>1</sup>Mediterranean Agronomic Institute of Zaragoza  
Av. Montañana 1005, 50059 Zaragoza (Spain)  
lopez-francos@iamz.ciheam.org

<sup>2</sup>Food Technology Department, Agrotecnio Center, University of Lleida  
Avda. Rovira Roure, 191, 25198 Lleida (Spain)  
vsanchis@tecal.udl.cat

### **I – Background and history**

Food safety is a concern to be approached globally, as international exchanges of foods and feeds and increase steadily as well as the movement of persons between countries, regions and continents. The urbanization of the population and the concentration and specialization of the food chains multiply the potential dimension of food outbreaks, and at the same time concerns on food related risks are strongly conveying societal debates and economic and politic strategies. Costs in terms of health and human losses are enormous as foodborne illnesses are prevalent throughout the world. In this context, the paradigm of risk analysis with the application of a science based approach is emerging since the decade of the 1990's as a rational framework for responding to food safety challenges effectively and efficiently and thus contributing to a reduction in the incidence of food-borne disease and to improve food safety. (FAO and WHO, 2005)

The Mediterranean region is experiencing the same trends and, together with extensive agro-food trade within Europe but also between the EU and the other Mediterranean countries, there are rather different control, regulation, institutional and experience levels in Mediterranean countries and regions regarding risk analysis.

In this context where science plays a fundamental role in applying risk analysis and its basis risk assessment, scientific cooperation between Mediterranean countries and between different research groups working on food safety is undoubtedly a tool that can contribute to food safety, improving the populations' health and preventing food crises and disruptions in the trade system and in the value chain of food products.

The International Centre for Advanced Mediterranean Agronomic Studies (ICAMAS in English or CIHEAM in French), is an intergovernmental Organisation created in 1962 under the auspices of the Council of Europe and the OECD, and it groups 13 countries from the Mediterranean region (.Albania, Algeria, Egypt, France, Greece, Italy, Lebanon, Malta, Morocco, Portugal, Spain, Tunisia and Turkey), aiming to provide complementary education and develop a spirit of international cooperation among private/public sector executive, academics-researchers and official. CIHEAM has four Mediterranean Agronomic Institutes (MAIs in English or IAMs in French) in Montpellier (France), Chania (Greece), Bari (Italy) and Zaragoza (Spain) which are the organs that mainly develop the mission of the Centre by implementing training and cooperative research programmes.

The Mediterranean Agronomic Institute of Zaragoza (IAMZ-CIHEAM) develops training programmes (Master of Science degrees and short specialised courses) and promotes cooperative research projects and networks in a wide range of topics that can be grouped in the areas of plant and animal production, rural development and environment, fisheries and

aquaculture and agro-food marketing, science and technology. This last working area has been enlarged since 2012 as originally it was restricted to marketing; following this strategic decision of the Institute, the idea of developing a networking action on the area started to materialize with the support of the call of proposals launched the same year by the CIHEAM General Secretariat to create new networks that could contribute to fulfill the objectives of the Centre. Food safety was identified as a topic of high priority that was not specifically covered by the CIHEAM (although punctual training and research activities had been carried out previously), and the first step of the creation of a network, was to invite Dr Vicente Sanchis from the University of Lleida, one of the IAMZ's collaborating experts on food science of the Institute, to debate and draft the network scope and structure and to identify a first activity to launch the initiative. The following step was to organize a coordination meeting in November 2013 in the premises of the Institute, where six relevant experts from five Mediterranean countries and from the European Food safety Authority (EFSA), debated with IAMZ the terms of reference of the Network, proposed a name and an acronym, selected some of the network focal points, and drafted the programme of what was going to be the kick of Meeting of the Network.

Thus, the Mediterranean scientific network on food safety was unofficially created in 2013 and named **SAMEFOOD** (the acronym of **Safe Mediterranean Food**).

As decided in the coordination meeting, a two days' workshop was organized as the launching activity of SAMEFOOD, and was programmed for 10-11 June 2014 entitled "**Food Safety Challenges for Mediterranean Products**". The present volume of *Options Méditerranéennes* publishes the proceedings of the Workshop, attended by 42 persons from 11 countries (Albania, France, Greece, Italy, Lebanon, Malta, Morocco, Portugal, Spain, Tunisia and Turkey) and 4 international organisations (EFSA, IAEA, OIE and IAMZ-CIHEAM). The participants were mainly scientists from universities and research centres involved in food safety risk assessment, and also officials from national food safety authorities / departments and international organisations involved in food safety.

Besides the scientific working programme of the Workshop, a networking session was carried out with all the participants, where the original terms of reference of SAMEFOOD were debated, modified and approved, the name of the Network was corroborated, the country focal points were designated the membership was defined, and some possibilities for SAMEFOOD future activities were proposed.

The next sections detail the nature, scope, objectives and structure of SAMEFOOD, developing the decisions taken in the previously defined process of creation of the Network. More information can be found at the website [www.iamz.ciheam.org/samefood](http://www.iamz.ciheam.org/samefood)

## II – Objectives and scope of SAMEFOOD

The general objectives of SAMEFOOD are:

- (i) To strengthen scientific cooperation for food safety in the Mediterranean Basin, focusing especially on North-South and South-South cooperation.
- (ii) To promote a scientifically-based risk approach in food safety risk assessment and communication in the Mediterranean countries.

A number of specific objectives have been defined for the Network in order to achieve the general ones:

- To identify and prioritise common food safety issues.
- To characterise region-specific drivers for emerging risks
- To facilitate the identification of experts
- To exchange information on planned or current activities
- To share data and existing risk assessment studies
- To develop an almanac of food safety governance

- To identify data needs and knowledge gaps
- To enhance capacity building on food safety in the region
- To facilitate and promote debate among stakeholders.
- To cooperate in projects and other joint actions

SAMEFOOD being a scientific network, it will focus on the assessment of risks, one of the three pillars of the risk analysis framework following FAO and WHO definition (FAO and WHO 1995; ). Secondly, risk communication actions can also be developed by SAMEFOOD for disseminating food safety science basis, findings or recommendations.

The Network will deal with issues of food safety risk assessment in the whole food chain, but stress will be placed on emerging risks, outbreaks control and new tools for risk analysis. Challenges and interactions between trade and food safety may be also specific topics to be dealt with, together with issues related to local foods and food safety. Because of its aims and nature SAMEFOOD will refrain from addressing governance, legislation, risk management issues, etc. that are attributions of national and international authorities (Fig. 1).

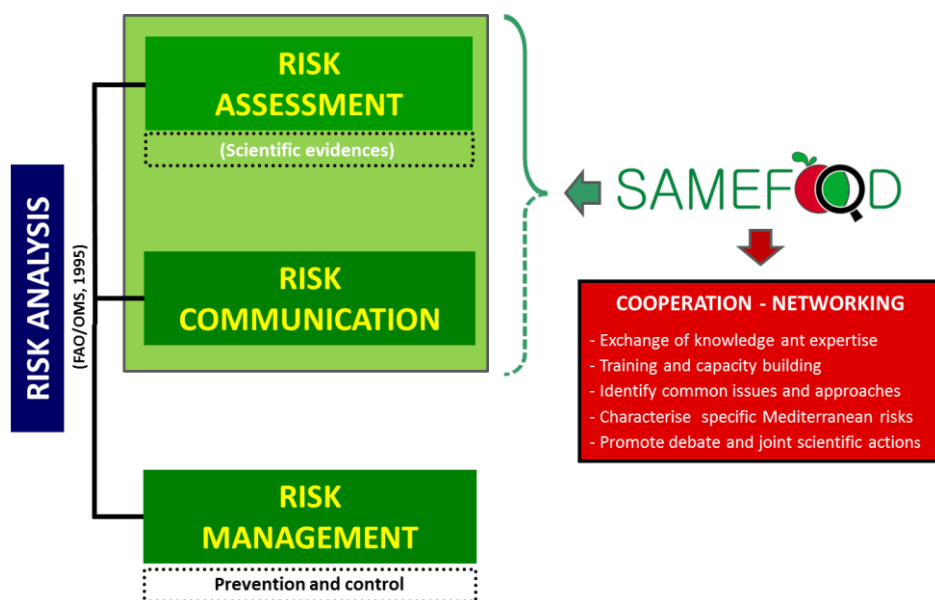


Fig. 1. SAMEFOOD place in the Risk Analysis framework model.

All of the Mediterranean basin countries will be covered, but particularly focusing on CIHEAM members (Albania, Algeria, Egypt, France, Greece, Italy, Lebanon, Malta, Morocco, Portugal, Spain, Tunisia and Turkey). However, synergies and cooperation may also be sought from other parts of the world.

### III – Structure, management and membership

SAMEFOOD is a network of persons and institutions whose professional interest is Food Safety. Professionals working on research, management, communication and in the private and public sectors on Mediterranean countries and international organizations are welcome.

The SAMEFOOD Network has a **light coordinating structure**. The coordination structure will be composed of a Network Scientific Coordinator, an Executive Committee and the Focal points (Fig. 2).

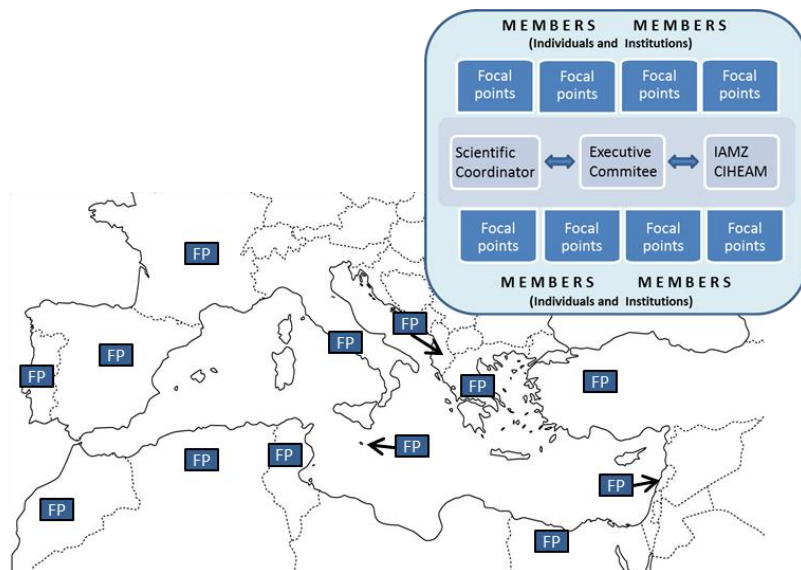


Fig. 2. Structure of the SAMEFOOD Network. FP: focal point.

The **Coordinator** is in charge of:

- (i) management and network monitoring,
- (ii) coordinating the flow of external and internal information,
- (iii) the organisation and direction of the Executive Committee meetings, implementation of decisions of the committee and distribution of minutes,
- (iv) dialogue with the administration,
- (v) where appropriate, providing support documentation for the projects/activities,
- (vi) reporting the situation and progress of the network.

The current coordinator of SAMEFOOD is Dr Vicente Sanchis, professor at the Department of Food Technology at the University of Lleida (Spain).

The **Executive Committee** is composed of five Focal points plus the Network Coordinator and a representative of IAMZ-CIHEAM. Members are selected by aiming at a geographic and thematic balance. The Committee will evaluate proposals of activities made by the network Focal points and other Network members, and will also propose activities for the Network. The activities will be approved on the basis of their interest for the Network and their feasibility (financial and organizational), and the Executive Committee will also be involved in the implementation and monitoring of those activities together with other Network members who might be involved in; ad hoc scientific, organising, editorial or other committees will be established for each activity carried out by the Network.

Each CIHEAM country (Albania, Algeria, Egypt, France, Greece, Italy, Lebanon, Malta, Morocco, Portugal, Spain, Tunisia and Turkey) has or will have a **Focal point** or node who is a

person of scientific relevance or someone in an official institution of food safety assessment or management. Focal points in key international institutions may also be part of the structure of the network; for the time being, EFSA and IAMZ-CIHEAM are involved, and it is advisable to have the participation of FAO and WHO. Focal points are not be official country delegates, but rather, persons interested in and committed to establishing contacts at national and international levels for proposing memberships and active in the consecution of the Network activities. Focal points will also propose actions, strategies, projects, etc. and are a key point of the transfer of network actions to their countries institutions.

The IAMZ-CHEAM is strongly committed with SAMEFOOD and will support the management of the Network with one of its officials engaged in its activities. The Institute also holds the website of the Network, and may if resources are available, financially support some of the activities.

**Membership** is open to any person and institution with professional interest in food safety and willing to participate in the Network activities, regularly or occasionally depending on their interest, will, availability of resources and time. Membership can be on an individual level and is, for the moment, free of charge. Members can participate regularly in all Network activities, or choose specific activities depending on their interest, will, availability of resources and time. Institutions can also incorporate as members of the SAMEFOOD network.

## IV – Type of activities foreseen

SAMEFOOD is open to organize, promote and participate in a wide range of activities that fit into its objectives, scope and geographical area of interest. Among the types of activities which SAMEFOOD can be involved in are:

(i) **Training courses.** Short specialised courses on different topics of interest are envisaged. In recent years IAMZ-CIHEAM has organised several specialised courses related to food safety (e.g. “Safety of food of animal origin: meat, poultry and eggs” and “Mycotoxins in cereal food/feed chains: Prevention and control strategies to minimise contamination”). After the establishment of SAMEFOOD, and with the collaboration of some of its experts, courses on Predictive Microbiology (February 2015), the Traceability on the food chain (March 2015) and Bivalve shellfish safety management (September 2015) have been organised. IAMZ programmes its course offer once a year in February, and is willing to organise advanced training courses proposed by the Network.

(ii) **Other Training activities through short exchanges** of researchers between different research groups. i.e. to master specific laboratory techniques, or to meet a certain team and learn of the work they are carrying out.

(iii) **Thematic meetings, symposiums and workshops.** A wide range of topics have been suggested by the Network members: mycotoxins, emergent pathogens, microbial typing methods, inter-regional coordination for risk management for Mediterranean products

(iv) **Data bases and information gathering and exploiting**, in particular an “almanac” on the food safety governance systems of the Mediterranean countries. The country profiles published in the present proceedings are in the line of such an almanac.

(v) Making specific **joint studies** on issues of common interest, publishing joint works, applying to international cooperative research calls, etc.

The structure of the Network with the focal points, is intended to convey information on topics of interest, potential activities, sources of funding, etc., and the activities project will be pursued in case if after positive evaluation of the Executive Committee, enough resources and commitment of persons and institutions is found.

As a general strategy, and if possible, the activities of the Network will be provided in coordination with EFSA and national agencies avoiding duplications. SAMEFOOD will refrain from addressing governance, legislation, risk management issues, etc. that are attributions of national and international authorities.

## V – Conclusion and future of SAMEFOOD

SAMEFOOD has started walking recently and has already carried out some activities, among them the publication of the present proceedings, and it has awoken the interest of many people and institutions beyond participants to the Kick-off Workshop or the courses that IAMZ has organized since then. We believe that institutions and people involved in food safety assessment and management in the Mediterranean countries (research community, assessment agencies and authorities) have an active interest in the objectives of scientific cooperation for which SAMEFOOD was created.

For the time being, new cooperative activities with EFSA are being envisaged, as well as a specific event on mycotoxins to be organised with the Moroccan members of the network. Another activity that we hope will see the light in the mid-term, at least at a small scale at the beginning, is the organisation of short stays of researchers of Southern and Eastern Mediterranean countries in Northern institutions and research groups.

SAMEFOOD lacks its own resources, and although fund raising is not an easy task in this days of crisis and hard concurrence, the fact of relying in a wide network of experts and organisations, and the interest of our partners and of society in general in the aims and topics of the Network permit to be optimistic in terms of continuity of SAMEFOOD. Cooperation with EFSA, that holds a Neighbourhood strategy which matches so well with the SAMEFOOD scope and nature will be probably and hopefully sustained in the future. Attracting other international institutions as FAO or the WHO to cooperate with SAMEFOOD is also one of the priorities. Synergies may also be created with national agencies in charge of food safety interested in cooperating with their homologous neighbour organisations or to benefit from technical training and exchanges. And the academic and research community will with no doubt benefit from the exchange of experiences and training opportunities that SAMEFOOD will try to continue offering in the future. Finally, the previously mentioned commitment of CIHEAM, an institution with more than 50 years' experience in scientific and technical training, research and networking, and providing a huge contact network of experts, organisations, companies and administrations at international level gives undoubtedly some guarantee for the sustainability of SAMEFOOD and its capacity to propose sound activities and play a role in the Mediterranean scientific cooperation on the area of food safety.

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# General tasks and structure of the European Food Safety Authority (EFSA) and its role on risk assessment for microbiological hazards

S. Correia, W. Messens, M. Hempen, T. da Silva Felicio, P. Stella,  
P. Romero Barrios and E. Liebana\*

\*Unit on Biological Hazards and Contaminants (BIOCONTAM), European Food Safety Authority (EFSA)  
Via Carlo Magno 1A, 43126 Parma (Italy)

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**Abstract.** The European Food Safety Authority (EFSA) is the keystone of European Union (EU) risk assessment for food and feed safety. EFSA provides independent scientific advice and information about existing and emerging risks following a farm to fork approach. When a food safety question on biological hazards is to be answered, which is under the remit of the EFSA's Scientific Panel on Biological Hazards (BIOHAZ), whenever possible and as a basis for their work, the risk assessment framework developed by Codex Alimentarius is applied. BIOHAZ opinions cover different approaches ranging from quantitative risk assessments over structured qualitative risk assessment/risk ranking to opinions with short deadlines summarising existing knowledge from the scientific literature. The approach taken depends on the terms of reference as received from the requestor, the available data and resources and the timeframe for the work. This paper reviews the integrated approach followed by EFSA towards risk assessment, with a special focus on human health and the whole food chain, and on science based interventions to lower the risk to consumers. The outcomes of some of the activities developed during the last two years (July 2012 until May 2014) by the current BIOHAZ Panel were summarised.

**Keywords.** EFSA – BIOHAZ – Risk assessment – Microbiological hazards.

## ***Fonctions générales et structure de l'Autorité européenne de sécurité des aliments (EFSA) et son rôle dans l'évaluation des risques microbiologiques***

**Résumé.** L'Autorité européenne de sécurité des aliments (EFSA) est la pierre angulaire de l'Union européenne (UE) pour ce qui concerne l'évaluation des risques relatifs à la sécurité des aliments destinés à l'alimentation humaine et animale. L'EFSA fournit des avis scientifiques indépendants ainsi qu'une communication claire sur les risques existants et émergents en suivant une approche de la ferme à la fourchette. Lorsqu'une question de sécurité alimentaire est adressée, qui relève du domaine de compétence du groupe scientifique de l'EFSA sur les dangers biologiques (BIOHAZ), il est appliqué autant que possible et en tant que base pour le travail du groupe, le cadre d'évaluation des risques développé par le Codex Alimentarius. Les avis du groupe BIOHAZ couvrent différentes approches allant de l'évaluation quantitative des risques liée à une évaluation qualitative structurée de risques/classification des risques à des avis sous délai rapide résumant les connaissances existantes à partir de la littérature scientifique. L'approche retenue dépend des termes de référence formulés par le demandeur, des données et ressources disponibles, et du délai imparti à ce travail. Cet article passe en revue l'approche intégrée suivie par l'EFSA concernant l'évaluation des risques, en particulier axées sur la santé humaine et la chaîne alimentaire dans son ensemble, et les interventions fondées sur la science visant à diminuer les risques pour les consommateurs. Finalement sont résumés les résultats de certaines activités menées par l'actuel groupe BIOHAZ sur les deux dernières années (de juillet 2012 à mai 2014).

**Mots-clés.** EFSA – BIOHAZ – Évaluation des risques – Dangers microbiologiques.

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## I – Introduction

The European Food Safety Authority (EFSA) was set up in January 2002, following a series of food crises in the late 1990s (Bovine Spongiform Encephalopathy - BSE, dioxin, foot and mouth disease, etc), as part of a comprehensive programme to improve European Union (EU) food safety systems, to ensure a high level of consumer protection and to restore and maintain confidence in the EU food supply. As the risk assessor, EFSA produces scientific opinions and advice to provide a sound foundation for European policies and legislation and to support the European Commission (EC), European Parliament (EP) and EU Member States (MSs) in taking effective and timely risk management decisions. EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. In all these fields, EFSA's most critical commitment is to provide objective and independent science-based advice and clear communication grounded in the most up-to-date scientific information and knowledge. In the EU, food legislation has to be based on "risk analysis" following the Founding Regulation EC No 178/2002 (EU, 2002), which establishes EFSA and the general principles governing food and feed safety. The risk analysis framework, as initially defined by FAO, WHO and the Codex Alimentarius Commission (CAC, 1999), consists of three separate but interconnected elements: risk assessment, risk management and risk communication. This paper aims to explain the mission and structure of EFSA and its role on developing risk assessments. It also describes the specific mission of the BIOHAZ Panel, the procedure of its work, the activities developed in the area of microbiological risk assessment, and its latest scientific opinions or reports related to food-borne diseases, food hygiene and BSE/TSE related issues.

## II – EFSA

### 1. Role and mission

EFSA's role is to assess and communicate on all risks associated with the food chain. Since its advice serves to inform the policies and decisions of risk managers, a large part of EFSA's work is undertaken in response to specific requests for scientific advice from the EC, EP and MSs. EFSA also undertakes scientific work on its own initiative (self-tasking). As defined in its Founding Regulation (EU, 2002), EFSA's main mission is to provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. The missions assigned to EFSA are: (i) issuing scientific opinions based on risk assessment, (ii) promoting and coordinating the development of risk assessment methodologies, (iii) commissioning scientific studies, (iv) collecting and analyzing scientific and technical data, (v) identifying emerging risks, (vi) establishing networks of relevant organisations, (vii) assisting the EC in crisis management, (viii) providing independent information on all matters within its mission with a high level of openness and transparency and (ix) communicate the risks. EFSA's activities are guided by a set of core values: excellence in science, independence, openness and transparency, and responsiveness.

### 2. Structure

EFSA is organised in five departments overseen by EFSA's Executive Director: Risk Assessment and Scientific Assistance (RASA), Scientific Evaluation of Regulated Products, Science Strategy and Coordination (the three science departments), Communications department and Resources and Support department. The RASA department supports EFSA's Scientific Panels to carry out risk assessments. Its Units also provide specialised support on data collection, exposure assessment and risk assessment methodologies. EFSA's Scientific Panels are responsible for EFSA's risk assessment work including delivering scientific opinions in the different areas of the food and feed chain. The Scientific Committee (SC) has the task of supporting the work of the ten Panels on cross-cutting issues and scientific matters of a horizontal nature. The SC and the Panels are

composed of independent scientific experts with a thorough knowledge of risk assessment and are supported by the above mentioned three scientific departments. EFSA is governed by an independent Management Board whose members are appointed to act in the public interest and do not represent any government, organisation or sector. EFSA's Advisory Forum connects EFSA with the national food safety authorities of all 28 MSs, Iceland and Norway, with observers from Switzerland and the EC.

### III – Risk assessment for microbiological hazards

#### 1. BIOHAZ Panel

The Panel on Biological Hazards (BIOHAZ Panel) provides independent scientific advice on biological hazards in relation to food safety and food-borne diseases, covering food-borne zoonoses, transmissible spongiform encephalopathies (BSE/TSEs), food microbiology, food hygiene and associated waste management issues (animal by products). The BIOHAZ Panel's risk assessment work is based on reviewing scientific information and data in response to requests for scientific advice (terms of reference) from risk managers (most commonly, the EC) or on its own initiative. The BIOHAZ Panel regularly sets up working groups involving external scientists with relevant expertise to focus on specific matters and help produce draft scientific opinions. The BIOHAZ Panel meets regularly in plenary sessions to discuss work in progress and to adopt finalised scientific opinions.

#### 2. Risk assessment methodologies for microbiological hazards

The risk assessments are usually provided to the risk manager in the form of scientific opinions and can be either quantitative or qualitative, depending on the scope and on the extent of data, resources and time available, or may also take the simpler form of risk profiles depending on the terms of reference provided (Romero-Barrios *et al.*, 2013). In general, the scientific opinions are structured according to the four well-established principles of microbiological risk assessment (CAC, 1999): hazard identification, exposure assessment, hazard characterization and risk characterization.

Since the appointment of the first mandate in 2003, the BIOHAZ Panel has evolved in its scientific advice to the risk managers. Until 2007, scientific opinions of the BIOHAZ Panel (with the exception of those on BSE/TSE) were mainly based on qualitative and in some cases semi-quantitative risk assessment (Hugas *et al.*, 2007). In September 2004, EFSA launched a project tender to formulate a strategy for quantitative microbiological risk assessment (QMRA) at the European level. The study commissioned to Havelaar (2005) identified many expected benefits such as: a more solid basis for common and more objective, science based criteria for food safety; support in evaluating possible risk mitigation options to be used at national level to reach common EU targets; increased transparency, enhancing risk communication between professionals and trust among stakeholders; increased sharing and optimal use of available data and resources, avoiding duplication of work between MSs, and a help to focus data collection efforts; and an useful tool to rank the relative contribution of different exposure pathways. In 2006 and 2009, respectively, EC requested to the BIOHAZ Panel to provided, for the first time, two full farm-to-fork QMRAs for the whole EU, with regard to *Salmonella* in slaughter and breeder pigs (EFSA, 2010b), and *Campylobacter* in broiler meat (EFSA, 2011a). These risk assessments, details about the models developed and other related activities are described by Romero-Barrios *et al.* (2013). Also in the field of setting targets for *Salmonella* in poultry populations (broiler flocks of *Gallus gallus* and flocks of fattening turkeys) quantitative assessments were used. More information can be retrieved in Messens *et al.* (2014).

The mandates by the EC increasingly ask for a quantitative evaluation of public health benefits and risks, which may require the development of mathematical models in order to answer to the questions in a sufficient depth. Moreover, models identify important data gaps or lacks of

knowledge thereby indicating future research priorities. In the scientific opinion "Reflecting on the experiences and lessons learnt from modelling on biological hazards" more information can be found (EFSA, 2012c).

### 3. Data collection for the risk assessment of microbiological hazards

Collection of accurate, harmonised and reliable data on hazards found in the food chain and on food consumption is a prerequisite for informed risk assessment and risk management at EU level. EFSA has an important role in collecting and analysing scientific data by working with the MSs to gather, share and analyse EU-wide data, as well as launching public consultations and calls for data to gather information from external sources.

In the area of zoonoses, data are particularly valuable for quantitatively estimating risks and/or for identifying to what extent a given control measure or intervention strategy can reduce the burden of a zoonotic disease in humans (Makela *et al.*, 2012). In the field of biological risks for human health, Directive 2003/99/EC (EU, 2003) lays down the requirement for an EU system for monitoring and reporting information, which obliges MSs to collect relevant and comparable data on zoonoses, zoonotic agents, antimicrobial resistance and foodborne outbreaks. Based on this data, every year EFSA prepares Community Summary Reports in close collaboration with the European Centre for Disease Control and Prevention (ECDC). Moreover, EFSA analyses the EU-wide baseline surveys on zoonotic agents, such as *Salmonella* and *Campylobacter*, in animal and food-populations and on antimicrobial resistance, assisted by the Task Force on Zoonoses Data Collection.

Finally, data and information for these risk assessments are also obtained through the two related scientific networks: on microbiological risk assessment (MRA) and on BSE-TSE and from the EFSA Food consumption data for exposure assessments as well from the collaboration with other EU Agencies (ECDC, European Medicines Agency (EMA), EU Joint Research Centre (EU-JRC)) and EU reference laboratories (EURLs).

### 4. Examples of scientific assessments by the BIOHAZ panel

From the beginning of the third mandate (07/2012) until now (May 2014) the BIOHAZ Panel has delivered 22 scientific outputs, of which 17 were opinions and 5 reports. Most outputs were related to food hygiene and associated waste management issues (animal by-products) (9), food-borne diseases (5), transmissible spongiform encephalopathies (BSE/TSEs) (6) and safety of microorganisms (2). In line with the farm to fork approach and looking for a high multidisciplinary component, the BIOHAZ Panel has been working in some cases in close collaboration with other agencies in the EU public health area such as the EMA and the ECDC.

#### A. Scientific assessment of food hygiene issues

##### a] Meat Inspection (EFSA, 2013 h,i,j,l)

During the referred period, four opinions dealing with meat inspection of solipeds, bovine animals, farmed game and small ruminants (EFSA, 2013 h,i,j,l) were published. EFSA was asked to identify and rank the main risks for public health that should be addressed by meat inspection at EU level, to assess the strengths and weaknesses of the current meat inspection, and to recommend new inspection or other methods fit for the purpose of meeting the overall objectives of meat inspection.

Relevant meat-borne hazards were identified and ranked based on their incidence and severity in humans, their prevalence on carcasses and the role of meat from these species as a risk factor for human disease. Following an assessment of current methods of meat inspection, alternatives or improvements were recommended, including how to address hazards not covered by current methods, both at farm level and during processing at abattoir. The hazards considered to be the most important were: verocytotoxin-producing *E. coli* (VTEC) and *Salmonella* for cattle; VTEC and *Toxoplasma* for sheep and goats; *Trichinella* for solipeds, *Toxoplasma* for farmed deer;

*Salmonella* and *Toxoplasma* for farmed wild boar. The public health related strengths identified were that the Food Chain Information (FCI) provides information on disease occurrence and veterinary treatments, enabling a focused inspection of animals with problems. On the other hand, the use of FCI for food safety purposes is today limited because the data that it contains is very general and does not address specific hazards of public health importance. Lastly, it was considered that palpation and incision techniques used during *post-mortem* inspection for some species could cause bacterial cross-contamination. It was concluded that to ensure effective control of the hazards of relevance, a comprehensive meat safety assurance, combining measures applied on-farm and at-abattoir, is necessary. A prerequisite for this system would be the setting of targets for these hazards to be achieved by food business operators at carcass level. Targets in primary production can be considered if intervention methods at the farm level exist.

#### **b] Public health risks related to mechanically separated meat (EFSA, 2013g)**

The public health risks linked to mechanically separated meat (MSM) types from pork and poultry were identified and compared with fresh meat, minced meat and meat preparations (non-MSM). Also methods to select, rank and suggest objective measurement methods and values for parameters to distinguish MSM types were assessed. Microbial hazards in MSM are expected to be similar to those in non-MSM, although the risk of microbial growth increases with the degree of muscle fibre degradation, thus with the separation pressure. For the distinction between the different types of MSM and non-MSM chemical, histological, molecular, textural and rheological parameters were considered as potential indicators. Published data suggested that calcium and, if confirmed cholesterol content, was the only appropriate chemical parameters which could be used to distinguish MSM from non-MSM products. A model was developed and it was determined that a calcium content of 100 mg/100 g, corresponds to a probability of 93.6% for a product to be classified as MSM. It was recommended that in order to improve methods for MSM identification, specifically designed studies for the collection of data obtained by standardised methods on indicators such as calcium and cholesterol should be undertaken, while studies based on combinations of different parameters could also be useful.

#### **c] Transport of meat (Part 1) (EFSA, 2014c)**

EFSA assessed whether or not it was possible to apply alternative core temperatures higher than the current requirement of 7 °C, in combination with specific transport durations for meat (carcasses) of domestic ungulates after slaughter without increasing the risk associated with the growth of pathogenic microorganisms. The growth of *Salmonella* spp., VTEC, *Listeria monocytogenes* and *Yersinia enterocolitica* during chilling was modelled. Combinations of maximum surface temperatures at carcass loading and maximum chilling and transport times that result in pathogen growth equivalent or less than that obtained when carcasses are chilled to a core temperature of 7 °C in the slaughterhouse were provided. The second part of the mandate (part 2) deals with minced meat and this activity is ongoing.

### **B. Scientific assessment of food-borne diseases**

#### **a] VTEC-seropathotype and scientific criteria regarding pathogenicity assessment (EFSA, 2013d)**

The seropathotype concept of Karmali *et al.* (2003) was reviewed. This empirical system classifies VTEC strains based on their reported frequency in human disease, their known association with outbreaks and the severity of the outcome including haemolytic uraemic syndrome (HUS) and haemorrhagic colitis (HC). This classification system utilises a gradient ranging from seropathotype A – high risk – to seropathotypes D and E – minimal risk. In addition, it was assessed whether the pathogenicity can be excluded for defined VTEC serotypes, and whether an alternative concept based on detection of verocytotoxins or genes encoding for verocytotoxins in isolates could be proposed. EFSA was also asked to assess the contribution by VTEC to diarrhoeal cases and to more severe outcomes in the EU.

During 2007-2010, 13 545 confirmed human VTEC infections were reported in the EU, including 777 HUS cases. The clinical manifestations were reported for 53% of cases; 64% of which presented with diarrhea alone and 10% with HUS. Isolates from 85 % of cases were not fully serotyped and therefore could not be classified using the Karmali seropathotype concept. It was concluded that there is no single or combination of phenotypic or genetic marker(s) that fully define 'pathogenic' VTEC. Isolates which contain the *vtx2* (verocytotoxin 2) in combination with the *eae* (intimin-encoding) gene or *aaiC* (secreted protein of enteroaggregative *E. coli*) and *aggR* (plasmid-encoded regulator) genes have been associated with a higher risk of more severe illness. A molecular approach targeting genes encoding VT and other virulence determinants is thus proposed to allow an assessment of the potential severity of disease that may be associated with a given VTEC isolate.

#### **b] Evaluation of molecular typing methods for major food-borne pathogens (Part 1) (EFSA, 2013c)**

An evaluation of molecular typing methods that can be applied to the food-borne pathogens *Salmonella*, *Campylobacter*, VTEC and *Listeria monocytogenes* was conducted. This evaluation was divided in two parts. Firstly, commonly used molecular typing methods were assessed against a set of predefined criteria relating to discriminatory capacity, reproducibility, repeatability and current or potential suitability for international harmonisation. Secondly, the methods were evaluated for their appropriateness for use in different public health-related applications. These applications included outbreak detection and investigation, attribution modelling, the potential for early identification of food-borne strains with epidemic potential and the integration of the resulting data in risk assessment. The results of these evaluations provided updated insights into the use and potential for use of molecular characterisation methods, including whole genome sequencing technologies, in microbial food safety. Recommendations were also made in order to encourage a holistic and structured approach to the use of molecular characterisation methods for food-borne pathogens. Currently, the BIOHAZ Panel is working on the follow-up of this opinion to evaluate the requirements for the design of surveillance activities for food-borne pathogens and to review the requirements for harmonised data collection, management and analysis.

#### **c] Food of non animal origin (FoNAO): a) Risk posed by pathogens in food of non-animal origin: Part 1 (EFSA, 2013b)/ b) Part 2: *Salmonella* and Norovirus in leafy greens eaten raw as salads (EFSA, 2014a)**

Food of non-animal origin (FoNAO) have the potential to be associated with large outbreaks as occurred in 2011 when sprouted fenugreek seeds were implicated in the major VTEC O104:H4 outbreaks in Germany and in France. In 2012, upon request by the EC, a comparison of the incidence of human cases linked to consumption of FoNAO and of food of animal origin (FoAO) was carried out. In order to identify and rank specific food/pathogen combinations most often linked to foodborne human cases originating from FoNAO in the EU, a model was developed using seven criteria: (i) strength of associations between food and pathogen based on the foodborne outbreak data from EU Zoonoses Monitoring (2007-11); (ii) incidence of illness; (iii) burden of disease; (iv) dose-response relationship; (v) consumption; (vi) prevalence of contamination; and (vii) pathogen growth potential during shelf life. The top five ranking food/pathogen combination found was *Salmonella* spp. and leafy greens eaten raw followed by (in equal rank), *Salmonella* spp. and tomatoes, *Salmonella* spp. and melons, *Salmonella* spp. and bulb and stem vegetables and pathogenic *Escherichia coli* and fresh pods, legumes or grain (EFSA, 2013b).

The outcome of this model in terms of specific food/pathogen combinations was used to identify the main risk factors, to recommend possible risk mitigating options and to consider microbiological criteria throughout the production chain. The first opinion out of five has been recently published and assessed the risk posed by *Salmonella* and Norovirus in leafy greens eaten raw as salads (EFSA, 2014a). It was concluded that each farm environment represents a

unique combination of numerous characteristics that can influence occurrence and persistence of pathogens in leafy greens production. It was proposed to define a *E.coli* Hygiene Criterion at primary production level. It was also concluded that a Food Safety Criterion for *Salmonella* in leafy greens could be used as a tool to communicate to producers and processors that *Salmonella* should not be present in the product. Studies on the prevalence and infectivity of Norovirus are limited, and quantitative data on viral load are scarce making establishment of microbiological criteria for Norovirus on leafy greens difficult.

It is foreseen that during 2014, additional Scientific Opinions will be adopted on the risk posed by: (i) *Salmonella* and Norovirus in berries; (ii) *Salmonella* and Norovirus in tomatoes; (iii) *Salmonella* in melons; and (iv) *Salmonella*, *Yersinia*, *Shigella* and Norovirus in bulb and stem vegetables, and carrots.

#### **d] Carbapenem resistance in food animal ecosystems (EFSA, 2013e)**

EFSA provides scientific support and advice on the possible emergence, spread and transfer to humans of antimicrobial resistance (AMR) EFSA cooperates closely with ECDC and EMA and also plays a role in the analysis of the monitoring data on AMR collected from food and animals throughout the EU.

EFSA produced a number of risk assessments in the AMR area over recent years, last one being on carbapenem resistance in food animal ecosystems This assessment reviewed the information available on the occurrence of carbapenem resistance in animals and food thereof and concluded that to date only sporadic studies have reported the occurrence of carbapenemase-producing (CP) bacteria in food-producing animals and their environment, and none in food derived from food-producing animals. The assessment proposed a methodology for the detection of CP strains of *Enterobacteriaceae* and *Acinetobacter* spp. The assessment concluded that active/passive monitoring and/or targeted surveys for CP bacteria should cover key zoonotic agents, animal pathogens and indicator organisms. The assessment also indicated that there are no data on the comparative efficacy of individual control options. It recommended continuing to prohibit the use of carbapenems in food-producing animals, and to decrease the frequency of use of antimicrobials in animal production in the EU, in accordance with prudent use guidelines.

### **C. BSE/TSE related risks**

EFSA activities in the TSE risk assessment area are mainly aimed to support the EC during the review of the TSE control measures envisaged by the TSE Roadmap 2<sup>1</sup>, an EC strategy paper for 2010-2015, listing the future policy options available for the control of TSEs. EFSA has been recently producing risk assessments in relation to: (i) the revision of the list/age limit for Specified Risk Material (SRM), EFSA provided a quantitative assessment of the BSE infectious load that might enter the food and feed chain yearly if bovine intestine and mesentery from animals born and raised in the EU would be re-allowed for consumption (EFSA, 2014d); (ii) the revision of the BSE surveillance, EFSA (2012a) provided an evaluation of the epidemiological trends of BSE in 25 EU MSs and assessed the design prevalence and the sensitivity of different BSE monitoring scenarios, EFSA has been also providing similar support to the European Free Trade Association (EFTA) Surveillance Authority, evaluating the ability of a proposed Norwegian BSE monitoring programme in detecting BSE, and the impact of the past use of fishmeal in feed for ruminants on the overall risk of BSE in Norway (EFSA 2013a); and (iii) the revision of scrapie eradication measures, EFSA provided advice on the provisional EURL results of a study on genetic resistance to scrapie in goats in Cyprus (EFSA, 2012b). An ongoing assessment is also evaluating the scrapie situation in the EU after 10 years of monitoring and control in sheep and goats. In addition, EFSA assessed the risk of transmission of classical scrapie via the transfer of in vivo derived embryo in ovines (EFSA, 2013m). This opinion confirmed that classical scrapie could be vertically transmitted in sheep. It

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<sup>1</sup> [http://ec.europa.eu/food/food/biosafety/tse\\_bse/docs/roadmap\\_2\\_en.pdf](http://ec.europa.eu/food/food/biosafety/tse_bse/docs/roadmap_2_en.pdf)

also concluded that the risk of transmitting classical scrapie due to the transfer of homozygous or heterozygous ovine ARR embryos can be considered negligible.

The relatively recent recognition of atypical forms of cattle BSE (L-type and H-type Atypical BSE), pose new challenges to the diagnosis and surveillance of the disease. In order to generate new data on the presence, distribution and infectivity level of these atypical agents in cattle, the EC recently asked EFSA to develop a protocol for further studies on samples from infected.

#### ***D. Evaluation of applications: decontamination treatments of food of animal origin and alternative treatments for disposal of ABP***

##### **a] Safety and efficacy of peroxyacids for decontamination of poultry carcasses (EFSA, 2014b)**

Article 3 (2) of Regulation (EC) No 853/2004 which lays down specific hygiene rules for food of animal origin provides a legal basis to authorise the use of substances other than potable water to remove surface contamination from products of animal origin. Before taking any risk management decisions on their approval, a risk assessment should be carried out by EFSA. In addition to the efficacy and safety of the substance, the potential emergence of reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials and the impact of the substance or its by-products on the environment are also matters of concern.

Since the revision of the guidance document (EFSA, 2010a), EFSA has published five scientific opinions on decontamination treatments: recycling hot water as a decontamination technique for meat carcasses (EFSA, 2010c), lactic acid for the removal of microbial surface contamination of beef carcasses, cuts and trimmings (EFSA, 2011d), Cecure® for the removal of microbial surface contamination of raw poultry products (EFSA, 2012e), Listex™ P100 for the removal of *Listeria monocytogenes* surface contamination of raw fish (EFSA, 2012f) and peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat (EFSA, 2014b). Commission Regulation (EU) No 101/2013 (EU, 2013) allows the use of lactic acid to reduce microbiological surface contamination on bovine carcasses. No other substances are currently authorised for this purpose within the EU.

##### **b] Bioreduction application (EFSA, 2013f)**

Regulation (EC) No 1069/2009 has introduced a procedure for the authorisation of alternative methods of use or disposal of animal by-products (ABP) or derived products. Such methods may be authorised by the EC following receipt of an opinion from the EFSA. The application procedure, including the detailed requirements for the technical dossier, is described under Article 20. ABP arise mainly during the slaughter of animals for human consumption, during the production of products of animal origin such as dairy products, and in the course of the disposal of dead animals and during disease control measures. Regardless of their source, they pose a potential risk to public and animal health and the environment.

EFSA published a statement on the format for applications for new alternative methods for animal by-products (EFSA, 2010e). Since then, EFSA published several opinions: 'Biomation' application for an alternative method for the treatment of ABP (EFSA, 2012d), on hatchery waste as animal by-products (EFSA, 2011b), capacity of oleochemical processes to minimise possible risks linked to TSE in Category 1 ABP (EFSA, 2011c) and on Neste Oil Application for a new alternative method of disposal or use of ABP (EFSA, 2010d). A method for on-farm containment of animal by-products (ABPs), called a 'Bioreduction' system, was recently assessed. The material for containment was of ovine origin and classified as a Category (Cat.) 1 ABP material. The Bioreduction system can reduce the risks related to pathogens such as non-spore forming bacteria and viruses. However, it is highly improbable that the risks related to more resistant biological hazards can be reduced. As the whole system could not be considered

as a closed system, it was not considered as a safe alternative method for on farm containment of animal by-products.

### ***E. Evaluation of the safety of microorganisms used as sources of food and feed additives, enzymes and plant protection products (QPS)***

A wide variety of microorganisms (including viruses) are intentionally added at different stages into the food chain, either directly or as a source of additives or food enzymes. EFSA is requested to assess the safety of these biological agents in the context of applications for market authorisation as sources of food and feed additives, enzymes and plant protection products received by EFSA.

In 2012 (EFSA, 2012g) the BIOHAZ Panel reviewed microorganisms previously assessed including bacteria, yeasts, filamentous fungi and viruses used for plant protection purposes and confirmed all taxonomic units and their qualifications previously recommended for the QPS list. Filamentous fungi and enterococci were not recommended for the QPS list. The 2013 update (EFSA, 2013n) reviewed previously assessed microorganisms and confirmed all taxonomic units and their qualifications previously recommended for the QPS list. Plant viruses were assessed for the first time and were recommended for the QPS list. Filamentous fungi and enterococci were not recommended for the QPS list following updating and reviewing of current scientific knowledge.

## **IV – Conclusions**

Food safety is a continuum in which each of the chronological steps in the food chain (e.g. feed production, food-producing animals, production/processing/serving of food) requires to be considered to assess the impact on human health. An integrated approach is essential for the achievement of EFSA's main objective, which is to provide independent scientific advice and clear communication on existing and emerging risks relating to food safety. When a question concerning any biological hazard which is capable of being transmitted to humans via food at any stage of its production (and processing) is being addressed, an Opinion or report is to be provided by the BIOHAZ Panel. The Panel also provides advice the best ways to collect data, the most suitable diagnostic tests and suggestions to improve the analysis of the data on zoonoses collected under Zoonoses Directive 2003/99/EC. The risk assessments done by the BIOHAZ Panel are in line with the EU strategy of one health, include a farm to fork approach and in many cases have a high multidisciplinary component. Whenever possible, the Panel applies this risk assessment framework developed by Codex Alimentarius as a basis for their work on food safety.

The outcomes of some of the activities developed by the current BIOHAZ Panel during the last years were summarised in this paper. From these it can be seen that the work covers different areas and approaches, ranging from quantitative risk assessments over structured qualitative risk assessment/risk ranking to opinions with short deadlines summarising existence knowledge from scientific literature. The approach taken depends on both the terms of reference as received from the EC, the available data and resources, and the time frame for the work following the risk managers' needs.

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# Chemical risks from an industrial perspective

A. Barranco

Food Research Division, AZTI-Tecnalia, Parque Tecnológico de Bizkaia  
Astondo Bidea 609, 48160 Derio (Spain)  
abarranco@azti.es

## I – Introduction

Food safety and, in particular, the occurrence of chemicals in food, are of great concern from many points of view: (i) *consumers* are demanding high quality food products with the confidence that they are safe and that no adverse health effects will be expected at short and long term; (ii) *authorities* have to set up and applied the legal requirements to guarantee and control the safety of food and the health of consumers; and (iii) *food industry* should comply with all legal requirements and produce safe food in order not to suffer economic losses. This lecture is focused mainly on the industrial perspective of chemical risks; however both the consumers' and authorities' perspectives have a lot of influence on how food industry faces these types of risks.

Many definitions of the term risk have been developed and usually they try to differentiate it from the term hazard. For example, the Codex Alimentarius (FAO/WHO, 2004) has adopted the following definitions:

**Hazard:** A biological, chemical or physical **agent** in, or condition of, food with the **potential to cause an adverse health effect**.

**Risk:** A function of the **probability** of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

As part of the project for the Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals, the International Programme on Chemical Safety (IPCS, 2004) has developed slight different definitions:

**Hazard:** Inherent property of an **agent** or situation having the **potential to cause adverse effects** when an organism, system or (sub)population is exposed to that agent.

**Risk:** The **probability** of an adverse effect in an organism, system or (sub)population caused under specified circumstances by exposure to an agent.

As it can be seen in both definitions the term risk is associated with the probability of occurring an adverse effect whereas hazard is related to the agent/property/condition causing that adverse effect. In general, chemicals and food are two words that people do not want to see together. Chemicals are bad considered and they usually cause more concern than microbiological contamination because the exposure to them is considered to be beyond consumers' control (Kher *et al.*, 2011). Moreover, fears are expressed regarding their capacity to cause long term effects. However, chemicals are commonly needed in everyday life and also contribute with beneficial effects when used in a proper way. Regarding food industry many chemicals are used as additives to improve the quality (color, flavor, odour, shelf life...) and safety (antimicrobials, functional ingredients...) of food products.

## II – Chemicals in the food industry

Several steps are needed to get food from the farm or fisheries to our table. This process includes the primary production, processing, distributing, retailing, consumption and at the end, the disposal of waste. In each step many chemicals can enter in contact with food, thus residues might occur in the final product and consumers' might be exposed to them. Next some examples of chemical in each step are presented:

### 1. Production

The continuous increase in the world population has brought up the need of the enhancement of agricultural activities, fisheries and stockbreeding. In order to secure enough food to satisfy the global demand, an improvement of production is needed. In this sense, chemicals can be of great help to improve production efficiencies and avoid the attack of pests or the appearance of animal illnesses. In the case of agriculture, fertilizers and phytosanitary products such as herbicides or pesticides are used to provide good protection against a range of pests that may decrease production causing important economic losses. Regarding aquaculture and stockbreeding veterinary products are used to maintain the health of animals. All these substances are intentionally added by producers and should be done following Good Manufacturing Practices (GMP). Unfortunately, due to different causes (e.g., excessive use/misuse, environmental pollution, and especially physical properties, such as chemicals solubility and stability), food products can contain residual amounts of a range of chemical substances.

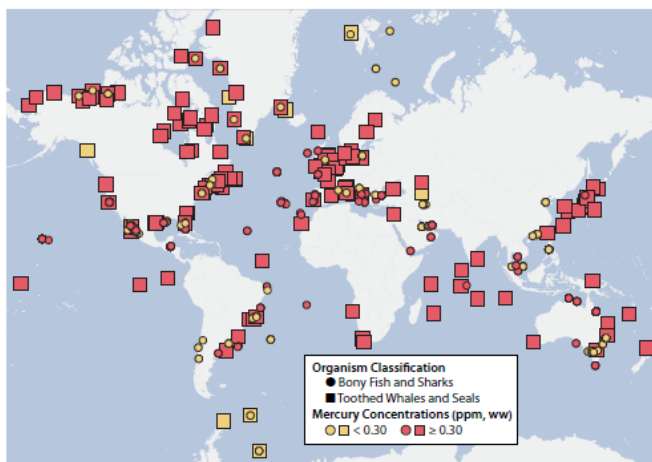
Apart from intentionally added substances another source of chemical substances is the environmental pollution. Ecosystems are suffering the direct emission of hazardous chemical substances to the environment coming from the expanded industrial activity and the increasing population which generates a negative pressure on the sustainability of the environment and leads to the occurrence of residues in food products. Even if GMPs are applied, food production is subject to be contaminated by toxic substances. Mercury is one example of this environmental contaminant. Hg is found in various forms (elemental, inorganic and organic), all with different toxicological properties. The most toxic to humans is the organic form, being methyl mercury (MeHg) the predominant form in fishery products. MeHg is largely produced from the methylation of inorganic Hg by microbial activity, particularly in marine and freshwater sediments (EPA, 2011). As Fig. 1 shows, MeHg is widespread distributed all around the world.

Several food safety agencies (EPA, EFSA, national agencies) have established dietary recommendations after performing a risk assessment. Certain vulnerable groups have been defined: women who might become pregnant, women who are pregnant, nursing mothers, young children; who are prone to exceed the maximum tolerable intake of this substance.

As a consequence of bad practices or environmental contamination hazardous substances might be present in our food stuff. Food producers might be aware of this fact and establish the necessary controls to guarantee safe products to consumers.

### 2. Processing

Some processing steps require the use of various chemical products such as extraction, solubilisation, deionization or other separation techniques. In the end, these chemicals should be removed and controlled in order to check that their concentration levels do not reach a limit to be considered as a risk. Also, cleaning operations constitute another source of chemicals (detergents, antimicrobials, acids, bases...) as strict hygiene requirements applied to food industry.



**Fig. 1. The global distribution of average mercury concentrations (ppm, wet weight) in sharks and rays, only fish, seals, and toothed whales from muscle tissue. Most samples exceed 0.3 ppm, the U.S. EPA human health criterion. Map from Biodiversity Research Institute, Gorham, ME, based on data summarized from published literature.**

Apart from these steps, other chemicals are intentionally added to perform certain technological functions, for example to colour, to sweeten or to help preserve foods. These substances are called Food Additives, they should be identified and included in the ingredients list of foods; and must be authorized before they can be used in foods (in Europe safety assessment is carried out by EFSA).

During processing there can also occur unwanted contamination by migration of chemicals from surfaces in contact with food (equipments, packaging...) and the generation of toxic by-products such as:

(i) Acrylamide. It has been found in certain foods, with especially high levels in potato chips, French fries, and other food products produced by high-temperature cooking. At high concentrations is known to be a risk for several types of cancer in animals.

(ii) Furan. It can be formed in a variety of heat-treated commercial foods and has been shown to be carcinogenic in animal experiments.

(iii) Ethyl carbamate. It is a known genotoxic and carcinogen in animals and probably carcinogenic in human beings. It can occur naturally in fermented food and beverages, such as spirits, wine, beer, bread, soy sauce and yoghurt.

(iv) Polycyclic aromatic hydrocarbons (PAHs). They can be formed as a consequence of thermal treatments of varying severity in food preparations and manufacture (e.g., drying), accidental contamination during food processing, addition of food additives such as liquid smoke flavourings, and cooking procedures.

Food scares where these substances were involved have been reported during the last decades such as the elevated levels of benzo[a]pyrene found in olive pomace oils coming from Spain or the acrylamide present in crisps and coffee. Consequently, this process creates a short-term negative impact upon consumer consumption/purchase behaviour as well as negatively impact upon the producer, manufacturer or retailer (Knowles *et al.*, 2007).

### 3. Distributing and retailing

These steps involve the storage, transport, distribution and sale of food products in supermarkets and other food establishments such as street-food vendors and market stalls. Also, it is important to mention these steps associated to the supply of materials to be in contact with food that should be done following safety measures to prevent chemical contamination. Usually, the challenge is to maintain proper refrigeration temperatures and to keep the "cold-chain" from breaking. This will ensure that the food products will reach consumers at the best conditions possible, avoiding the proliferation of specific spoilage microorganisms. However, chemicals can also contact food during these procedures resulting in contaminated food products.

The migration of chemicals from pallets or packaging is one important source of exposure to chemicals as well as the cleaning and sanitizing operations. Moreover there are other factors that can result in the supply of unsafe products. This is especially important when different kind of products are transported or stored nearby. Cross-contamination may occur and a risk can be generated. In this sense, the case of food contamination with allergens can be highlighted. The estimated prevalence of the food allergies is about 2% in adults and 4-7% in children, thus affecting more than 20,000,000 people in the European Union, and its incidence seems to be increasing in the developed countries, causing an important sanitary expense, and severely affecting the life quality of affected persons. It is important that this is taken into consideration when assembling pallets, staging or storing in addition to how allergens containing foods are located in a distribution center.

Cross-contamination with non-food products should be also avoided and since the terrorist attacks of 2011 in the US terrorism has become another issue that requires special provisions with regard to the food products control. Possible threats should be examined and actions should be taken to prevent any intentional attack on the food supply.

Food industry should ensure the supply of safe food products to consumers, but when a risk is identified procedures for the immediate recall of adulterated products from trade and consumer channels (this applies to processors, transporters, and wholesale and retail distributors).

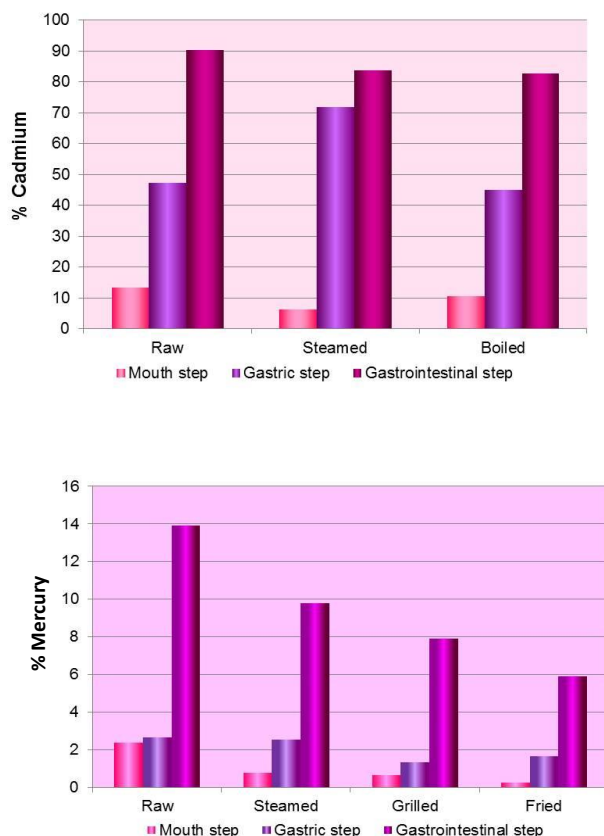
Relevant chemical contamination incidents can be found regarding storing, distributing and retailing. For instance, the presence of toxic substances in baby food that comes from packaging is of great concern as infants are a very vulnerable population and special preventive measures should be taken. Other cases of using contaminated containers or cans can be mentioned: vinegar contaminated with antifreeze products was distributed in China and cause a food poisoning outbreak; and the Coca Cola incident of 1999. In the latter incident the absence of relevant concentrations of hazardous substances made difficult to identify this fact as the main reason for the observed symptoms in students. Nevertheless, this incident resulted in substantial financial costs to The Coca-Cola Company and in considerable damage to its global image and reputation.

### 4. Consumers

Food industry should also consider consumers as an important factor when planning the control of the safety of their products. Foods are stored in different conditions (chilling, freezing, room temperature) and risks coming from cross-contamination with other food or non-food products can also occur.

Culinary treatments play a key role in the bioavailability of chemical contaminants. On the one hand, steaming, grilling or frying affect the structure of foods and can make contaminants more available for absorption due to the breakdown of the interaction of contaminants with the food matrix. On the other hand, chemicals can undergo degradation process under high temperatures that lead to metabolites which in some cases might be even more toxic than the

parent compound. Figure 2 shows the bioavailability of cadmium and mercury under different culinary treatments.



**Fig. 2. Biavailability of cadmium from edible crab and mercury from blackscabbard fish. Source: Maulvault *et al.*, 2011.**

While cadmium is slightly affected by culinary treatments and high bioavailability (80-90%) is achieved, less than 10% of mercury is available after treatments. This information is important for risk assessment and for establishing preventive measures.

### III – Food policy

In the last decades food safety issues have been gaining significant political, scientific and societal concern. In this context, food scares and incidents have alerted and informed consumers about hazardous substances present in our foods and the potential risk involved. Nowadays, consumers have a lot of information available and we chose food products according to our perception of risks. Social media, consumers associations, NGO and of course, scientists, have played an important role in the dissemination of all this information. In Table 1 a summary of main food scares in Europe are shown.

As a consequence, EU food policy has put emphasis on consumers in order to guarantee public health through the availability of safe foods. In this sense, the European Food Safety Agency



(EFSA) was created as well as many other national agencies and a lot of work has been done in the harmonization of risk assessment and testing methodologies in order to unify a regulatory framework within Europe. One of the most important characteristic of this framework is the "precautionary principle". In those cases where scientific data do not permit a complete evaluation of the risk, recourse to this principle may, for example, be used to stop distribution or order withdrawal from the market of products likely to be hazardous.

**Table 1. Summary of main food scares (1996-2006). Data from Knowles *et al.*, 2007**

Year	Contaminant
<b>1989</b>	Alar pesticide (EU) Sewage contamination of fresh meat (Fr)
<b>1990</b>	Benzene in Perrier bottled water (EU)
<b>1999</b>	Dioxins in animal feeds (EU) Fungicide/poor carbon dioxide in Coca-Cola (EU)
<b>2001</b>	Olive oil contamination (Sp/UK)
<b>2002</b>	Nitrofurantoin in prawns (UK) Nitrofen in wheat (EU) Acrylamide (EU)
<b>2003</b>	Mercury poisoning in swordfish (UK) Sudan I (EU)
<b>2004</b>	Lasalocid in eggs (UK) PCBs and Dioxins in salmon (UK) Sudan I (EU)
<b>2005</b>	Sudan I (EU) Para Red (EU)
<b>2006</b>	Benzene in soft drinks (Fr/UK) Dioxins in animal feeds (Be/Ne)

Regarding chemical contaminants many families of substances are under controlled: veterinary products, phytosanitary products, food contact materials, residues of contaminants, flavourings and additives. There are list of approved substances that can be used for food production and also maximum residue (MRLs) limits have been set up taking into account the toxicity and dietary exposure among other information.

As in Europe other countries have established their own agency and regulatory framework. In the USA the Federal and Drug Administration (FDA) serve an important role in these activities. In this case food safety policy and decision making incorporates precaution and science-based risk analyses too (IFT, 2009). Also residue limits have been established and there are lists of approved substances. However, a new term has been defined: GRAS (Generally Recognized As Safe). Under this definition are lots of substances that are exempted from food additive status and therefore free from the usual regulatory requirements. These decisions are based on generally available data and information; it does not require the same quantity or quality of scientific evidence needed for food additive approval and can be done by the food industry itself who can voluntarily inform the FDA. Nevertheless, FDA can perform complete studies of these substances (373 substances have been already reviewed) (FDA, 2014).

## IV – Food industry perspective

Food industry is facing numerous pressures coming from the consumer, the economic situation, new policies, accidents, attacks, competitors and the new information provided by the science. These factors force the food industry to be in continuous innovation, looking for solutions not to

lose competitiveness and demand a high responsibility to ensure the supply of safe food to the market. Therefore, these factors might be seen as a threat because imply new investments; increasing the cost of production and the need to be continuously aware of possible new inputs from these factors. However, it can also be an opportunity to develop new strategies of production or new products to gain the confidence of the consumers.

Food safety and chemical risks are a big challenge for food industry. New and lower residue limits are usually being established and new substances are included in the regulatory framework. In the end, a lot of substances have to be controlled and sometimes at very low concentration levels. With this purpose, new rapid, cheap and easy detection systems are highly demanded. Moreover, this analytical effort is usually performed out of the industries' facilities because the recommended measurement techniques are based on complex instruments that only can work in a laboratory environment. That means that the results are not available in rapid way, so the fabrication process should be adapted. The economic cost is greater in the case of SMEs due to their smaller production. Another challenge is the satisfaction of consumers' demands for new and safe food requiring a high adaptation and more costs for the food industry. Furthermore, food industry should be looking to be better than competitors and flexible enough to adapt to new situations in a rapid manner.

Apart from the regulated chemicals there are also unknown and emerging risks that all agents involved in the food production chain should be aware of. In this context, scientific community has to work on providing the necessary information in order to be able to define new risks and how to deal with them.

These challenges can also be transformed into opportunities for the implementation of new technologies to improve quality, safety and production efficiency. This modernization will bring new products, specialized products (for a certain group of population) to satisfy the consumers' demand. The involvement of all agents in the food production chain will bring also new opportunities. In this sense, several contaminant-free products can be found in the market. Packaging industry has moved on to the development of new products not using hazardous substances (BPA-free) and improving the capabilities of their products. There are also food producers certifying the absence of contaminants.

## V – Conclusions

Food industry views food safety as one priority and make a lot of effort to produce safe food. However, the food production chain is complex and cooperation among producers, ingredient suppliers, food scientists, processors and other food technologists, distributors, and authorities is critical in ensuring the safety of the global food supply and maintaining consumer trust and confidence.

The mere presence of a chemical in a food does not mean that the substance necessarily poses a risk to health. However, new procedures and technologies are needed to analyse the scope of the issue and determine an appropriate type of response. There will be always chemicals in our foods but risk-benefit analysis should be performed in order to guarantee public health.

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# Food-borne outbreak investigation

C. Varela Martínez

National Centre of Epidemiology, Public Health Institute Carlos III, 28019 Madrid (Spain)

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**Abstract.** The aim of food-borne outbreaks investigation is the identification of the causative agent, the implicated food and the contributory factors that led to the food-borne outbreak, in order to control them and prevent the occurrence of similar outbreaks. There are several steps in the investigation of food-borne outbreaks: outbreak detection, defining and finding cases, generating hypotheses, testing the hypotheses and finding the source, and controlling the outbreak. Different steps can happen at the same time. Pathogens typing information added to the epidemiological data are of great value in the investigation of food-borne outbreaks. At European level, the European Centre for Diseases Prevention and Control (ECDC) is supporting molecular typing initiatives. Web based tools together with social networks can facilitate the investigation of food-borne outbreaks. Investigation of food-borne outbreaks varies among the European Union Member States. Almost half of the food-borne outbreaks reported in Spain are supported by microbiological or epidemiological evidence. In order to improve control and prevention of food-borne outbreaks it would be essential to have more outbreaks supported with strong epidemiological and/or microbiological evidence.

**Keywords.** Food-borne outbreak – Microbiology – Epidemiology – Control – Public Health.

## *Investigation des flambées épidémiques d'origine alimentaire*

**Résumé.** La finalité de l'investigation des flambées épidémiques d'origine alimentaire est l'identification de l'agent causal, des aliments impliqués et des facteurs favorables ayant mené à ce désordre lié aux aliments, afin de les contrôler et d'empêcher la survenue de flambées similaires. Il y a plusieurs étapes dans l'investigation des flambées épidémiques d'origine alimentaire : détecter la flambée, définir et trouver des cas, émettre des hypothèses, tester les hypothèses et trouver la source, et contrôler la flambée épidémique. Des étapes différentes peuvent avoir lieu en même temps. L'information sur les types de pathogènes ainsi que les données épidémiologiques sont d'une grande valeur pour l'investigation des flambées épidémiques d'origine alimentaire. À l'échelle européenne, le Centre Européen pour la Prévention et le Contrôle des Maladies (ECDC) apporte son soutien aux initiatives de typage moléculaire. Des outils basés sur le web ainsi que les réseaux sociaux peuvent faciliter l'investigation des flambées liées aux aliments. L'investigation des flambées d'origine alimentaire varie parmi les États membres de l'Union européenne. Près de la moitié des flambées d'origine alimentaire rapportées en Espagne sont étayées par des preuves microbiologiques ou épidémiologiques. Afin d'améliorer le contrôle et la prévention des flambées d'origine alimentaire, il serait essentiel d'avoir davantage de flambées étayées par de fortes preuves épidémiologiques et/ou microbiologiques.

**Mots-clés.** Flambée épidémique d'origine alimentaire – Microbiologie – Épidémiologie – Contrôle – Santé publique.

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## I – Introduction

According to Directive 2003/99/EC, a food-borne outbreak is an incidence, observed under given circumstances, of two or more human cases of the same disease an/or infection, or a situation in which the observed number of human cases exceeds the expected number and where the cases are linked, or are probably linked, to the same food source.

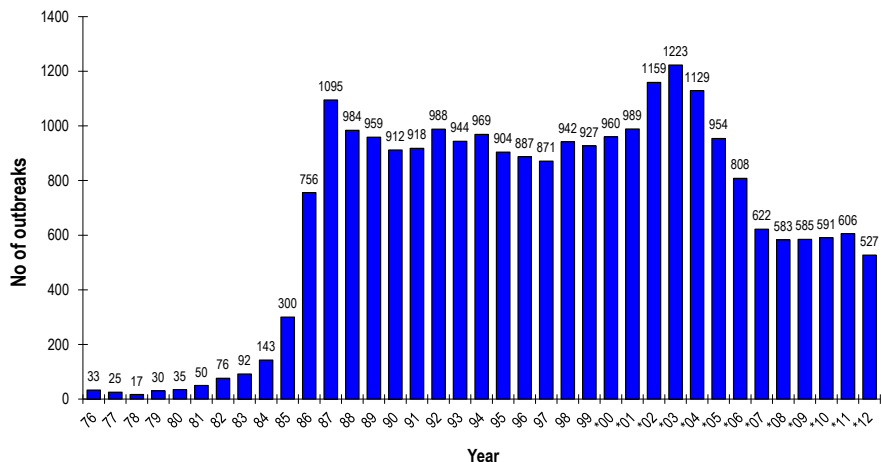
The aim of food-borne outbreaks investigation is the identification of the causative agent, the implicated food and the contributory factors that led to the food-borne outbreak, in order to

control them and prevent similar outbreaks.

There are several steps in the investigation of food-borne outbreaks: outbreak detection, defining and finding cases, generating hypotheses, testing the hypotheses and finding the source, and controlling the outbreak. Different steps can happen at the same time.

## II – Outbreak detection

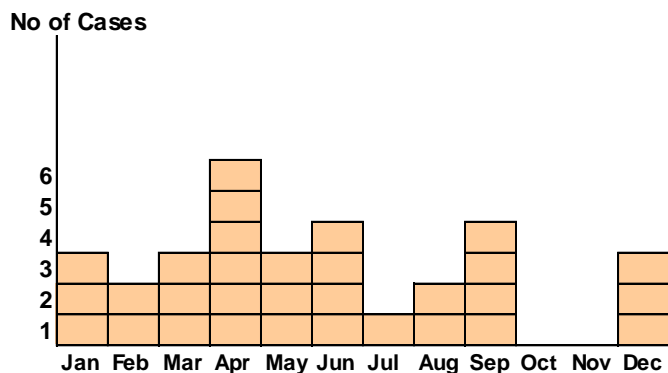
The first step for outbreak investigation is detection. Sometimes it is not easy to detect an outbreak if the ill persons are not in a specific place or apparently are not over the expected number. Human and technical resources are crucial for outbreak investigation. As an example Fig. 1 shows food-borne outbreaks reported to the National Centre of Epidemiology (CNE) in Spain, from 1976 to 2012. There was an increase in the number of outbreaks reported around 1985-1986. The increase was due to a decentralization of the health competencies in Spain and to the assignment of people and money to the autonomous regions for public health activities.



**Fig. 1. Food-borne outbreaks, Spain 1976-2012\*** (Source: National Network of Epidemiological Surveillance; Elaboration: National Centre of Epidemiology).  
\*Provisional data.

Pathogens typing (serotyping, phagotyping, pulse field gel electrophoresis (PFGE), etc.) helps to detect clusters/outbreaks that otherwise could have been missed. At EU level, alleged food-borne events (called urgent inquiries (UI)) are shared through the Food and Waterborne Diseases (FWD) network, coordinated by the European Centre for Diseases Prevention and Control (ECDC). Members of the network are: EU MS, Australia, Canada, Iceland, Japan, New Zealand, Norway, South Africa, Switzerland, Liechtenstein, Turkey and United States. The main objective of the sharing of UI is to allow the detection of multi-country outbreaks and thereafter facilitate the investigations. For sharing UI, ECDC launched a web based secured communication platform. This platform is the Epidemic Intelligence Information System for FWD (EPIS-FWD). The participation in EPIS is voluntary. Moreover, European Union (EU) Member States (MS) have to communicate some public health events to the Early Warning and Response System (EWRS) (European Commission and Council of Europe, 2013) and to World Health Organization (WHO) according to the International Health Regulations (World Health Organization, 2008).

In December 2010, two EU countries communicated through EPIS, an increase about *Salmonella* Poona. This information led to an investigation of the *S. Poona* cases detected in Spain in that year. Epidemiological information together with microbiological information from the National Reference Laboratory for *Salmonella* identified an outbreak that started at the beginning of 2010 and continued until the second half of 2011 due to *S. Poona* of a specific PFGE pattern. The outbreak was not detected previously due to the small number of cases per month (Fig. 2) (Red Nacional de Vigilancia Epidemiológica, 2011).

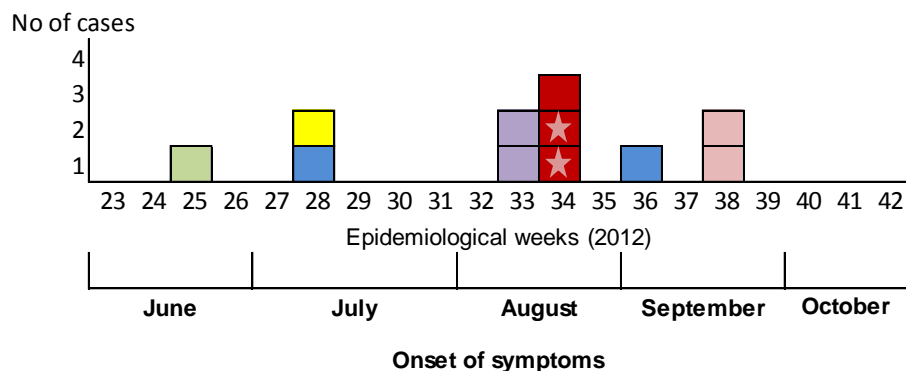


**Fig. 2. *Salmonella* Poona cases. Spain 2010 (Source: National Network of Epidemiological Surveillance; Elaboration: National Centre of Epidemiology).**

A molecular typing pilot project for food and water borne diseases, coordinated by ECDC, started at the end of 2012. The project included human isolates of *Salmonella*, *Listeria monocytogenes* and Shiga toxin-producing *Escherichia coli* (STEC). The number of Member States (MS) voluntarily participating in the pilot project, increased from 11 MS at the beginning to 18 at the end.

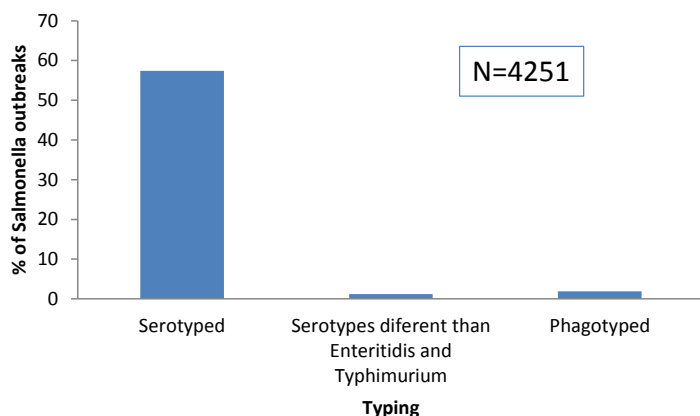
The objective of the project was to “improve the detection and verification of dispersed clusters and outbreaks of *Salmonella*, *Listeria* and STEC by setting up real-time molecular surveillance for human cases and link up and harmonise these typing methods with food, feed, and animal strains”. Molecular typing could facilitate early detection of national or international outbreaks.

Spain participates in the molecular typing pilot project for *Salmonella* and STEC, but not *Listeria*. Nevertheless, PFGE is carried out for *Listeria* outbreaks investigation. In September 2012 the CNE was informed of two listeriosis cases in pregnant women from the same autonomous region, with onset of symptoms one day apart, that consumed the same type of cheese bought in two shops of the same type. Epidemiological information together with microbiological information (same PFGE patterns) led to prospective and retrospective identification of 11 cases belonging to the outbreak. The number of cases was small and they appeared along four months in six different autonomous regions. Usually outbreaks with few cases, that are spread out and not restricted to a relatively short period of time are difficult to identify.



**Fig. 3. Listeria cases. Spain 2012.** Each colour shows one autonomous region. ★ Index cases (Source: National Network of Epidemiological Surveillance; Elaboration: National Centre of Epidemiology).

Whole genome sequencing is the typing technique which has the highest discriminatory power. However, for food-borne outbreaks investigation, methods with lower discriminatory power are sufficient for many diseases as far as public health is concerned. As figure 4 shows, *Salmonella* serotyping in Spain is performed at least in 57.4% of the *Salmonella* outbreaks, serotypes different from Enteritidis and Typhimurium are reported in 1.2% of the *Salmonella* outbreaks. These less frequent serotypes are not detected on a routine basis by many laboratories, but information on rare serotypes could help to identify an outbreak. Phagotyping of more frequent serotypes is carried out in Spain only at the National Reference Laboratory; this technique is not performed by all EU Member States.



**Fig. 4. Salmonella food-borne outbreaks, Spain 2002-2012\*** (Source: National Network of Epidemiological Surveillance; Elaboration: National Centre of Epidemiology). \*Provisional data.

### III – Defining and finding cases

Case definition will be defined in order to decide if a person belongs to the outbreak under investigation. Case definitions may include features of the illness, the pathogen (including molecular typing information), restrictions on time, place and person. Case definition should be simple and practical. At the beginning of the investigation it could be more sensitive to find as many cases as possible, being more specific as more information is available. There might be different case definitions for confirmed, probable and possible cases. The representation of the number of cases over time is the epi curve.

To look for cases, epidemiological surveillance records, laboratory records, hospital admission records, etc could be used. Recently web based tools and social networks have been used with this purpose too. As an example, gastroenteritis cases among people attending the Nowhere festival in 2013 in Spain were reported by the participants to the festival organizers through e-mail. The NOrg team (Nowhere Organisation team) creates an online questionnaire in order to receive more information on the sicknesses involved, together with information coming from e-mails and social media discussions (Judith, Olivier, Christen, 2013).

Another example is shown on the *Salmonella Poona* outbreak occurring in Spain in 2010 related to infant formula. A very active facebook group was created among parents of the cases. As a result of that, many cases were identified, including 9 asymptomatic persons. Moreover, more cases were identified as epidemiologists were alerted in order to send *Salmonella* isolates from children under 1 year old to the National Reference Laboratory for serotyping and molecular typing (Red Nacional de Vigilancia Epidemiologica, 2011).

### IV – Generating hypotheses

Description of the situation would lead to the generation of hypotheses. Questionnaires are developed in order to analyse possible exposures. Information related to the disease (clinical symptoms) and the causative agent, place (municipality, restaurant, school, class room, etc.), time, person features (age, sex, occupation, etc) and exposures (food, travel, animals, etc.) is collected through the questionnaires.

For the *Salmonella Poona* outbreak occurring in Spain in 2010-2011, 83% of cases were under one year old, and 93% of those from 0 to 6 months old. Description of cases generated the hypotheses that infant formula could be involved in the outbreak (Red Nacional de Vigilancia Epidemiologica, 2011).

Answers to the questionnaire depend on memories of cases. For the *Salmonella Poona* outbreak the first questionnaire developed included information on food consumed 72 hours before onset of symptoms and as the median time for interviewing cases with onset of symptoms in 2010 was 8 months, it included food preferences too. Questions focused on infant formula consumption were easier to be remembered the time later than consumption of other foods (Red Nacional de Vigilancia Epidemiologica, 2011).

### V – Testing hypotheses and finding the source

To test the hypotheses different methods could be used. Two main methods are analytic epidemiologic studies and food testing. According to the European Food Safety Agency (EFSA), epidemiological evidence (whether descriptive or analytical) can be strong or weak, although good analytical evidence is superior to evidence from the systematic evaluation of cases. Similarly, microbiological evidence can be strong or weak (European Food Safety Authority, 2014).



Last EU summary report on zoonoses, zoonotic agents and food-borne outbreaks from EFSA and ECDC (EFSA and ECDC, 2014) shows wide variability in the type of evidence for outbreak investigation among EU MS. For some countries where the evidence for all the outbreaks reported was strong and some other countries where all the outbreaks reported were supported by weak evidence. In line with that, the proportion of outbreaks in which analytical versus descriptive studies has been performed, varied among the countries. The same report shows that the proportion of outbreaks with strong evidence varies with the causative agent.

Spanish data on food-borne outbreaks from 2002 to 2012 shows that the proportion of outbreaks where the causative agent is not known is 32% (Fig. 5). This percentage decrease from 33.4% in the period 2002-2009 to 28.2% for 2010-2012, being statistical significant ( $\chi^2=17$   $p<0.001$ ).

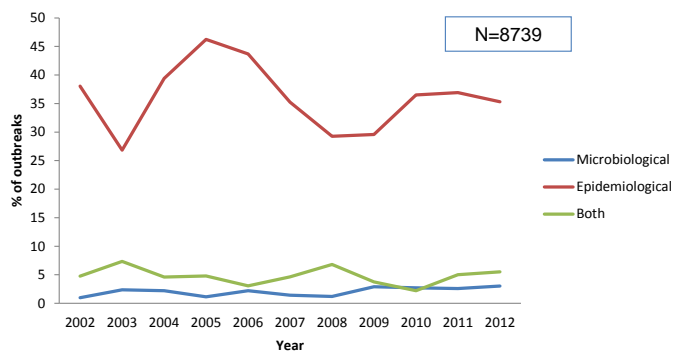


**Fig. 5. Food-borne outbreaks with unknown causative agent. Spain 2002-2012\*** (Source: National Network of Epidemiological Surveillance; Elaboration: National Centre of Epidemiology). \*Provisional data.

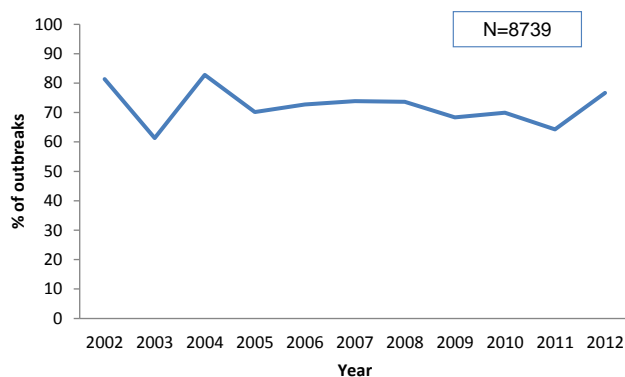
Food-borne outbreaks from Spain show that epidemiological evidence is more frequently used than microbiological evidence (Fig. 6), 43% of outbreaks reported any type of evidence (whether epidemiological and/or microbiological). Difficulties to obtain evidence are: starting of the investigation long after the outbreak occurred (cases cannot remember exposures, food items are not available), difficulties to detect the pathogen in the foodstuff (for instance, low quantity of *Salmonella* in infant formula is common), multiple foodstuffs contaminated or foods that are difficult to remember as herbs and spices. In the 8739 food-borne outbreaks reported in Spain, from 2002 to 2012, no outbreak was linked to herbs or spices.

Figure 7 shows the outbreaks where at least one sample (from cases, food, environment, or food handler) has been analysed. There were 27% of outbreaks with no sample analysed.

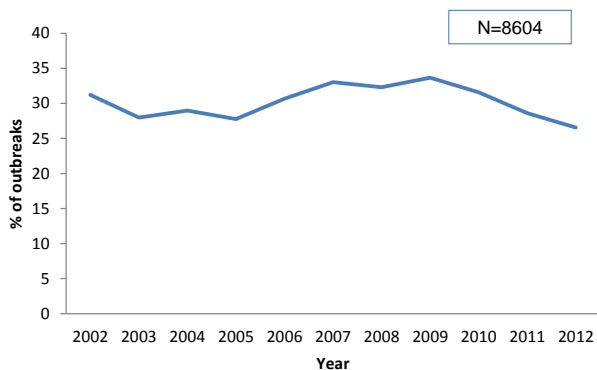
No foodstuff was mentioned in 30% of outbreaks, as it is shown in Fig. 8. Eggs and egg products were reported in 45% of the outbreaks, followed by shellfish with 8% of the outbreaks, as is shown in Fig. 9.



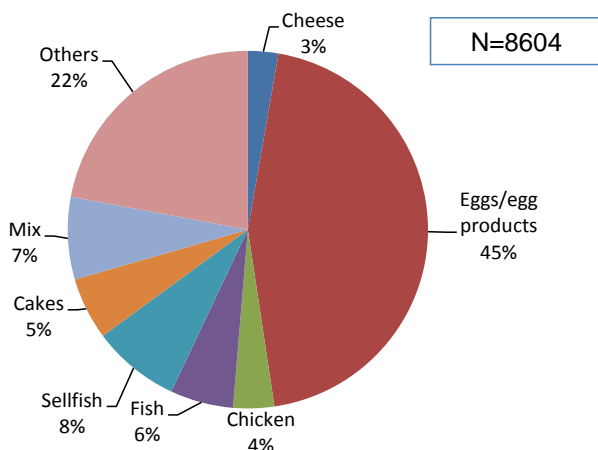
**Fig. 6. Food-borne outbreaks according to type of evidence, Spain 2002-2012\*** (Source: National Network of Epidemiological Surveillance; Elaboration: National Centre of Epidemiology). \*Provisional data.



**Fig. 7. Food-borne outbreaks with at least one sample analysed, Spain 2002-2012\*** (Source: National Network of Epidemiological Surveillance; Elaboration: National Centre of Epidemiology). \*Provisional data.

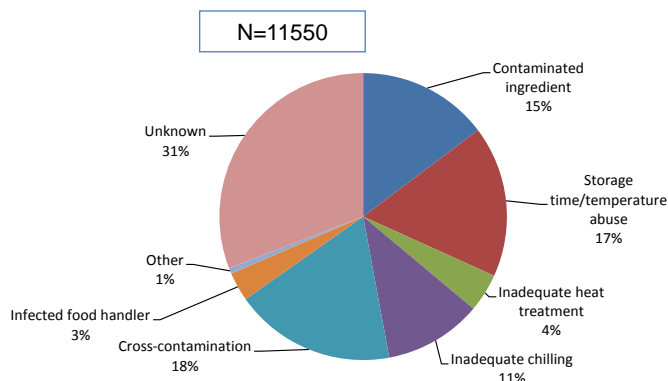


**Fig. 8. Food-borne outbreaks mentioning a specific food, Spain 2002-2012\*** (Source: National Network of Epidemiological Surveillance; Elaboration: National Centre of Epidemiology). \*Provisional data.



**Fig. 9. Food-borne outbreaks according to reported food, Spain 2002-2012\*** (Source: National Network of Epidemiological Surveillance; Elaboration: National Centre of Epidemiology). \*Provisional data.

Regarding contributory factors, 31% of the outbreaks did not report any contributory factor. Cross contamination was mentioned among 18% of the contributory factors, followed by storage time and/or temperature abuse, and contaminated ingredient (Fig. 10).



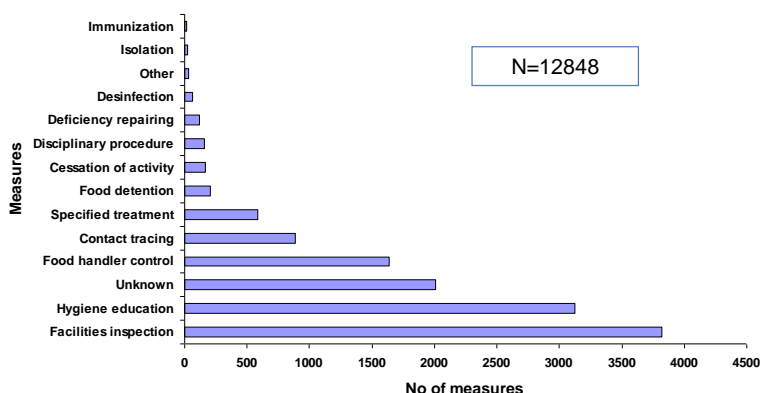
**Fig. 10. Contributory factors reported in food-borne outbreaks, Spain 2002-2012\*** (Source: National Network of Epidemiological Surveillance; Elaboration: National Centre of Epidemiology). \*Provisional data.

## VI – Controlling the outbreak

Control of the outbreak has to be done along the investigation, measures can be adapted according to the results of the investigation. It is not necessary to wait for the epidemiological or microbiological evidence, public health authorities should act according to the precautionary principle in order to protect public's health.

It has to be decided when the outbreak is over, after cases stopped, surveillance has to continue to be sure that cases do not start again.

Implemented measures for the food-borne outbreaks reported in Spain from 2002 to 2012 were shown in Fig. 11. Main implemented measures were facilities inspection and hygiene education.



**Fig. 11. Food-borne outbreaks according to implemented measures, Spain 2002-2012\*** (Source: National Network of Epidemiological Surveillance; Elaboration: National Centre of Epidemiology).  
\*Provisional data.

## VII – Conclusions

Pathogen typing information added to the epidemiological data is of great value in the investigation of food-borne outbreaks. At European level ECDC is supporting molecular typing initiatives.

Web based tools together with social networks can facilitate the investigation of food-borne outbreaks.

Investigation of food-borne outbreaks differs among EU Member States.

To achieve a higher proportion of food-borne outbreaks supported by strong epidemiological and/or microbiological evidence would lead to better prevention and control of them.

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# Exposure assessment: Total Diet Studies

C. Le Donne, G. Lombardi-Boccia, M. Lucarini, L. D'Evoli, V. Tesone, and A. Turrini<sup>1</sup>

Consiglio per la Ricerca e la Sperimentazione in Agricoltura (CRA) – Centro di Ricerca per gli alimenti e la Nutrizione (CRA-NUT), Via Ardeatina 546, 00178 Rome (Italy)

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**Abstract.** *Total diet studies (TDS)* are designed to assess dietary exposure to both beneficial and harmful substances. Average dietary intake of chemicals is estimated in a two-phase approach, whereby the food consumption data collection to estimate the reference diet represents the first phase and the total diet study the second one. In this stage a representative food shopping list is elaborated and food samples are market basket collected to reproduce the reference diet, then the foods are prepared according to the most popular home treatments of food, and finally chemically analyzed to estimate the content of target substances. TDS provide a useful informative basis to complement food monitoring and surveillance programs either for screening purpose or refined exposure assessment. A need for structuring a harmonized European TDS approach was identified by the European Food Safety Authority and a specific project – TDS-exposure project, was undertaken in the context of the 7<sup>th</sup> Framework Program. The present work starts from the definition of dietary exposure estimated from a TDS to illustrate the TDS process also highlighting some critical points to tackle in achieving the goal.

**Keywords.** Total Diet study – Exposure assessment – Population study.

## **Évaluation de l'exposition : études de l'alimentation totale**

**Résumé.** *Les études de l'alimentation totale (EAT) sont conçues pour évaluer l'exposition alimentaire à la fois à des substances bénéfiques et néfastes. L'apport alimentaire moyen est estimé dans une approche en deux phases : la collecte de données sur la consommation alimentaire pour évaluer le régime de référence représente la première phase et l'étude de l'alimentation totale la deuxième. A ce stade, un panier représentatif de la consommation est collecté pour reproduire le régime de référence, puis les aliments sont préparés selon les modes de préparation domestiques les plus courants, et sont enfin analysés chimiquement pour estimer leur teneur en substances cibles. Les EAT constituent une base d'information utile pour compléter les programmes de surveillance que ce soit dans une procédure de criblage ou pour une évaluation de l'exposition raffinée. Le besoin de structurer une approche européenne harmonisée pour les EAT a été identifié par l'Autorité européenne de sécurité des aliments et le projet TDS- exposition a été lancé dans le cadre du 7<sup>e</sup> programme-cadre de recherche. Le présent travail s'appuie sur la définition de l'exposition alimentaire estimée à partir d'une EAT pour illustrer le processus des EAT, tout en soulignant certains points critiques à traiter afin d'atteindre les objectifs.*

**Mots-clés.** *Etude de l'alimentation totale – Exposition alimentaire – Étude de la population.*

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## **I – Introduction**

It is worldwide recognized that the availability of reliable and detailed occurrence data for chemicals in food is essential in order to perform dietary risk assessment. For estimating dietary exposure of the population, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) recommend the use of the total diet studies (TDS) approach (EFSA/FAO/WHO, 2011a). The primary purpose of total diet studies is to measure the average amount of each chemical ingested by different age/sex groups living in a country (Moy, 2013). In TDSs, representative samples of widely consumed foods are collected and analysed for the constituents of interest (Kroes *et al.*, 2002).

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<sup>1</sup>On behalf of the WP3 contributors and the TDS-exposure project Consortium ([www.tds-exposure.eu](http://www.tds-exposure.eu)).

In general, a TDS is designed to assess dietary exposure to both beneficial and harmful substances (EFSA/FAO/WHO, 2011a). A huge amount of work have been done since the '60s initially to face the exposure to environmental contaminants of food only, but subsequently extended to estimate nutrients (see as an example, Turrini and Lombardi-Boccia, 2002).

In fact, the TDS approach is particularly helpful in evaluating substances not regularly occurring in foods either because these are not structural constituents of foods and then irregularly occur (natural toxicants, migrated substances, substances generated by the food production process, etc.) or because even usually being structural part of the food the distributions is not easy estimated in short survey period (e.g., trace elements). Average dietary compounds intakes are estimated in a two-phase approach, whereby the food consumption data collection to estimate the reference diet represents the first phase and the TDS the second one (Saba *et al.*, 1992). Differently, when a dietary study concerns structural food constituents with a well-known distribution like some nutrients are, a preliminary estimate of intake is often performed applying food composition tables to food intakes (Leclercq *et al.*, 2001). Nevertheless, TDS is suitable also in this case either as validation tool (Carnovale *et al.*, 2000; WHO, 2007a) or as tool when up-to-date food composition data are not available (Turrini and Lombardi-Boccia, 2002; WHO, 2007a).

The accuracy of population intakes estimated using TDS results depends on the extent to which the foods analysed represent important dietary sources of the chemicals. International organisations like the FAO and the WHO have been supporting the TDS approach since the 1970s and have provided general guidelines (EFSA/FAO/WHO, 2011a). Nevertheless, there has so far been no attempt towards an agreement on a generally harmonized TDS approach. At the beginning of 2010, a Working Group of experts on TDS was established and coordinated by European Food Safety Authority (EFSA). Participants from European Member States, FAO and WHO covered the needs for expertise and knowledge on TDS at European and international level. The Working Group aimed at preparing a review of the state of the art on TDSs worldwide with a particular emphasis on activities in Europe and at developing a guidance document for a harmonised TDS approach (EFSA/FAO/WHO, 2011a, 2011b).

In line with EFSA activities, the EU Total Diet Study Exposure project (TDS-Exposure, <http://www.tds-exposure.eu/>) was approved for financial support in the EU 7<sup>th</sup> Framework Programme (FP7) to perform a research aimed at: (i) to identify clearly what kind of information TDS studies can provide for exposure and risk assessment; (ii) to encourage the development of total diet studies across Europe and worldwide; (iii) to propose a harmonized method; (iv) to build and test a European database of TDS studies useful for risk assessors and risk managers; and (v) to develop or adapt existing exposure assessment models to TDS studies and to assess uncertainties.

In the present work the methods of evaluating the dietary exposure through the implementation of a TDS provides the input to identify some critical points to tackle in order to achieve the goal and contributing to the brainstorming about the implementation of an European TDS system.

## II – Material and methods

The reports of the joint guidance of EFSA/FAO/WHO 'Towards a harmonized Total Diet Study approach: a guidance document' (EFSA/FAO/WHO, 2011a) have been the starting point to analyze the available literature.

A literature search have been conducted using the keywords used for the specific purposes were "food shopping list"; "total diet study", and "food market basket" (Boolean operator OR). Subsequently the term "reference diet" was added to capture works dealing with the formulation of the food list only.

A database of papers was compiled with the contribution of TDS-exposure partners involved in this specific task of the project. Non-English publications have been examined thanks to the translation by each of them.

Papers from 19 countries have been included in June 2012, comprehending the WHO reports (WHO 1999; 2002; 2004, 2007a,b) specifically dedicated to TDS, have been overall reviewed. The literature search has been widened to include the most recent publications on TDS (Moy and Vannoort, 2013).

### III – Results and discussion

#### 1. Exposure assessment

Exposure assessment starts from a simple assumption: dietary exposure is obtained by multiplying food intake and concentration of chemicals in foods (EFSA/FAO/WHO, 2011a; Boorman *et al.*, 2013a). However,

In TDS three possible methods can be used for long-term dietary exposure (Boorman *et al.*, 2013a):

- (i) Point estimate of concentration and food consumption per each food analyzed:

$$\text{Dietary exposure}_k = \sum_j \text{intake}_j \times \text{concentration}_{kj}$$

where

$j=1, \dots, t$  and  $t$  is the number of TDS foods containing the substance  $k$

- (ii) Point estimate of concentration by distribution of food consumption

$$\text{Dietary exposure}_{ik} = \sum_j \text{intake}_{ji} \times \text{concentration}_{kj},$$

where

$i=1, \dots, n$  and  $n$  is the number of individuals in the total sample

$j=1, \dots, t$  and  $t$  is the number of TDS foods containing  $k$

- (iii) Combining food consumption distributions and food chemical concentration in a probabilistic approach so multiplying the two functions  $f(\text{intake}_{ijk}) * g(\text{concentration}_{kj})$

All the above considered approaches require that the food sample collection is representative for the diet otherwise unpredictable and non-evaluable inconsistencies could occur.

Secondly, the food category should be thoroughly aligned. This aspect defined also as food mapping (Boorman *et al.*, 2013b) can be incorporated in the procedure at both food description and food aggregation level (Charrondiere, 2013). In this line each food sample needs to be: (i) described in detail and in a standardized way, possibly using the LanguaL standard ([www.langua.org](http://www.langua.org)) in order to facilitate the identification of the specific item; and (ii) categorized adopting a classification criteria shared at international level, like the FoodEX system implemented by EFSA (2011a).

This issues must be considered when treating the information in the collection of food sample to verify when the food shopping list for each food category in the food list is completed. The information will be maintained along the whole TDS process, i.e., when the purchased food products will be prepared and then pooled to form the composite samples for the chemical analyses so determining the occurrence of substances (EFSA/FAO/WHO, 2011a).

This will be extremely useful at a subsequent stage in the same study (interpretation of the results) or in comparative analyses of different studies. Food intake profiles differ across population groups and region/countries so resulting in different level of foods consumption but also in the brand and/or



varieties of food products included in each category depending on the specific trend of food demand. This is certainly reflected in the national food lists and shopping strategies (Moy and Vannoort, 2013).

## 2. Food samples collection

Food samples collections is a multi-stage process including two organizational steps and one implementation steps. The results of these activities led to the market basket of products that will be prepared for consumption and pooled for chemical analyses (EFSA/FAO/WHO, 2011a).

TDS provide a useful informative basis to complement food monitoring and surveillance programs either for screening purpose or refined exposure assessment. This has effects on the length of the food list because a most refined exposure assessment is aimed to identify foods representing the sources of the target substances other than the overall dietary content (EFSA/FAO/WHO, 2011a).

The effectiveness of the food products collection in obtaining a representative sample of the TDS food list is a crucial aspect. A conceptual representation helps in identifying critical points in the process that can limit the correct interpretation of the results. Critical points concerns the available information trying to answer the questions: which, where, when, and how much food purchase? According to the first question (*which*), critical issues are the availability of food intake data and the possibility to disaggregate food items, home treatment and recipes information, the possibility to have data for the relevant food categories for prioritized chemicals and population groups of concerns, market share/varieties. The second question (*where*) requires information on the relevant parameters characterizing the territory, the retail system. The knowledge of food procurement habits helps partly to identify where people buy foods and *when*. This allows for the evaluation of seasonality from the demand point of view, so complementing the seasonality assessed at offer level (production + import). Combination of different situation can occur and tracking the process enhances the reliability of the results. Finally, recording the information in ad hoc designed databases will allow for comparison (EFSA/FAO/WHO, 2011a). Source of information and information derived at each stage in planning a food products collection in a TDS according to the selected papers are synthesized in the diagram in Fig. 1.

Food consumption data provide the informative basis to extract food categories and the respective amount daily eaten on average by the population (reference diet). The more detailed are the easier is the selection in accordance to the kind of substances whose exposure is object of study. The more substances are taken into account the more detailed is required the list to be (EFSA, 2011a).

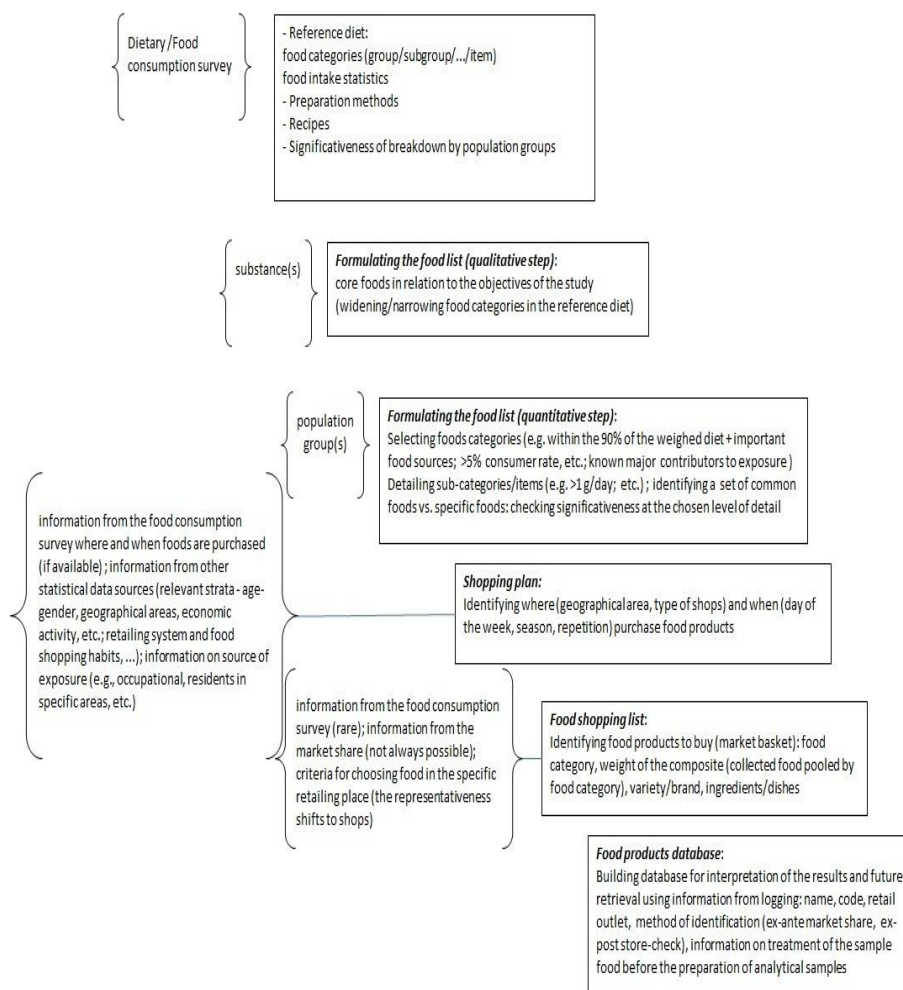
The detail facilitates the process of aggregation in case of small quantities and/or very low consumers rate (<5%) for food not relevant for the target substances (EFSA/FAO/WHO, 2011a). This also reduce the possibility that a food category needs to be split in different subcategories to match the inherent classification, so requiring either a step of data processing on the food intake database when individual data are available, or an indirect estimation.

Relevant breakdown of food intake must be considered for estimating figures at population group level taking into account the specificity of each of one. The question whether a food category is representative or not will be repeated for the formulation of each specific food list (EFSA/FAO/WHO, 2011a).

The determination of food products to be included to represent each category can be obtained applying information taken from the dietary survey of from other sources (Table 1), like production/trade statistics on varieties of raw foods and market share data for processed foods (EFSA/FAO/WHO, 2011a).

Geographical distribution and Information on the food distribution system are used to map the territory and the type of shops where to buy the food products. Diverse seasons should also be considered for those items with different availability along the year (EFSA/FAO/WHO, 2011b).

Information on home food treatments for preparation of foods will be applied because the pooled sample for chemical analyses will contain foods as consumed (EFSA/FAO/WHO, 2011a; Moy and Vannoot, 2013).



**Fig. 1. Information used in the food products collection in a total diet study (TDS).**

**Table 1. Sources of food consumption data (Source: EFSA/FAO/WHO, 2011a)**

<b>Food consumption data</b>	<b>Method</b>
Food Balance Sheets (FBS)	Food disappearance data
Household Budget Survey (HBS)	Food expenditure with/without quantities record
Dietary Surveys	Food record: Recall; Food Frequency Questionnaire
Trade statistics	Current statistics
Combinations	

The more comprehensive the information are at each stage the higher representativeness will be reached and the more reliable will be the estimate of exposure. In this way, the subsequent problems related to analytical parameters like the level of detection (LOD) and the level of quantification (LOQ) (Aerts *et al.*, 2013) will regard the particular substances and the analytical method only.

Overall, variability and uncertainty are inherent parts of the statistical treatment from the sampling design, to the collection plan, and, finally, the evaluation. When these aspects are under control both effects can be measured (WHO/FNU/FOS, 1995). Otherwise, unpredictable errors could occur without possibility to quantify its amount.

This can make really difficult to manage when several chemicals are analysed, i.e., the usual situation in a TDS.

The following Table 2 reports the list of chemicals studied through TDS in Australia and Italy.

**Table 2. Examples of groups of substances studied in a TDS**

<b>Country: Australia (Moy &amp; Vannoort, 2013)</b>	
Agricultural chemical residue screen	Chlorinated organic pesticides, organophosphorus pesticides, synthetic pyrethroid, fungicides, selected carbamates and fungicides, piperonyl butoxide
Contaminants	Antimony, total arsenic, cadmium, copper, lead, mercury, selenium, tin, zinc, aflatoxins, polychlorinated biphenyls
Natural toxicants	Aflatoxins and ochratoxin A a
Inhibitory substances	Penicillin G, streptomycin, oxytetracycline a
Additives	Sulphites, nitrates, nitrites, benzoates, sorbates
Essential trace elements	Iodine, chromium, molybdenum, selenium and copper
<b>Country: Italy (D'Amato <i>et al.</i>, 2013)</b>	
Non-essential trace elements	Al, inorganic As, Cd, Pb, methyl-Hg, inorganic Hg, U
Radionuclides	<sup>40</sup> K, <sup>134</sup> Cs, <sup>137</sup> Cs, <sup>90</sup> Sr

Procedures and check list to monitor the work and to analyse information at fixed critical points helps to follow the advancement of the study and to plan corrective actions if needed. Once the information basis is arranged mathematical/probabilistic models can be applied to estimate exposure and statistical analysis can be performed to evaluate the reliability of the results (Lavrakas, 2008).

## IV – Conclusions

TDS are helpful tool to complement and complete information for risk assessment in the phase of the exposure assessment.

A conceptual structure of the whole process allows for identifying critical points and the systematic cross-country harmonization of the procedures and wherever possible establish standard operational process.

The food sample collection is a delicate stage of a TDS to ensure the diet being adequately represented in its variety and articulation.

This and all the other stages and steps of the whole TDS are considered in the TDS-exposure project for the design of an European system.

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Project coordinator: Dr. Jean-Luc Volatier, Agency for Food, Environmental and Occupational Health Safety, France.

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WP3 Contributors		Country
Bundesinstitut fuer Risikobewertung	Heinemeyer Gerhard; Oliver Lindtner	DE
Universidad de Granada	Martínez-Victoria Emilio; Alba Martínez Burgos	ES
University College Dublin, National University of Ireland, Dublin	Kelleher Cecily; Breige McNulty; Anne Nugent; Aine Hearty	IE
Hrvatska Agencija za Hranu	Sokolic-Mihalak Darja; Martina Jurković	HR
Partikas Un Veterinarais Dienests	Ozolins Gatis; Dace Santare	LV
Institute of Food Safety, Animal Health and Environment Bior	Inese Sikсна	LV
Agencia Española de Seguridad Alimentaria y Nutrición	M. Teresa Lopez; Pedro Mario Fernández	ES
Instituto Nacional de Saúde Doutor Ricardo Jorge	Oliveira Luisa; Maria da Graça Dias; Elsa Vasco	PT
Instytut Żywności i Żywienia	Sekula Włodzimierz; Katarzyna Stos; Maciej Oltarzewski	PL
Istituto Superiore di Sanità	Francesco Cubadda; Federica Aureli; Marilena D'Amato	IT
Türkiye Bilimsel Ve Teknolojik Arastırma Kurumu	Özer Hayrettin; Canan Doğan; Imge Oktay	TR
Universitat Rovira i Virgili	Domingo José Luis; Martí Nadal; Gemma Perelló	ES
Livsmedels Verket	Darnerud Per Ola	SE

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# Risk prioritization

## Tools and recent methodologies

P.N. Skandamis

Lab. Food Quality Control & Hygiene, Dep. Food Science & Technology  
Agricultural University of Athens, Iera Odos 75, 118 55, Athens (Greece)

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**Abstract.** Risk profile is the first step of stochastic quantitative process risk models, by identifying the potential pathogen-matrix combinations of safety concern, then enabling the risk ranking of these combinations. This in turn may assist food industries about existing or emerging food safety issues and the authorities (risk managers) in making informed decisions on further commissioning a systematic quantitative risk assessment to address public health concerns. Risk ranking can be based on a variety of criteria, associated with exposure to and the severity of a hazard. Among the most recent and popular ones is the Disability or Quality Adjusted Lost Years (DALYs), which assesses the relative impact of different diseases based on incidence rate, cost of illness, hospitalizations and deaths. There is also a great number of tools for risk ranking publicly available either in the form of XL-based software (e.g., Risk Ranger) or as web-based platform (e.g., iRisk). As a follow up, there has been an increasing trend of developing strategies for prioritizing risks based on critical questions addressing all the aforementioned issues. A detailed list of such approaches is appended here and advantages or the concerns for a universally accepted methodology are discussed.

**Keywords.** Risk ranking – Hazard prioritizing – Severity exposure – Assessment – Epidemiology – Profiling tools – Ranger – SIEFE DALYs – QALYs – Disability Lost.

### **Priorisation des risques. Outils et méthodologies récentes**

**Résumé.** Le profil de risque est la première étape des modèles de risques de processus stochastiques quantitatifs, qui identifie les combinaisons pathogène-matrice potentielles en matière de sécurité sanitaire des aliments, et permet ainsi de classer les risques liés à ces combinaisons. Ceci, ensuite, peut être d'utilité aux industries alimentaires en ce qui concerne les enjeux existants ou émergents de sécurité des aliments, et aux autorités (gestionnaires de risques) pour la prise de décision informée quant à poursuivre par une évaluation quantitative systématique des risques pour aborder les préoccupations de santé publique. Le classement des risques peut être basé sur différents critères, liés à l'exposition à un danger et à sa gravité. Parmi les plus récents et les plus connus figure celui des années de vie corrigées de l'incapacité (DALY) ou des années de vie ajustées par leur qualité, qui évalue l'impact relatif de différentes maladies en se basant sur le taux d'incidence, le coût de la maladie, les hospitalisations et les décès. Il existe aussi un grand nombre d'outils pour classer les risques, qui sont disponibles publiquement soit sous forme de logiciel basé sur XL (p.ex., Risk Ranger) ou de plate-forme basée sur le web (p.ex., iRisk). Depuis lors, il y a eu une tendance croissante au développement de stratégies pour la priorisation des risques, fondées sur des questions critiques qui abordent tous les enjeux cités auparavant. Une liste détaillée de ces approches est annexée ici, et une discussion est présentée portant sur les avantages ou les préoccupations pour une méthodologie acceptée universellement.

**Mots-clés.** Classement des risques – priorisation des dangers – Gravité de l'exposition – Évaluation – Épidémiologie – Outils de profilage – Ranger – SIEFE DALYs – Années de vie ajustées par leur qualité (QALYs) – Années perdues du fait d'une incapacité.

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## I – Introduction

Risk assessment (RA) is used to systematically assess the level of risk associated with particular hazards. It helps building an inventory of "typical" risk contributing factors and elaborate possible risk mitigation strategies. As a mission statement, RA constitutes an official science-based decision support methodology for Risk Managers, such as Competent Governmental Authorities, in their effort to protect public health from threats posed by exposure to contaminated foods with existing or emerging hazards. It is typically performed by focussing on one hazard in a (range of) food (categories). At a risk management level, which is commonly governmental or sometimes industrial, RA may assist in the following:

(i) Addressing aspects that have the highest impact on risk in a case, enabling the design and application of measures for risk mitigation.

(ii) Identification of foods that pose greater risk when cases are compared and suggest focussing resources, e.g., for monitoring, surveillance, studies, risk mitigation, etc.

(iii) Identification of vulnerable groups and improper (flawed) hygiene during food handling in domestic environments.

(iv) Establishment of food safety policies, in terms of risk-based food standards, which are necessary benchmarks for industry's food production safety assurance.

Risk managers are confronted with numerous public health challenges. In response to each of these challenges, they need to make a series of decisions associated with immediate (first) action to address the health problem, allocation of time and resources for informed decision-making and identification of best course of action, also balancing the societal and financial burden of the targeted public health issue with the help of stakeholders. The immediate action is based on the urgency and the priority of the problem and the outcome of risk profiling. This will further suggest or not the need for commissioning a full RA, setting risk mitigation strategies and determining risk management options.

## II – Risk profiling

Risk profiling is a compilation of overviews for each of the pathogens that may be found in the various food products (Mataragas *et al.*, 2008). This allows identification of relevant pathogens-food chain (or food matrix) combinations of concern and lead to the development of risk ranking and risk matrix. The types of information required for conducting risk profile basically stem from the principles of RA and particularly are associated with the following: (i) hazard identification and/or their toxins that may be found in foods (problem statement); (ii) assessment of exposure in terms of how the food becomes contaminated, and whether/how the hazard changes along the food chain, frequency of consumption and uptake of illness causing dose; (iii) severity of the hazard, i.e., the illness-causing dose, host sensitivity, attack rates, etc.; and finally (iv) risk rating/ranking based on serving size and the integration of the above. Potential resources include literature reports, epidemiological data, expert opinion, industrial feedback, current legislation aspects or risk mitigation strategies, etc. (Pointon *et al.*, 2006). From the Food Industry standpoint, risk profiles can be used as preliminary food safety information, whereas at governmental level risk profiling constitutes the first step in risk ranking and a basis to identify priority issues for examination via the development of quantitative stochastic risk process models.

As far as the risk process models are concerned, as a rule of thumb, the risk of foodborne disease can be simply converged to the product of **exposure** (*P*) to a certain hazard at the time of consumption multiplied by the **severity** (*S*) of the hazard (i.e.,  $P \times S$ ). The exposure is a

function of hazard dynamics along the food supply chain, i.e., increase or reduction of chemical contaminant corresponding to growth or death for microbial hazards, as well as of the amount and frequency of consumption. The severity component of risk is commonly quantified by its ability to cause acute or chronic damage ('sequelae') and can be mathematically represented by dose-response models, which also define the minimum infectious dose or the No Adverse Effect Level (NOAEL). Based on that, the Accepted Daily Intake and the more recent risk metrics, such as Appropriate Level of Protection and Food Safety Objectives may be set as the publicly available standards for food safety nationwide or worldwide.

### III – Risk ranking

In a science- and risk-based food safety system, risk managers prioritize food safety hazards and preventive interventions using the best available data on the distribution of risk and how risk can be reduced most effectively and efficiently. As stated before, for foodborne pathogens, this requires an answer to the question: which pathogens in which foods cause the greatest impact on public health?

Risk ranking can be based on a variety of tools and methodologies, depending on the level of available information, and the expected accuracy and purpose of the estimate. It is important however that each methodology is encompassing both the impact of exposure and severity of different hazards in different foods. The tools that have been globally proposed include *Stepwise and Interactive Evaluation of Food safety by an Expert system (SIEFE)* (van Gerwen et al. 2000), *Risk Ranger* (Ross and Sumner 2002), *iRisk* (Chen et al. 2013) and the newly introduced metrics of disease burden, such as *Disability (or Quality) Adjusted Life Years (DALYs or QALYs)* (Batz et al., 2011; Gkogka et al., 2011). A detailed review of the risk ranking tools, also including comparisons and discussing on the utility and pros and cons of each tool can be found in the 2012 report series of Institute of Life Science Europe (ILSI Europe: "Tools for Microbiological Risk Assessment"; Bassett et al., 2012) and the recent opinion of European Food Safety Authority on the development of a risk ranking framework on biological hazards (EFSA Journal 2012;10(6), page 2724).

In the following paragraphs, the aforementioned tools will be briefly described as an introduction to the most sophisticated and epidemiological based **risk prioritization** methodologies which have been recently released at Nation levels, for prioritizing both existing and emerging risks.

**SIEFE** is comprised of two levels, both applying the risk assessment principles (van Gerwen et al., 2000). The first level is a semi-quantitative approach that could also be characterized as risk profiling coupled with risk ranking and aims to identify the risk-determining phenomena. Based on the outcomes and guidelines of this level, a thorough and systematic risk assessment is carried out in the second level, with particular numerical outputs, potentially accounting for variability and uncertainty, too (van Gerwen et al., 2000; Perni et al., 2009).

**Risk ranger** is a simple publicly available XL spread-sheet which is based on eleven questions answered in nominal, ordinal, or continuous numerical scale, including user-defined values (Ross and Sumner 2002). As such, inputs include qualitative statements and quantitative data about risk-factors associated with specific food-hazard combination and target a specific population of concern along the food supply chain from farm to table. Through a series of mathematical and logical steps based on spread sheet functions, the software returns a risk ranking value on a logarithmic scale from 0 to 100, as well as an estimated number of cases *per annum* for the population of concern or the probability of illness per day and per consumer, attributed to the target food-hazard combination. Notably, the software is not a database, and thus, does not rely on epidemiological or literature evidence, nor does it require *a priori* knowledge of the food-hazard combination. Its outputs derived only from simple (mostly multiplicative) calculations which depend on the inputs of the user, without engaging any sophisticated mathematical (e.g., predictive models) or statistical (e.g., Monte Carlo simulations)



to describe variability and uncertainty. Nonetheless, it remains a simple and easy-to-interpret tool for rapid risk ranking based of food-pathogen combinations based on empirical food process and post-process stages and consumer consumption data.

**DALYs** integrate incidence data with indices of severity and duration. This in turn enables the relative ranking on the same DALY scale of diseases attributed to different causative agents the dose of which is estimated on different scales, such as chemical vs microbial, as well as of diseases with acute (e.g., an invasive foodborne infection or direct intoxication) or chronic impact (e.g., cardiovascular disease, cancer, etc.) (Havelaar *et al.*, 2012). DALY is the sum of two components (equation 1), one reflecting the years of life lost (YLL) due to mortality of a specific disease, and one representing the numbers of years lived with disability, also due to a certain disease (YLD).

$$\text{DALY} = \text{YLL} + \text{YLD} \quad (1)$$

YLL is calculated by adding all fatal cases ( $d$ ) due to all health outcomes ( $l$ ) of that specific disease, each case multiplied by the expected individual life span ( $e$ ), at the age of death, with a life expectancy according to models life tables proposed by WHO (equation 2):

$$\text{YLL} = \sum_i d_i \times e_i \quad (2)$$

YLD is calculated by accumulation over all cases ( $n$ ) and all health outcomes ( $l$ ) of the product of the duration of the illness ( $t$ ) and the disability weight ( $w$ ) of a sporadic disease:

$$\text{YLD} = \sum_i n_i \times t_i \times w_i \quad (3)$$

The following Table 1 shows a representative ranking of some well-known foodborne infections and intoxications caused by microbial hazards. The major criteria taken into account are the numbers of cases, the number of hospitalizations, the number of deaths and the average estimated financial burden of each disease, due to medical costs and productivity losses. It is evident that ranking of these diseases would not be realistic if it was solely based on a single criterion, because it would have ignored other aspects of the disease burden which are critical for the individuals or the society. For instance, the number of illnesses is not enough to place Norovirus on top of the ranking because the QALYs of *Salmonella*, which causes on average 5 times less cases than Norovirus, are increased due to the higher number of hospitalizations and deaths associated with this infection. Likewise, even though *L. monocytogenes* is the pathogen with the lowest number of cases in Table 1, it is not ranked at the end, due to the high fatality rate, which approximates the 20% of confirmed cases. EHEC is placed above *Clostridium perfringens*, inspite of causing 10-times less cases, apparently because it has higher hospitalization rate and mortality than *Cl. perfringens*.

**iRisk** is a publicly available web-based platform that performs ranking of multiple food-hazard combinations, according to their disease burden (DALYs) and targeting (consumer) populations of varying disease sensitivity (Chen *et al.*, 2013). Ranking is based on user-inputs through data entry templates and friendly interface for scenario building, in relation to particular food-hazard combinations and consumer groups of specific sensitivity to the relevant disease. The output of the system is determined by built-in mathematical functions and Monte Carlo simulations, based on the provided inputs and Analytica Decision Engine. The generic built-in risk scenario of iRisk is composed of a total of seven elements, of which three are the major grouping elements, namely (i) the food, (ii) the hazard and (iii) the population. These three are further divided into another four sub-modules as follows: (iv) the process model that determines the spatiotemporal behaviour of the hazard within the food matrix and along the entire food supply chain from primary production to consumption; (v) the consumer model containing the necessary information on consumption patterns; (vi) the hazard characterization component representing the severity of the hazard through a dose response model; and (vii) the DALY template, which is

defined as the product of duration and severity of the disease according to the figures of cost, morbidity and mortality associated with the disease.

**Table 1. Ranking of foodborne diseases according to QALYs (adopted by Batz *et al.*, 2011).**

Pathogen	Ranking based on QALYs	QALYs	Cost of Illness (\$ mil.)	Cases	Hospitalizations	Deaths
<i>Salmonella</i> spp.	1	16.782	3.309	1.027.561	19.336	378
<i>Toxoplasma gondii</i>	2	10.964	2.973	86.686	4.428	327
<i>Campylobacter</i> spp.	3	13.256	1.747	845.024	8.463	76
<i>Listeria monocytogenes</i>	4	9.651	2.655	1.591	1.455	255
Norovirus	5	5.023	2.002	5.461.731	14.663	149
<i>Escherichia coli</i> O157:H7	6	1.565	272	63.153	2.138	20
<i>Clostridium perfringens</i>	7	875	309	965.958	438	26

## IV – From risk ranking tools to strategies for risk prioritization

Recently, there have been some efforts in developing nation-wide risk prioritization strategies for ranking existing public health risks. Table 2 summarizes the risk ranking strategy adopted by three of these approaches, in New Zealand (McKenzie *et al.*, 2007), Belgium (Cardoen *et al.*, 2009) and Canada/USA (Ng and Sargeant, 2013). Due to the long-term heterogeneity in the existing methodologies for risk prioritization, such strategies aim to establish a universally accepted benchmarked strategy that quantitatively prioritizes diseases. The majority of risk prioritizing methodologies rely on the setup of measurable criteria for assessing the impact of various disease and food combinations, the definition of levels for each criterion and assignment of weights for the specified levels and/or criteria, thereby reflecting the relative importance of each criterion on the overall risk prioritization and finally aggregation of all inputs by additive or multiplicative formulas in order to numerically estimate the overall risk level.

The major concerns of the current (classical) methodologies are associated with the extent to which the selection of criteria and their levels are arbitrary, whether they sufficiently address the impact of interaction between criteria and quantitatively elicit the impact of factors contributing to the public health risk and the comparability of the numerical output. To remedy the scientific and mathematical bottlenecks, more sophisticated supporting-algorithms for these approaches have been introduced including Conjoint Analysis (Ng and Sargeant, 2013), Hierarchical Bayes and Classification and Regression Trees (CART) (Cardoen *et al.*, 2009). From public health perspective, it is of utmost importance that the outputs of risk prioritization of different methodologies are measurable and comparable, so that international validation is likely in the future. To do that, the available strategies should provide a reference risk-ranking output of universal acceptability, such as DALYs, or at least provide normalized outputs that can be expressed along a common scale. The Netherlands developed an advanced strategy of risk ranking using multiple criteria analysis (MCA) method for prioritizing risks by emerging zoonoses, based on their transmission between animals, from animals to human and between humans, also taking into account economic damage and the disease burden as a function of morbidity and mortality (Havelaar *et al.*, 2010). A pre-defined epidemiological database of selected disease is embedded in the platform and can be freely accessed at

<http://ezips.rivm.nl/>. The mathematical methodology of this approach shares some features with the conjoint method of the Canadian/UA system. The criteria are relatively weighted based on expert consultation as indicated in Table 2 and transformed in order to facilitate further calculations of relative risk. The weights are extracted from the collective analysis of scores assigned to multiple random disease transmission scenarios by Risk managers, disease specialists and students from medical or veterinary schools. The diseases are ranked in a normalized scale from 0 to 1, whereas the user may introduce newly emerging diseases, through parameterization of disease attributes in relation to the seven prioritization criteria. The total number of criteria to be used, as well as the scale, the levels and the weights of each criterion are amenable for modifications by the user. Then the user-defined disease is graphically ranked relatively to the built-in zoonoses from the system database on the same normalized scale.

**Table 2. Overview of nation-wide risk prioritization strategies**

Study	Criteria	Scores per criterion	No of diseases Food/Hazard combination	Algorithm	Type of output
McKenzie <i>et al.</i> (2007) New Zealand	Probability of entry (POE)  Likelihood of spread (LOS)  Consequence of spread (COS)  LOS/COS assessed for: Free-living wildlife, humans, captive wildlife, livestock and companion animals	<ul style="list-style-type: none"> <li>• POE: 0.2, 0.4, 0.6, 0.8, 1</li> <li>• LOS: 1, 2, 3, 4</li> <li>• COS: 1, 2, 3, 4</li> </ul>	48 exotic and 34 endemic wildlife pathogens	Product of POE x LOS x LOS	Numerical for different sub-populations as indicated in column 'criteria'
Cardoen <i>et al.</i> (2009) Belgium	<b>Public Health</b> 1. Severity to humans 2. Occurrence in the Belgian population <b>Animal Health</b> 3. Occurrence in live animals in Belgium 4. Severity for animals Commercial/economic impact for the sector <b>Food</b> 5. Occurrence in food or in carcasses	Score 0 to 4 or ND/?:  <b>Occurrence criteria</b> <ul style="list-style-type: none"> <li>• Rare</li> <li>• Moderate</li> <li>• Significant</li> <li>• High</li> <li>• ND/?</li> </ul> <b>Severity criteria</b> <ul style="list-style-type: none"> <li>• Benign</li> <li>• Weak</li> <li>• Moderate</li> <li>• Severe</li> <li>• Lethal</li> </ul>	35 experts x 51 food and water zoonotic agents	XL spreadsheet Weights decided by managers based on Las Vegas methodology Groups of importance identified by CART Uncertainty calculated with bootstrapping with <i>R</i>	Ranking according to the sum of weighted scores Scale 0-20

**Table 2 (cont.). Overview of nation-wide risk prioritization strategies**

Study	Criteria	Scores <i>per</i> criterion	No of diseases Food/Hazard combination	Algorithm	Type of output
Havelaar <i>et al.</i> (2010) The Netherlands	1. Probability of entry 2. Transmission between animals 3. Economic damage in animal reservoir 4. Transmission from animals to human 5. Transmission between humans 6. Morbidity 7. Mortality	1. %/year 2. Prevalence /100.000 animals 3. Million Euros per year 4. Prevalence /100.000 humans 5. Prevalence /100.000 humans 6. <0.03, 0.03-0.1, 0.1-.3, >0.3 7. % (0 to 100)	Built-in database of zoonoses: selection from 1415 human pathogens of which, 868 are zoonoses Expert consultation: • Risk managers from Dutch Ministries of Agriculture and Public Health Authorities • Infectious disease specialists • Students in medical/veterinary faculties	Multiple Criteria Analysis Uncertainty by Monte Carlo Simulation CART for clustering	Normalized result in a scale from 0 to 1
Ng and Sargeant (2013) US and Canada	<b>21 characteristics</b>  <b>a) Assessed separately for human and animals</b> Case-fatality Duration Severity 5-years trend 5-years incidence Efficacy of control measures High risk groups Scientific knowledge  <b>b) For humans</b> Economic burden Transmission from animals to humans Transmission between humans  <b>c) For animals</b> Economic and social burden on trade Transmission between animals Transmission from human to animals	Categorical and numerical levels Magnitude differed with criteria	62 existing and emerging diseases Evaluated by 707 Canadian and 764 US experts	Conjoint Analysis (CA) Hierarchical Bayes Monte Carlo Markov Chain Metropolis/Hastings algorithm	Disease score from –infinity to +infinity based on (CA): Important scores <i>per</i> criterion (weights) Part-worth utility values

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# Molecular typing methods for major food-borne microbiological hazards and their use for attribution modelling, outbreak investigation and scanning surveillance

A. Ricci<sup>1</sup>, M.T. da Silva Felicio<sup>2</sup>, L. Vivas-Alegre<sup>3</sup>, P. Butaye<sup>4</sup>, R.H. Davies<sup>5</sup>, T. Hald<sup>6</sup>, A. Havelaar<sup>7</sup>, B.-A. Lindstedt<sup>8</sup>, M.C.J. Maiden<sup>9</sup>, E.M. Nielsen<sup>10</sup>, G. Scavia<sup>11</sup>, M. Struelens<sup>12</sup>, J. Threlfall<sup>13</sup> and D.L. Baggesen<sup>6</sup>

<sup>1</sup>Istituto Zooprofilattico Sperimentale delle Venezie (Italy)

<sup>2</sup>European Food Safety Authority (Italy)

<sup>3</sup>European Commission DG RTD (Belgium)

<sup>4</sup>Ross University (St Kitts and Nevis)

<sup>5</sup>APHA Veterinary Investigation Centre (United Kingdom)

<sup>6</sup>Technical University of Denmark, National Food Institute (Denmark)

<sup>7</sup>University of Florida, Emerging Pathogens Institute, USA

<sup>8</sup>Akershus University Hospital (AHUS), Norway

<sup>9</sup>University of Oxford, Department of Zoology (United Kingdom)

<sup>10</sup>Statens Serum Institut (Denmark)

<sup>11</sup>Istituto Superiore di Sanità, Dip. Sanità Pubblica Veterinaria e Sicurezza Alimentare (Italy)

<sup>12</sup>ECDC, European Centre for Disease Prevention and Control (Sweden)

<sup>13</sup>Health Protection Agency (United Kingdom)

**Abstract.** The paper presents a recent Opinion of the Biohaz Panel of EFSA, which provides an evaluation of molecular typing methods that can be applied to the food-borne pathogens *Salmonella*, *Campylobacter*, Shiga toxin-producing *Escherichia coli* and *Listeria monocytogenes*. This evaluation is divided in two parts. First, commonly used molecular typing methods are assessed against a set of predefined criteria relating to discriminatory power, reproducibility, repeatability and current or potential suitability for international harmonisation. Secondly, the methods are evaluated regarding their appropriateness for use in different public health-related applications. These applications include outbreak detection and investigation, attribution modelling, the potential for early identification of food-borne clones with epidemic potential and the integration of the resulting data in risk assessment. The results of these evaluations provide updated insights into the potential use of molecular characterisation methods, including whole genome sequencing technologies, in microbial food safety. Recommendations are also made in order to encourage a holistic and structured approach to the use of molecular characterisation methods for food-borne pathogens; in particular, on the importance of structured co-ordination at international level to help overcome current limitations in harmonisation of data analysis and interpretation.

**Keywords.** Genotyping – Molecular typing – Whole genome sequencing – Outbreak – Source attribution – Epidemic potential.

**Les méthodes de typage moléculaire pour les principaux dangers microbiologiques liés aux aliments et leur utilisation pour la modélisation de l'attribution, l'investigation des flambées épidémiques et la surveillance passive.**

**Résumé.** Cet article présente un avis récent du groupe scientifique de l'EFSA sur les dangers biologiques (BIOHAZ), qui évalue les méthodes de typage moléculaire pouvant être appliquées aux pathogènes liés aux aliments tels que *Salmonella*, *Campylobacter*, *Escherichia coli* Shigatoxigène (STEC) et *Listeria monocytogenes*. Cette évaluation est divisée en deux parties. D'abord, les méthodes de typage moléculaire couramment utilisées sont évaluées selon un ensemble de critères prédéfinis concernant le pouvoir de discrimination, la reproductibilité, la répétabilité et l'adaptation actuelle ou potentielle à l'harmonisation internationale. En deuxième lieu, les méthodes sont évaluées en vue de leur utilisation dans différentes applications liées à la santé publique. Parmi ces applications figurent la détection et l'investigation des flambées épidémiques, la modélisation de l'attribution, les possibilités d'identification précoce des souches

d'origine alimentaire à potentiel épidémique et l'intégration des données résultantes dans l'évaluation des risques. Les résultats de ces évaluations permettent une vision actualisée de l'utilisation et du potentiel des méthodes de caractérisation moléculaire, y compris les technologies de séquençage du génome entier, pour la sécurité microbienne des aliments. Des recommandations sont également formulées afin d'encourager une approche holistique et structurée de l'utilisation des méthodes de caractérisation moléculaire concernant les pathogènes présents dans les aliments ; en particulier est soulignée l'importance d'une coordination structurée au niveau international afin de surmonter les limitations actuelles quant à l'harmonisation de l'analyse et l'interprétation des données.

**Mots-clés.** Génotypage – Typage moléculaire – Séquençage du génome entier – Flambée épidémique – Attribution des sources – Potentiel épidémique.

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## I – Introduction

Molecular typing can be defined as the classification of microorganisms on the basis of variation in the genotype, and/or the presence or absence of specific genes, such as those which may contribute to the pathogenicity of the organism or to its ability to survive in less favourable environments (Hallin et al., 2012). 'Genotype' has been defined as the genetic constitution of an organism, as assessed by a molecular method (van Belkum *et al.*, 2007).

According to the European Centre for Disease Prevention and Control (ECDC), molecular typing refers to the application of laboratory methods capable of characterizing, discriminating and indexing subtypes of microorganisms. Molecular typing of pathogens that cause infectious diseases complements traditional epidemiological surveillance by providing appropriate discriminatory analyses to: (i) allow the rapid and early detection of outbreaks; (ii) investigate transmission chains; (iii) determine the relatedness of strains; and, (iv) detect the emergence of antimicrobial resistance and new evolving pathogenic strains. Molecular typing can also support studies to trace-back the source of an outbreak and identify new risk factors, by linking isolates more accurately to epidemiological and clinical data (ECDC, 2007 and 2013).

Genetic methods for bacterial typing have progressively replaced phenotypic assays during the last two decades, even though the phenotypic methods are still widely used by reference laboratories for routine surveillance and outbreak detection, as reported in an EU-wide survey (EFSA, 2009). The current practice is to use a combination of different phenotypic and genotypic typing methods.

During the last three decades, a large number of genotyping methods have been developed and applied in various contexts, mostly by research institutions or reference laboratories dealing with local or national outbreaks. Difficulties in standardisation and harmonisation of the results have often made data difficult to share. For some methods, standardisation and harmonisation has been developed to a degree that has made application of the methods suitable for wider international use (e.g. Pulsenet International).

Recently, the Biohaz Panel of EFSA has adopted an opinion (EFSA, 2013) in which the main molecular typing methods that are currently used and prospective methods for epidemiological typing of the main food-borne bacteria (*Campylobacter*, *Salmonella*, Shiga-toxin producing *Escherichia coli* (STEC) and *Listeria* by national and international reference laboratories are considered. These were evaluated in terms of: (i) discriminatory power (i.e. degree of discrimination between strains of different genotype); (ii) reproducibility and repeatability (i.e. consistency of results within and between laboratories, and over time); (iii) current international harmonisation (i.e. status with regard to availability and use of standard operational procedures; external quality assurance systems, harmonised nomenclature and data management tools), and, (iv) the potential for future international harmonisation in situations where any of the sub-criteria under (iii) may not be currently harmonised.

The document highlights that all bacteria are subject to genetic change (e.g. in response to environmental stress and human interventions such as antimicrobial or heavy metal use or vaccination, or by natural genetic drift), by mutation or by acquisition or loss of genetic elements. These changes can be followed by clonal expansion in the case of biologically successful organisms. Ongoing evolution driven by genetic change and selection has given rise to organisms that are able to exploit and expand into novel niches and extend their host range. Such evolution may also be linked to the emergence of various 'epidemic' strains of pathogens, such as *Salmonella*, in combination with other biological factors and epidemiological opportunities for dissemination. The molecular characteristics of organisms provide markers for investigation of outbreaks, attribution studies, and assessment of potential virulence or epidemic potential. The Opinion also points out that even with high-resolution molecular approaches, up to and including WGS analysis, it is not possible to establish how closely two isolates are related without an appreciation of the structure and diversity of the bacterial population in question. Further, to properly evaluate typing methodologies, data from strain characterisation should be linked with epidemiological data and, as far as is possible, the strain selection must be unbiased and statistically representative of the population. International harmonisation of molecular characterisation outputs by means of standardisation or appropriate quality control procedures is essential. This includes controlling the accuracy of production of DNA sequences from WGS and the further interpretations of annotation pipelines.

## II – Molecular serotyping

Molecular serotyping describes methods developed to identify serotypes of organisms by analysing DNA. There are several ways in which DNA-analysis can be used to achieve this. The most common methodology uses either one of these two key principles: (a) examination of the genetic loci known to produce the serologically reactive components used in traditional serotyping; or, (b) examination of variations in the genome, which are indirectly associated with known serovars or serotypes. These variations may include various kinds of polymorphous regions, as long as they show a strong association to the traditional serovars/serotypes.

Molecular serotyping is considered to provide a low to moderate discriminatory capability. This is normally similar or marginally higher than traditional serotyping as sub-types can often be recognised within serotypes. 'Reproducibility and repeatability' are high, but may be reduced if large arrays are used, due to the complexity of the technology. 'Internationally harmonised standards' for molecular serotyping are not in place except for *L. monocytogenes*; nevertheless, the existing software tools could be employed at international level. Molecular serotyping is based on a well-known and implemented methodology, and thus has a high capability for 'future international harmonisation'. Molecular serotyping will, in most instances, provide results within a day from receiving the isolate. Molecular serotyping using MLST derived from whole genome sequencing is likely to be increasingly used in future, replacing the array-based methods that are in current use.

## III – Restriction Fragment Length Polymorphism (RFLP) analysis

In RFLP, a target DNA sequence known to show polymorphism between strains of a bacterial species, is cut with one or more restriction endonucleases to generate fragments of varying length. The earliest versions of the RFLP method involved several time-consuming steps. The whole process could in some cases take up to four weeks to produce an interpretable result.

In PCR-RFLP typing the target sequence is amplified at high annealing temperatures to maximise stringency. The amplified product is cut with one or more restriction endonucleases and the type is determined by comparing RFLP patterns after gel electrophoresis. PCR-RFLP typing has provided limited discrimination.



When RFLP analysis is directed at genes encoding ribosomal ribonucleic acid (rRNA) the method is usually referred to as 'Ribotyping'. Ribotyping has successfully been automated, and fully automated ribotyping is commonly referred to as 'riboprinting' after the RiboPrinter® commercial system (DuPont Qualicon, Wilmington, DE). Automated riboprinters require minimal input and technical skill by the operator, but the cost of equipment is high, so this method is largely used by commercial food companies.

RFLP analysis may be regarded as providing a moderate to high 'discriminatory capability' for at least some of the four pathogens considered in this manuscript. Within and between laboratories' reproducibility and repeatability is low to moderate for PCR-RFLP and traditional ribotyping, but high in the case of fully automated riboprinting systems. At present, the riboprinting platform provided by DuPont Qualicon® appears to be the only RFLP typing that provides for 'internationally harmonised standards'. Nevertheless, RFLP typing tools other than riboprinting also may have the 'potential for international harmonisation' in spite of the current lack of systems operating to achieve this.

## IV – Pulsed-Field Gel Electrophoresis (PFGE) analysis

PFGE was first described in 1984 and is currently the most frequently used DNA-based typing method for food-borne bacterial pathogens. The PFGE-method standardization and rigid quality control introduced by PulseNet International has resulted in PFGE becoming the most commonly used method for outbreak identification, surveillance and investigation for a number of important pathogens, in particular *Salmonella*, STEC and *Listeria* (Ribot *et al.*, 2006). Thus, for these pathogens, the performance of new typing methods will be measured against PFGE.

PFGE fingerprinting has a high 'discriminatory power' for most pathogens considered, but for the species *Salmonella enterica* there are some notable exceptions, namely *S. typhimurium* DT 104, and *S. Enteritidis* PT 4. For these two, the fact that they are subtypes of a subspecies and their recent emergence has led to a high degree of clonality. The discriminatory power of PFGE depends on the number and distribution of restriction sites throughout the genome, including extra-chromosomal DNA, which define the number and sizes of bands in the profile, and can be increased by using different or combinations of restriction endonucleases. Within and between laboratory 'reproducibility and repeatability' of results, based on the experience gained in the context of PulseNet International and PulseNet Europe, can be high, but the technique may be considered to be laborious and time consuming. PFGE may require several days for completion, with time increasing with the number of restriction enzymes used. 'Harmonised standards' are available, with the exception of a harmonised nomenclature, although for *Salmonella* a harmonised and agreed nomenclature is used within the EU. Nevertheless, achieving a uniform international nomenclature for 'future harmonisation' should be possible.

## V – Multiple-Locus Variable number tandem repeat Analysis (MLVA)

All bacterial MLVA-assays simultaneously measure the length of variable number of tandem repeat (VNTR) loci by PCR amplification and electrophoresis, and use this information to create a genotype to distinguish between isolates of the same species.

MLVA has several advantages: it has a high discriminatory power, which can be easily adjusted by inclusion or exclusion of loci to be investigated; handling of pathogenic bacteria is low, which increases laboratory safety; rapidity, as both PCR and electrophoresis times can now be greatly reduced due to improved technology.

MLVA typing has a high discriminatory power for *Salmonella*, STEC and *L. monocytogenes* but not for *Campylobacter*. Only *S. typhimurium* MLVA has so far been validated for international

reproducibility and repeatability, and results indicate high reproducibility and repeatability when strict guidelines and a reference strain collection are used. MLVA allows direct digital storage of results as discrete-character numeric data. For inter-laboratory comparability and the correct assignment of the numeric profile, calibration of measured fragment sizes has to be performed in each laboratory (Larsson *et al.*, 2009). A proposed standardisation scheme also exists for *S. Enteritidis*. Thus, international harmonisation appears well advanced, in particular for *S. Typhimurium*. Furthermore, the potential for future international harmonisation for *Listeria* and STEC, but not for *Campylobacter*, should be possible based on the experience with *S. typhimurium*. MLVA results can be obtained within 24 hours of receiving isolates.

## VI – Sequence-based typing methods

### 1. Single Locus Sequence Typing (SLST)

SLST describes the sequencing of a single gene or genetic locus, which displays enough polymorphism to be used in a typing scheme. Usually one single locus is sequenced and compared between strains to determine the genetic distance. The SLST method thus entails the same operational steps as running Multi locus sequence typing (MLST, see below) the only difference is the number and choice of the target loci. Equipment and analysis software used will in most instances be the same. Sequencing of the *flaA* short variable region (SVR) may be used for typing of *Campylobacter* (Meinersmann *et al.*, 1997). This provides good discrimination within *C. jejuni* and *C. coli*, and an international nomenclature is established (via the pubMLST database). The *flaA*-SVR is often used as an additional locus to the seven MLST loci to improve the discriminatory power of MLST.

SLST has a high discriminatory power for subtyping known STEC STX-producing variants, and moderate capability for *Campylobacter* spp. *flaA* SVR typing. For *Salmonella* and *Listeria*, SLST is not commonly used. Reproducibility and repeatability are considered high but current international harmonisation requires the establishment of international SOPs and EQA procedures, although harmonised nomenclature and data management tools are already in place. These could be developed without major difficulties, so the method could have a high capability for future international harmonisation SLST methodology is well proven, and typing results in most cases will be available with 24 hours.

### 2. Multi locus sequence typing (MLST)

MLST indexes sequences variation at a number (usually seven) genetic loci distributed around the chromosome (Maiden, 2006). These are ideally housekeeping genes, i.e. genes encoding enzymes that are involved in primary metabolism of the organism in question and which are therefore present in all isolates. Such genes are stable, in that the metabolic function must be conserved. With this method an allelic profile or sequence type (ST) is created for each pathogen. The STs are also assigned unique arbitrary identifiers so that the sequence variation can be summarised as a single number. The existence of web-accessible databases of allele definition, STs and isolate data enables the unambiguous comparison of data collected in different laboratories. A number of analysis approaches can be used to examine structure within MLST datasets and establish relationships among STs which are crucial for identifying membership of higher groups, known as clonal complexes.

The discriminatory power of MLST is moderate to high depending on the pathogen and gene subset typed; usually the discriminatory capability for food-borne pathogens is too low for outbreak investigations and thus additional typing data is needed when used in this context. 'Reproducibility and repeatability' are high and current international harmonisation is well advanced, although international SOPs could benefit from standardising an assay for each pathogen, rather than allowing different methodologies to be used.

## VII – Whole Genome Sequence (WGS) analysis

Most of the prominent new technologies are the sequence-based. Several versions of new sequencing technologies, employing different principles, are in existence, all of which are designed with the aim of rapid sequencing of whole genomes. An often-used term is 'Next Generation Sequencing' (NGS), which is commonly used to refer to the post-Sanger and Maxam–Gilbert sequencing methods (Struelens and Brisse, 2013).

There are four approaches currently in use: (i) pyrosequencing, exemplified by the Roche 454 platform which can generate longer but fewer reads and with potential miscalling of polynucleotide sequences (this platform is about to be discontinued and can be considered to be redundant); (ii) Illumina sequencing technology, which produces shorter but more sequence reads; (iii) IonTorrent, also produces shorter sequence reads, and with a potential for miscalling polynucleotide tracts; and (iv) the PacBio SMRT sequencing system, which can produce very long sequences and epigenetic features such as DNA methylation, but with relatively high error rates and cost; (v) Nanopore technology, another single molecule sequencing approach was in late-phase testing at the time of writing. These technologies, especially those that depend on nanopores and PacBio, are all in rapid development so no exhaustive review will be made here as it is likely to become outdated almost immediately. Of note is that the Roche 454 system is currently already out of production. Compared to 'Sanger' sequencing all of the current methods generate individual sequence reads with high error rates and error correction is achieved with very high sequence coverage.

The discriminatory capability of WGS is very high as it samples the whole genome, including extra-chromosomal DNA. Reproducibility and repeatability are also high. Current international harmonisation is lacking except for the availability of data management tools and annotation guidelines – however the latter does not provide a fully harmonised nomenclature. The potential for future international harmonisation is currently uncertain, but should be considered high from a technical point of view.

## VIII – Evaluation for use in different public health-related applications

With regard to the review of the appropriateness of use of the different food-borne pathogen sub-typing methodologies for different food-safety related public health applications (i.e. detection and investigation of food-borne outbreaks of disease, food-borne source-attribution, early identification of food-borne organism with epidemic potential and their integration in risk assessment), it is concluded that detection of outbreaks and their investigation in real-time would be enhanced by the generation of fully comparable molecular typing data from human, veterinary and food laboratories prior to submission to a central or connected databases. Some molecular typing methods (e.g. MLST, PFGE, MLVA) have been harmonised to a greater or lesser extent for the purpose of outbreak detection and investigation. The international development of harmonised platforms for WGS-generated data should be encouraged.

In relation to source-attribution analysis of food-borne pathogens, the Panel concluded that a major challenge of using data generated from molecular typing methods in source attribution models, in particular WGS data, will be to define meaningful subtypes providing an appropriate level of discrimination for source attribution. A high level of discrimination is not necessarily the best option. The applied method has to allow for some genetic diversity between isolates from human and animal/food sources, but only to the degree so that it can still be assumed that they originate from the same source. Independent of the choice of molecular typing method and approach for source attribution, it is important that the data included from human and potential sources are related in time and space. Source attribution analysis is, therefore, facilitated by integrated surveillance providing a collection of isolates from all (major) sources that should, to the extent possible, represent what the human population is exposed to.

The epidemic potential of a food-borne strain within a bacterial species, or even within a subtype varies considerably, and is a function of its inherent genetic characteristics and their expression combined with ecological factors including the opportunities to spread in the food chain. Prediction of the public health risk and epidemic potential of emerging strains of food-borne pathogens has not yet been possible. Nevertheless, if an epidemic strain has already emerged in a certain region such a strain can be rapidly characterised employing current molecular typing methods and thus serve to identify the occurrence of such strains in other regions for risk management purposes. High throughput WGS technologies offer new opportunities to characterise bacterial strains in great detail. The genetic information that these technologies provide will, however, need to be considered together with gene expression, host and ecological factors, including the opportunities to spread in the food chain. Finally, although there are differences between bacterial species, the principle of assessing the gene content in relation to fitness as a means to assess risk potential that has been used for the four organisms considered in this opinion should be applicable to any bacteria.

Eventually, in the document a series of recommendations are made on important issues to be considered as these methods, in particular WGS analysis, have limitations when using the data they generate. Thus, modern molecular typing methods provide many opportunities for rapid and accurate determination of the genealogical relationships among bacterial isolates. Interpretation of the results generated by these methods for different public health applications requires this information to be placed in the context of the diversity, degree of genetic change (e.g. during storage of isolates or mutation during an outbreak and in reservoirs) and population structure of the particular pathogen in question. Therefore, large scale carefully co-ordinated studies are required to fully elucidate this. The development of more informative and easier to use bioinformatic tools for analysis of WGS data is needed. Multidisciplinary and integrated research programs are needed to develop and validate the use of detailed genetic information for 'predictive' hazard identification, accounting for gene expression and how this affects the fate of pathogens in the food chain and their interaction with human and animal hosts. Further recommendations are made on particular issues to aid the use of these methods and the data they generate for the different applications considered.

## IX – Conclusions

The Biohaz Panel concluded that molecular typing methods should ideally provide appropriate discriminatory power, reproducibility, capability for international harmonisation and reduced handling of and exposure to pathogens in the laboratory. No current typing method, whether phenotypic or molecular, complies with all these expectations. Several methods are often used in combination in order to obtain the resolution needed. The methods applied depend on the pathogen and on the application sought. These methods have proven track records of use and for some of them, notably MLST and PFGE, extensive databases of valuable typing data have been collected. Further, methods based on WGS are increasingly replacing the numerous different methodologies currently in use in human and veterinary reference laboratories, and the same methods can be used for all organisms. An essential precondition is the availability of quality control methods, to ensure the reliability and consistency of molecular data generated, coupled with high quality bioinformatics support for the analysis of the data generated. Regarding WGS, limited knowledge is available in relation to the technical errors that occur during sequencing and analysis and on the effect of genetic drift in the different bacterial populations over time, which may complicate the interpretation of results. The international development of harmonised platforms for WGS-generated data and suitable databases that can link strain and epidemiological data whilst still allowing for confidentiality of personal or commercially sensitive information should be encouraged

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# Predictive tools and strategies for establishing risk-based Microbiological Criteria in Foods

A. Valero

Department of Food Science and Technology, Faculty of Veterinary, University of Cordoba,  
Campus de Rabanales s/n, Edif. Darwin-Anexo (Spain)

**Abstract.** One of the fundamental objectives of food legislation is the assurance of an appropriate level of health protection, as already stated in the EC Regulation No. 178/2002 concerning the food safety and hazard analysis policies. However, the increasing food exports between countries to a large number of consumers give rise to the need of a further harmonization of the control procedures leading to increase food safety. To date, due to the lack of homogeneity in the development of scientific risk assessments for different pathogens in foods, a sufficiently cohesive and integrated food safety policy has not been yet developed. To make feasible the implementation of food safety management schemes, the routine and successful use of software applications by the food industry, governments or educational agencies, should be promoted. One useful way is to create decision-support tools assessing the behaviour of potential microbial hazards along the food chain and their impact on public health. Their use might depend on the availability of user-friendly software, which encompass predictive modelling tools and risk assessment modules to allow different users to retrieve information from them in a rapid and convenient way. The performance of risk-based metrics and the establishment of microbiological criteria could help to identify critical steps along the food chain that influence on the final risk associated to a specific pathogen. Throughout this paper, some examples on how to elucidate microbiological criteria basing on established risk-based metrics (namely, Performance Objectives and/or Food Safety Objectives) set as (i) numerical limit of pathogen concentration; (ii) frequency or proportion terms; and (iii) in qualitative to non detectable values.

**Keywords.** Microbiological Criteria – Performance Objectives – Food Safety Objectives – Sampling plans – Predictive modelling.

**Instruments de prédiction et stratégies visant à établir des critères microbiologiques fondés sur le risque pour les denrées alimentaires**

**Résumé.** Un des objectifs fondamentaux de la législation relative aux aliments est l'assurance d'un niveau approprié de protection de la santé, comme le manifestait déjà le Règlement CE N° 178/2002 concernant les politiques de sécurité des denrées alimentaires et d'analyse des risques. Néanmoins, l'augmentation des exportations alimentaires entre pays vers un grand nombre de consommateurs, rend nécessaire une harmonisation plus poussée des procédures de contrôle pour une meilleure sécurité des aliments. Actuellement, en raison du manque d'homogénéité en matière de développement de l'évaluation scientifique des risques pour différents pathogènes d'origine alimentaire, on n'est pas encore parvenu à une politique de sécurité des aliments qui soit suffisamment cohésive et intégrée. Pour permettre la mise en place de démarches de gestion de la sécurité des aliments, il conviendrait de promouvoir l'utilisation routinière et performante de logiciels par l'industrie alimentaire, les gouvernements ou les instituts de formation. Une façon d'aller dans ce sens consisterait à créer des outils d'aide à la décision évaluant le comportement des dangers microbiens potentiels sur toute la chaîne alimentaire ainsi que leur impact sur la santé publique. Leur exploitation pourrait dépendre de la disponibilité de software convivial, englobant les outils de modélisation prédictive et les modules d'évaluation des risques pour permettre aux différents usagers d'en extraire des informations de façon rapide et appropriée. Les performances de métrique basées sur les risques et la définition de critères microbiologiques pourraient contribuer à identifier les étapes critiques sur toute la chaîne alimentaire ayant une influence sur le risque final lié à un pathogène spécifique. Dans cet article, quelques exemples sont présentés sur la façon d'élucider les critères microbiologiques en se basant sur la métrique établie concernant les risques (à savoir, Objectifs de Performance et/ou Objectifs de Sécurité des Aliments) en tant que (i) limite numérique de la concentration de pathogènes ; (ii) termes de fréquence ou de proportion ; et (iii) valeurs allant de qualitatives à non détectables.



## I – Introduction

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs has established specific guidelines for different food commodities regarding the compliance with microbiological limits. This regulation introduced two different types of criteria: Food Safety Criteria (FSC) and Process Hygiene Criteria (PHC).

Regarding the establishment of FSC for pathogenic microorganisms harmonized standards on the acceptability of food are provided for both authorities and industry within the EU and for products imported from third countries. FSC will impact the entire food chain, as they are set for products placed on the market.

Implementation of FSC may be achieved through the establishment of risk-based metrics, namely Performance Objectives (PO) or Food Safety Objectives (FSO). A PO is a risk-based metric that allows government risk managers and food operators to quantify the stringency of a food safety management system in a particular point in the food chain. An FSO is defined as the maximum frequency and/or concentration of a hazard in a food at the moment of consumption that provides or contributes to reach an Appropriate Level of Protection (ALOP) for human health. These metrics are usually proposed by the competent authority although they can also be set by the food business operators as a part of their management systems. In any case, actions are taken throughout the food process in order to meet with such objectives. The International Commission on Microbiological Specifications for Foods (ICMSF, 2002) established the link between a public health measures and food safety management concepts throughout the food chain.

Microbiological Criteria (MC) constitute tools for lot acceptance or rejection under specific targets implemented by food operators. To evaluate if the PO is accomplished for a specific food/risk combination the establishment of MC can be set at different stages of the food chain. However, they should not be considered without other aspects of EU food legislation, in particular Hazard Analysis of Critical Control Points (HACCP) principles and official controls to audit food business operators' compliance. Microbiological food safety targets are international theoretical concepts already included in several documents (Codex Alimentarius Commission, 1997; ICMSF, 2002; EFSA, 2007). However, microbiological testing alone may convey a false sense of security due to the statistical limitation of sampling plans, particularly in the cases where the hazard presents an unacceptable risk at low concentrations and/or low and variable prevalence.

To articulate a MC coming from a PO, several decisions must be taken:

- (i) Assumption of the distribution of the pathogen in the lot of food.
- (ii) Definition of the 'maximum frequency/concentration' of the hazard that will be used to specify the PO/FSO. Regarding this, the risk manager can set different targets to know the most probable concentration limits that must satisfy the PO.
- (iii) Specification of the level of confidence needed to ensure that a non-conforming lot is detected and rejected by the specific number and size of samples taken (generally, the default value is set at 95%).
- (iv) Finally, the analytical procedure used is specified in case of qualitative tests, enrichment, and enumeration techniques.

The sampling plan appropriate to assess an MC depends on the specific situation for which the PO is established. Note that the PO can be translated into frequency and/or concentration terms. At low concentration values, prevalence and concentration are not independent so that qualitative tests or enrichment techniques are applied. On the contrary, when dealing with high contaminated samples, PO limits are established on concentration terms.

The stringency of an MC is defined by the values of  $n$  (number of samples taken from a food lot),  $c$  (maximum allowable number of samples exceeding a certain limit),  $m$  (lower microbiological limit) and  $M$  (upper microbiological limit). Overall, when more samples are needed with a smaller number of acceptable positive units ( $c$ ) and/or lower limits are chosen; or sample unit is larger, the sampling plan becomes more stringent.

Throughout this paper three generic examples applicable to different microbial food/risk combinations are presented to provide guidance on how to derive an MC from a PO. The examples were elaborated in accordance with the established principles stated by the Codex Alimentarius Commission (CAC, 2004), as well as other relevant published papers about setting Food Safety Criteria and sampling procedures (Stringer, 2005; Whiting *et al.*, 2006; Van Schothorst *et al.*, 2009; Zwietering *et al.*, 2010).

## II – Establishment of a MC from a PO that is set in concentration terms

For the purpose of this scenario, we assumed that the competent authority has established a PO for the concentration of a microbial foodborne pathogen in a specific matrix.

The PO can be established at different points in the food chain. For illustration purposes, a PO could be stated as a pathogen level lower than 4 log cfu/g for 99.75% of the samples comprising the lot. This can be understood as 'no more than 0.25% of the sampling units in the lot will have a concentration higher than 4 log cfu/g'.

Following the steps above described, we must have an approximate knowledge of the distribution of the microbial concentration in the lot. Where such data are not available, it is a good choice to assume a log normal distribution of concentrations. Furthermore, we know that the standard deviation ( $\sigma$ ) is 0.8 (taken as a reference value for solid foods, as shown in van Schothorst *et al.*, 2009).

The 99.75 quantile ( $x_{99.75}$ ) corresponding to a PO ( $\leq 4$  log cfu/g) belongs to a log normal density distribution with  $\sigma = 0.8$  with a specific unknown mean ( $\mu$ ). However, it can be calculated by means of the quantiles of the standard normal distribution  $z_{\sigma} = 0.9975$ :

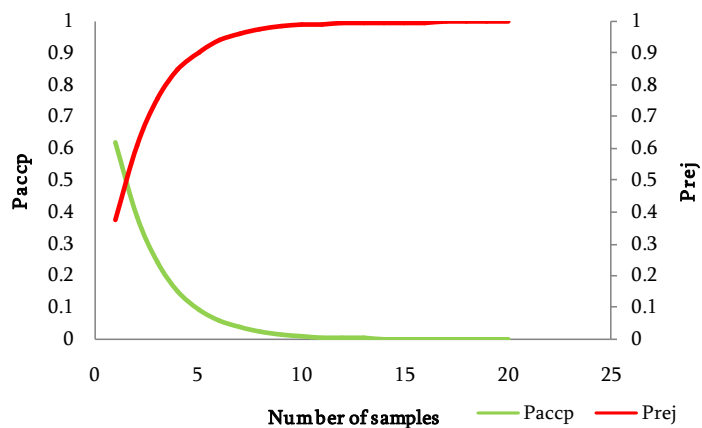
$$\mu = x_{99.75} - z_{\alpha} * \sigma, \quad \text{which is in our case} \quad 1.75 \log \text{ cfu/g} = 4 \log \text{ cfu/g} - 2.81 * 0.8$$

This means that 2.5% of all sampling units of a lot of broiler carcasses with a mean concentration  $\mu = 1.75$  log cfu/g and a standard deviation  $\sigma = 0.8$  of *Listeria monocytogenes* are expected to exceed the predefined PO  $\leq 4$  log cfu/g.

The next step is to decide the most suitable MC so that the PO is accomplished. This MC should be based on the establishment of a microbiological limit ( $m$ ) such that the sampling plan is feasible in reality. This decision corresponds to food safety managers and food operators, in such a way the sampling procedure can be effectively done and PO is accomplished.

By setting 2 log cfu/g as value of  $m$ ; if 1 sample is taken from the lot, the probability of acceptance ( $P_{accp}$ ) is 0.62, while there is a probability of 0.38 to reject the lot ( $P_{rej}$ ).  $P_{accp}$  is understood as the probability that 1 sample taken from the lot is below  $m$  (2 log cfu/g).





**Fig. 1. Illustration of the probability of acceptance ( $P_{accp}$ ) and rejection ( $P_{rej}$ ) of the food lot if 1-20 samples are taken.**

Figure 1 shows the  $P_{accp}$  and  $P_{rej}$  for 1-20 samples taken from the lot. If the confidence limit with which a non compliant lot should be rejected is set at 95%, 7 samples must be tested ( $0.62^7 = 0.035$ ).

Please note that several other aspects of an MC and the underlying sampling plan need to be additionally defined, such as the microbiological characteristics of the food/lot concerned, the analytical method used etc.

If alternative MC are set, the number of samples can vary, as shown in Table 1. This would give alternative designs of the sampling plan that can detect/reject non compliant lots with the same confidence.

**Table 1. Number of samples required to reject the food lot (95% CL) by setting different microbiological limits (m, log cfu/g) for a two-class sampling plan (c is assumed to be 0)**

m (cfu/g)	m (log cfu/g)	n
10	1.0	2
31.62	1.5	4
<b>100</b>	<b>2.0</b>	<b>7</b>
316.23	2.5	16
1000	3.0	50
3162.28	3.5	208

For reference purposes, the sampling plan can be formulated as indicated on Table 2.

**Table 2. Sampling plan formulated**

Analysis	Standard/Guideline			Assessment	
	n	c	m	Satisfactory	Unsatisfactory
<i>Pathogen</i>	7	0	2	< m/g	> m/g in any of the subsamples tested

### III – Establishment of an MC from a PO that is set in prevalence or proportion terms

In this case, the PO will be established at any point of the food chain using bacterial prevalence (i.e. analytical tests to verify presence/absence of the microorganism in a certain quantity of lots).

As an example, we consider absence of the pathogen in the tested sample after an enrichment technique is carried out. A PO can be set as the absence of the pathogen in  $\leq 20\%$  of the samples. In other words, the minimum proportion of non contaminated units in the food lot should be higher than 80%.

The first step is to calculate the  $P_{accp}$  of the food lot by taking  $n$  samples.  $P_{accp}$  would be the probability that, if taking  $n$  samples, the proportion of contaminated units is lower than the established PO ( $\leq 20\%$ ). In this case, the contamination rate is 20%. Therefore, the probability of having a negative sample would be  $1 - 0.20 = 0.80$ .

In the following table, several values of  $n$  are presented, corresponding to different probabilities of having negative samples:

Subsequently, a decision must be made regarding the level of confidence of the sampling plan, to accept or reject the lot. In this case, a 95% probability is deemed to be appropriate.

Given the PO, there is a less than 5% probability that lots with a 20% contamination rate or higher would be accepted by a sampling plan with  $n = 14$  samples (0.044).

Alternatively, the negative binomial distribution can be used:  $= \text{NEGBINOMDIST}(0; 14; 0.8) = 0.044$ , where 0 reflects the number of defective units tolerated in the lot; 14 is the number of samples required to reject defective lots, and 0.8 is the probability of non contaminated units tolerated.

In such a case the number of sample is unrealistic; we should note that additional requirements may be defined before establishing a practical sampling plan. If the concentration of the pathogen is relatively high, it can be detected by using traditional enumeration methods (i.e. ISO). For that specific case, a two-class sampling plan can be applied. If this sampling plan is too stringent (i.e. it has a very high discriminatory power to accept/reject lots), the value of  $c$  should be different from 0; or alternatively, a three-class sampling plan can be formulated.

Table 3. Sampling plan formulated

Analysis	Standard/Guideline			Assessment	
	$n$	$c$	$m$	Satisfactory	Unsatisfactory
<i>Pathogen</i>	14	0	absence	Not detected	Present

### IV – Establishment of an MC from an FSO that is set in qualitative terms to non detectable concentration values

In this example, an FSO is set at time of consumption as the maximum concentration that can be present in a food in order to not produce adverse effects for human health.

Subsequently, a PO can be articulated in one or more food chain steps so that the established FSO does not exceed. Once POs are established, suitable MC should be defined for the verification of lots meeting the PO.

For the purpose of this example, we assumed that the FSO has been set as no more than 1% of the lot units will have a pathogen concentration higher than 10 cfu/g.

Firstly, we must decide about the candidate distribution for the pathogen. As in the previous examples, we could start with a log normal distribution where the estimated standard deviation is equal to 0.95. We can proceed in this case in the same way as explained in the first example; i.e. determining the mean concentration of the lot units that would exactly comply with the suggested FSO.

Lots with a mean concentration of -1.21 log cfu/g would match the established FSO (10 cfu/g = 1 log cfu/g).

$$P_{\text{normal, cumulative}}(1; -1.21; 0.95) = 0.99$$

A sampling plan based on quantitative analysis seems not practical in this case, because a very high number of samples (298) would be necessary to reject the lot at 95% CL.

Our aim is to determine whether the mean log concentration in the lot is such that less than 1% of the units exceed the FSO (Van Schothorst *et al.*, 2009).

If we consider the as overall probability of detecting a cell from any sample drawn in the lot as the product of that concentration occurs in the lot and the probability of detecting a cell (based on sample size), we are following a Poisson Log normal approach.

Therefore, in such a case, a quantitative test should be moved to a qualitative test (with enrichment). If we consider a 25 g sample, the probability to detect/reject the lot if we take 1 sample is 0.6497.

The following  $P_{\text{rej}}$  values can be calculated for n samples:

**Table 4. Resulting probabilities of rejection at different values of n**

n	$P_{\text{reject}}$
1	0.650
2	0.877
3	0.957
4	0.985
5	0.995

In this case, to reject a lot with 95% CL, 3 samples of 25 g each should be taken.

It is noted that this approach is applicable to verify the compliance with an FSO; which is defined as the maximum allowable concentration at time of consumption.

The mean log concentration can be derived at earlier points in the food chain to evaluate the compliance with a PO.

To determine Performance Criteria it can be applied the inequation proposed by the ICMSF (2002) and Zwietering *et al.* (2010). The inequation, in a few words, considers the effect of different processes and sub processes along the food chain (growth, inactivation, cross contamination, etc.) to reach a FSO:

$$H_0 + \sum I + \sum R \leq FSO \quad (1)$$

$H_0$  is the initial population of microorganisms,  $I$  is a factor of increase and  $R$  is a factor of reduction. The terms are expressed in log.

If we consider a reduction of 0.59 log (sd = 0.27) and an increase during storage of 1.1 log (sd = 0.8), then the initial concentration ( $H_0$ ) will be:

$$FSO = H_0 - R + I$$

$$H_0 = FSO + R - I = -1.21 + 0.59 - 1.1 = -1.72$$

$$s^2(FSO) = s^2(H_0) + s^2(R) + s^2(I)$$

$$s^2(H_0) = s^2(FSO) - s^2(R) - s^2(I) = 0.952 - 0.272 - 0.82 = 0.19$$

$$s(H_0) = 0.435$$

A lot containing an initial mean log concentration equal to -1.72 log cfu/g and a standard deviation of 0.435 has a 99% probability of having a concentration below 1 cfu/g.

Given the values of the lognormal distributions for reduction ( $R$ ) and increase ( $I$ ) this PO can be well articulated with the established FSO.

Finally, a suitable MC must be set in order to reject the lot by means of sampling. The microbiological limit ( $m$ ) chosen is absence of the pathogen in 25 g.

The probability of one sample being negative (mean = -1.72 log cfu/g; sd = 0.435 log cfu/g) is 0.426. Thus, if one sample is taken, the probability of rejecting a non-compliant lot is 42.6%.

The following  $P_{rej}$  values can be calculated for  $n$  samples:

**Table 5. Resulting probabilities of rejection at different values of  $n$**

<b>n</b>	<b><math>P_{reject}</math></b>
1	0.426
2	0.671
3	0.811
4	0.892
5	0.938
6	0.964

Therefore, in order to reject the lot at 95% CL, 6 samples must be taken.

Given the increases and decreases (with their variability) of the pathogen level after the PO, these lots would comply with the FSO ( $\leq 1\%$  of units below 10 cfu/g) at time of consumption.

**Table 6. Sampling plan formulated**

	<b>n</b>	<b>c</b>	<b>m</b>	<b>Satisfactory</b>	<b>Unsatisfactory</b>
Pathogen	6	0	Absence*	Not detected	Present

\*after sample enrichment

## V – Conclusions

In this study, microbiological criteria (MC) were derived from risk management metrics for three different situations. In order to illustrate the process, data needs and risk management decisions are required when operationalizing a PO/FSO. In all three cases, MCs could successfully be established, but to do so required specific data. When such data were not available, estimations or informed risk management decisions/assumptions were made regarding key parameters. In addition, risk management decisions relating to the discriminatory power of an MC should be made. For some specific cases, underlying distribution of the microbial contamination is needed and information regarding variability within and between lots. While a risk management metric relates the stringency for hazard control at a specific point in the food chain with public health protection, the MC derived from it allows one to verify in practice whether the food safety management system in place at the relevant point in the food chain actually meets the required stringency. In many cases, ICMSF schemes still offer a too high number of samples to be analyzed to ensure that FSO is accomplished. However, they constitute valid risk-based approaches for examining food lots.

## Acknowledgments

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# Data handling: Observatories / databases / data storage / legal framework

## EFSA data collection

M.B. Gilsenan

Evidence Management (DATA) Unit, European Food Safety Authority (EFSA)  
Via Carlo Magno 1A, 43126 Parma (Italy)

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**Abstract.** The European Food Safety Authority (EFSA) is responsible for food safety risk assessments at EU level. It provides independent scientific advice on risks associated with the food chain to support EU risk management decisions. Since its establishment, EFSA has created a unique hub of European data on food consumption and occurrence of food-borne chemical and biological hazards with support from Member State data providers. These data are used to underpin many of EFSA's risk assessments. Increasing transparency in risk assessments is a core objective of EFSA and access to the data used is pivotal in this regard. This paper presents an overview of the core data collections of food-borne chemical and microbiological hazards within EFSA's remit as well as their underpinning regulatory framework. Progress towards standardisation of data from several food safety domains using the Standard Sample Description (SSD), the EFSA standard for receipt of analytical occurrence data on food-borne hazards, is described. The establishment of an EFSA data warehouse is described, which aims to provide several stakeholders with web access to European data at different levels of aggregation. Finally, opportunities and challenges of moving towards more open data are discussed.

**Keywords.** Data – Contaminants – Food consumption – Zoonoses – Legislation – Data Warehouse – Standard Sample Description (SSD).

**Traitement des données : Observatoires/bases de données/stockage des données/cadre juridique. Collecte des données à l'EFSA**

**Résumé.** L'Autorité européenne de sécurité des aliments (EFSA) est responsable de l'évaluation des risques liés à la sécurité des aliments au niveau de l'UE. Elle formule des avis scientifiques indépendants sur les risques associés à la chaîne alimentaire de façon à étayer les décisions de l'UE en matière de gestion des risques. Depuis sa création, l'EFSA a mis en place un pôle unique de données européennes portant sur la consommation alimentaire et la présence de dangers biologiques et chimiques d'origine alimentaire, avec le soutien des données fournies par les États membres. Ces données sous-tendent un grand nombre de travaux d'évaluation des risques de l'EFSA. Le renforcement de la transparence dans l'évaluation des risques est un objectif central de l'EFSA et, à cet égard, l'accès aux données exploitées est essentiel. Cet article propose un aperçu des principales collectes de données réalisées sur les dangers microbiologiques et chimiques d'origine alimentaire relevant de la compétence de l'EFSA, ainsi que les cadres réglementaires qui les régissent. Une présentation est également donnée des progrès réalisés en vue de normaliser les données émanant de plusieurs domaines de sécurité des aliments différents grâce à l'utilisation de la « description type des échantillons » (SSD), la norme de l'EFSA pour la réception de données analytiques sur les dangers d'origine alimentaire ; une description de la manière dont sont gérées les données est aussi proposée. L'article décrit en outre la mise en place d'un entrepôt de données de l'EFSA, qui vise à fournir à plusieurs parties prenantes un accès via le site web aux données européennes à différents niveaux d'agrégation. L'article évoque enfin les opportunités et les défis liés à une évolution des pratiques vers des données ouvertes.

**Mots-clés.** Données – Contaminants – Consommation alimentaire – Zoonoses – Législation – Entrepôt de données – Description type des échantillons (SSD).

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## I – Introduction

The European Food Safety Authority (EFSA), established in 2002, is responsible for food safety risk assessments at EU level. Its remit covers food and feed safety, animal health and welfare, plant health and nutrition. Within the remit of food and feed safety, EFSA provides scientific advice on the safety of regulated ingredients (pre- and post-market) and of contaminants unintentionally present in the food chain. EFSA's advice is mainly in the form of Scientific Opinions agreed by an independent panel of experts who are appointed through an open selection procedure. Other EFSA outputs include guidance, statements, reasoned opinions as well as scientific and technical reports (Pintado, 2014). EFSA's risk assessments are used to inform risk management decisions by EU risk managers (European Commission, Member States and European Parliament). Such decisions may entail, for example, authorisation of an ingredient for use in food or feed, the establishment or amendment of maximum legal limits or the establishment of codes of practice.

Food safety risk assessments comprise four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation. Hazard identification and hazard characterisation typically entail a review of the pertinent toxicology literature. Hazard identification entails identification of known or potential adverse health effects (e.g. carcinogenicity) that may be caused by exposure to a particular agent, whereas hazard characterisation entails a qualitative and/or quantitative evaluation of the nature of the adverse effects at different levels of exposure (e.g. using dose response studies). The third step, exposure assessment, requires data on the amount of food consumed as well as the levels and fate of the hazard in food. The last step, risk characterisation, combines data from hazard characterisation and exposure assessment to estimate a likelihood of risk associated with a given exposure. EFSA works in close collaboration with EU Member State data providers to collect data for its risk assessments, in particular for dietary exposure assessments. EFSA has collated a wealth of food consumption data as well as data on occurrence of chemical and biological hazards in food data from European data providers to support its risk assessment activities. The majority of occurrence data sent to EFSA comes from laboratories involved in national monitoring programmes and are submitted to EFSA by national competent authorities in EU Member States. Other data providers include the food industry (mainly via associations), universities, consumer associations and, in some cases (e.g. perchlorate), the European Commission (DG SANCO). EFSA has established several data collection networks, composed of representatives of national competent authority data providers, to support its data collection activities. In addition, when there is a scarcity of data for a particular risk assessment opinion, EFSA issues ad hoc calls for data collection through grants and/or procurements within the framework of scientific co-operation with Member States.

## II – Regulatory framework

As the EU's food safety risk assessment body, EFSA's founding regulation, Regulation (EC) No. 178/2002, as amended, lays down an overarching legal obligation on EFSA to collect, collate and summarise relevant scientific and technical data to inform EU risk assessments and to work in close co-operation with all operators in the field of data collection to achieve this aim (article 33). This overarching legal framework is reinforced by sector specific EU legislation pertaining to different chemical and biological hazards.

In the case of pesticide residues, Member States have a legal obligation to monitor pesticide residues in food commodities from national and EU co-ordinated sampling programmes and to submit monitoring results to EFSA and to the European Commission (Regulation (EC) No. 396/2005, as amended). In practice, some 14 million analytical records from Member State data providers are sent directly to EFSA annually. EFSA is responsible for preparing an annual European summary report on pesticide residues (EFSA, 2013a) based on these data.

In area of biological hazards, Member States have a legal obligation to monitor trends and sources of zoonoses, zoonotic agents and antimicrobial resistance (AMR) and to transmit the results of monitoring programmes to the European Commission, which should be subsequently forwarded to EFSA (Directive 2003/99/EC). In 2004, the European Commission entrusted EFSA with the task of setting up an electronic reporting system and a database concerning monitoring of zoonoses (EFSA mandate No. 2004-0178<sup>1</sup>). Thus, in practice, data are sent directly from Member State data providers to EFSA. In 2013, detailed rules were laid down concerning harmonised monitoring and reporting of antimicrobial resistance by Member States within the framework of Directive 2003/99/EC (Commission Implementing Decision 2013/652/EU). EFSA is responsible for the compilation and publication of an annual summary report on trends and sources of zoonoses, zoonotic agents and AMR in the EU (EFSA, 2014 a, b). Under the general legal framework of EFSA's data collection activities (article 33 of EFSA's founding regulation), on request from the Commission (EFSA mandate No. 2013-0082<sup>1</sup>), EFSA is in the preparatory phase of establishing a European data collection on molecular typing (DNA fingerprinting) in food and feed isolates of food-borne infections to complement a database on humans (TESSy MSS) managed by the European Centre for Disease Prevention and Control (ECDC). It is envisaged that this database will facilitate epidemiological investigations of food-borne outbreaks and the identification of emerging health threats.

In the field of food additives and flavourings, sector specific legislation lays down a requirement for Member States to maintain systems to monitor the consumption and use of these intentionally added ingredients using a risk-based approach and to report their findings with appropriate frequency to the European Commission and to EFSA (Regulation (EC) No. 1333/2008, as amended; Regulation (EC) No. 1334/2008, as amended). A common methodology for the collection of data by Member States on the consumption and use of food additives and flavourings is not yet in place. In the case of food additives in particular, Regulation (EC) No. 257/2010 lays down a requirement for the safety of all food additives permitted for use before January 2009 to be re-evaluated by EFSA. To fulfil this obligation, EFSA collates data on food additive occurrence and usage from several stakeholders (e.g. Member State competent authorities, industry associations and consumer associations) through specific calls for data, and has evaluated the safety of some 50 food additives to date within the framework of the EU food additive re-evaluation programme.

In the area of contaminants, Commission Regulation (EC) No. 1881/2006, as amended, lays down maximum levels for several contaminants (e.g. industrial and environmental) in foodstuffs. This regulation also lays down a requirement for Member States to monitor and report findings on several contaminants such as nitrates in vegetables, aflatoxins, dioxins, dioxin-like polychlorinated biphenyls (PCBs), non-dioxin-like PCBs, ochratoxin A and fusarium toxins, to the Commission. One amendment to this regulation, (Commission Regulation (EC) No. 629/2008), lays down a requirement for Member States to report findings directly to EFSA on acrylamide and furan, respectively. In 2010, the European Commission entrusted EFSA with the task of collecting data from Member State data providers on the occurrence of contaminants in foodstuffs on a continuous basis (EFSA mandate No. 2010-0374<sup>1</sup> thus transferring the task of data collection on contaminants from the Commission to EFSA. Since then, EFSA has established a continuous annual call for data on contaminants in food and feed. More recently, specific Commission Recommendations have been published on acrylamide (Commission Recommendation 2010/307/EU), ergot alkaloids (Commission Recommendation 2012/154/EU), ethyl carbamate (Commission Recommendation 2010/133/EU), perfluoroalkylated substances (Commission Recommendation 2010/161/EC) and cadmium (Commission Recommendation 2014/193/EU) all of which request Member States to monitor and report occurrence data

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<sup>1</sup>EFSA Register of Questions: <http://bordeaux-as2:8080/raw-war/login> [Enter mandate number from this page].



directly to EFSA. In 2013, EFSA collated some one million analytical records on contaminants in food and feed to support its risk assessment activities in the field of contaminants.

In the area of veterinary drug residues, Council Directive 96/23/EC requires Member States to adopt and implement a national residue monitoring plan for specific groups of residues. The directive lays down sampling levels and frequency as well as the group of substances to be monitored for each category of live animals or animal products. Member States must submit to the Commission, on an annual basis, national monitoring plans together with the results of monitoring for the previous year. Monitoring data are reported in aggregated format (i.e. not sample based results). In 2009, the European Commission asked EFSA for assistance in preparing an annual technical report on the results of residue monitoring in food of animal origin from Member States (EFSA mandate No. 2009-0257<sup>1</sup>). In practice, the Commission provides EFSA access to the veterinary residues database managed by the Commission to analyse the results and subsequently prepare an annual technical report. Thereafter, the Commission sends to the European Parliament and the Council an annual communication on the results and actions taken at regional, national or EU level. EFSA has recently received a request from the European Commission to set up an annual European data collection on veterinary drug residues at sample based level. Given EFSA's previous experience of setting up data collections at European level, EFSA plans to run a pilot data collection as a first step. Until such time as a robust European data collection at sample based level is tested and in place, Member States will continue to send data on veterinary drug residues to the Commission.

Under the general regulatory framework of EFSA's data collection activities (article 33 of Regulation (EC) No. 178/2002, as amended), EFSA established the Comprehensive Food Consumption Database, which is a compilation of food consumption surveys at individual level from respective data providers in Member States (EFSA, 2011b; Merten *et al.*, 2011). It comprises 3.6 million food consumption records from 32 dietary surveys carried out in 22 Member States, covering infants to elderly. The database is currently the best available database of food consumption data at European level and is the primary source of food consumption data used in EFSA exposure assessments. EFSA is engaged in a collaborative project with Member States (2011-2020) to collect more harmonised food consumption data at EU level using a more standardised dietary survey methodology (EU Menu project).

### III – Data management

Since its establishment, EFSA has received an increased volume of data from several data sources covering several food safety domains (i.e. pesticides, contaminants, zoonoses) rendering their manual processing unfeasible. In order to manage the high volume of data received, EFSA developed the Standard Sample Description (SSD), in collaboration with Member States, which is the EFSA standard for transmission of analytical occurrence data to EFSA. The SSD data model contains approximately 80 standardised data elements (fields) that describe the characteristics of an analytical sample and result (e.g. laboratory sample code, analytical method, limit of detection of the analytical method, country of origin etc.), of which approximately 20 are mandatory. In addition, it contains in-built controlled terminologies (e.g. standard lists of analytical methods, names of chemicals etc.) and business (validation) rules (e.g. whether data pertaining to data elements have been submitted in the required format) to guarantee a minimum level of data quality. The IT protocol to transmit data to EFSA using the SSD standard data model is described in a complementary guidance document, *Guidance on Data Exchange* (EFSA, 2010). Data providers transmit data through the EFSA Data Collection Framework (DCF) web-based interface providing also functionalities of automatic validation of the incoming messages. The system checks for the correct completion of mandatory fields and compliance with business rules, after which data providers receive automatic feedback. Different file formats can be used to transmit data via the DCF (i.e. Microsoft Excel®, Comma Separated Values (CSV) and Extensible Markup Language (XML)). XML is the preferred file

format to be used for the capability of providing natively an initial file validation through its XML schemas. After transmission, data are stored in an Oracle database. A further data cleaning step is carried out using standardised procedures in SAS®. During data analysis, additional data checks are performed as well as clarification requests to data providers in the case of anomalous results. Initially developed with a focus on pesticide residues and contaminant occurrence data in food and feed, the SSD has been extended (EFSA, 2013b) to encompass food additives, food contact materials, as well as sample based biological monitoring data within the framework of the zoonoses directive (Directive 2003/99/EC) and several European countries are currently testing its practical implementation as part of a pilot study (EFSA mandate No. M-2013-0254<sup>1</sup>). The added value for Member State data providers is that occurrence data from several food safety domains can be reported to EFSA in a standardised format. EFSA provides financial and technical support to official reporting organisations in Member States to implement the SSD in their data management systems. Consequently, the SSD is becoming the accepted European standard for describing and reporting monitoring results for food-borne hazards. An additional benefit at national level is that Member States are accumulating a large volume of data from their national control and monitoring activities in a harmonised format. These data can also be used to support risk assessment activities at national level. In the case of pesticides, Member States have a legal obligation to report residue monitoring data from samples tested in 2013, 2014 and 2015 from the EU coordinated multiannual control programmes in SSD format to EFSA (Commission Implementing Regulation (EU) No. 788/2012).

## IV – Data accessibility

Within the scientific community there is a strong shift towards the principles of ‘open data’ as a mechanism to improve the transparency and reproducibility of scientific research (UK Royal Society, 2012). The movement towards open data has also entered the radar of European public institutions with a general acknowledgement of the added value of re-use of public sector data to boost research and innovation (Commission Open Data Strategy for Europe, 2011) and to increase transparency in risk assessments. Although EFSA has unique access to a European hub of food consumption and food-borne hazard occurrence data, in most cases, Member State data providers maintain ownership of their data and therefore EFSA does not have an automatic right to share raw data with third parties. In the area of contaminant occurrence data in particular, rules regarding use, disclosure and re-use have been agreed with Member States at the former European Commission Standing Committee on the Food Chain and Animal Health (SCFCAH)<sup>2</sup>, section on toxicology in the food chain (SCFCAH, 2010). These rules also encompass transmission of contaminant occurrence data for use in the joint Food and Agriculture Organisation of the United Nations (FAO)/World Health Organisation (WHO) Expert Committee on Food Additives (JECFA) risk assessments (EFSA, 2014c). In practice, requests from third parties to access or re-use raw data from EFSA’s data hub data require contact with relevant data providers on a case-by-case basis to seek their agreement. In the long term, this approach is neither efficient nor aligned with EFSA’s goal and stakeholders’ need for more openness and transparency in EFSA’s risk assessments (EFSA, 2009).

EFSA is currently developing a data warehouse which aims to provide Member State data providers, as well as EU citizens, web-based access to EU risk assessment data at different levels of aggregation using simple query and download functionality (Fig. 1).

The data warehouse needs to be supported by a policy on access to the database, e.g. who can access the data, at which level of granularity and which restrictions (if any) should be applied. Therefore, in parallel to technical developments, EFSA is engaging with the European

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<sup>2</sup>The name of this committee has changed to Standing Committee on Plants, Animals, Food and Feed (PAFF)

Commission and Member States through respective sections of the Standing Committee on Plants, Animals, Food and Feed to seek agreement on proposed data warehouse access rules applicable to different stakeholders.

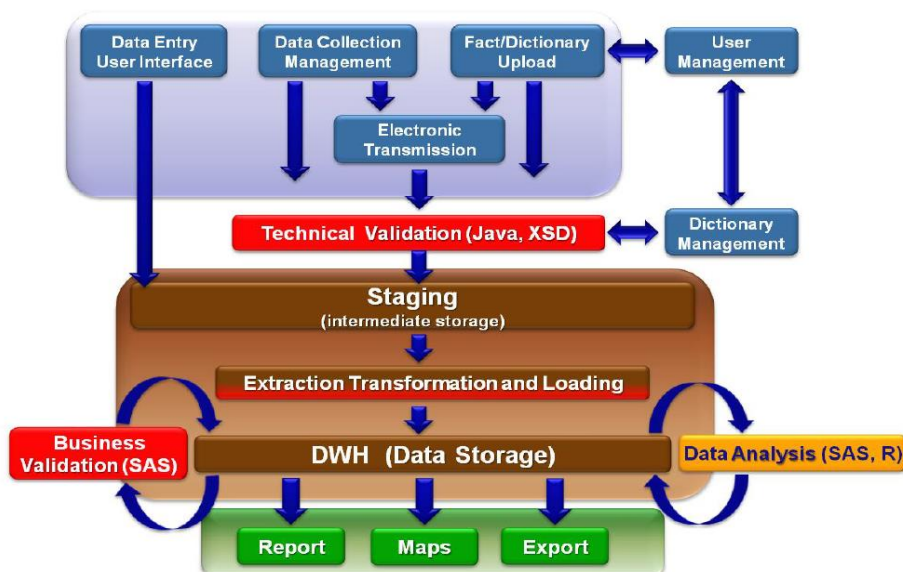


Fig. 1. Graphical depiction of the data workflow within the EFSA data warehouse (EFSA, 2011a).

Building on the EFSA data warehouse initiative, EFSA envisages continued liaison with Member State data providers and the Commission to explore and agree legitimate boundaries for more openness of risk assessment data. A greater focus on working with sister EU agencies and other international organisations to promote sharing/access to data for risk assessment purposes is also envisaged. EFSA is already collaborating with ECDC to develop joint standards for molecular typing and arthropod vector distribution, and has established a collaboration with the WHO concerning sharing of contaminant occurrence and food consumption data for use JECFA risk assessments.

Following a decade in which EFSA focused heavily on data collection, EFSA's priority in the data arena for the coming years is to further enhance data standardisation and to work with Member States to improve data accessibility of EU risk assessment data for EFSA's stakeholders.

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# Food-borne threats in the Med Region and the role and principles of OIE in the framework of food safety strategy

R. Bouguedour and A. Ripani

OIE, Sub-Regional Representation for North Africa  
17, Av. d'Afrique, El-Menzah V, 2091 Tunis (Tunisia)

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**Abstract.** The food safety must guarantee to consumers that foods are produced, handled, stored and distributed in a safe manner so as to be not harmful for citizens up to their consumption since it represents for people a fundamental right. The Sanitary and Phytosanitary agreement of the World Trade Organization laid down the reference principles for food safety, animal health and zoonoses indicating the recommendations set by the World Organisation for Animal Health (OIE) and Codex Alimentarius Commission (CAC) as the international standards to be applied for safe international trade. In the framework of food safety strategy and, in particular, within the concept "from farm to fork" the Veterinary Services play a key role in protecting society and the veterinarian has two crucial functions in this context such as prevention and control of foodborne diseases of animal origin at the farm and prevention and control of food contamination along the food chain to protect the consumer. For all countries, the best way to address the problems associated with foodborne illness is to rely on integrated surveillance systems with high performance as well as a continuum commitment in the veterinary public health.

**Keywords.** Veterinary services – Food safety – Surveillance system – Foodborne hazard.

## ***Principes de l'OIE et rôle des Services vétérinaires dans le cadre de la stratégie de sécurité sanitaire des aliments***

**Résumé.** La sécurité sanitaire des aliments doit garantir aux consommateurs des aliments produits, manipulés, stockés et distribués sans nocivité pour la santé des citoyens jusqu'à leur consommation car cela représente un droit fondamental pour les personnes. L'accord sanitaire et phytosanitaire de l'Organisation Mondiale du Commerce a établi les principes de référence pour la sécurité alimentaire, la santé animale et les zoonoses indiquant que les normes internationales et les recommandations établies par l'Organisation Mondiale de la Santé Animale (OIE) et la Commission du Codex Alimentarius (CAC) doivent être appliquées pour assurer la sécurité sanitaire des aliments dans les échanges internationaux. Dans ce cadre et, en particulier, dans le concept «de la ferme à la table», les Services Vétérinaires jouent un rôle clé dans la protection de la société et le vétérinaire a deux fonctions essentielles, la prévention et le contrôle des maladies animales au niveau de la ferme et la prévention et le contrôle des aliments tout au long de la chaîne alimentaire afin de protéger le consommateur. Pour tous les pays, la meilleure façon de répondre aux problèmes associés aux maladies d'origine alimentaire est de s'appuyer sur des systèmes de surveillance intégrés performants ainsi qu'un engagement continu dans le cadre de la santé publique vétérinaire.

**Mots-clés.** Services vétérinaires – Sécurité sanitaire des aliments – Systèmes de surveillance – Dangers d'origine alimentaire.

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## **I – Introduction**

The amplified worldwide movement (in speed and volume) of persons, animals, foods and feedstuff could allow pathogens to spread worldwide in a very short time so as to keep the entire world constantly on the alert as an outbreak that occurs in a given location may quickly have a significant impact at the global level. The food safety must guarantee to consumers that foods are produced,

handled, stored and distributed in a safe manner in order to be not harmful for citizens up to their consumption since it represents for people a fundamental right. In addition, a healthy and safe diet improves health and productivity and lays the foundation for the development of countries while reducing poverty. According to the Statistics Division of the Food and Agriculture Organization of the United Nations (FAO) from 1961 to 2011 the average meat consumption in the world increased from 23 to 43 Kg per capita/year and milk consumption increased from 75 to 87 kg per capita/year. The projections of the Agricultural Outlook 2013, also indicate that this rate of consumption will continue to be higher than the population growth in the next ten years.

The United Nations projections show that world population could reach 9.15 billion by 2050 and indicate that global agricultural production in 2050 will be 60 percent higher compared with the years 2005/2007 raising the concern how it can be achieved sustainably. Meat production - for instance - would increase from 258 to a total of 455 million tonnes in 2050; of which a significant percentage in the developing countries. Although population growth is the most important driver of future food demand other factors should be taken into account such as rising incomes, changing age composition and changing diet which is encouraged by trends such as urbanisation and the spread of supermarkets (Alexandratos and Bruinsma, 2012).

During the past decades, we observed serious outbreaks of food-borne diseases, which were reported everywhere on almost all continents, revealing their extent and impact on the society and public health. For instance, a set of food safety crises like BSE and dioxin affecting Europe during the 1990s, created food scares among European citizens and loss of confidence of consumers by showing inadequacy of food safety legislation. In fact - before the European Union (EU) underwent complete revision following these crisis - the food safety legislation had some weaknesses such as fragmentation of controls, legislation focused on final products control, lack of controls on animals feeding and deficiencies in risk analysis. As earlier mentioned, these crisis led to the revision of the European legislation on food safety in the early 2000s by introducing new legislation principles such as the application of horizontal approach for all type foods, the concept from the farm to the fork, a risk-based approach along the food chain as well as some key obligations for food and feed business operators about responsibility, transparency and traceability.

The food safety systems in the world show similarities with most of the EU principles. In particular, it is worldwide recognised that for ensuring food safety of products actions are needed during the primary production at the farm level. Many food safety risks arise at the pre-slaughter or pre-harvest stages, and these can be reduced or prevented using disease prevention policies and good practices recommended by the World Organisation for Animal Health (OIE) and FAO. Moreover, it is in parallel imperative to continue improving the control measures to reduce the risks also during the food preparation, storage and distribution phases including the consumer behavior.

The Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization laid down the reference principles for food safety, animal health and zoonoses indicating the recommendations set by the OIE and Codex Alimentarius Commission (CAC) as the international standards to be applied for facilitating international trade. The remaining third international organisation formally recognised by the SPS Agreement is the International Plant Protection Convention (IPPC) in charge of setting standards for plant health.

The recent severe *Escherichia coli* O104:H4 outbreaks occurred in Germany and France in 2011 - which epidemiological investigation led to the identification of fenugreek seeds imported from Egypt as the most likely source of the sprouts linked with the two outbreaks (EFSA, 2011) – confirmed that in this era of globalisation ensuring hazard-free food is a supranational matter consolidating the concept that international cooperation and initiatives are necessary for early detection and rapid response in the case of outbreaks. In this respect, foodborne diseases surveillance systems can vary from sophisticated to rudimentary from countries to countries and from region to region (Dewaai *et al.*, 2010). However, valid, reliable and effective surveillance systems have been established at the national, regional and international level by demonstrating their utility through the collection of data on foodborne diseases and animal diseases to rapidly detect outbreaks.

Examples of these surveillance systems are the OIE's World Animal Health Information System (WAHIS/WAHID), the International Food Safety Authorities Network – INFOSAN- (Joint initiative WHO/FAO), the Rapid Alert System for Food and Feed – RASFF – (European Union), Foodborne Diseases Active Surveillance Network – FoodNet – (CDC/USA) and PulseNet International.

The consequence of globalisation is also affecting Countries in the Mediterranean basin that are more and more developing agricultural trade. For instance, the report published by the International Centre for Advanced Mediterranean Agronomic Studies (CIHEAM) - while describing differences for each country - reported that imports of bovine meat in countries in the region passed from 1,142.9 ('000 tcw) for the period 2001-2003 to 1,737.1 ('000 tcw) for the period 2009-2011 with an increasing average rate of 5.4% per year (Beaumont, 2014). These data confirm that in both shores of the Mediterranean region there was an increase in the volume of trade in the last decade for animal and animal products supporting the concept that a continuous improvement and development of harmonised national, regional and international food control strategies in line with the international standards – including food disease surveillance system - are needed.

## II – Foodborne diseases

Foodborne hazard can be classified as biological, chemical or physical and within the biological hazards, foodborne diseases can be caused by bacteria (e.g. *Salmonella*, *Campylobacter*, *Listeria monocytogenes*, *E. Coli*, *Brucella*, *Mycobacterium bovis*), viruses (e.g. norovirus, rotavirus, hepatitis A and E virus) or parasites (e.g. *Toxoplasma gondii*, *Trichinella*, *Echinococcus granulosus* and *multilocularis*). Amongst foodborne zoonotic diseases caused by bacteria, brucellosis and tuberculosis continue to have considerable social and economic impact in Southern Mediterranean countries due to the high prevalence of these diseases maintained mostly by traditional behaviours (e.g. animal-rearing practices that support the spread of infections) (Seimenis, 2010). By contrast, the situation of these diseases in Northern Mediterranean countries had improved over the last decades due to the implementation of specific control and elimination programmes (FCEC, 2011). Although the estimation of the global impact of foodborne diseases caused by parasites is considered difficult, it is recognised that some diseases such as Echinococcosis can have significant impact in some areas. In fact, while the geographical distribution of *E. multilocularis* is limited to the northern hemisphere, the *E. granulosus* is present worldwide and can pose significant public health or economic problems in many rural areas of the world and where sheep farming is predominant such as in the Northern African countries (Acha and Szyfres, 2005; Torgerson *et al.*, 2014; Willingham and Stein, 2014; Seimenis *et al.*, 2006; Macpherson *et al.*, 2000).

A recent publication classified – for the purpose of the paper - diseases and foodborne diseases of animal origin into four groups: (i) diseases that are mainly an animal health problem but can have foodborne public health implications; (ii) diseases that are both an animal health and foodborne public health problem [e.g. *Paratyphoid Salmonella*, including *Salmonella* Enteritidis and *S. Typhimurium*]; (iii) diseases that are primarily or only a public health concern [e.g. *Campylobacter jejuni* /*coli* and *Escherichia coli* O157:H7]; and (iv) diseases that are only an animal health problem and have no public health significance but some of these diseases pose a food-related public health concern in terms of biological residues [e.g. residues in treating Coccidial infections in poultry] (Berman and Shimshony, 2013).

However, data published in the literature or presented during dedicated conference demonstrates that, regardless of the type of classification that may be used, foodborne diseases occur worldwide and are of concern in both developed and developing countries.

A total of 5,363 food-borne outbreaks were reported in the European Union in 2012, resulting in 55,453 human cases, 5,118 hospitalisations and 41 deaths. Amongst the causative pathogens of the most of reported outbreaks were *Salmonella* and *Campylobacter* (EFSA, 2014).

The Center for Disease Control and Prevention (CDC) in the USA estimates that each year 48 million Americans are affected by foodborne diseases causing 128,000 hospitalizations and 3,000



deaths. Amongst the pathogens which cause the most illnesses, hospitalizations, and deaths each year there are Norovirus, Salmonella non-typhoidal, *Listeria monocytogenes*, *Campylobacter* spp. and *E. coli* (STEC) O157 (CDC, 2011).

Brazilian Ministry of Health has registered - between 2000 and 2013 – a total of 8,857 foodborne outbreaks with 163,425 infected people and 112 deaths due to foodborne illnesses (Ritter and Tondo, 2014).

In the 2nd Congress on the foodborne diseases in the Maghreb region - held in December 2011 in Hammamet (Tunisia) it was reported that foodborne disease outbreaks were reported in Algeria, Morocco and Tunisia. In Algeria in the period ranging from January 2010 to October 2011 a total of 169 outbreaks affecting 5,697 people and causing 9 deaths were registered. In Morocco, from 1992 to November 2011 a total of 19,625 cases of foodborne diseases were reported with 5,688 hospitalizations and 221 deaths. Finally, in Tunisia, 121 outbreaks were notified from January 2012 to November 2011 affecting 1,244 persons. Epidemiological investigations of these outbreaks in the Maghreb region identified some of the risk factors such as: (i) problem in the maintenance of the cold chain during storage of food; (ii) cross-contamination; (iii) use of raw materials of questionable quality; (iv) insufficient heat treatment; and (v) significant delay between preparation and consumption of food.

### III – Veterinary services in the food safety strategy

In the framework of food safety strategy and, in particular, within the concept "from farm to fork" the Veterinary Services play a key role in protecting society. In this context, the objectives of animal and human health are converging and the veterinarian has two crucial functions: (i) prevention and control of foodborne diseases of animal origin at the farm; and (ii) prevention and control of food contamination along the food chain to protect the consumer since veterinarians are well equipped to assume this unique role.

To this end, Veterinary Services should conduct surveillance at all stages along the food chain: (i) control at the farm (animal health, animal feed, antimicrobial use, identification and animal traceability, animal welfare); (ii) meat inspection (ante and post mortem inspection in the slaughterhouse); (iii) animal welfare in the slaughterhouses; (iv) control during the phases of preparation, storage and distribution of animal products; and (v) certification of animal products for international trade.

An essential component of food safety strategy is the capacity for countries to prioritise pathogens responsible for foodborne illness. An appropriate surveillance system should be in place in order to allow the Competent Authority to obtain information for ranking pathogens and give priority in designing targeted surveillance. Countries that have a national surveillance system integrated "from farm to fork" may have access to the necessary information to quickly detect foodborne disease outbreaks or food safety hazards, (potential or ongoing occurrence along the food chain) for identifying the contaminated foods and activate recall mechanism as appropriate (e.g. from the market).

In this respect, it is likewise evident as inter-sectorial collaboration between all the actors involved in the food safety is crucial to make this system efficient and effective. Each country should have this inter-sectorial collaboration regulated through an appropriate and updated veterinary legislation establishing roles, responsibilities, rights and obligations of the different actors in the food chain which represent one of the pillar for ensuring good veterinary governance.

Additional essential components of food safety strategy are the identification and traceability of animals and animal products from the farm to the table since it is the link between the health of animals, food safety and organoleptic characteristics related to their foods. Animal traceability and traceability of products of animal origin should be linked for identifying contaminated foods in the market or food safety hazards throughout the food chain in order to provide answers to possible

incidents quickly and effectively. In parallel – if a functional traceability system is in place, unjustified trade barriers between countries may be avoided since it provides safety guarantees of imported and exported foods.

As stated earlier, one of the activities of the OIE is to produce scientifically based standards on animal production food safety being complementary to the Codex Alimentarius Standards for food safety. To this end, in 2002, the OIE created a permanent Working Group on Animal Production Food Safety with the objective of coordinating food safety activities of the OIE and formulating recommendations in this field. This Working Group includes internationally recognised experts also from FAO, World Health Organisation (WHO) and the CAC to ensure an harmonised and consistent work on food safety to avoid overlapping and the contradictions in setting international standards. The Edition 2013 of OIE Terrestrial Animal Health Code contains relevant Chapters in this respect such as identification and traceability of animals, control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection, control of antimicrobial resistance, control of hazards in animal feed and Salmonella in poultry.

The OIE Terrestrial Animal Health Code also contains a dedicated chapter on the role of the Veterinary Services in food safety with the aim of providing guidance to Member Countries in regard to the role and responsibilities of the Veterinary Services in food safety and for assisting them in meeting the food safety objectives laid down in their national legislations and assure good governance in this field.

## **IV – Conclusions**

For all countries, the best way to address the problems associated with foodborne illness is to rely on integrated surveillance systems with high performance as well as a continuous political commitment in the veterinary public health. This can be achieved through the collaboration of international partners and Organisations working together with the primary objective of protecting the consumers by considering that data collection and targeted food safety policies are priorities.

At present, the infrastructure and the capacity to coordinate and implement national programmes for foodborne diseases varies from country to country and – most of the time – they are not integrated to cover the entire food chain. The availability of reliable, relevant and rapid information is the cornerstone for any surveillance system to facilitate the decision-making process. In addition, timely access to accurate information on the type of contamination, the distribution of products and the number of human cases allow a rapid and adequate response to avoid the dissemination of products and the spread of disease.

International Organisations have an important role to play in promoting the integration and harmonisation of surveillance systems to ensure food safety at national, regional and global level. Today, products can be dispatched in several countries in less than 24 hours with the risk of distributing contaminated foods from country to country very quickly. Therefore, the exchange of information between all stakeholders to establish a good network to ensure food safety should be transparent and rapid in order to quickly detect outbreaks or food safety hazards along the food chain in a given country so as to put in place appropriate control measures to protect the consumers all over the world.

The OIE and CAC had been coordinating their efforts to ensure food safety in the framework of their respective mandates by formulating complementary international standards. In particular, the OIE sets standards relevant to animal production food safety, covering hazards that arise on-farm and at slaughter, with a primary focus on measures applicable at the animal production level while CAC elaborates standards pertinent from primary production to marketing and consumption. Even if different international organizations are in charge of setting specific standards along the food chain, it is undoubtedly recognised the key role played by the Veterinary Services along the steps of the food chain in the continuum "farm to fork" to ensure food safety to the consumers, especially the safety of foods of animal origin.

Therefore it is critical for countries to adhere to the international standards and upgrade their legislation in order to quickly respond to the new challenges on food safety due to globalisation. It is also important to encourage inter-sectorial collaboration at the national level and to support a regional approach in addressing food safety issues (e.g. Mediterranean region) and implement an effective data management system able to generate reliable data for the decision makers on a regular basis.

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# Changes in nutritional habits in the Mediterranean region

N. Mokhtar and T. Becic

Nutritional and Health-related Environmental Studies Section, Division of Human Health, International Atomic Energy Agency, PO Box 100, Wagramer Str. 5, A-1400 Vienna (Austria)

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**Abstract.** Great interest has been placed on the Mediterranean dietary patterns identified in early 1960s due to better health of populations living in countries around the Mediterranean basin as compared to United States of America or Northern Europe. Epidemiological and clinical trials have both confirmed the health benefits of traditional Mediterranean diets particularly with regard to cardiovascular health. Recent research has also confirmed the effectiveness of this diet in other aspects, such as lower risk for metabolic syndrome and cancer, reasoning for the promotion of Mediterranean diet in the primary prevention of major chronic diseases. Drastic changes can be observed in many Mediterranean countries with populations across age groups moving away from traditional dietary habits towards a modern, Western-like diet rich in calories, saturated fats and refined sugars. This raises serious concern as concomitant changes in the health status of the populations can be observed. Many countries of the region are in the very centre of health challenges in Europe, as vast increases in the prevalence of non-communicable diseases continue to burden the health systems and take a high death toll. Building up evidence in support of traditional Mediterranean diets as effective means in tackling the modern health challenges in the region is therefore warranted. In this paper, we provide an overview of important aspects related to this topic - traditional Mediterranean dietary habits and its health benefits, nutritional transition in the countries, and the current health status of the populations.

**Keywords.** Dietary pattern – Mediterranean diet – Non-communicable diseases – Modern diet.

## **Changements des modes alimentaires dans la région méditerranéenne**

**Resumé.** Les modes alimentaires méditerranéens identifiés au début des années 1960 font l'objet d'un grand intérêt, car les populations vivant dans les pays du bassin méditerranéen avaient une meilleure santé comparées à celles des États-Unis d'Amérique ou d'Europe du Nord. Il a été confirmé, par enquêtes épidémiologiques aussi bien que cliniques, les bienfaits santé des diètes traditionnelles méditerranéennes en ce qui concerne les maladies cardiovasculaires. Des recherches récentes ont également confirmé l'efficacité de cette diète à d'autres égards, tels qu'un moindre risque de syndrome métabolique et de cancer, raisons pour promouvoir la diète méditerranéenne dans la prévention primaire des principales maladies chroniques. Des changements drastiques sont observés dans de nombreux pays méditerranéens dont les populations de tout âge s'écartent des modes alimentaires traditionnels pour se tourner vers une diète moderne, occidentalisation et riche en calories, gras saturés et sucres raffinés. Ceci soulève de sérieuses préoccupations au vu des changements concomitants de l'état de santé des populations. Nombreux sont les pays aux prises avec ces enjeux de santé en Europe, conséquemment à la prévalence grandissante des maladies non transmissibles qui pèse lourd sur les systèmes de santé et entraîne un fort bilan de mortalité. Il s'avère donc nécessaire d'étayer le bien-fondé des diètes traditionnelles méditerranéennes comme moyen efficace de répondre aux défis modernes de santé dans la région. Cet article passe en revue des aspects importants liés à cette question - les modes alimentaires traditionnels méditerranéens et leurs bienfaits santé, la transition nutritionnelle dans les pays, et l'état actuel de santé des populations.

**Mots-clés.** Modes alimentaires – Diète méditerranéenne – Maladies non transmissibles – Diète moderne.

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## I – Introduction

Countries in the Mediterranean basin are very diverse in socioeconomic and cultural perspective. Yet, this set of countries is unique in many aspects and is often considered as a single region, especially in sociocultural-based analyses. What is mostly defined as the Mediterranean region typically encompasses all the countries that have access to the Mediterranean Sea. This includes a range of countries in three different continents – Europe, Africa, and Asia: Cyprus, Greece, Albania, Montenegro, Bosnia and Herzegovina, Croatia, Slovenia, Italy, Malta, France, Spain, Morocco, Algeria, Tunisia, Libya, Egypt, Israel, Lebanon, Syria and Turkey. However, the appropriateness of the cultural, rather than the geographical definition of the Mediterranean region, becomes clear on the example of Portugal – although the country does not have a Mediterranean shore, its socio-cultural heritage can be described as even more typically Mediterranean than some of the above.

Dietary patterns are an important lifestyle constituent of this region and are deeply seeded in the culture. Although these patterns are not uniform and vary between sub-regions, countries and even regions within a single country, there are many common elements present that make the diet of the Mediterranean region unique. Efforts have been made to analyse the specificity of Mediterranean countries since it was recognized in large epidemiological studies that their populations generally experience lower rates of chronic diseases and have higher life expectancy. This notion could not be explained by socioeconomic factors, because a large proportion of the countries had poorer economic indicators than those whose populations were not as healthy. The importance of nutritional habits, in combination with other factors, e.g. physical activity in promoting good health in the Mediterranean region was increasingly recognized.

The pivotal importance of nutritional habits became even more greatly acknowledged after a clear correlation between nutritional transition and vast increases in rates of chronic diseases over time could be established. Namely, Mediterranean countries are not exception to global trends of shifting once traditional to modern diets. Drastic lifestyle changes accompanied by demographic changes seriously burden the health and other systems of these countries. What are the modern challenges of countries where traditional dietary components like olive oil, fruits and vegetables are being increasingly replaced by fast food and how can the return to traditional diets and lifestyle contribute to solving the growing health problem?

## II – Mediterranean cuisine and the Mediterranean diet

The general belief that all countries in the Mediterranean follow a pretty uniform diet is a misconception. Traditional dietary habits in these countries are an integral part of their cultures and an expression of centuries long continuum. Consequently, the traditional cuisine of each country in the region has unique elements in every aspect, beginning from the way in which the food is prepared to when and how frequently is being eaten.

As for the food commodities per se that are consumed, they depend very much on the socio-cultural characteristics of a country, e.g. religion. Consumption of pork meat in any form, a tabu in the cuisine of predominantly Islamic countries of the Levant, North Africa, and in Turkey, is an integral part of the diet in other countries. In Spain, the consumption of pork meat is traditionally high, and has stayed well above the average of the European Union (EU) throughout the 2008-2013 period, reaching 50.2 and 40.0 kg/capita in 2013 for Spain and EU-27, respectively. A proportionally large consumption is also seen in Portugal and Italy (42.7 and 40.9 kg/capita, respectively), while below the average rates are found in France (32.2 kg/capita)<sup>1</sup>.

Consumption of alcohol follows similar patterns. In many European countries of the Mediterranean region, alcohol and particularly wine consumption on regular basis has been a traditional element of the diet for centuries. Although the consumption of wine in Italy has

dropped in the past 5 decades, it still makes up 66% of total alcohol consumption according to the World Health Organization (WHO). Similarly high proportional wine consumption can still be observed in France (56%), Portugal (55%), Greece (47%), Montenegro (47%), and Croatia (45%). Even with constantly dropping rates of wine and total alcohol consumption, recently observed rates of total consumption in Spain, Portugal, Croatia, and France still remain above the European average. On the other hand, rates of alcohol consumption in Turkey are set far below the European standards (2.0 vs. 10.9 of litres of pure alcohol/capita during 2008-2010, respectively) <sup>2</sup>.

Despite existing differences, numerous similarities characterize the traditional diets of the Mediterranean. These similarities are particularly evident when comparing the diets of neighbouring countries, giving rise to what could be called sub-regional traditional diets. Some of the dietary elements, however, reach far beyond the borders of sub-regions and are identical or highly similar in countries located on total geographical opposites of the Mediterranean basin.

Major focus was placed on lifestyle patterns of populations residing in the Mediterranean in the mid 20<sup>th</sup> century to unravel the contribution of traditional diet to good health that these populations were experiencing at the time as compared to others. The first study to thoroughly analyse the dietary habits in a population group in a Mediterranean country was conducted by the Rockefeller foundation in late 1940s. Based on the efforts of the Greek government to increase the standard of living in the population habitant to one of its main islands, a spectrum of factors ranging from dietary habits and health to agricultural practice was inspected and results were published in 1953. It was stated by Leland G. Allbaugh, the epidemiologist in charge of the study, that 'although the basic diet is probably much the same as it was in 2000 B.C., modified by the addition of sheep and some fruits in the Doric era and citrus fruits and tomatoes in the past millennium, the average diet of even the lowest group was adequate in total energy value and not grossly inadequate in any important aspect' <sup>3</sup>. Plant foods were the primary energy source in the diet of the inspected population constituting 61% of total energy intake, while only 7% were coming from food commodities of animal origin. For comparison, American food supply data at the time showed that considerably lower energy rates were derived from plant sources, and higher rates from animal foods (37% and 29%, respectively). Although roughly a double amount of energy in the Cretan diet (29%) was derived from fat and oils as compared to the American food supply data (15%), the absolutely most abundant fat source was olive oil and olives <sup>4</sup>. Although a direct comparison between dietary intake and food supply data is not strictly indicative, these findings suggest that more optimal nutritional habits were attributable to the Cretan population.

The characteristics of the Cretan diet at that time continued to provoke interest in the nutritional and overall health community as well as wider public up until nowadays. Similar dietary patterns could be found in other regions of the Mediterranean, such as southern Italy <sup>5</sup>. Its main constituents were included in the so called Mediterranean diet – modern nutritional recommendations based on the traditional cuisine of some Mediterranean countries or their regions. Mediterranean diet is not, however, limited on Greece and Italy, as some of its elements are found in countries located on geographically distant parts of the Mediterranean basin – e.g. Syria, Turkey, Lebanon, and Tunisia, Morocco, Portugal and Spain. Interestingly, this diet is particularly based on the traditional dietary patterns of countries that had a strong olive cultivation in the 1960s <sup>5</sup>.

The main food constituents of the Mediterranean diet, as illustrated in the nutritional pyramid below (Fig. 1), include fresh, largely non-processed plant foods (e.g., vegetables, fruits cereals, legumes, nuts, seeds), which are consumed in high amounts; frequent consumption of bread; low to moderate consumption of food commodities of animal origin, such as meat (red meat, poultry, fish), dairy products (cheese and yogurt), and eggs. Additionally, moderate and meal-accompanying consumption of wine is a typical element of the Mediterranean diet, albeit being limited to non-Islamic countries. Differences as to which food commodity is specifically consumed exist according to the sub-region, e.g., couscous is a traditional constituent of North-

African diet, pasta is frequently consumed in southern Europe, while bulgur is commonly eaten in countries of eastern Mediterranean. The composition of dietary fat in the Mediterranean diet is pretty unique. Olive oil is a vital constituent of the diet – it is consumed frequently and represents the main source of dietary fat. To the contrary, consumption of saturated fat is set to very low levels, the upper limits being 7-8% of energy derived from this type of dietary fat. Importantly, dietary elements are accompanied by another important, health-promoting lifestyle characteristic – physical activity on regular basis<sup>5</sup>.



Fig. 1. Mediterranean diet: nutritional pyramid<sup>6</sup>

Recognizing the integrity and importance of the nutritional habits as a lifestyle element, rather than being simply a diet of the population resident to countries of the region, UNESCO acknowledged the Mediterranean diet as an intangible cultural heritage of Cyprus, Croatia, Spain, Greece, Italy, Morocco and Portugal. It was recognized that ‘the Mediterranean diet involves a set of skills, knowledge, rituals, symbols and traditions concerning crops, harvesting, fishing, animal husbandry, conservation, processing, cooking, and particularly sharing and consumption of food. Eating together is the foundation of cultural identity and continuity of communities throughout the Mediterranean basin’<sup>7</sup>.

### III – Effects of the Mediterranean diet on health

The importance of diet, among other lifestyle factors, in developing risk factors and subsequently cardiovascular diseases was postulated in mid 20<sup>th</sup> century. Positive effects of the Mediterranean dietary habits were initially recognized in the Seven Countries Study. Started in 1958, this large longitudinal epidemiological study investigated the relationship between dietary habits and other lifestyle factors with cardiovascular health in middle-aged men in seven different countries – United States, Finland, Netherlands, Italy, former Yugoslavia, Greece and Japan. The pivotal importance of the study lies in identifying important risk factors for developing cardiovascular conditions, such as high blood pressure and elevated serum cholesterol levels, as well as establishing a clear correlation between the intake of saturated fat and serum cholesterol levels, saturated fat and incidence of coronary heart disease (CHD), and serum cholesterol levels and CHD incidence<sup>8</sup>.



The central role of dietary patterns in promoting good cardiovascular health became clear as results of the study showed that there is a significantly higher rate of coronary death in Northern Europe and United States when compared to southern Europe, even when controlled for variables such as serum cholesterol and blood pressure. Typically, population cohorts in Greece consumed high levels of olive oil and fruits, the Italian diet was characterized by high consumption of vegetables, while the Dalmatian cohort residing on the Adriatic shore of former Yugoslavia had the highest levels of fish consumption in their diet. Accordingly, these cohorts experienced much lower CHD death rate<sup>8</sup>. Similarly, negative correlation between adherence to the Mediterranean diet and risk for CHD and stroke was found in middle-aged women in the Nurses' Health Study<sup>9</sup>. The incidence of fatal as well as non-fatal cardiovascular disease is negative correlated with greater adherence to the Mediterranean diet in initially health middle-aged adults<sup>10</sup>. Significant value of the Mediterranean diet in promoting overall health was also found in elderly men and women in the HALE Project. Specifically, diet characterized by high consumption of bread, legumes, fruits, vegetables, fat with high content of unsaturated fatty acids, moderate consumption of fish and low intake of dairy products and meat was associated with lower all-cause mortality in 70-90 year olds<sup>11</sup>. In line with these results, a significant reduction in mortality caused by CHD and cancer was also found in a cohort of wider age range (20-86) adhering to Mediterranean diet<sup>12</sup>.

Individuals already diagnosed with CHD experience lower risk of death when eating as recommended by the diet<sup>13</sup>. Moreover, this diet can generally reduce the severity of CHD, clinically apparent by biochemical indicators of myocardial damage<sup>14</sup>. Furthermore, combining the diet with other health-promoting lifestyle factors, such as physical activity, can also reduce the risk of recurrent cardiac events<sup>15</sup>. The protective role of the diet is most likely due to protective nature of its individual constituents, as moderate fish consumption<sup>16</sup> or exclusive use of olive oil<sup>17</sup>, as recommended by the Mediterranean diet, can lower the likelihood of developing acute coronary syndromes. Also, long-term, exclusive olive oil use can also reduce the risk of developing cardiac dysfunction after the event<sup>18</sup>. To the contrary, consumption of red meat, which according to the Mediterranean diet should be consumed only in low amounts, is positively correlated with the likelihood of developing cardiac events<sup>19</sup>. Dairy products, such as yogurt and cheese, are an integral part of the diet, and they are suggested to offer a strong protective effect against heart disease<sup>20</sup>. Adherence to the Mediterranean diet seems to promote not only cardiac, but general cardiovascular health, as it is suggested to reduce inflammation and improve endothelial function<sup>21</sup>. Mediterranean diet, which addresses the type of fat that should be consumed but does not suggest low fat intake, seems to be more appropriate than low fat dietary regimes in terms of clinically relevant changes in cardiovascular risk factors and inflammation<sup>22</sup>.

Emerging evidence suggest that traditional Mediterranean dietary habits to be associated with protective effects not only in the cardiovascular system, but promote overall health, including lower risk for cancer<sup>23</sup>. Adhering to such dietary patterns could, for instance, offer protective mechanisms against pancreatic cancer<sup>24</sup>, gastric cancer<sup>25</sup>, colorectal cancer<sup>26</sup>, liver cancer<sup>27</sup>, prostate cancer<sup>28</sup>, and breast cancer<sup>29, 30</sup>. Greater adherence to the diet is suggested to significantly lower the risk of overall cancer mortality (10%), with a remarkable 56% reduction in aerodigestive cancer-associated deaths<sup>31</sup>.

Mediterranean diet is also suggested to be beneficial for metabolic health, as it was revealed in clinical and epidemiological studies that it positively influences components of the metabolic syndrome, such as blood pressure and lipid and glucose levels<sup>32</sup>, as well as reduces vascular inflammation associated with metabolic syndrome<sup>33</sup>. Furthermore, nutritional habits close to the Mediterranean diet are correlated with a reduced risk of developing diabetes<sup>34</sup>. Its potential in weight loss management has also been reported<sup>35</sup>.

Positive health effects of Mediterranean dietary patterns have also been suggested with regard to depressive disorders<sup>36</sup>, cognitive decline in elderly<sup>37, 38</sup> as well as middle-aged adults<sup>39</sup>, cerebral tissue loss associated with Alzheimer's disease<sup>40</sup>, and Parkinson's disease<sup>41, 42</sup>.



Usefulness and effectiveness of the Mediterranean diet in the primary prevention of major chronic diseases carries is important for the public health perspective <sup>43</sup>.

## IV – Changes in the nutritional habits in the Mediterranean region

Similar to the rest of the European continent and in accordance with general global trends, the Mediterranean region has experienced great demographic and socio-cultural changes, that have transformed once very typical traditional diet into a modern one. A clear Westernization of dietary habits is present in a large part of Mediterranean countries <sup>44</sup>.

Substantial changes have been reported in the dietary habits in the Cretan population over a 30 years period (1960-1991), which typically adhered to the standard definition of Mediterranean diet in the Seven Countries Study. A decrease in consumption of bread (51%), potatoes (67%), fruit (51%), eggs (62%), milk (22%), edible fats including olive oil (39%), sugar, honey, pastries and ice cream (15%), and alcohol (49%) was reported. In parallel, there was an increase in consumption of cereals (366%), legumes and pulses (288%), vegetables (46%), meat (24%), fish (244%), and cheese (100%) <sup>45</sup>.

Fat represents an important macronutrient in the traditional Mediterranean diet, and typically delivers an equal amount of calories as carbohydrates (slightly about 40%), while 15% of energy requirements are covered by dietary protein. Concomitantly, the plant-animal fat ratio defined by the diet is 2.1, while 2.5% of energy were derived from alcohol and fiber intake was set on 27 g/day <sup>46, 47</sup>. According to a study from 2002, 17.8% of energy in Algerian subjects was derived from protein, while 34.5% and 47.3% were coming from fat and carbohydrates, respectively. In Egypt, protein and fat energy were slightly lower (15.8% and 26%, respectively), with carbohydrates delivering more than half of calories (58.1%). Similarly, in the Italian capital of Rome, the largest part of energy was derived from dietary carbohydrates (48%), while 18.1% was attributable to protein and 29.6% to fat. Subjects from Greece had a higher fat percentage than prior countries (37.9%), with carbohydrate levels slightly above 40%, and 13.6% energy being derived from protein. Notably, different fat-carbohydrates ratio than the one described above could be observed in all four inspected countries, with a shift in favor of dietary carbohydrates. In parallel, Greece was the only country where the plant-animal fat ratio was shifted in favor of plant food (2.7), while a marked shift in favor of animal fats was observed in Algeria and Italy/Rome (1.3), and a slight decrease in Egypt (1.8). A small increase in alcohol consumption was reported in Italy/Rome and Greece, delivering slightly more than 4% and 3% of total calories, respectively. Decreased fiber intake was reported in all subject countries except Egypt, where a slight increase could be observed – 21.2 g/day in Algeria, 31.4 g/day in Egypt, 18.1 g/day in Italy/Rome, and 23.2 g/day in Greece. In short, the relative consumption of animal fats and dietary carbohydrates is higher than the defined at the cost of fat and plant foods, a characteristic of modern Western diets <sup>44</sup>.

Consumption of a range of food commodities in selected cohorts from the Seven Countries Study <sup>48</sup> and Multi-centre study of the Mediterranean Group for the Study of Diabetes (MGSD) <sup>44</sup> in male subjects in Greece and Italy is summarized in Table 1. In Greece, a decreased consumption of bread, potatoes, vegetables, fruit, eggs, milk, and fats can be observed, while a higher consumption of cereals, legumes, alcohol, meat, fish, cheese, sugar, pastries and other foodstuffs can be observed. In Italy, bread, vegetables, alcohol, meat, eggs, cheese, fats and sugars were consumed less, whilst potatoes, legumes, fruit, fish, milk, pastries as well as the consumption of other food commodities increased. Typical for the Mediterranean diet, fruits were consumed in highest net amounts in Greece and vegetables in Italy in early 1960s compared to other foodstuffs.

Diet of populations residing in Mediterranean countries has not only changed with regard to the relative composition in specific food commodities, but also in terms of the total amount of calories consumed by an average individual. In general, a more energy-rich diet is nowadays

consumed in Mediterranean countries. In the past 50 years (1961-2011), Libyan diet was modified in the way that it delivers more than double the amount of energy (107%). Comparably large increases in the total number of calories consumed on daily basis can be observed in Algeria (99%). Egyptian (71%), Tunisian (50%), and Moroccan diet (63%) have also become considerably more energy-dense. Relatively smaller increases can be observed in Turkey (24%), Greece and Spain (21%), and Italy (20%). However, it should be emphasised that an average person in these four countries consumed substantially more calories in early 1960s than an individual in Tunisia or Libya did. Therefore, the relatively small increase in these countries sums up to considerably high number of total calories consumed in 2011 <sup>49</sup>. Consumption of a more energy-dense diet as apparent by the number of calories consumed is not indicative of the dietary quality. Thus, it remains questionable whether such energy-rich diets are also nutrient-rich, considering the fact that vitamin and mineral deficiencies are still highly prevalent in some of the Mediterranean countries, particularly in those located in the southern part of the basin.

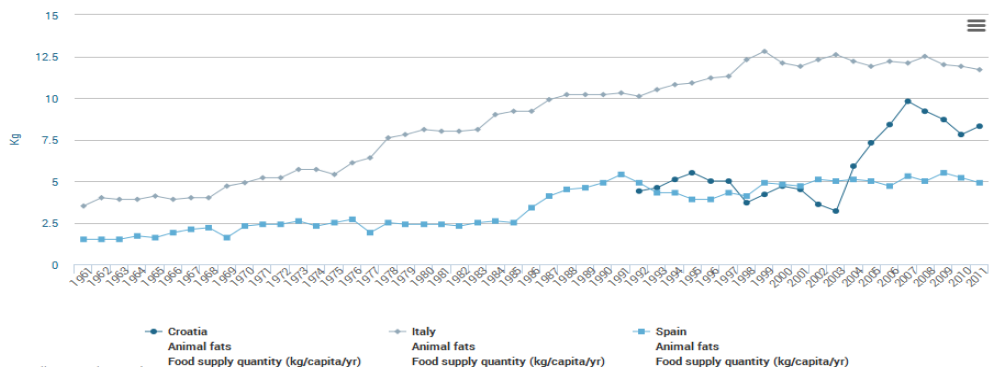
**Table 1. Changes in consumption of food commodities in g/day in Greece and Italy over time, <sup>a</sup>Seven Countries Study (Greece – Crete cohort, Italy – Rome railroad cohort) <sup>48</sup>, <sup>b</sup> Men from the Multi-centre study of the Mediterranean Group for the Study of Diabetes (MGSD), Italy – Rome area only included <sup>44</sup>**

	Greece <sup>a</sup>	Greece <sup>b</sup>	Italy <sup>a</sup>	Italy <sup>b</sup>
Bread	380	269	249	144
Cereals	30	76	113	113
Potatoes	190	47	29	31
Legumes	30	43	6	51
Vegetables	191	168	260	214
Alcohol	15	24	65	32
Fruit	464	354	150	236
Meat	35	82	226	101
Fish	18	33	30	40
Eggs	25	11	25	11
Cheese	13	67	33	29
Milk	235	153	77	126
Fats	95	42	51	13
Sugar	20	32	19	13
Pastries	0	45	12	103
Rest	107	390	56	165

**Table 2. Total daily calories intake in selected Mediterranean countries in 1961 and 2011 <sup>49</sup>**

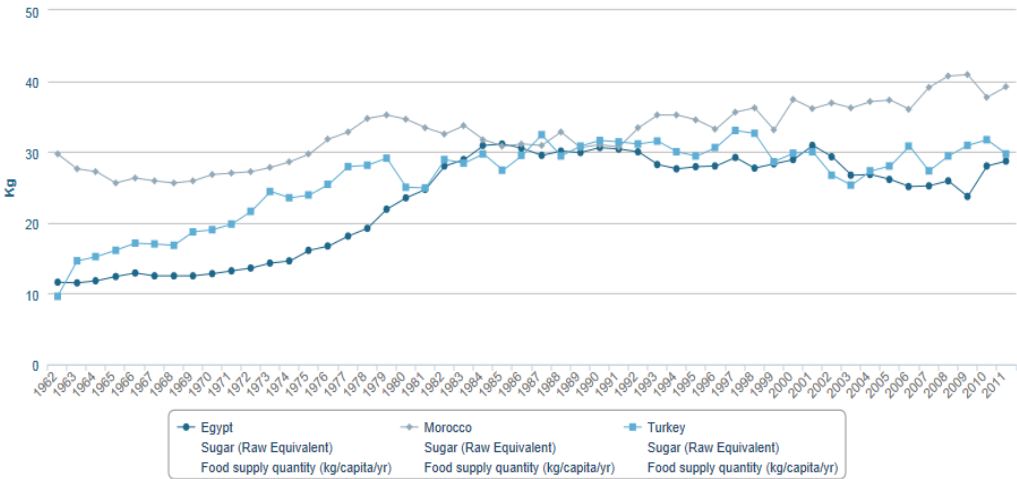
Country	Kcal/day (1961)	Kcal/day (2011)	Relative change
Italy	2955	3539	+ 20%
Greece	2824	3433	+ 21%
Spain	2632	3183	+ 21%
Turkey	2957	3680	+ 24%
Tunisia	2240	3362	+ 50%
Morocco	2047	3334	+63%
Egypt	2076	3557	+ 71%
Algeria	1619	3220	+ 99%
Lybia	1549	3211	+ 107%

Increase in the consumption of animal fats, which are not a major constituent of the Mediterranean diet, is a clear sign of the nutritional shift affecting the populations of some of the Mediterranean countries. Figure 2 depicts the consumption of animal fats (kg/capita/yr) over a 50 year period (1961-2011) in Spain and Italy, and a 9 year period (1992-2011) in Croatia. An approximate 3-fold increase can be observed in Italy (3.50 vs 11.70 kg/capita/yr) and Spain (1.50 vs 4.90 kg/capita/yr), while a roughly 2-fold increase is attributable to the Croatian diet (4.40 vs 8.30 kg/capita/yr) <sup>49</sup>.



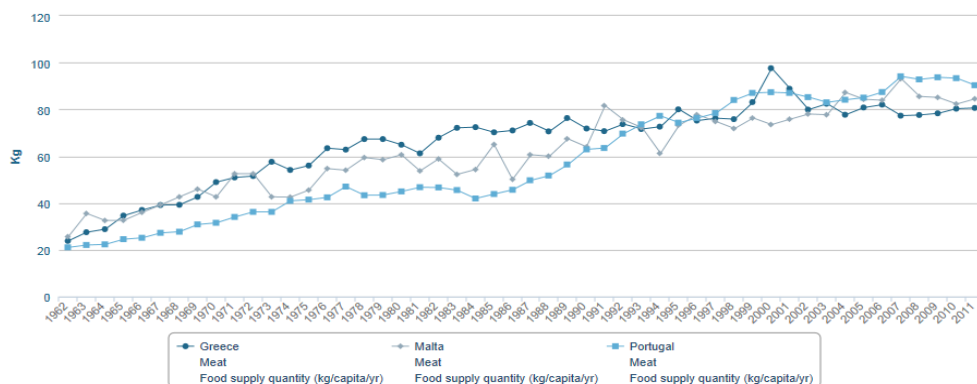
**Fig. 2. Consumption of animal fats in Croatia, Italy and Spain over a 9- and 50-year period, respectively (kg/capita/yr) <sup>49</sup>.**

Higher intake of sugar, in line with global trends, can be observed in many countries of the region. The consumption of sugar in Egypt, Morocco, and Turkey through 1962-2011 is shown in Fig. 3. In Turkey, the annual consumption of sugar increased more than 4 times (6.80 vs 29.70 kg/capita/yr), while increasing roughly 3 times in Egypt (10.60 vs 28.70 kg/capita/yr). In Morocco, sugar intake was set relatively high even in early 1960s (27.90 kg/capita/yr), but has still increased over time reaching very high levels (37.70 kg/capita/yr) <sup>49</sup>.



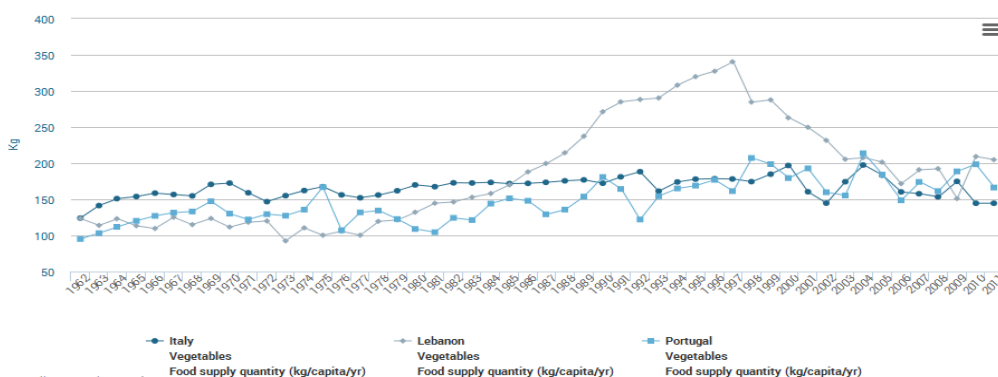
**Fig. 3. Consumption of sugar (raw equivalent) through 1962-2011 period in Turkey, Morocco and Egypt (kg/capita/yr) <sup>49</sup>.**

Moving away from traditional Mediterranean dietary pattern towards a modern Western-like diet becomes apparent when analysing the ratio of plant foods vs animal-origin food. Substantial increases in meat consumption can be observed in many Mediterranean countries. Concomitantly, the consumption of vegetables has stayed fairly stable in parts of the region, with only minimal increases. In Greece, Malta and Portugal, meat consumption was set on similar levels in 1962 (21.00, 23.80 and 25.60 kg/capita/yr for Portugal, Greece and Malta, respectively) (Fig. 4). Overall, meat intake in these countries increased roughly 4 times over a 50-year period, reaching 80.60 kg/capita/yr in Greece, 84.50 kg/capita/yr in Malta, and 90.30 kg/capita/yr in Portugal<sup>49</sup>.



**Fig. 4. Consumption of meat through 1962-2011 in Greece, Malta and Portugal (kg/capita/yr)<sup>49</sup>.**

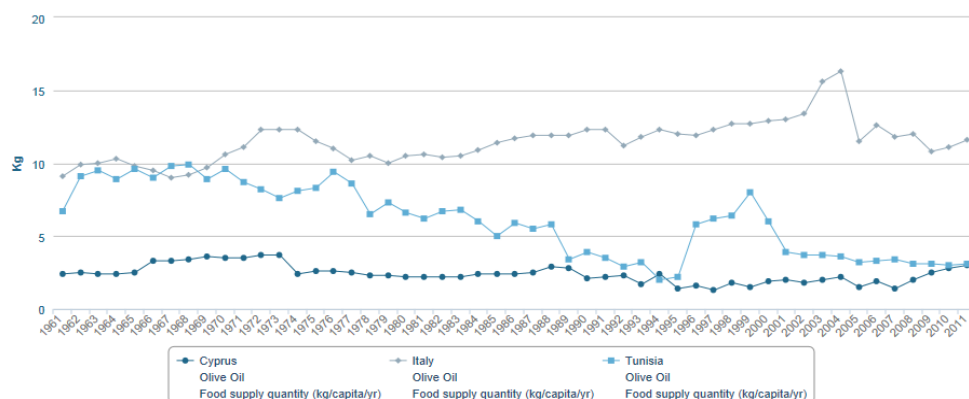
In Portugal, vegetable intake in 1962 was 95.00 kg/capita/yr, while comparably high levels were found in Lebanon and Italy (123.60 and 124.00 kg/capita/yr, respectively). In Italy, vegetable intake grew only minimally and reached 144.50 kg/capita/yr in 2011, while higher increases were reported in Portugal (166.20 kg/capita/yr) and Lebanon (204.80 kg/capita/yr)<sup>49</sup> (Fig. 5).



**Fig. 5. Consumption of vegetables through 1962-2011 in Italy, Lebanon and Portugal (kg/capita/yr)<sup>49</sup>.**

Olive oil, a vital food commodity in the traditional Mediterranean diet, is being increasingly replaced by other fat sources, such as saturated fat typically found in red meat. That is, olive oil intake in many Mediterranean countries has remained at fairly stable levels in the past 50 years, or has even decreased in some countries. In 1962, olive oil intake was fairly low in Cyprus (2.50 kg/capita/yr), and it remained at the same level over the past 50 years, reaching 3.00

kg/capita/yr in 2011. Similarly, its consumption stayed stable in Italy in this period (9.90 and 11.60 kg/capita/yr in 1962 and 2011, respectively). Remarkably, a Tunisian individual consumed 3 times less olive oil in 2011 than it did in 1962 (3.10 and 9.10 kg/capita/yr, respectively)<sup>49</sup> (Fig. 6).



**Fig. 6. Consumption of olive oil through 1962-2011 in Cyprus, Italy, and Tunisia (kg/capita/yr)<sup>49</sup>.**

Strong deviations from Mediterranean diet have been reported in younger adults<sup>50, 51, 52</sup>, particularly in low intake of fruit and vegetables and high intake of meat and dairy products<sup>50</sup>. In addition, levels of adherence to the Mediterranean diet as low as 5% can be found in this population group, in conjunction with generally low diet quality<sup>50</sup>. Marked nutritional changes can also be observed in children, although adherence to the Mediterranean diet generally contributes to diet quality in this age group<sup>53</sup>.

## V – Health trends

The nutritional shift that most Mediterranean countries have experienced has brought marked changes in the health status of its populations. For instance, in the Cretan cohort of the Seven Countries Study, with changing dietary patterns, negative health-associated effects could also be observed. Significant increases were reported in total serum cholesterol ( $5.7 \pm 0.7$  vs  $5.3 \pm 0.7$  mmol/L), body mass index ( $25.7 \pm 3.5$  vs  $24 \pm 2.4$  kg/m<sup>2</sup>), as well as systolic ( $152 \pm 13.4$  and  $134.4 \pm 11.1$  mmHg) and diastolic blood pressure (4<sup>th</sup> phase:  $97.1 \pm 8.8$  vs  $89.2 \pm 8.8$  mmHg), in conjunction with marked, but not significant changes in weight ( $69.4 \pm 9.03$  and  $64.5 \pm 7.2$  kg) for 1991 and 1960, respectively<sup>45</sup>.

The global epidemic of obesity has also taken its toll in Mediterranean countries (Table 3). With the nutritional shift and diets that are becoming more energy-dense reaching levels as high as 3500 kcal/day, as presented above, and increasingly sedentary lifestyle, the number of overweight and obese individuals in many of the countries has reached alarming levels. In some countries, such as Turkey (61.9%), Spain (62%), and Egypt (67.9%), overweight has become a major public health problem affecting roughly two thirds of the population<sup>54</sup>.

This dramatic upsurge in overweight and obesity clearly goes hand in hand with a high prevalence of non-communicable diseases, which account for between 63% and 95% of all deaths in the Mediterranean region (63% in Algeria, 72% in Tunisia, 82% in Egypt, 85% in Turkey, 87% in France, 90% in Malta, and 95% in Montenegro)<sup>54</sup>.

**Table 3. Obesity rates in selected countries in 2008 (%)** <sup>55</sup>

Country	Obesity (%)
Morocco	16.4
France	18.2
Italy	19.8
Tunisia	22.3
Portugal	24.0
Croatia	24.2
Turkey	27.8
Egypt	33.1

## VI – Conclusion

Traditional Mediterranean dietary patterns, as described in early 1960s, are an important lifestyle factor that served as a pillar of general health and well being in the population compared to other regions of the world at that time. Nutritional habits such as high consumption of olive oil, fruits and vegetables, and low intake of meat and other animal foods, is associated with a range of health benefits, such as decreased risk of cardiovascular diseases, metabolic conditions or even cancer. However, a clear ‘Westernization’ can be observed in many countries of the region over the past 50 years, introducing trends such as increasing intake of saturated fats and foodstuffs of animal origin. This nutritional shift is affecting a wide percentage of population, including children and young adults, and is accompanied by general lifestyle changes, such as decreasing levels of physical activity. These unfavorable changes are associated with negative health outcomes, such as the increasing prevalence of metabolic conditions and drastic upsurge of overweight and obesity in many of the countries. With a very high proportional mortality associated with non-communicable diseases, Mediterranean countries have been losing the reputation that they have enjoyed for a long time. Once known as the model region of good nutrition-good health relationship, the modern Mediterranean carries a huge burden of non-communicable diseases. A reverse in the nutritional transition and higher adherence to traditional dietary patterns represents an effective means in combating the modern health challenges in these countries and should be promoted through existing health systems.

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# Climate change and food safety

A. Ariño

Veterinary Faculty of the University of Zaragoza  
c/ Miguel Servet, 177, 50013 Zaragoza (Spain)

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**Abstract.** Worldwide, climate change is already affecting the biology and ecology of some organisms because of changing patterns in crop production and livestock intensification, as well as altering the transport pathways of chemical contaminants. Consequently, climate change is expected to aggravate feed and food safety problems during all phases of food production and supply. Temperature increases and changes in rainfall patterns will have an impact on the persistence and patterns of occurrence of bacteria, viruses, parasites, fungi, and harmful algae and the patterns of their corresponding foodborne diseases and the risk of toxic contamination. Chemical residues of pesticides and veterinary medicines in plant and animal products will be affected by changes in pest pressure. The food risks of heavy metals and persistent organic pollutants (i.e. dioxins, polychlorinated biphenyls) could rise following changes in soils and long-range atmospheric transport, though quantitative estimates are scarce. This short review presents data on the effect of climate change on biological and chemical food safety hazards, as well as it discusses the need for scientific research and development of improved tools, techniques and practices to adapt the current risk management systems.

**Keywords.** Climate change – Food safety – Foodborne diseases – Contaminants – Risk assessment.

## **Le changement climatique et la sécurité alimentaire**

**Résumé.** Dans le monde, le changement climatique affecte déjà la biologie et l'écologie de certains organismes en raison de l'évolution des modes de production agricole et de l'intensification de l'élevage, ainsi que de la modification des voies de transport des contaminants chimiques. Par conséquent, le changement climatique devrait aggraver les problèmes d'alimentation animale et de sécurité alimentaire à toutes les étapes de la production alimentaire et de l'approvisionnement. Les hausses de température et les changements des précipitations auront un impact sur la persistance et les modes d'apparition des bactéries, virus, parasites, champignons et algues nuisibles et sur les configurations des maladies d'origine alimentaire correspondantes et le risque de contamination toxique. Les résidus chimiques de pesticides et de médicaments vétérinaires dans les produits végétaux et animaux seront affectés par les changements de la pression épidémique. Les risques alimentaires des métaux lourds et des polluants organiques persistants (c'est-à-dire les dioxines, les biphényles polychlorés) pourraient augmenter en raison des changements dans les sols et du transport atmosphérique sur grande distance, bien que les estimations quantitatives soient rares. Cette brève revue présente des données concernant les effets du changement climatique sur les risques biologiques et chimiques de sécurité sanitaire des aliments, et examine les besoins de recherche scientifique et de développement de meilleurs outils, techniques et pratiques pour adapter les systèmes de gestion des risques actuels.

**Mots-clés.** Changement climatique – Sécurité alimentaire – Maladie transmissible par l'aliment – Contaminant – Évaluation du risque.

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## **I – Introduction**

There is widespread agreement that greenhouse gas emissions, among other driving forces, are leading to climate change and this will have a number of impacts, which will include changes in food security and food safety (Lake *et al.*, 2012). Anthropogenic activities have increased concentrations of carbon dioxide, methane, nitrous oxide, and chlorofluorocarbons in

the atmosphere, resulting in environmental warming. For instance, current atmospheric carbon dioxide concentrations (400 ppm) have increased by more than 40% from pre-industrial times (280 ppm), and they are expected to reach 550 ppm by the end of 2050 (Challinor *et al.*, 2014). Projections for Europe suggest that climate change will result in warming of 2.1-4.4°C by 2080, with Northern and Eastern Europe expected to become wetter, while the Mediterranean supposed to become drier. Predictions about extreme events are highly uncertain, but heat waves are expected to be more intense, frequent, and longer lasting, whereas extreme precipitation events will increase in northern and Western Europe (EEA, 2007).

In the literature, there is much focus on the effects of climate change on food security (Lobell *et al.*, 2011), defined as when all people at all times have access to sufficient, safe, nutritious food to maintain a healthy and active life (WHO, 2014). Additionally, climate change and related disturbances are considered important factors that can cause changes in the nature and occurrence of food safety hazards at various stages of the food chain, from primary production to consumption (Tirado *et al.*, 2010). There are many pathways through which climate related factors may impact food safety including: changes in temperature and precipitation patterns, increased frequency and intensity of extreme weather events, ocean warming, and changes in the transport pathways of complex contaminants.

Temperature increases and changes in rainfall patterns have an impact on the persistence and patterns of occurrence of bacteria, viruses, parasites and fungi and the patterns of their corresponding foodborne diseases and the risk of toxic contamination (Tirado *et al.*, 2010). Climate change may alter the seasonal patterns and abundance of pests and diseases, which may affect pesticide use in plants (Boxall *et al.*, 2009). Elevated temperatures may also lead to the emergence and re-emergence of pathogens and vectors, resulting in greater use of biocides and veterinary medicines in livestock management (Kemper, 2008). Responses will differ between crops and animal production systems and between geographical locations, but changes in pest and disease control measures may have implications for the presence of chemical residues in the food chain. Consequently, an increase in the prevalence of antibiotic-resistant pathogens in animal and human populations is likely (FAO, 2008). The risk of emerging zoonosis may also increase due to climate related changes in the survival of zoonotic agents in the environment, changes in migration pathways, carriers and vectors and changes in the natural ecosystems.

Extreme weather events such as floods and droughts may lead to contamination of soil, agricultural lands, water and food and animal feed with pathogens, chemicals and other hazardous substances, originating from sewage, agriculture and industrial settings. Ocean warming and subsequent physico-chemical changes of marine water may also affect the persistence and patterns of occurrence of pathogenic bacteria, harmful algal blooms and chemical contaminants in fish and shellfish. Climate change may affect the transport of chemicals into food, including aerial inputs of volatile and dust-associated contamination, flooding, and increased bioavailability of heavy metals due to changing environments and soil properties (Boxall *et al.*, 2009).

## **II – Climate change and biological hazards**

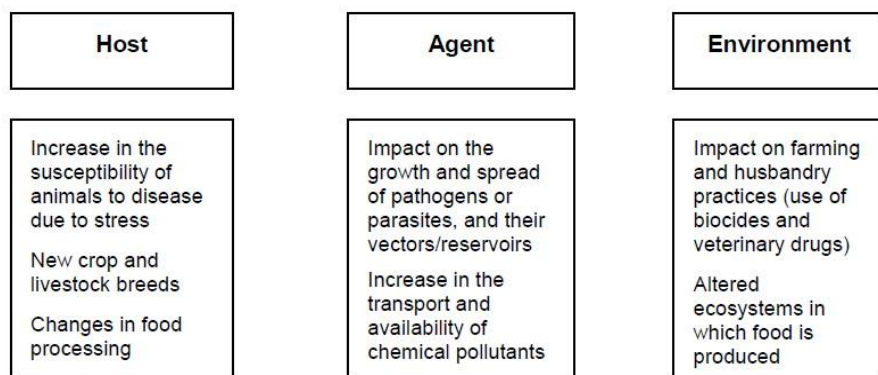
Climate change could affect existing pathogens or lead to the emergence of new pathogens in food through effects on animal husbandry and animal-to-animal transmission, pathogen survival, and other mechanisms (Tirado *et al.*, 2010). The fact that most foodborne bacterial pathogens can grow at room temperature with faster growth favoured at elevated temperatures means that increases in ambient temperatures may also speed up the rate of pathogen proliferation along the food chain with the subsequent increase in the number of cases (FAO, 2008). Climate change may increase the demand for irrigation water, elevating pathogen risks by manure and sewage contamination. Particularly temperature increase and changes in

precipitation pattern have a close relationship not only with the fate and transport of enteric bacteria, but also with their growth and survival. For instance, Liu *et al.* (2013), in a study of the impacts of climate change on the microbial safety of pre-harvest leafy green vegetables, predicted that the contamination risks by pathogenic *Escherichia coli* and *Salmonella* are likely to increase.

Some pathogens probably to be affected by climate change are those with low-infective doses (e.g. *Shigella*, *E coli* serovars) where small changes in distribution or abundance could lead to large outbreaks. Other certainly affected pathogens are those with significant persistence in the environment (e.g. enteric viruses and parasitic protozoa) (FAO 2008). Pathogens with good stress tolerance responses to temperature and pH (e.g. *Salmonella*) may also compete better against other pathogens under climate change. Another aspect to consider is that gene transfer between bacterial species is a common contributor to pathogenicity and antibiotic resistance and is likely to be impacted by changes in the environment caused by climate change.

Gastroenteritis and diarrhoeal disease are important causes of illness in the world and they are climate sensitive, showing strong seasonal variations (Kovats and Tirado, 2006). Higher temperature has been found to be strongly associated with increased episodes of diarrhoeal disease in adults and children worldwide. For instance, diarrhoeal reports in Peru increased 8% for each degree of temperature increase (Checkley *et al.*, 2000). Increased rates of water-borne diarrhoeal diseases such as cholera, cryptosporidiosis and typhoid fever have been reported after flood events (Tirado *et al.*, 2010).

As reviewed by Van der Spiegel *et al.* (2012), there are several ways in which climate change may affect infectious diseases (Fig. 1). First, hot and humid conditions can cause heat stress in livestock, which will induce a higher vulnerability to diseases. Climate change may bring about substantial shifts in disease distribution, and outbreaks of severe disease could occur in previously unexposed animal populations. Second, higher temperatures may increase the rate of development of pathogens or parasites, which may lead to larger populations. Changes to winds could affect the spread of certain pathogens and vectors. In turn, other pathogens that are sensitive to high temperatures and moist or dry conditions may have their survival compromised and decrease with climate warming. Also, there may be several impacts of climate change on the distribution and the abundance of disease vectors (e.g. flies, ticks, mosquitoes). Finally, farming and husbandry practices (including the use of veterinary drugs) will be affected due to climate related changes.



**Fig. 1.** Some pathways through which climate related changes and variability may impact all three elements of the epidemiologic triad: host, agent, and environment. Adapted from Tirado *et al.*, 2010.

Foodborne diseases that have been identified as a priority because of changing climate conditions include salmonellosis, campylobacteriosis, vibriosis, other bacterial infections, viral diseases, and parasitic infections (ECDC, 2007).

## 1. Salmonellosis

Previous research has demonstrated that *Salmonella* infections in humans are positively associated with temperature. A time series analysis study on human salmonellosis in several European countries showed that, in general, cases of salmonellosis increased by 5–10% for each one-degree increase in weekly ambient temperature (Kovats *et al.*, 2004). Infection with *Salmonella* Enteritidis appeared to be more sensitive to the effects of environmental temperature, at least as compared with infections caused by *Salmonella* Typhimurium.

## 2. Campylobacteriosis

The role of climate related parameters such as short-term increases in ambient temperature on human campylobacteriosis is unclear (Kovats *et al.*, 2005). Although associations between human cases and weather exist, the seasonality is less pronounced and the biological mechanisms underpinning these associations are not fully understood, which makes it difficult to predict the effects of climate change on campylobacteriosis infection.

## 3. Vibriosis

Higher temperatures, flooding and changes in water salinity may all have an impact on water microbiota including aquatic human pathogens such as the pathogenic *Vibrio* spp. (FAO, 2008). Large outbreaks attributed to the consumption of oysters contaminated with *Vibrio parahaemolyticus* have been linked to higher mean water temperatures in the Gulf Coast of the US. Additionally, changes in epidemiology have been noted since new serovars of *V. parahaemolyticus* such as O3:K6 have emerged and spread, even though a definitive relationship to global climate change has yet to be made (Tirado *et al.*, 2010). The global epidemiology of foodborne *V. vulnificus* infection revealed a statistically significant increase in the number of cases when summer temperatures peaked. Infection by the enteric pathogen *Vibrio cholera*, which is usually transmitted to humans through contaminated water, is endemic in certain tropical and subtropical regions of the world. In these areas, there are characteristic epidemic peaks which are frequently seasonal (Marques *et al.*, 2010).

## 4. Viral foodborne diseases

Viruses do not grow in foods and many of the viruses which cause gastroenteritis in human do not have a readily demonstrated relationship to ambient temperature. Three major routes of viral contamination of foods have been identified: human sewage and faeces; infected food handlers; and animals for zoonotic viruses (FAO/WHO, 2008). All these routes may be influenced by climate-induced changes. For example flooding can result in the overflow of untreated human sewage, resulting in increased likelihood of enteric virus contamination during the production of fresh produce and molluscan shellfish.

## 5. Parasitological agents and foodborne diseases

There is a causal relationship between climate change and emerging parasitic diseases (Poulin and Mouritsen, 2006). Several studies in different geographical regions of the US and Europe show that climate related variability, such as changes in precipitation affect the incidence of parasitological foodborne and water-borne diseases transmitted by protozoan parasites such as

cryptosporidiosis and giardiasis (ECDC, 2007). Likewise, global warming and increased temperature may affect the transmission cycle of foodborne trematodes of public health significance such as *Fasciola*, *Clonorchis*, *Schistosoma* and *Paragonimus* (Poulin and Mouritsen, 2006), which are transmitted by the consumption of raw or undercooked freshwater fish, crabs, crayfish and plants. All trematodes use molluscs (generally snails) as first intermediate hosts for the production of infective cercariae, and an increase in temperature is almost invariably coupled with a larger cercarial output.

### III – Climate change and chemical hazards

The chemical safety of food (toxins, contaminants, residues) varies by food type and where it is produced, making it difficult to assess associated changes in food safety when consuming different types of food produced in different geographical areas. Mycotoxins, an important public health concern, are formed through complex interactions between fungi and crops and are affected by weather conditions such as temperature, humidity and precipitation. A recent review indicated increasing problems of aflatoxins in parts of temperate Europe and the United States as climate change-associated temperature rises approach the optimal level for production of aflatoxins, one of the most important mycotoxins from a public health point of view (Paterson and Lima, 2010).

Freshwater and coastal environments are likely to be especially vulnerable to climate change because aquatic ecosystems are fragile (FAO, 2008). A number of human illnesses are caused by consuming seafood (especially shellfish) containing natural toxins produced by algal blooms, which are predicted to be more common and more widely distributed in coming decades (FAO, 2008).

It is generally accepted that climate change may lead to altered chemical inputs to food. Greater use of biocides, pesticides and veterinary medicines is likely in some areas, increasing the presence of chemical residues as well as the prevalence of antibiotic-resistant pathogens. Changes in transport pathways may also affect contaminant inputs to agricultural systems and food (Miraglia *et al.*, 2009). Flooding is one mechanism for transporting chemical contaminants onto agricultural land and may increase due to climate change (Boxall *et al.*, 2009). In addition altered contaminant inputs to surface waters may have impacts upon aquatic species that are subsequently consumed. Increases in the aerial inputs of volatile and dust-associated contamination may also occur, posing increased risks for human health and the environment.

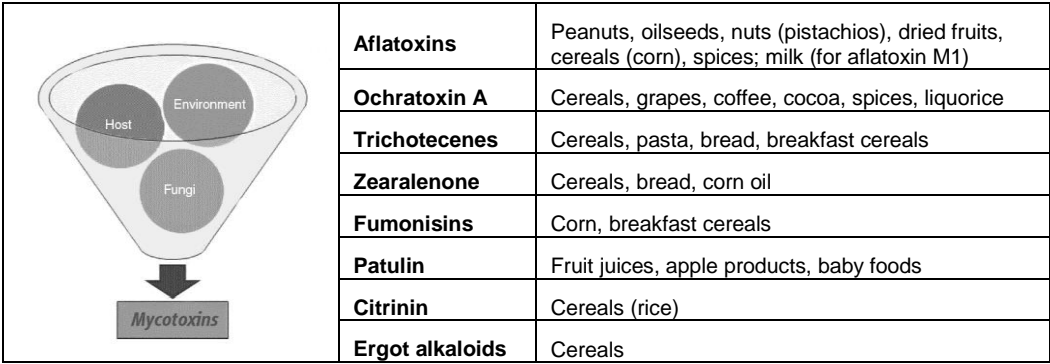
#### 1. Mycotoxins

Environmental factors such as favourable temperature and water activity are crucial for mycotoxigenic fungi and mycotoxin production both in pre-harvest and post-harvest scenarios (Fig. 2). In general, if the temperature increases in cool or temperate climates, the relevant countries may become more liable to mycotoxins such as aflatoxins during harvest and storage. Aflatoxins mycotoxins represent a serious health hazard as aflatoxin B1 is classified as IARC Group 1 carcinogenic to humans (Iqbal *et al.*, 2013). This imposes an additional threat to human health since this toxin is transferred to milk when lactating dairy cattle are fed with aflatoxin B1 contaminated feedstuffs (van der Spiegel *et al.*, 2012).

Environmental conditions such as temperature, humidity, gas composition and sunlight, affect the growth of mycotoxigenic fungi. The major toxins that contaminate maize and small grain cereals (wheat, triticale, barley) are deoxynivalenol and zearalenone, as well as fumonisins and aflatoxins on maize; type-A trichothecene mycotoxins T2 and HT2 affect mainly oats and barley. Recent studies by van der Fels-Klerx *et al.* (2012a; 2013) indicated that climate change could increase deoxynivalenol contamination of wheat in north-western Europe by up to 3 times, while for maize, an overall decrease in deoxynivalenol contamination was projected. However,

variability between regions and crop years was large, illustrating the need of carefully considering both direct and indirect effects when assessing climate change impacts on crops and related food safety hazards. An important indirect factor is that the feeding rate of many arthropod vectors (i.e. corn borers) increases at higher temperatures, thus increasing exposure of crops to mycotoxigenic fungi (i.e. *Fusarium* spp.), and hence the spread of mycotoxins.

Thermotolerant fungal species are adapted to warmer climate, and, for example, *Aspergillus flavus* (i.e. aflatoxins) may become more problematic than *Penicillium verrucosum* (i.e. ochratoxin A) in temperate Europe (Paterson and Lima, 2010). As another example of the effect of climate on fungal disease, increasing atmospheric CO<sub>2</sub> concentration will directly increase the amounts of *Fusarium* Head Blight and the subsequent risk of trichothecene mycotoxins (Chakraborty and Newton, 2011). This increased susceptibility is probably due to changes in the host physiology and morphology rather than a more infective pathogen.



**Fig. 2.** The system of fungi, host and environmental conditions must be all functioning for mycotoxin production in susceptible commodities. Adapted from Iqbal *et al.*, 2013 and Patterson and Lima, 2010.

## 2. Algal toxins

Some algal species (mainly dinoflagellates and diatoms) produce toxins usually when they bloom, and these marine biotoxins can accumulate in filter-feeding shellfish and some fish species and cause food poisonings in humans, which can be very serious. The most common illnesses associated with algal toxins are ciguatera fish poisoning (CFP), paralytic shellfish poisoning (PSP), amnesic shellfish poisoning (ASP), azaspiracid shellfish poisoning (AZP), diarrhetic shellfish poisoning (DSP), and neurotoxic shellfish poisoning (NSP). Global increase of harmful algal blooms in recent decades has been linked to eutrophication of water bodies, the transport of harmful algae species in ships' ballast water, and climate changes (Marques *et al.*, 2010). The observed increase in frequency, duration, and geographic scope of algal blooms has been associated with warmer than usual conditions, so projected warming is likely to result in even greater problems in the future. A study of climate change projections for the years 2030-2050 (van der Fels-Klerx *et al.*, 2012b) reported that the frequency of harmful algal blooms of *Dinophysis* spp. may increase, but consequences for contamination of shellfish with diarrhetic shellfish toxins are uncertain.

### 3. Chemical contaminants

Human activities have resulted in the release of several chemical contaminants into the environment in the last decades. These include toxic metals (e.g. mercury, cadmium, lead) and persistent organic chemicals, like dioxins and polychlorinated biphenyls (PCBs), among others (Marques *et al.*, 2010). For instance, chemical contaminants enter marine ecosystems via direct discharges from land-based sources (e.g. industrial and municipal wastes), atmospheric deposition from local and distant sources, and ships (Schiedek *et al.*, 2007). Many contaminants accumulate in sediments, where they can remain for very long periods, and in the food-web where they can reach high concentrations in top-level predators and ultimately affect human health. Climate change impacts on hydrographic conditions are expected to directly influence the availability and toxicological effects of chemical and biological contaminants. Warmer water temperatures and changes to precipitation and stream flow patterns may exacerbate many forms of water pollution with toxic metals and persistent organic chemicals.

The salinity of coastal and estuarine systems will experience fluctuations arising from changes to precipitation and stream flow patterns. Salinity may affect the toxicity of various classes of toxic metals due to either bioavailability or physiological factors. In particular, metals like cadmium and mercury are taken up more rapidly by molluscs and crustaceans at reduced salinities (Hall and Anderson, 1995). Likewise, temperature-related increases in the uptake, bioaccumulation and toxicity of metals have been reported for crustaceans, echinoderms and molluscs (Wang *et al.*, 2005). Warmer water temperatures facilitates mercury methylation, and the subsequent uptake of methyl mercury by fish and mammals has been found to increase by 3–5% for each 1°C rise in water temperature (Booth and Zeller, 2005). Similarly, cadmium bioaccumulation by blue mussel *Mytilus edulis* was higher at 12°C than at 2°C, as well as lead uptake increased at 26°C as compared to 6°C.

## IV – Conclusions

In the future, food systems are likely to change for a number of reasons, including climate change as a very important factor. An altered climate will mean that food will be produced under different environmental conditions and, coupled with adaptations to and mitigations against climate change, food production will be very different in the future. These changes will result in emerging pathogens, altered use of pesticides and veterinary medicines and will likely affect the main transfer mechanisms through which contaminants move from the environment to food, with implications for food safety.

Some pathogens and chemicals are transferred from animals to humans, so monitoring of animal health may enable us to detect threats before human infection occurs. Development of rapid detection methods for pathogens and chemicals in food, and surveillance systems to report these quickly, may enable action to be taken in a timely manner. Furthermore, it is recommended to closely monitor levels of mycotoxins and marine biotoxins, in particular related to risky situations associated with favourable climatic conditions for toxin producing organisms.

The common theme arising for food safety is altered risks and increasing unpredictability and change (Jacxsens *et al.*, 2010). Greater unpredictability suggests the need for increased surveillance to identify potential hazards before they occur, and greater speed in addressing emerging threats. Risk managers are encouraged to pay attention to the continuity of collecting the right data, and the availability and accessibility of databases, as well as the harmonisation of terminology and data collection. The situation demonstrates the need for scientific research and development of improved tools, techniques and practices to adapt the current risk management systems.



## Acknowledgments

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# Mediterranean food trade and Non-Tariff Measures

J.M. García Álvarez-Coque, L. Tudela Marco and V. Martínez-Gómez

Universitat Politècnica de València  
Camino de Vera s/n, 46022 Valencia (Spain)

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**Abstract.** Since the last decades, Southern and Eastern Mediterranean Countries (SEMCs) are following a process of progressive trade liberalization. As a consequence of such process, the significance and interest on Non-Tariff Measures (NTMs) has increased. The aim of this paper is to discuss the underlying factors affecting the implementation of NTMs. NTMs include specific food safety concerns. However, there could also be economic and political reasons affecting the frequency of implementation of food safety measures (border alerts). We thus explore the significance of two hypotheses that provide an explanation of NTMs in Mediterranean countries. The first one is the “reputation effect” or the influence of past history of notifications on border rejections. The second one refers to the policy substitution hypothesis or the trade-off between NTMs and tariffs. These two approaches intend to give an overview of the implementation of NTMs situation across Mediterranean trade food area. Both suggest that there are economic and political factors affecting NTM implementation.

**Keywords.** Non-tariff measures – Southern and Eastern Mediterranean countries – Trade protection – Agro-food trade.

## **Commerce alimentaire et mesures non tarifaires dans la Méditerranée**

**Résumé.** Depuis les dernières décennies, les pays du Sud et de l'Est de la Méditerranée suivent un processus de libéralisation progressive des échanges. Comme conséquence de ce processus, l'importance et l'intérêt des mesures non tarifaires a augmenté. Le but de cet article est de considérer les facteurs sous-jacents pour l'application des mesures non tarifaires au-delà des préoccupations spécifiques en matière de sécurité alimentaire. Pour ce faire, nous examinons l'importance de deux hypothèses qui fournissent une explication aux MNT dans les pays méditerranéens. La première est l'«effet de réputation» ou l'influence du passé historique des notifications sur les refus à la frontière. La deuxième fait référence à l'hypothèse de la politique de substitution ou compromis entre les mesures non tarifaires et les tarifs douaniers. Ces deux points de vue visent à donner une image de la mise en œuvre et la situation des MNT dans le commerce alimentaire méditerranéen. Les deux hypothèses suggèrent qu'il existe des facteurs économiques et politiques qui affectent la mise en œuvre des MNT.

**Mots-clés.** Mesures non tarifaires – Pays du Sud et de l'Est de la Méditerranée – Protection des échanges – Commerce agro-alimentaire.

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## I – Introduction

Tariffs on imports have been reduced to relatively low levels in the EU and Southern and Eastern Mediterranean Countries (SEMCs) especially as the result of the periodic rounds of multilateral and bilateral trade negotiations. This process has led to an increasing interest in the extent to which existing Non-Tariff Measures (NTMs)<sup>1</sup> may distort or restrict international trade. On one side, regulations are often necessary to alleviate market failures, but on the other side, domestic

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<sup>1</sup>Bradford (2005) defines non-tariff barriers as political or governmental practices, in addition to tariffs, which increase the domestic price of a well above their import price. In this paper, we use the more general term “Non-Tariff Measures” because these measures could be welfare improving when they provide information to consumers and decrease the impact of asymmetric information problem (Bureau *et al.*, 2001; Movchan, 1999; Disdier *et al.*, 2008).

regulations may be imposed simply to restrict imports from foreign competitors (Beghin, 2008). In order to address the issues involving the impact of NTMs, accurate and reliable studies on the actual reasons that explain NTMs are needed.<sup>2</sup>

What explains NTMs? There are, of course, health and technical justifications. NTMs are employed for many purposes, including the correction of information asymmetries and market failures very frequently related to food safety concerns. The use of NTMs is endorsed by the implementation of the WTO Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT), which provide an international legal framework to regulate the implementation of NTMs. When countries implement such measures, they are protecting values such as public health, animal or vegetal health, or consumers' rights. However, they may also have potential protectionism purposes. While tariff barriers have been alleviated under multilateral liberalization agreements, NTMs have become a common trade restriction. NTMs can be used as disguised protection aiming at restricting the entrance of foreign produce (Hoeckman and Nicita, 2008; Nimenya *et al.*, 2012).

Harmonization of NTMs in the Euro-Mediterranean regions is a basic goal of the deep and comprehensive free trade area (DCFTA) launched by the EU and most SEMCs. The process, agreed in 1995 in Barcelona, and its follow-up, the Union for the Mediterranean (2008) has aimed at creating an area of shared prosperity, which is translated in the economic field by the establishment of a free trade area between the EU and its Mediterranean partners. Particularly, the agro-food trade has followed a gradual liberalization process over the last decades, as subsequent revisions of the Association Agreements have eliminated or reduced the trade barriers in a preferential and reciprocal basis. Nowadays, the most of agro-food products from SEMCs enter at the EU in a duty-free basis, but NTMs still appear as significant obstacles and their removal or harmonization involve a pre-condition for a deep integration process.

To date, the EU has largely dominated the agricultural trade relations of SEMCs. Morocco shows a positive agricultural trade balance with the EU but other SEMCs, in particular Algeria and Egypt, show a large deficit vis-à-vis the EU (Tudela *et al.*, 2014). According to EU data (European Commission, 2013), trade between the EU and the SEMCs in agricultural and fishery products shares about 5.5% of total EU imports and about 7.6% of total EU exports nowadays. With respect to the products traded, Petit (2009) explains that EU exports to SEMCs are much more diversified than the reverse trade flows from SEMC to the EU. In fact, SEMCs exports are concentrated on fruits and vegetables, with slight and continuous yearly increases. In these goods, SEMCs exploit their competitive advantage, as well as the traditional trade linkages, the aforementioned trade preferences and the geographical proximity to EU markets. On the other hand, in agricultural goods the EU main exporting section is some processed goods such as beverages or prepared foodstuffs. Other relevant agricultural products exported from the EU to SEMCs are dairy products and cereals, mostly wheat that helps to balance the low food self-sufficiency ratio suffered in many SEMCs.

In parallel and partially linked to the bilateral EU-SEMC agreements, some SEMCs are involved in a multilateral South-South integration. This process, namely the Agadir Agreement, has incorporated since 2007 Morocco, Tunisia, Egypt and Jordan in a gradual trade liberalization process. To date, its impact seems to be minor in agro-food trade.

Together with the Association Agreements between the EU and SEMCs, the institutional framework devised in the Euro-Mediterranean partnership has included financial instruments to foster the development of SEMCs. The process is supported by the Support to the European Neighbourhood Programme for Agriculture and Rural Development (ENPARD)<sup>3</sup>, which is a

<sup>2</sup> Detailed descriptions on NTMs and their quantification can be found in Deardoff and Stern (1999), Bora *et al.* (2002), and Ferrantino (2006).

<sup>3</sup> In April 2014 CIHEAM launched a web site providing information regarding the ENPARD on SEMCs. The website presents various activities developed in the Southern Mediterranean countries which are partners of EU through the South ENPARD programme. See <http://www.enpard.iamm.fr/en/>

policy initiative that is part of the EU's commitment to inclusive growth and stability in its neighbourhood, recognising the importance of agriculture in terms of food security, sustainable production and rural employment. Among the axis of action in ENPARD, emphasis is put on achieving food security objectives, and, simultaneously, contributing to increasing food safety and raising quality standards to better benefit from export markets. Then, it is expected that in the next years these programs contribute to a further strengthening in the value chains of key exports from SEMCs to the EU. Such strengthening would imply a better ability of countries involved to comply with public and private standards on imported products.

Most of the literature dealing with NTMs in the Mediterranean region focuses on the role of NTMs on exports from SEMCs to the EU. Emlinger (2010) analysed the implications of NTMs in the entry of fruits and vegetables from different sources into the European markets. Cieslik and Hagemeyer (2009) found that even though the new EU Association Agreements liberalised imports of EU products from SEMCs, they did not contribute to the expansion of their exports to the EU markets. This happens as SEMC export success not only depends on a greater access to EU markets, but also on production adaptation to the EU standards, oriented to enhance quality systems and good agricultural practices (González Mellado *et al.*, 2010; Rau and Kavallari, 2013).

With this background, this paper presents the results of the recent research carried out at the Universitat Politècnica de València to analyze the underlying factors that affect the use of NTMs applied on agricultural and food trade. We focus on two hypothesis, which are: (i) whether the implementation of NTMs by the EU is motivated by a systematic behaviour, guided by economic and political considerations beyond the appearance of specific food alerts and safety concerns; and (ii) whether the implementation of NTMs in SEMCs is related to the removal of tariffs to trade, so a substitution of policies could take place. In summary, we are interested in dealing with an explanation of the NTM implementation that is not directly or solely linked to food safety issues.

To do so, in the next section, we will explore the EU behaviour expressed by the agro-food notifications on food alerts by the EU on imports with Mediterranean origin. Afterwards, the links between tariffs and non-tariff measures will be investigated by looking at the possible trade-off between tariff and non-tariff protection. The last section summarizes the main findings and offers some policy conclusions.

## II – Explaining EU food alerts

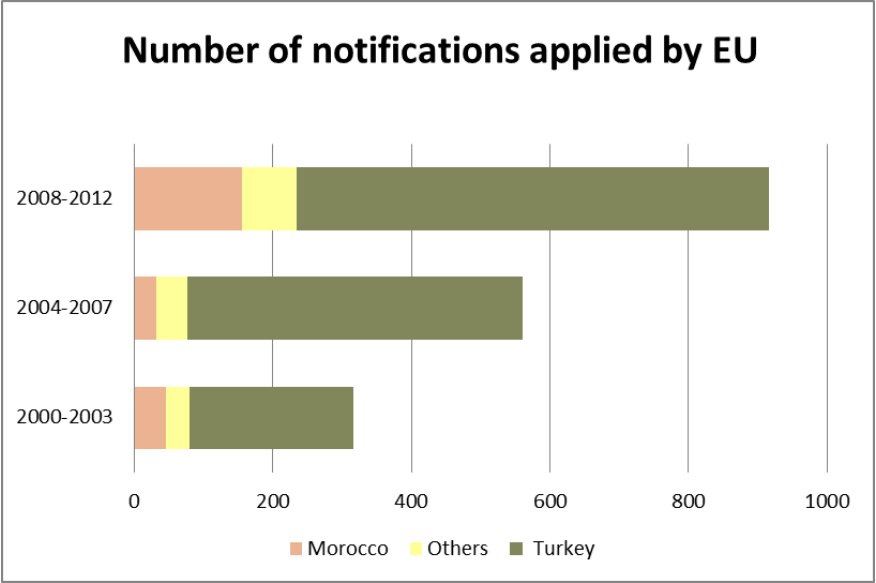
As mentioned above, the EU is a major agro-food trade partner for SEMCs. Accomplishing the EU sanitary and safety standards is a challenge for Mediterranean exporters (García Álvarez-Coque *et al.*, 2012). A way of dealing with this issue is to monitor border rejections, since they are indicators of exporting countries to comply with food safety and quality requirements imposed by importing countries. During the period 2003 – 2008, the European Rapid Alert System for Food and Feed (RASFF) reported a total of 1,123 border rejection notifications concerning fruits and vegetables imported from the SEMCs to the EU (Grazia *et al.*, 2009).

RASFF supplies information on food alerts and border rejections. This database provides a direct measure of NTMs, expressed by the number of notifications of SPS measures applied by EU countries on imports from its trade partners. RASFF does not provide information of food alerts expressed in terms of notifications in given trade chapters of the Harmonized System (HS)<sup>4</sup>, which could facilitate their analysis. To solve that, we designed an Excel lexicographic tool to facilitate the conversion of over 1792 observations from the RASFF dataset into notifications classified by HS code.

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<sup>4</sup>Harmonized Commodity Description and Coding Systems, used to describe products in trade statistics at 6-digit, 4-digit and 2-digit levels.

Focusing on notifications from the main EU importers concerning SEMCs as origin countries, Fig. 1 shows the number of notifications applied by EU authorities on exports from Turkey, Morocco and others SEMCs with destination to Spain, Netherlands, France, UK and Germany, between 2000 and 2013. Figure 2 reflects the notifications of the considered dataset classified by trade chapter at 2-digit level. Figure 3 provides its classification by type of food alert.



**Fig. 1. Number of notifications applied by selected EU Member States<sup>a</sup> on agrofood SEMC<sup>b</sup> exports (a: Spain, Netherlands, France, UK and Germany, b: Morocco, Tunisia, Turkey, Egypt, Lebanon, Algeria and Jordan). Source: Authors' calculations from RASFF database.**

The number of food alerts in the EU has increased in recent years. The observed increase can probably be attributed to the rise in notifications for products found to be unfit for consumption, but also, due to the increased control related to regulations and standards imposing reinforced checks for a list of products from outside the EU. Turkey is one of the countries –overall in the world, not only in the SEMC group- with highest number of notifications, which is highlighted in every RASFF annual report (see, for example, RASFF 2012). When border rejections are measured as a frequency, expressed in rejections per 1000 imported tons, Grazia *et al.* (2009) report an average rejection rate of 0.0493 rejections per 1000 tons of imported fruit and vegetables from the Mediterranean region, with Turkey having a frequency rate of 0.0975/1000 tons.

Figure 2 shows those trade chapters that accumulate more notifications. The significant number of notifications in the product category "Fruits and nuts" (HS 08) is mainly due to the notifications on aflatoxins in dried figs from Turkey. The 111 notifications in the category "Tea and spices" relate to different spices such as: chilli powder, paprika, curry powder and camomile tea, etc. Concretely 89 notifications concern spices and herbs originating from Turkey and 15 from Egypt. Table 1 summarises the main problems appeared on EU imports from selected SEMCs.

Fish and crustaceans (HS03) is the most-notified category of food of animal origin. In this case, the results show clearly that heavy metals and bad hygienic state are still the most reported hazards.



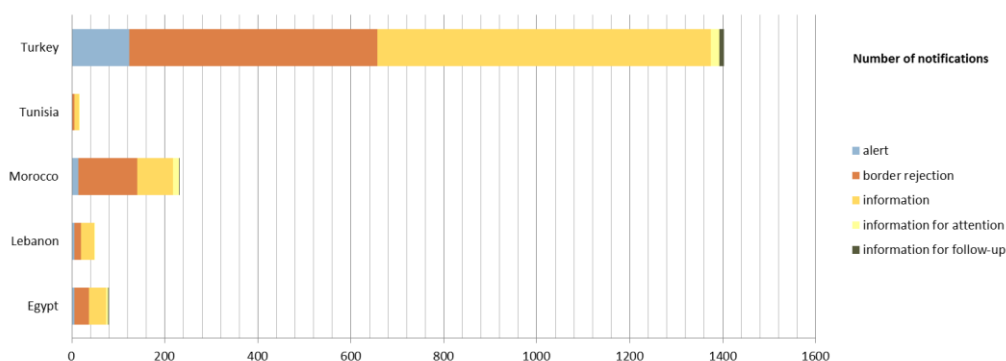
**Fig. 2. Notifications at different trade chapters, by selected EU Member States<sup>a</sup> on agrofood SEMC<sup>b</sup> exports a: Spain, Netherlands, France, UK and Germany, b: Morocco, Tunisia, Turkey, Egypt, Lebanon, Algeria and Jordan) Source: Authors' calculations from RASFF database.**

**Table 1. Main hazard type, origin and product category (2012). Notifications by selected EU Member States<sup>a</sup> on agrofood SEMC<sup>b</sup> exports. Source: Authors calculations based on RASFF**

Origin	Main risks	Main products
Egypt	Aflatoxins Methomyl	Groundnuts and peanuts Fresh strawberries
Morocco	Too high content of sulphite and Heavy metals Bad hygienic state and parasitic infestation	Fresh and frozen fish
Tunisia	Mycotoxins Aflatoxin	Pistachios and hazelnuts Dried Figs.
Turkey	Too high content of sulphite Aflatoxins Methamidophos	Dried apricots Dried figs and hazelnut Green peppers
Lebanon	Aflatoxins	Pistachios and nuts

a: Spain, Netherlands, France, UK and Germany; b: Morocco, Tunisia, Turkey, Egypt, Lebanon, Algeria and Jordan.

Figure 3 shows the different types of classifications based on RASFF. Since 2008, RASFF differentiates between "market notifications" (alerts and information) "border rejections" and "news information" (notifications for attention and for follow-up). Market notifications are about products found on the Community territory for which a health risk was reported, 1919 in total for the countries and period covered. Products that are subject of a border rejection never entered the Community and were sent back to the country of origin, destroyed or sent to another destination, accounting to 712 cases.



**Fig. 3. Classification by type of food alert and by year, by selected EU Member States<sup>a</sup> on agrofoodSEMC<sup>b</sup> exports (a: Spain, Netherlands, France, UK and Germany, b: Morocco, Tunisia, Turkey, Egypt, Lebanon, Algeria and Jordan). Source: Authors' calculations from RASFF database.**

Impacts of NTMs largely depend on the type of standard required and policies designed by EU with their partners (Disdier *et al.*, 2008; Anders and Caswell, 2009; Disdier and Maret, 2010; Martí-Selva and García Álvarez-Coque, 2007). The literature shows that NTMs have basically two contradictory sets of effects for developing countries. Essaji (2008) found that the NTMs lead to increasing production and compliance costs. By contrast, Maertens and Swinnen (2009) suggested that foreign standards push up the production quality and help firms to realize beneficial productivity gains. In the same line, Chemnitz *et al.* (2007), state that SPS and TBT measures can bring significant social benefits even to low income countries, such as reduced agrochemical use and a framework that guides good agricultural and management practices. The EU is an attractive destination for emerging countries exporters, given its relevant agro-food demand size, the historical relations of trade and the geographical proximity in the case of Mediterranean partners. Despite the harmful effect of NTMs, they may aid to improve the quality level representing strong motivation to develop trade flows of agro-food products through countries.

Taghouti and García Álvarez-Coque (2013) provided a test for the hypothesis that one product's border rejections in one year may affect the probability of future rejections, and that such effects may appear at product, sector and country level. Thus, the quoted authors tested to which level that past history of food alerts or notifications, that is to say "reputation", significantly influences EU behaviour on actual notifications<sup>5</sup>. At each year (t), the EU authorities may implement NTMs based on present risk assessment criteria, but they are also influenced by the past. Hence, the hypothesis that the product notifications of the year (t-1) and previous years could raise the notifications of the year (t) was examined.

Taghouti and García Álvarez-Coque (2013)<sup>6</sup> applied a conditional fixed-effects negative binomial regression to determine the effects of certain variables in the number of notifications in the year (t). Among the explanatory variables, the "reputation effects" refer to notifications issued at (t-1) on the same product (4-digit HS code), on the sector where such product belongs to (similar products of the corresponding 2-digit HS code), to the country of origin, and to the corresponding geographic area (e.g. Mediterranean region, South America). Other explanatory variables influencing current notifications are the per capita GDP of the originating country, and the import volume and growth.

<sup>5</sup>By doing that, Taghouti and García Álvarez-Coque introduce the reputation effects in the analysis of EU agricultural imports, which is comparable to the studies carried out in the USA by Jouanjean *et al.*, 2012.

<sup>6</sup>See also Taghouti (2013)



The per capita GDP was taken as a measure of economic development and capacity of the exporting country to face NTMs. The level of development of partner countries is expected to be negatively correlated with border rejection figures. Indeed, in the quoted study, the per capita GDP was statistically significant at 1% significance level which means that the EU rejections depend on variables correlated by the per capita GDP of the countries (infrastructure, human capital, etc). Import growth was also found a relevant determinant of the total number of refusals, as EU behaviour could be affected in agri-food trade by a protectionist behaviour. Indeed, the positive coefficient of this variable means that, as a general trend, a sharp import flow increase from a given exporter with a history of non compliance is accompanied by a stricter control in the borders so more rejections and notifications by the EU authorities could be expected. The impact of the sector and country reputation were also found to be statistically significant.

The variable representing the reputation effect of countries belonging to the Mediterranean region was statistically significant but came with a negative sign. In the case of SEMCs, given their export specialization in products competing with Southern European production (fruit and vegetables and olive oil), the historical partnership and the geographical proximity in the case of SEMC might have a positive effect on the compliance to the required standards.

Linking these results with the figures depicted earlier, there is no evidence that the EU shows a specific protectionist behaviour against products from the Mediterranean region, compared to products from other regions. Moreover, it is true noting that significant EU investments in the agro-exporting sectors in these countries help to overcome NTMs. Such relation can improve the capacity of these countries to achieve the quality and standards required by the EU, as the financial tools like ENPARD can do as well.

### **III – Non-Tariff Measures applied in Southern and Eastern Mediterranean countries**

#### **1. The hypothesis of policy substitution**

As a part of their integration process, SEMCs are in different stages of harmonization of their NTMs (González-Mellado *et al.*, 2010). Providing knowledge on NTM harmonization in the Mediterranean area may be helpful to foster trade rather than restricting it. Tudela *et al.* (2013, 2014) used the estimates of ad valorem equivalents of NTMs (AVEs) by Kee *et al.* (2009) to identify "peak levels" in several SEMCs. The AVEs reflect what would be the theoretical tariff levels that would produce equivalent effects to the NTMs applied by a given country on a given product. It was found that most SEMCs have AVEs that can be considered as "peaks"<sup>7</sup>. It appears that stringency of applying measures by the own SEMCs seems to be relatively stronger at the borders as compared to a less effective monitoring in the domestic market (De Wulf *et al.*, 2009).

Some authors have suggested the hypothesis of "policy substitution" between tariffs and NTMs. The policy substitution hypothesis in the context of large-country terms-of-trade motives for tariffs and regulations has been studied in Staiger and Sykes (2009). Going deeper into the subject, results by Gourdon *et al.* (2012) suggest the presence of correlation between the use of NTMs and traditional forms of trade policy. In fact, the possibility emerges that tariff and NTMs can act as substitute or complementary, in both cases showing the impact to domestic political economic pressures (Bown and Tovar, 2011). The evidence is not conclusive as the restrictiveness of NTMs can be seen as depending on the sector or the country income (Dean *et al.*, 2009).

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<sup>7</sup>This paper kept the "usual" criteria for identifying peaks: literature identifies as tariff peaks those above 20% (mentioned in ICSTD, 2009).

In order to explore possible interdependence between NTMs and tariffs in agro-food trade we studied NTMs situation in a subset of SEMCs gathering the available data for comparing tariffs and NTMs equivalents. The products include the whole range of agro-food products at the 6-digit level of the Harmonized System (HS chapters 01 to 22).

The NTMs are collected from the data on AVE of Non-Tariff Measures (labelled from now on as Non-Tariff Equivalents NTEs) estimated by Kee *et al.* (2009). NTEs are expressed as percentage of the value of the product, which make them directly comparable with tariffs. The countries selected are those in the Agadir Agreement, due to their relevant level of integration across SEMCs.

The tariffs data are collected from the World Integrated Trade Solution (WITS) database. Concretely for the study, the Most Favoured Nation (MFN) applied tariffs at HS 6-digit were collected, corresponding to the same period when the NTE were available.

Obviously, these estimates are not free of limitations<sup>8</sup>. We are also aware that the tariffs selected in WITS database are multilateral, so they only reflect the general trade policy of a country and not the expression of the bilateral trade policy with specific partners.

## 2. Is trade protection significant?

We first explore the overall scope of agricultural protection. Descriptive statistics on the incidence of tariffs and NTMs in terms of frequency, mean, standard deviation and ratio NTE/tariffs were calculated, in order to get a general overview. Table 2 depicts the simple average NTEs and tariff levels on agricultural imports. The table shows the relatively high protection level in the set of countries studied<sup>9</sup>, with the exception of Jordan. The situation changes from one HS chapter to another, as indicated by the relatively high standard deviations calculated, with some chapters with low protection -in particular fish- and some others with relatively high protection. Across countries, Egypt shows the highest level of standard deviation due to almost prohibitive tariffs in HS chapters 21 and 22. Tariffs and NTE figures displayed in Table 2 are "multilateral", showing the general orientation of trade policy (total agricultural imports of the selected set of countries). Figures don't correspond to the bilateral trade liberalization undertaken among countries in the region or with respect the EU.

**Table 2. Non-Tariff Equivalents and Tariffs on agricultural imports<sup>a</sup> in Agadir countries (ad valorem %). Source: Authors' calculations**

	Tunisia	Morocco	Jordan	Egypt
<b>NTEs</b>				
Mean	41.1	35.9	6.4	44.2
Standard deviation	55.2	53.5	25.0	56.2
<b>Tariffs</b>				
Mean	73.5	52.9	21.9	66.6
Standard deviation	53.2	45.9	24.2	376.0
Ratio NTE/Tariff	0,56	0.68	0.29	0.66

Note: Calculations carried out including HS Chapters 1 to 22.

<sup>8</sup>Kee *et al.* (2009) offer a comprehensive set of NTEs. Other estimates with a different or more limited scope can be found in Deardoff and Stern (1999), Dean *et al.* (2003) and Vaughan (2005). Nimenya *et al.* (2010) extended the price comparison method to account for imperfect substitution and factor endowment under monopolistic competition. Sanjuán *et al.* (2013) suggest an alternative way of measuring NTE based on the gravity equation.

<sup>9</sup>Although the list of countries can be extended to more SEMC, care was taken for incomplete datasets or inconsistent figures, so the sample of countries is limited in this paper.

### 3. Are trade policies transparent?

In average, NTEs are lower than tariff levels in the four countries considered, although ratios of NTEs to multilateral tariffs range from 0.29 in Jordan to 0.68 in Morocco and Algeria. This indicates that although tariff liberalization remains an issue in agricultural trade, non-tariff protection is also relevant, in particular because NTMs are not as transparent as tariff protection. The fact that the ratios NTE/tariffs are lower in some countries than others suggests that transparency of trade policies is not uniform in SEMCs. In the next paragraphs we explore protection and transparency in trade rules, showing that both concepts may not necessarily overlap.

The comprehensive set of data regarding protection extracted from the sources quoted in Section 3.1 can be classified with the aim of creating a systematic or "taxonomy" of the protection. The frequency of the so-called "peak" equivalents was measured, to highlight both tariff and NTEs exceeding a certain threshold. To define such peaks, the starting point was the modalities document prepared by the Committee of Agricultural Negotiations circulated in the Doha current negotiations (WTO, 2008). For developing countries, it suggests that the highest tariffs reductions shall be done in those products where the bound tariff or ad valorem equivalent is greater than 75 per cent. Besides, when the tariff values are between 0 and 30 per cent, the lowest rates of reduction shall be applied. After that, two alternative thresholds for tariffs peaks were established at 30% and 75%. On the same token, we identified as NTE peaks those values greater than 75%, with the aim of identifying cases where the price effects of NTMs were of utmost magnitude.

Thus, for each country, the taxonomy of products according to their trade protection pattern was developed combining the NTE and the tariff level. This allows comparing protection across countries and groups of products. To do so, four categories have been defined:

(i) High protection: The first category contains all products where tariffs are relatively high (above 30 or 75 per cent) and also high NTM are applied (NTEs greater than 75 per cent).

(ii) Disguised protection: The second category contains all products where tariffs are relatively low (less than 30 or 75 per cent) but high NTM are applied (NTEs greater than 75 per cent).

(iii) Low protection: The third category contains all products where tariffs are relatively low (less than 30 or 75 per cent) and also low NTM are applied (NTEs below 75 per cent).

(iv) Transparent protection: The fourth category contains all products where tariffs are relatively high (above 30 or 75 per cent) but low NTM are applied (NTEs below 75 per cent).

Thus, the protection for some products can rely on high tariffs and low NTEs, which means a protectionist approach but transparent in the sense that tariffs are less trade-distorting. On the other extreme, there are products with relatively low tariffs but the NTMs applied have high NTEs, situation that has been considered as "Disguised" protectionism. There are of course groups of "High Protection" and "Low Protection", grouping products where both tariffs and NTEs are high or low, respectively.

The taxonomy of protection is illustrated in Table 3, which shows that a significant number of products can be considered as receiving transparent or low protection levels.

Disguised protection is significant in Morocco, Tunisia and Egypt if thresholds are set at 75%, ranging from 19 percent of total products in Tunisia to 26 percent in Egypt. When thresholds are lowered for tariffs to 30%, the disguised protection group diminishes in Morocco and Tunisia, but in turn, the high protection group increases in both countries to 22 percent in Morocco and

23 percent in Tunisia. This indicates that, in spite of the criterion for setting the level of tariff peaks, the NTE keep a protective role in a significant number of cases.

**Table 3. Taxonomy of agricultural trade protection (Percentage of products in each group) Source: Authors' calculations**

Category of protection	Egypt		Jordan		Morocco		Tunisia	
	%	Highest frequency HS chapter	%	Highest frequency HS chapter	%	Highest frequency HS chapter	%	Highest frequency HS chapter
<b>Thresholds: NTE 75% and Tariff 75%</b>								
High	1	22	0	-	2	02	9	02,03
Disguised	26	08	4	02	21	03	19	03
Low	71	03	95	03	71	03	48	03
Transparent	1	22	2	22	5	02	25	07
<b>Thresholds: NTE 75% and Tariff 30%</b>								
High	6	20	0	-	22	03	23	03
Disguised	21	08, 15	3	02	2	12	5	12
Low	57	03	52	03	15	15	14	12
Transparent	15	20	45	08	61	03	58	03

Note: HS chapters: 02: Meat and edible meat offal; 03: Fish and crustaceans; 07: Edible Vegetables; 08: Edible Fruits and Nuts; 12: Oil seeds and oleaginous; 15: Animal or vegetable fats and oils; 20: Preparations of vegetables and fruits; 22: Beverages.

Jordan shows a low protection level, irrespective of the criteria set. It does not have products in the high protection group, and the percentage of products in the disguised group is only 4 percent taking the first criterion (75%, 75%) and 3 percent in the second criterion (75%, 30%). In Egypt, the high protection group keeps at only 6 percent of total products with the same thresholds but the disguised protection group still represents 21 percent of products for the same criterion. As a conclusion, data on tariff and NTE show that: (i) high NTE are still significant in several SEMCs countries; and (ii) high NTE appear both in products with relatively high and in products with relatively low tariff levels.

## IV – Concluding remarks

In this paper, the protection applied by SEMCs to agro-food products is analyzed. The general argument to be explored was that NTMs are affected by economic and political reasons that are not necessarily connected to specific sanitary and safety concerns. This was approached following two main specific hypotheses. The first is that EU import border rejections and food alerts are explained by a range of variables, including the history of past notifications ("reputation" effect), the import volumes and growth, and per capita GDP of exporting countries. The second hypothesis deals with the possibility of a policy substitution or complementarity between tariffs and NTMs. Both hypotheses were investigated in the context of the Euro-Mediterranean DCFTA.

EU Notifications included in the RASFF database appeared to have been influenced by real SPS and TBT problems. However, beyond specific safety problems, there is a wider common behaviour on the way standards are applied. EU notifications are affected firstly by the own reputation of a product and the sector reputation in a given zone, with relatively stronger effect of the reputation built at a product level. Notifications are also pushed up by the import volume,

with a clear response of the alert system to import growth, suggesting possible protectionist reactions. Implementation of NTMs by the EU vary according the per capita GDP of the exporter, suggesting that investment in infrastructure and human capacities favour the integration of agro-exporting firms in the global value chains to comply with EU requirements regarding the quality of imported products.

However, no special disguised protection was found in the way EU policies affect export flows from Mediterranean countries to the EU member states, compared to flows originated in other world's regions.

The policy substitution analysis was carried out by combining information regarding the protection via tariffs and via NTMs, using comprehensive datasets, which allow a product-by-product detailed view of the issue. Means of achieving agricultural protection are varied in the Mediterranean region. There are different possibilities at stake: only-tariff protection, in other cases NTMs may be used as a substitute for tariffs, while in other cases significant NTMs coincide with tariffs.

To ascertain these elements, a taxonomy or categorization of the products has been made, considering simultaneously the protection via tariffs and via NTMs. The dominant category observed is low protection. However, the general picture shows that a relatively high level of transparent protection (e.g., high tariffs and relatively low NTEs) still remains as well as significant disguised protection (e.g. low tariffs and relatively high NTEs) in the four countries considered. Nevertheless, there are some country differences, as Jordan and Egypt seem to have lower number of products with significant protection. The general conclusion is consistent with other estimates (see Rau and Kavallari, 2013). In addition, another remarkable fact is that the values of the NTEs are lower than the tariffs.

The level of protection in the considered sample of SEMCs varies depending on the products, although certain product chapters 02 (meat), 03 (fish), 20 and 22 (processed fruit and vegetables) are more protected which is in line with some previous results from Tudela *et al.*, (2013).

While this analysis indicates that there could be certain relationship between NMTs and tariffs, it cannot be stated that SEMCs are implementing NTMs as a substitute of the (gradually declining) protection via tariffs; neither a clear complementarity among both types of protection takes place. Consequently, future research could consider a more detailed statistical analysis on how the NTE levels depend on tariff levels and on a range of product specificities.

Our results suggest that the food safety policies in the Mediterranean region do not respond to a systematic behaviour or general logic of relationship between NTEs and tariff levels. In any case, the analysis requires further exploration at the country level, with focus on identified SPS and TBT problems.

As pointed out in OECD (2011), the challenge for NTMs remains to separate protectionist and non-protectionist policies and to identify alternative approaches for trade policies, in particular in processes involving DCFTAs. In the case of the SEMCs and their bilateral liberalization, the results described above highlight the role of harmonization in NTMs. Indeed, as the NTMs applied in the region do not appear to be motivated by tariff liberalization, a case-by-case approach could be helpful to foster the harmonization of SPS and TBT standards across the countries involved. Such approach could merit from the support of the institutions fostering trade liberalization, or from other funds like the ENPARD program.

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**Country Profiles:  
Food Safety Institutional Maps  
and Governance Systems**

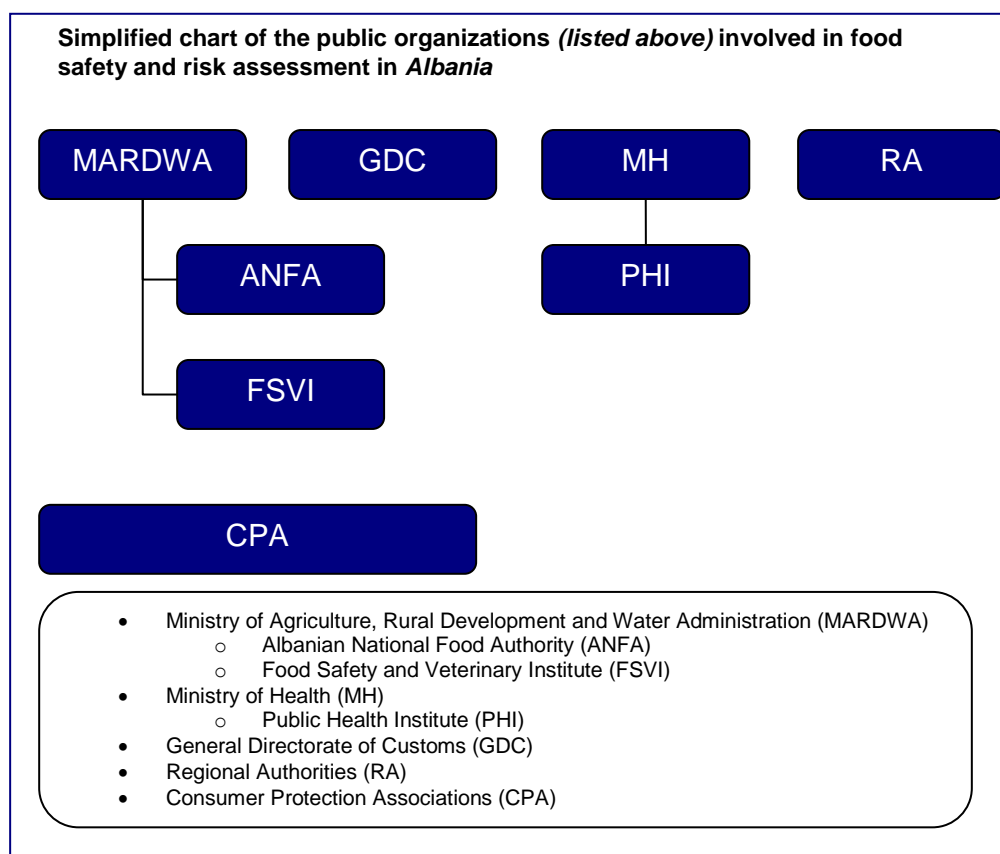


# Country Profile: Albania<sup>i</sup>

## I – Key priorities for risk assessment

- National establishment of high risk products
- International cooperation for risk assessment
- Emerging risks

## II – Major public actors involved in food safety (including risk assessment, management and communication)



## Main public organisations involved in food safety and roles – Albania

Organisation	Main areas of remit (in term of risk assessment/ management/ communication)	Risk assessment	Risk management	Risk communication
<b>MARDWA</b> – Ministry of Agriculture, Rural Administration and Water Administration	Plant health, animal health – incl. aquaculture, agricultural products, feed; overview of food issues	x	x	x
<b>ANFA</b> – Albanian National Food Authority	Food, food contact material, plant health and agricultural inputs, plant protection, inspection of non-animal origin products, inspection of animal origin products, veterinary medicines, foodstuff for particular use, laboratory coordination support	x	x	x
<b>FSVI</b> – Food Safety Veterinary Authority	Physic – chemical analyses, microbiological, diagnosis of diseases, residue analyses of medicals in animal origin products, pesticide residues in non-animal origin products	x		x
<b>MH</b> – Ministry of Health	Draft the legislation which determines the relations in the area of preserving and protecting human health.	x	x	x
<b>PHI</b> – Public Health Institution	Studies and monitors risk factors, laboratory reference and manages vaccination programs.	x		x
<b>GDC</b> – General Directorate of Customs				x
<b>RA</b> – Regional Authorities			x	x
<b>CPA</b> – Consumer Protection Associations				

### *Food safety legislation in Albania*

#### The status food law in Albania

- Law No. 9863, dated 28.1.2008 "On Food";
- DCM No.1081, dated 21.10.2009 "On the organization and functioning of the National Food Authority".
- Law No. 9362, dated 24.3.2005, "For plant protection service";
- Law No.8691, dated 16.11.2000, "On production and trading of tobacco and cigarettes";

- Law No. 71/2013, dated 24.03.2005, "On some amendments and additions of the Law No. 9362, dated "On plant protection service" amended Law No. 10 433, dated 16.6.2011, "On inspection in the Republic of Albania";
- Law No. 9908, dated 24.4.2008, " On some amendments and additions of the Law No.. 9352, dated 24.3.2005 "For plant protection service";
- Law No. 10 465, dated 29.9.2011, "On veterinary service in the Republic of Albania";
- Law No. 10 465, dated 29.9.2011, "On veterinary service in the Republic of Albania"; (amended)"
- Law No.9441, dated 11.11.2005, "On production, collection, processing and trading of milk and its products";
- Law No. 8411, dated 1.10.1998, "On livestock feed";
- Law No. 10 137, dated 11.5.2009, "On some amendments in the legislation into force for licenses, authorizations and permits in the Republic of Albania";
- Law No. 8443, dated 21.1.1999, "On vineyards, wine and other products deriving from grapes";

### **Veterinary Sector**

- Law No. 9863, dated 28.1.2008 "On Food";
- Law No. 8411, dated 1.10.1998, "On livestock feed";
- Law No.7908 , dated 5.4.1995 "On fishery and aquaculture";
- Law No.10 433, dated 16.6.2011 "On inspection in the Republic of Albania";
- Law No. 10 465, dated 29.9.2011, "On veterinary service in the Republic of Albania";
- Law No. 9441, dated 11.11.2005, "On production, collection, processing and trading of milk and its products".
- Regulation No. 3 dated 17.03.2006 "On food hygiene";
- Normative act of CM No. 4, dated 16.8.2012 "On establishing rules for animal slaughtering and trading their meat".

### **Plant Protection Sector**

- Law No. 8531, dated 23.9.1999 "On fertilizers control service";
- Law No. 10 416, dated 7.4.2011 "On planting material and herbal multiplier";
- Law No. 8880, dated 15.4.2002 "On the rights of plants' breeder";
- Law No. 10390, dated 3.3.2011 "On fertilizers used in vegetation";
- Law No. 8443, dated 21.1.1999 "On vineyards, wine and other products deriving from grapes";
- Law No. 9362; dated 24/03/2005 "On plant protection service".

### **Normative acts, regulations and decisions**

- Law No. 87/2012 On approval of normative act with the power of law no. 4, dated 16.8.2012, of the Council of Ministers "On establishment of rules for animal slaughtering and trading their meat";  
Act Agreement, dated 2.5.2006 "On increasing affectivity in animal, poultry, live fish, plants, other livestock import, and export and transit control. Also of other animal origin products and raw material for food industry".

### **On Aquaculture**

- Regulation No.2 dated 17.05.2007 "On fish and aquaculture licensing";
- DCM No. 8763, dated 2.4.2001 "On an addition in Law No. 7908, dated 5.4.1995 "On fishery and aquaculture".

## ***Ministry of Agriculture, Rural Development and Water Administration (MARDWA)***

In terms of Food Safety, the strategic objective of the Ministry of Agriculture, Rural Development and Water Management (MBZHRAU) is to guarantee the highest degree of Albanian citizens' health and perfection of the system of supervision and food safety. This system will serve to better protect the health of consumers from illnesses / injuries as a result of the consumption of food products of animal or plant origin. On the other hand and will guarantee a fair competition on the market of food business operators.

Vision, priorities and strategic goals aimed at strengthening a fully functioning system of food safety and consumer protection, from the farm to the table, covering the whole country and modern monitoring and control in accordance with EU standards. The importance of establishing food and nutrition policy as a key goal of development policy is a strategic objective and reflects global and local trends. Every single link in the chain must be very strong in the case of consumer health aims to be fully protected. This principle is valid regardless of whether foods produced or imported into Albania from other countries. For this reason the Albanian government will have in its attention to strengthening the control and monitoring of foodstuff sold in the Albanian market intended for human consumption and used for feed.

**Website:** [www.bujqesia.gov.al](http://www.bujqesia.gov.al)

## ***Albanian National Food Authority (ANFA)***

### **History**

National Food Authority (Autoritetit Kombëtar të Ushqimit, AKU, in Albanian) was established as an integrated part of the program to create and guarantee a food safety system in Albania.

ANFA, as an institution under the Ministry of Agriculture, Rural Development and Water Administration provides a high level of protection for citizens and aims not only to build trust but also to guarantee it for the food products in our country.

ANFA was established with a Ministers Council Decision No. 1081 date 21. 10. 2009 and it was officially inaugurated from the Prime Minister, Mr. Berisha on 20 May 2010. This institution is set up with the assistance of international experts with EU funds since 2007, period which grounded the first steps for ANFA conception. Today the institution has 12 regional directorates all over Albania.

### **Tasks**

- Leads the risk assessment process in food, feed and plant protection field. Plans, coordinates and realizes official controls of food and feed and plant protection.
- Ensures the official control practices unification for food, feed and plant protection at national level.
- Coordinates authorized laboratories activities in food, feed and plant protection official controls.
- Performs preliminary controls to prove if the technical-technological, hygiene-sanitation, phytosanitary and veterinary requirements are met and also to verify the necessary documentation for registering and licensing the food business operators and plant protection.
- Blocks temporarily or permanently the activity of food and feed business operators in stages of production, processing, delivery and marketing of food or feed when is proved that food or feed and respective business operators do not meet food safety standards, determined in the legislation into force.
- Carries out necessary scientific researches on risk assessment in the field of food and feed safety and plant protection.

- Provides technical, administrative and scientific support to enable the activity of scientific committee and scientific panels.
- Informs the public on food and feed safety and plant protection.

**Website:** [www.aku.gov.al](http://www.aku.gov.al)

### ***Food Safety and Veterinary Institute (FSVI)***

#### **Tasks of FSVI**

Food Safety and Veterinary Institute is the only of this kind in the territory of Albania and operates under the Ministry of Agriculture, Rural Development and Water Administration. FSVI is a national reference center developing scientific research and application activities in areas of animal health and food quality, foodstuff residues and veterinary products registration and plant protection.

It serves as a reference center for:

- Confirmation of diagnosis performed in other laboratories;
- Conducting standardization of methods of analysis, in collaboration with national and /or international laboratories.
- Uses and disseminates official methods of analysis.
- Organizes training courses for specialists in other laboratories.
- Supplies other laboratories with new regulations and everything related to the field of research.
- Collaborates with reference centers of the European Community.
- Provides the Ministry of ARDWA with assistance and scientific laboratory information and suggests further measures to be taken in the field for issues that arise regarding the scope of FSVI.

**Website:** [www.isuv.gov.al](http://www.isuv.gov.al)

### ***Ministry of Health (MH)***

Ministry of Health's mission is the implementation of health policies of Government programs. Ministry of Health compiles health policies at the national level and determines the development and planning of health services nationally and regionally.

The MH drafts legislation that defines the relationships in the conservation and protection of health and rigorously implements legislation in the field of health. It designs health development strategies and tactics in the implementation of Government programs.

The MH studies and designs investment programs for the infrastructure development of health services and performs operational management of the health services nationally and regionally. For the realization of its functions it operates under the organizational structure approved.

**Website:** [www.shendetesia.gov.al](http://www.shendetesia.gov.al)

## ***Public Health Institute (PHI)***

### **Tasks**

- In the food safety sector: Development and application of plans for the verification of food supply.
- In the nutritional sector (food): (i) Development and application of research plans in food sectors: macro- and micro-nutrients, (ii) Monitoring of nutrition of population.

**Website:** [www.ishp.gov.al](http://www.ishp.gov.al)

## ***General Directorate of Customs (GDC)***

After the Clearance, the Control Directorate (retrospectively):

- Carries out documentary and physical checks, after the release of goods, order verification and control of all trade documentation and any other information related to import-export operations of EO and on all actions that have to further trade related to these goods. These checks will be made at the premises of economic operators and customs practices through a review of the premises of the customs branches.
- Carries out documentary and physical checks, after the release of goods, order verification and control of all trade documentation and any other information related to import-export operations of EO and on all actions that concern further trade related to these goods. These checks will be made at the premises of economic operators and customs practices through a review of the premises of the customs branches.
- Undertakes on their initiative or at the request of the economic operator to review and verify the accuracy of the data of the customs declaration. This review will be done on an occasional basis, or on a possible doubt for committing customs offenses.
- Prepares and analyzes reports on a statistical basis which will be used as criteria for preparing risk work plans and controls that will be performing.
- Processes and analyzes the data obtained through other structures of customs administration and customs through various bilateral agreements, signed by them.
- Coordinates and controls the work of post-clearance specialists who are near the customs branches.
- Cooperates with all other departments and branches of Customs, in order to fulfill effective controls.

**Website:** [www.dogana.gov.al](http://www.dogana.gov.al)

## ***Regional Authorities (RA)***

They function under the General Directorate in different regions implementing the laws and regulations above mentioned and other sub-legal acts from the General Director.

Mainly their daily activity is in field inspections to verify and check compliance of the food business operators to the law and EU standards.

Regional NFAs are situated in 12 regions of the country, covering also the Border Inspection Points.

### III – Food safety alerts management in Albania

1. Does the competent authority (or authorities) for food safety have an established mechanism to evaluate and react to food safety crises (crises management mechanism)?	<b>Yes</b>
2. If the reply to Q1 is yes, does this mechanism include a committee or a body with pre-determined representatives?	<b>No</b> (committee/committees are formed ad hoc, depending on the needs of the crises)
3. If there is an established mechanism for crisis management (the reply to Q1 is Yes):	
3a. Do actors with risk assessment capacity participate directly in this mechanism?	<b>Yes</b>
3b. Do actors with risk management capacity participate directly in this mechanism?	<b>Yes</b>
3c. Do actors with risk communication capacity participate directly in this mechanism?	<b>Yes</b>

#### ***Rapid Alert System for Food and Feed (RASFF)***

Rapid Alarm System for Food and Feed (RASFF) is a fast and effective tool for exchange of information between competent authorities, when risk is ascertained for human health along the food chain. This quick way of information sharing allows all member states to immediately verify the network if they are also affected by the problem. Although the product is still on the market and may not be consumed, the authorities have the position to take immediate action, including immediate provision to inform the public, if necessary. Rapid exchange of information about risk in food for human consumption and livestock feed, provides quick and safe measures from all members of the RASFF system. This is an important contribution to food security.

### IV – Characteristics of the food sector in Albania

**Number of enterprises<sup>1</sup>:** Total **22290**

**% of the industrial sector:** 18 % of the enterprises

**% of the industrial workforce:** Approximately 15 %

**% of industrial turnover:** N/A

**Top subsectors (in terms of number of enterprises):**

- Producers (A+B): 347
- Manufactures (A+B): 1028
- Distributors (A+B): 18527
- Plant Protection Products: 1803

(A+B) meaning animal and non-animal origin foodstuff

**Top subsectors (in terms of turnover):** N/A

<sup>1</sup> Albanian National Food Authority; AKU-net system; Ministry of Agriculture, Rural Development and Water Administration.

## V – Civil Society Organisations

Consumer Protection Associations aim at protecting and promoting consumers rights.

Tasks:

- Protect the rights and interests of consumers through an administrative division at central and regional level and the compliance through statutes and laws.
- Influence the decision making process through information, counseling, negotiation to make it easier the problem solution of consumers' complaints.
- Educate consumers, essentially in comprehending and adapting laws.
- Solving requests and complaints in respective sectors.

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<sup>i</sup> **Country profile elaborated by:**  
**Pamela RADOVANI**  
National Food Authority (NFA)  
E-mail: Pamela.Radovani@aku.gov.al

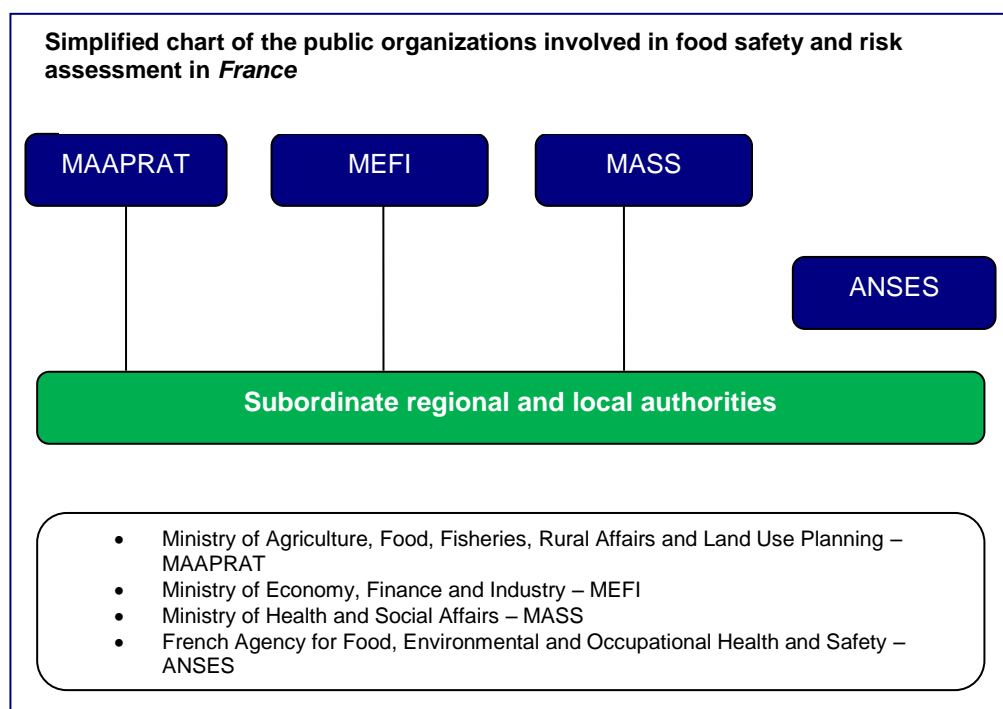


# Country Profile: France<sup>i</sup>

## I – Key priorities for risk assessment

- Use of weight of evidence approach for risk assessment
- Uncertainties in risk assessment
- Cumulative and aggregate exposure assessment to chemicals
- Nutritional benefits and risks
- National food observatory
- Consumer phase in risk assessment
- Risk based microbial criteria
- Harmonization of risk assessment methodologies

## II – Major public actors involved in food safety (including risk assessment, management and communication)



## Main public organisations involved in food safety and roles – France

Organisation	Main areas of remit (in term of risk assessment/ management/ communication)	Risk assessment	Risk management	Risk communication
<b>MAAPRAT</b> – Ministry of Agriculture, Food, Fisheries, Rural Affairs and Land Use Planning	Prepares draft legislation in food safety area and is also responsible for control and inspection. MAAPRAT uses risk assessments prepared by ANSES. MAAPRAT is also responsible for risk communication. MAAPRAT's portfolio encompasses plant protection products, including residues, veterinary medicinal products, GMOs and zoonoses plant health and animal health and welfare		x	x
<b>MEFI</b> – Ministry of Economy, Finance and Industry	Responsible for consumer policy including state food inspections of all products of non-animal origin. The MEFI uses risk assessment from ANSES. The portfolio of the MEFI includes food supplements, novel foods, mineral water, residues of plant protection products and GMOs in food of non-animal origin. MEFI is also involved in risk communication activities.		x	x
<b>MASS</b> – Ministry of Health and Social Affairs	MASS prepares draft legislation in the field of mineral and drinking water and is responsible for state drinking water inspections. MASS uses the risk assessments from ANSES. MASS is in charge of investigations on foodborne diseases. Another main area of MASS is risk communication.		x	x
<b>ANSES</b> – French Agency for Food, Environmental and Occupational Health and Safety	ANSES is responsible for risk assessment in the area of food safety, environmental and occupational health. ANSES also identifies (re)emerging health risks and prepares recommendations for risk management measures. ANSES is also active in the area of risk communication and conducts and participates in research.	x		x

The 1998 Act on health monitoring and safety control of products intended for human beings is the central foundation for food legislation in France.

Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are based on scientific risk assessment. However, the final decision on the legality of governmental measures rests with the courts.

In France risk assessment and risk management are institutionally separated. Risk assessments, scientific opinions and other statements are published on the Internet unless prohibited by statutory provisions.

France consists of 26 regions and 101 departments (five departments are located overseas). Feed and food inspections are carried out by regional and local offices of MAAPRAT and MEFI. Public authorities in the departments are also offices of the national ministries and report to the central government.

### ***Ministry of Agriculture, Food, Fisheries, Rural Affairs and Land Use Planning (MAAPRAT)***

#### **Tasks of MAAPRAT:**

- Agricultural policy, food safety
- Risk management
- Risk communication
- RASFF Contact Point

**Website:** <http://agriculture.gouv.fr>

MAAPRAT is responsible for agricultural policy, the safety of food of animal or plant origin and the safety of animal feed. MAAPRAT prepares draft legislation in this area and is also responsible for control and inspection. MAAPRAT uses risk assessments prepared by ANSES as the scientific foundation for risk management measures. MAAPRAT is also responsible for risk communication.

MAAPRAT's portfolio encompasses plant protection products, including residues, veterinary medicinal products, GMOs and zoonoses.

The area of work of MAAPRAT extends beyond food safety to plant health, plant protection, animal health and animal welfare. In France there are two RASFF Contact Points, one is at MAAPRAT the other at MEFI.

### ***Ministry of Economy, Finance and Industry (MEFI)***

#### **Tasks of MEFI:**

- Consumer policy, food safety
- Risk communication
- Risk management
- RASFF Contact Point

**Website:** <http://www.minefe.gouv.fr>

The MEFI is responsible for consumer policy including state food inspections of all products of non-animal origin. The MEFI uses risk assessment from ANSES as the scientific foundation for management measures.

The portfolio of the MEFI includes food supplements, novel foods, mineral water, residues of plant protection products and GMOs in food of non-animal origin (other aspects with regard to GMOs are covered by the High Council for Biotechnologies). The MEFI is also involved in risk communication activities

### ***Ministry of Health and Social Affairs (MASS)***

#### **Tasks of MEFI:**

- Health policy, food safety
- Risk communication
- Risk management

**Website:** <http://www.sante.gouv.fr>

MASS deals with health policy and food safety. MASS prepares draft legislation in the field of mineral and drinking water and is responsible for state drinking water inspections. MASS uses the risk assessments from ANSES as the scientific foundation for management measures. In collaboration with MAAPRAT, MASS is in charge of investigations on foodborne diseases. Another main area of MASS is risk communication.

### ***French Agency for Food, Environmental and Occupational Health and Safety (ANSES)***

#### **Tasks of ANSES:**

- Risk assessment
- Risk communication
- EFSA Focal Point
- Research, scientific & technical support

**Website:** <http://www.anses.fr>

ANSES is responsible for risk assessment in the area of food safety, environmental and occupational health. ANSES is supervised by five ministries, three of which have responsibilities in the area of food safety and risk management. These ministries use risk assessments prepared by ANSES as basis for risk management measures. ANSES also identifies (re)emerging health risks and prepares recommendations for risk management measures. ANSES is supported by national experts in 16 scientific advisory panels and related ad hoc working groups. ANSES is also active in the area of risk communication. ANSES actively conducts and participates in research. Eleven laboratories, holding numerous reference mandates (65 national, 12 OIE, 9 EU, 1 FAO and 1 WHO) are attached to ANSES.

In the area of food and feed safety, the activity of ANSES covers novel foods, food supplements, nutrition, drinking and mineral water, plant protection products, plant health, residues of veterinary medicinal products, animal health and welfare. ANSES is also responsible for the assessment of the safety of GMOs in the food and feed sector.

The National Agency for Veterinary Medicinal Products (ANMV) is a part of ANSES, and is the regulatory authority for veterinary medicinal products.

## **III – Food safety alerts management in FRANCE**

1. Does the competent authority (or authorities) for food safety have an established mechanism to evaluate and react to food safety crises (crises management mechanism)?	<b>Yes</b>
2. If the reply to Q1 is yes, does this mechanism include a committee or a body with pre-determined representatives?	<b>Yes</b>
3. If there is an established mechanism for crisis management (the reply to Q1 is Yes):	
3a. Do actors with risk assessment capacity participate directly in this mechanism?	<b>Yes</b>
3b. Do actors with risk management capacity participate directly in this mechanism?	<b>Yes</b>
3c. Do actors with risk communication capacity participate directly in this mechanism?	<b>Yes</b>

## IV – Characteristics of the food sector in France

**Number of enterprises<sup>1</sup>:** 13 500

**% of the industrial sector:** 19%

**% of the industrial workforce:** 19%

**% of industrial turnover:** 159 billion with 12 billion value added, 16.5% of added value in French industry

**Top subsectors (in terms of number of enterprises):** Meat processing (2,462), manufacture of pastry/bakery products and pasta (1,336), manufacture of dairy products (1,250) and processing of fruit and vegetables (1,082). The meat and dairy industries account for 41% of employees in the agri-food sector.

**Top subsectors (in terms of turnover):** The meat and dairy industries account for 38% of total revenue and 41% of employees in the agri-food sector. In 2011, the dairy industry revenue was € 25.5 million. French wines and dairy products such as cheese and butter are famous worldwide. In 2011, dairy products exportations represented € 6,179 million (17.7% of French agrofood exports) and wine exportations represented a revenue of € 7,171 million.

The agrofood industry is also contributing significantly to the health of French economy. France is one of the world's biggest producers and exporters of food worldwide. In 2011, the agrofood sector represented €159 billion in revenues (including small retail businesses), making it the leading sector in French industry and far ahead of the automotive industry. With €12 billion in added value, the agrofood sector produces just over 16.5% of added value in French industry. It represents the second French trade surplus with a 14% increase in sales in one year.

In 2011, the agrofood industry employed 576,325 people. This figure makes it the largest employer of the industrial sector in France, with 19.4% of industrial sector employees, 18.8% of its total revenue. 50% of employees work in firms composed by 250 employees or more. The agrofood industry is composed of 13,500 firms. 97% of them are either small-medium-sized enterprises (SME) (less than 250 employees) or small office/home offices (SOHO) (between 10 and 20 employees).

In 2011, with a production of € 151 billion, France was the largest agricultural producer in Europe (it produced 19% of all European agricultural goods). Agrofood production in volume has increased by 3.6% between 2010 and 2011. French agrofood industries transform 70% of the French agricultural production.

## V –Civil Society Organisations

**UFC-Que Choisir** - Union Fédérale des Consommateurs

**Web:** [www.quechoisir.org](http://www.quechoisir.org)

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***Country profile elaborated by:***

**Moez SANAA**

*Agence Nationale de Sécurité Sanitaire (ANSES)*

*Direction Evaluation des Risques*

*E-mail : moez.sanaa@anses.fr*

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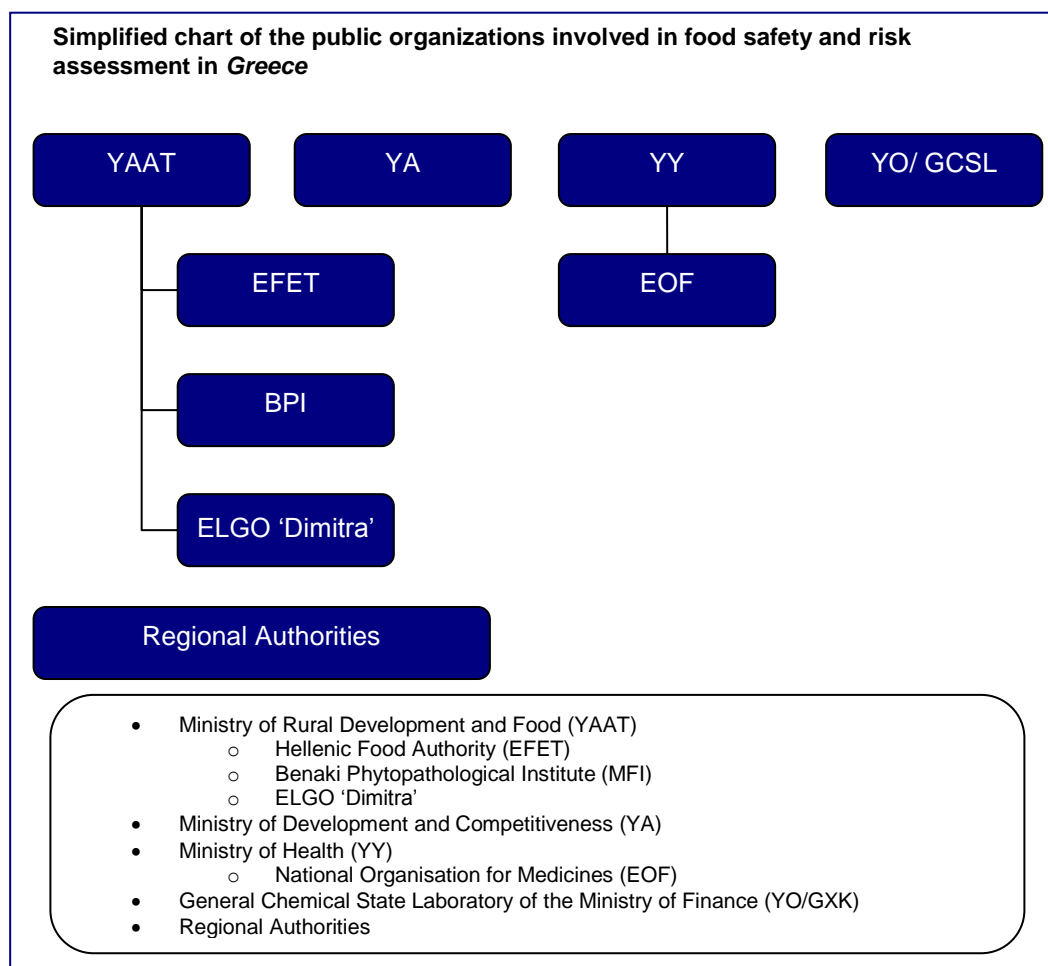
<sup>1</sup>INSEE-ESANE restatement of French Office of Statistics and Studies (SSP) of the Ministry of Agriculture, Food and Forestry. <http://www.insee.fr>

# Country Profile: Greece<sup>i</sup>

## I – Key priorities for risk assessment

- Emerging risks
- International cooperation for risk assessment
- Tools for risk assessment

## II – Major public actors involved in food safety (including risk assessment, management and communication)



## Main public organisations involved in food safety and roles - Greece

Organisation	Main areas of remit (in term of risk assessment/ management/ communication)	Risk assessment	Risk management	Risk communication
<b>YAAT</b> – Ministry of Rural Development and Food	Plant health, animal health – incl. aquaculture, agricultural products, feed; overview of food issues	x	x	x
<b>YA</b> – Ministry of Development and Competitiveness	Function of the market, consumer policy		x	x
<b>YY</b> – Ministry of Health	Mineral and drinking water, health policy	x	x	x
<b>EFET</b> – Hellenic Food Authority	Food (excl. agricultural products), food contact materials	x	x	x
<b>BPI</b> – Benaki Phytopathological Institute	Plant health and plant protection agents	x		x
<b>ELGO</b> ‘Dimitra’	Agricultural production	x		
<b>EOF</b> – National Organisation for Medicines	Veterinary medicines, foodstuffs for particular nutritional uses, food supplements	x	x	x
<b>YO/GCSL</b> – General Chemical State Laboratory (Ministry of Finance)	Chemical analyses of foodstuffs	x	x	

Regulation (EC) No. 178/2002 is the central legal foundation for food legislation in Greece. In the case of infringements of food law, the courts decide on measures under criminal law and, in cases of dispute, about consumers' damage claims *vis a vis* food businesses. Likewise, when it comes to the legality of state measures that are also frequently based on risk assessments, the courts are the ultimate decision-making body.

In Greece there is no institutional separation of risk assessment from risk management. Risk assessments are not, normally, published.

Greece participates in the EU policy making processes and in the relevant European Agencies and Bodies. Greece also participates in the work of Codex Alimentarius.

### ***Ministry of Rural Development and Food (YAAT)***

#### **Tasks of YAAT<sup>1</sup>:**

- Agricultural policy, food safety
- Risk assessment
- Risk communication
- Risk management

<sup>1</sup> Partial list including those tasks with relevance to food safety and risk assessment/ management/ communication

**Website:** [www.minagric.gr](http://www.minagric.gr)

YAAT deals with agricultural policy and, more particularly, with the food safety of **agricultural products** in Greece. In this area it implements horizontal and vertical legislation on food and feed and is responsible for the co-ordination of veterinary inspections. The basis for YAAT management measures are the risk assessments undertaken by YAAT itself and, in some cases, of bodies it supervises. Another focus of its work is transparent communication with the public at large.

The area of activity of YAAT includes, amongst other things, feed, residues of plant protection products and veterinary medicinal products, GMOs and zoonoses. In this context it monitors the carrying out of inspections by the local authorities. YAAT is the regulatory authority for plant protection products in Greece. By contrast, the National Organisation for Medicines is the regulatory authority for veterinary medicinal products.

15 National Reference Laboratories come under the remit of YAAT pursuant to Regulation (EC) No. 882/2004.

The area of work of YAAT extends beyond food safety to, for instance, plant health, plant protection, animal health, animal welfare and biocides.

### ***Ministry of Development and Competitiveness (YA)***

#### **Tasks of YA<sup>1</sup>:**

- Consumer policy
- Risk Management
- Risk Communication

**Website:** [www.mindev.gov.gr](http://www.mindev.gov.gr)

YA oversees, amongst others, the function of the market and the adherence of enterprises to the relevant law. The General Secretariat of Consumers is under YA and deals with consumer policy.

### ***Ministry of Health (YY)***

#### **Tasks of YY<sup>1</sup>:**

- Health policy, food safety
- Risk assessment
- Risk communication
- Risk management

**Website:** [www.moh.gov.gr](http://www.moh.gov.gr)

YY deals with health policy. It is responsible for risk assessment, risk communication and risk management in the field of mineral waters and drinking water.

### ***Hellenic Food Authority (EFET)***

#### **Tasks of EFET<sup>1</sup>:**

- Risk assessment
- Risk communication
- Risk management
- EFSA Focal Point
- RASFF Contact Point
- Codex Alimentarius Contact Point
- Training



**Website:** [www.efet.gr](http://www.efet.gr)

EFET is a public body under the supervision of YAAT. EFET deals with food supervision and food inspections in Greece, including food contact materials and bottled water but not including primary production facilities. Risk assessments undertaken by EFET itself are the basis for management measures and communication by EFET. EFET assesses food risks independently of any scientific, political or social interests. Another focus of its work is transparent communication with the public at large.

The area of activity of EFET includes, amongst others, novel foods, GMOs and residues of plant protection products. EFET has in-house laboratory facilities, however, in the framework of the needs of official control and risk assessment cooperates closely with other public bodies with relevant analytical capacity, including YO/GCSL, BPI, the Veterinary Services of YAAT, etc.

EFET is the national EFSA Focal Point, RASFF Contact Point and, also, Contact Point for Codex Alimentarius in Greece.

20 National Reference Laboratories are attached to EFET pursuant to Regulation (EC) No. 882/2004.

The area of work of EFET extends beyond food safety to, for instance, nutrition and labelling.

### ***Benaki Phytopathological Institute (BPI)***

#### **Tasks of BPI<sup>1</sup>:**

- Risk assessment for plant health/ plant protection products
- Risk communication
- Laboratory analyses
- Research
- Training

**Website:** [www.bpi.gr](http://www.bpi.gr)

BPI is a public body under the supervision of YAAT. When established, in 1929, it was the first Greek research institute to have a broad focus on plant health and plant protection. Amongst its other tasks and roles, BPI specialised in risk assessment and advice on the safe use of agricultural chemicals with regards to the protection of human health and of the environment. BPI has the infrastructure to perform all needed analyses and engage in relevant research projects.

### ***Hellenic Agricultural Organisation “Dimitra” (ELGO ‘Dimitra’)***

#### **Tasks of ELGO ‘Dimitra’<sup>1</sup>:**

- Agricultural research in support of risk assessment
- Certification of agricultural production systems and products
- Preparation and publication of optional sectoral standards and quality assurance specification for agricultural products
- Quality control of milk production
- Training

**Website:** [www.elgo.gr](http://www.elgo.gr)

ELGO ‘Dimitra’ is a public body under the supervision of YAAT. It includes units working on applied agricultural research, standards development and certification for agricultural processes and products, monitoring of milk production and training. While not directly aiming at risk assessment, ELGO ‘Dimitra’ can contribute to food safety via research, training and advice focused on the primary production sector.

### ***The National Organisation for Medicines (EOF)***

#### **Tasks of EOF<sup>1</sup>:**

- RASFF management

**Website:** [www.eof.gr](http://www.eof.gr)

EOF is responsible for medicinal products for veterinary use, foodstuffs intended for particular nutritional uses and food supplements.

### ***The General Chemical State Laboratory of the Ministry of Finance (MF/GCSL)***

#### **Tasks of MF/GCSL<sup>1</sup>:**

- Laboratory analyses
- Risk assessment

**Website:** [www.gcsf.gr](http://www.gcsf.gr)

GCSL, with its regional Services (Chemical Services), operates within the Ministry of Finance, is mainly responsible for the laboratory analysis of foodstuffs. At central level, GCSL co-ordinates and oversees the Chemical Services that carry out the official analysis. Further to that, GCSL has the capacity to undertake risk assessment or support risk assessment activities.

GCSL facilitates the operation of the Supreme Chemical Council, a body within the Ministry of Finance, which carries out legislative work and produces formal opinions on food product specifications and market requirements.

## **III – Food safety alerts management in Greece**

1. Does the competent authority (or authorities) for food safety have an established mechanism to evaluate and react to food safety crises (crises management mechanism)?	<b>Yes</b>
2. If the reply to Q1 is yes, does this mechanism include a committee or a body with pre-determined representatives?	<b>Yes</b> (however, ad hoc committees are also possible depending on the type of the incident)
3. If there is an established mechanism for crisis management (the reply to Q1 is Yes):	
3a. Do actors with risk assessment capacity participate directly in this mechanism?	<b>Yes</b> (however, there is also a separate body for risk assessment)
3b. Do actors with risk management capacity participate directly in this mechanism?	<b>Yes</b>
3c. Do actors with risk communication capacity participate directly in this mechanism?	<b>Yes</b>

## IV – Characteristics of the food sector in Greece

**Number of enterprises<sup>2</sup>:** 17000 (approximate), 95% of which correspond to very small enterprises (under 10 employees)

**% of the industrial sector:** 23% of the enterprises

**% of the industrial workforce:** 23%

**% of industrial turnover:** 26.2% corresponding to sales value of EUR 9.74 bn (2<sup>nd</sup> in rank)

**Top subsectors (in terms of number of enterprises):** Flour and bakery products; Production of fats and oils of plant or animal origin; Confectionary products, cocoa, spices.

**Top subsectors (in terms of turnover):** Dairy products; Drinks; Flour and bakery products.

## V – Civil Society Organisations

In Greece there are several CSOs with relevance to the food sector. Some focus on consumer rights and consumer protection (not necessarily foodstuff-specific), while others, within their mission objectives, act directly or indirectly towards food security (e.g., by offering food to vulnerable groups such as homeless people, etc.).

Amongst those, the consumer associations engage in the public dialogue for new legislation or market regulation regarding foodstuffs representing the interest of the consumers. Further to that, consumer associations often act as information multipliers towards consumers and also help strengthen consumer demand for quality food products.

Currently, there are 44 registered consumer associations, including associations with regional-only and nation-wide coverage.

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<sup>i</sup> **Country profile elaborated by:**  
**Gorgias GAROFALAKIS**  
Dpt. Nutrition Policy & Research  
Hellenic Food Authority  
E-mail: ggarofalakis@efet.gr

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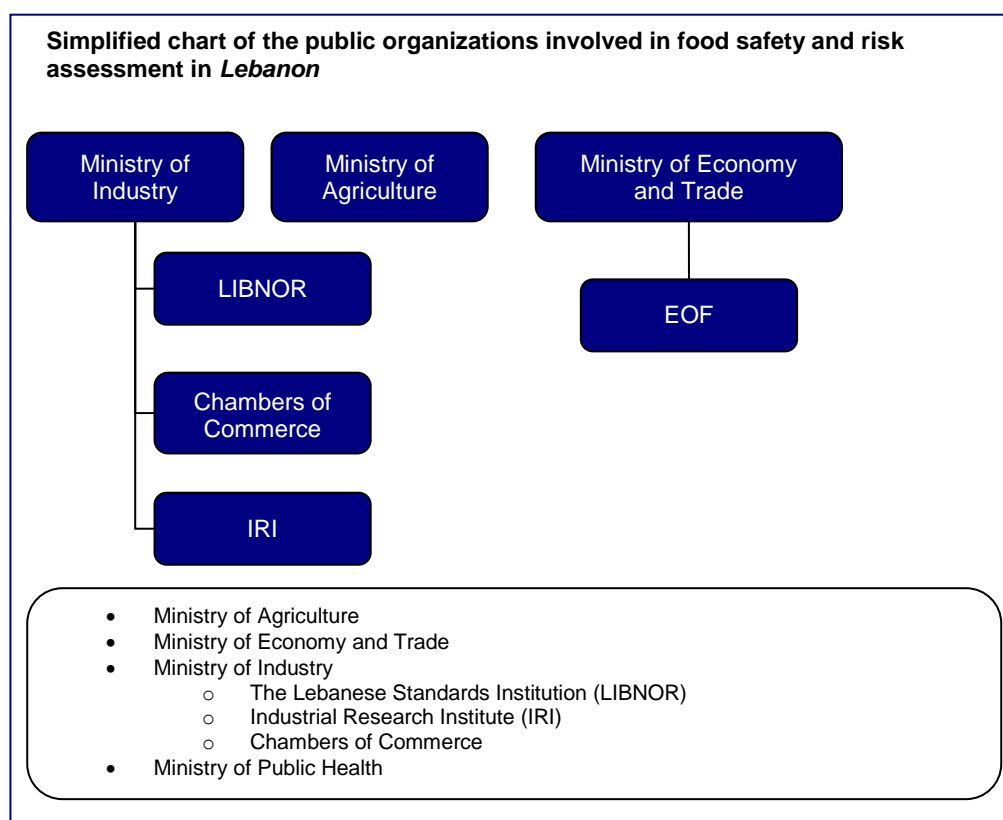
<sup>2</sup> Data referring to the characteristics of the secondary sector; Source: Foundation for Economic & Industrial Research (IOBE) 2011 (based on data of 2009).

# Country Profile: Lebanon<sup>i</sup>

## I – Key priorities for risk assessment

- Tools and funding for risk assessment
- A strategy for risk management and communication
- Emerging risks

## II – Major public actors involved in food safety (including risk assessment, management and communication)



## Main public organisations involved in food safety and roles – Lebanon

Organisation	Main areas of remit (in term of risk assessment/ management/ communication)	Risk assessment	Risk management	Risk communication
<b>Ministry of Agriculture</b>	Plant health, animal health, Food safety in farms/bakeries/fisheries/customs	x		x
<b>Ministry of Economy and Trade</b>	Food safety in retail outlets for goods and services	x		x
<b>Ministry of Industry</b>	Food safety in factories/manufacturing businesses	x		x
<b>Ministry of Public Health</b>	Raising awareness of hazards in food products			x
<b>LIBNOR – Lebanese Standards Institution</b>	Issuing of standards, certifying products with NL conformity mark, awareness of standards among industrialists	x		x
<b>IRI – Industrial Research Institute</b>	Biological and chemical analysis of food samples	x		x
<b>Chambers of Commerce</b>	Biological and chemical analysis of food samples	x		x

The Lebanese Standards Institution is the sole authority capable of issuing food standards. These standards do not become law until they have been reviewed and adopted by the Council of Ministers. The standards must then be published in the official gazette. Three months after publication, the law is reviewed (as an assessment of feasibility and practicality) by the council and made mandatory. A Minister of a certain Ministry is entitled to pass a law if there is a critical situation that may need to be immediately addressed.

In Lebanon, there is no separation between risk assessment and management. Risk assessments are not made available to the public and the government offers advice that may be considered risk management, but the business owners are obliged to carry out the risk management at their own expense.

LIBNOR is a member of the ISO and adopts most of ISO standards for Lebanese products. Lebanon is also involved with CODEX (not in creating standards but using standards already present).

Whilst keeping in mind that Lebanon is a developing country, it is very important to note that the constant political and security instability directly affects the work of ministries and governmental organizations.

## ***Ministry of Agriculture***

### **Tasks of the Ministry of Agriculture:**

- Risk Assessment of Food Safety in Farms/Factories/Fisheries/Customs
- Risk communication

**Website:** <http://www.agriculture.gov.lb/Arabic/Pages/Main.aspx>

The Lebanese Ministry of Agriculture is responsible for Food safety in the agricultural and livestock sectors. It is responsible for formulating and implementing legislation regarding the safety of livestock and crops, the work ethics required in farms, wheat factories and fisheries. It is also responsible for the monitoring of plant and animal products imported through customs.

The Ministry has regional offices in the 7 regions of Lebanon, and the Head of each regional office is responsible for monitoring food safety in the Office's regional jurisdiction. The Head of the individual offices will often send trained inspectors to farms or factories with a risk assessment and set list of requirements applicable in these facilities. Reports are then given to the owners of the facilities being inspected if improvements need to be made. If the facility fails to comply with requirements and does not make improvements, warnings are given and the file (which includes the reports, warnings, checklists, risk assessments) may be given over to the Ministry of Justice and other Legal authorities for further action to be taken.

The work of the Ministry often overlaps with the work of other Ministries, such as that of the Ministry of Industry, when inspections of manufacturing factories, are undertaken by the Ministry of Agriculture instead of the Ministry of Industry. This overlapping is not necessarily detrimental to the regulation of food safety, but may potentially lead to wasting of effort or time if more than one Ministry ends up performing the same work instead of organizing efficiently together, conflicts between ministries may occur.

For the processing of samples taken from inspection sites and other research generally related to the Ministry, the Ministry employs the IRI and the Chambers of Commerce and Trade. It also employs private laboratories such as those belonging to the American University of Science and Technology (AUST) and the American University of Beirut (AUB).

## ***Ministry of Economy and Trade***

### **Tasks of the Ministry of Economy and Trade:**

- Risk assessment of retail outlets for goods and services
- Risk communication
- Raising public awareness

**Website:** <http://www.economy.gov.lb/index.php/home/2>

The Ministry of Economy and Trade in Lebanon is responsible for the national economy and its competitiveness on the global scale. One of the units or bodies within the Ministry is the Directorate for Consumer Protection. The Directorate is responsible for the rights of consumers and ensuring that consumers receive the highest quality of goods and services available.

The Directorate has several different functions, which include receiving complaints and inquiries from consumers, inspecting retail outlets for goods and services, and educating the public on the rights of the consumer.

The Directorate has a special hotline for the public to call 24 hours a day (after hours messages are taken) and receives complaints by email and occasionally, from the Ministry of Telecommunications.

Retail outlets are subjected to random inspections, where the conditions of the workplace and safety of the products are assessed and samples are taken for laboratory analysis. Trained professionals from different fields carry out inspections on retail outlets for goods and services ranging from corporate companies to franchises, to small shops and restaurants.

The Directorate educates the public through seminars and awareness campaigns it runs. However, one of the main achievements of the Directorate and the Ministry of Economy and Trade is the publishing of the Law of Consumer Protection, available in English on this site: <http://www.brandprotectiongroup.org/pdf/consumer.pdf>. The Law has been published in the Official Gazette and is available online in English and Arabic.

## ***Ministry of Industry***

### **Tasks of the ministry of Industry:**

- Risk assessment in Factories
- Risk communication

**Website:** <http://www.industry.gov.lb/Arabic/Arabic/Pages/default.aspx>

The Lebanese Ministry of Industry is committed to the enhancement of the industrial sector and to the implementation of industry laws in all its domains. The Ministry implements food safety laws and decrees by carrying out regular inspections on all factories in the country, advising the requirements needed to meet standards, and issuing warnings in some cases. In extreme cases, the Ministry has the right to close industrial businesses if these businesses fail to comply with warnings. The Ministry may also carry out random inspections if a business owner wishes to receive a license for their business, or if complaints are made against a certain business company/factory/etc.

The Ministry has patronage over a number of public agencies that are involved in food safety. These include LIBNOR and the Chambers of Commerce, which will be discussed in this document. The Ministry is hence involved in acting as the link between these agencies and the Council of Ministers, and is involved in the election of members and the passing of legislation in these agencies.

## ***Ministry of Public Health***

### **Tasks of the Ministry of Public Health:**

- Public awareness
- Health safety

**Website:** <http://www.moph.gov.lb/Pages/Home.aspx>

The Ministry of Public Health is concerned with raising public awareness against certain hazards in food samples.

## ***The Lebanese Standards Institution (LIBNOR)***

### **Tasks of LIBNOR:**

- Issuing of standards
- Certifying products with NL conformity mark
- Contact point for ISO

**Website:** <http://www.libnor.org/>

LIBNOR was established in 1962, under the patronage of the Ministry of industry. It remains the sole institution with the right to issue and amend Lebanese standards. LIBNOR issues and

publishes vertical and horizontal standards pertaining to international and local products (food products that are only produced in Lebanon). LIBNOR is a member of the International Organisation for Standardisation (ISO) and often uses ISO to issue standards on food products unique to Lebanon. LIBNOR is also involved with CODEX.

In addition to issuing and publishing standards, LIBNOR gives products the NL conformity mark, which certifies that a product meets the required safety standards relating to it. LIBNOR has no responsibility to monitor products in the market, but may conduct assessments on products with the NL mark, to ensure the products still meets the required standards.

### ***Industrial Research Institute (IRI)***

#### **Tasks of IRI:**

- Research
- Analysis of samples

**Website:** <http://www.iri.org.lb/>

The IRI is a public research facility linked to the Ministry of Industry and is responsible for analysing the food samples to assess if standards and qualifications are met. General scientific research is also conducted in the IRI. However this function of the IRI is currently non-operational.

### ***Chambers of Commerce***

#### **Tasks of Chambers of Commerce:**

- Analysis of product samples

**Websites:** <http://www.ccib.org.lb/en/>

<http://www.ccias.org.lb/index.php?lang=en>

<http://www.cciaz.org.lb/en/TrainingCenter.aspx>

The Lebanese Chambers of Commerce were enacted in 1967 by the decree 36/67, however chambers of commerce were established in Lebanon before the Lebanese Republic by the Ottoman Empire.

There are four chambers in Lebanon:

1. The Chamber of Commerce, Industry and Agriculture of Beirut and Mount-Lebanon.
2. The Chamber of Commerce; Industry and Agriculture of Tripoli and the North.
3. The Chamber of Commerce, Industry and Agriculture of Saida and the South.
4. The Chamber of Commerce, Industry and Agriculture of Zahle and the Bekaa.

These chambers are committed to the smooth running of the economy and businesses in the country. They are often employed by the government and the private sector to conduct analysis of food product samples. They assess whether the products meet standards set by LIBNOR.



### III – Food safety alerts management in Lebanon

1. Does the competent authority (or authorities) for food safety have an established mechanism to evaluate and react to food safety crises (crises management mechanism)?	<b>No</b>
2. If the reply to Q1 is yes, does this mechanism include a committee or a body with pre-determined representatives?	<b>No</b> (no committees are formed specifically for crisis management)
3. If there is an established mechanism for crisis management (the reply to Q1 is Yes):	
3a. Do actors with risk assessment capacity participate directly in this mechanism?	-
3b. Do actors with risk management capacity participate directly in this mechanism?	-
3c. Do actors with risk communication capacity participate directly in this mechanism?	-

### IV – Characteristics of the food sector in Lebanon (referred to as the Agro-food sector in Lebanon)

**Number of enterprises<sup>1</sup>:** 736 companies

**% of the industrial sector:** 18.2%

**% of the industrial workforce:** 24.9%

**% of industrial turnover:**

**Top subsectors (in terms of number of enterprises):** Bakery, Milk and Dairy products, and preserved vegetables and Fruits.

**Top subsectors (in terms of turnover):**

### V – Civil Society Organizations

There is a small number of NGOs in Lebanon that are involved in food safety. The main goals of these organizations are raising public awareness of the potential hazards that exist in food, the proper methods for food handling, and healthy diet alternatives. Some of these organizations often pressure the government to improve the regulation of food safety in the country and may adopt and bring to light cases of fatal or critical food poisoning.

Civil society members feel that the government falls short of regulating food safety because of the political instability in the country. They also feel that their requests for improvement are ignored and that they need to wait for the opportune moment when there is some stability and security to tackle the government with these issues.

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<sup>i</sup> **Country profile elaborated by:**

**Zeina KASSAIFY**

*Faculty of Agricultural & Food Sciences, American University of Beirut*

*E-mail: zeinakassaify@gmail.com*

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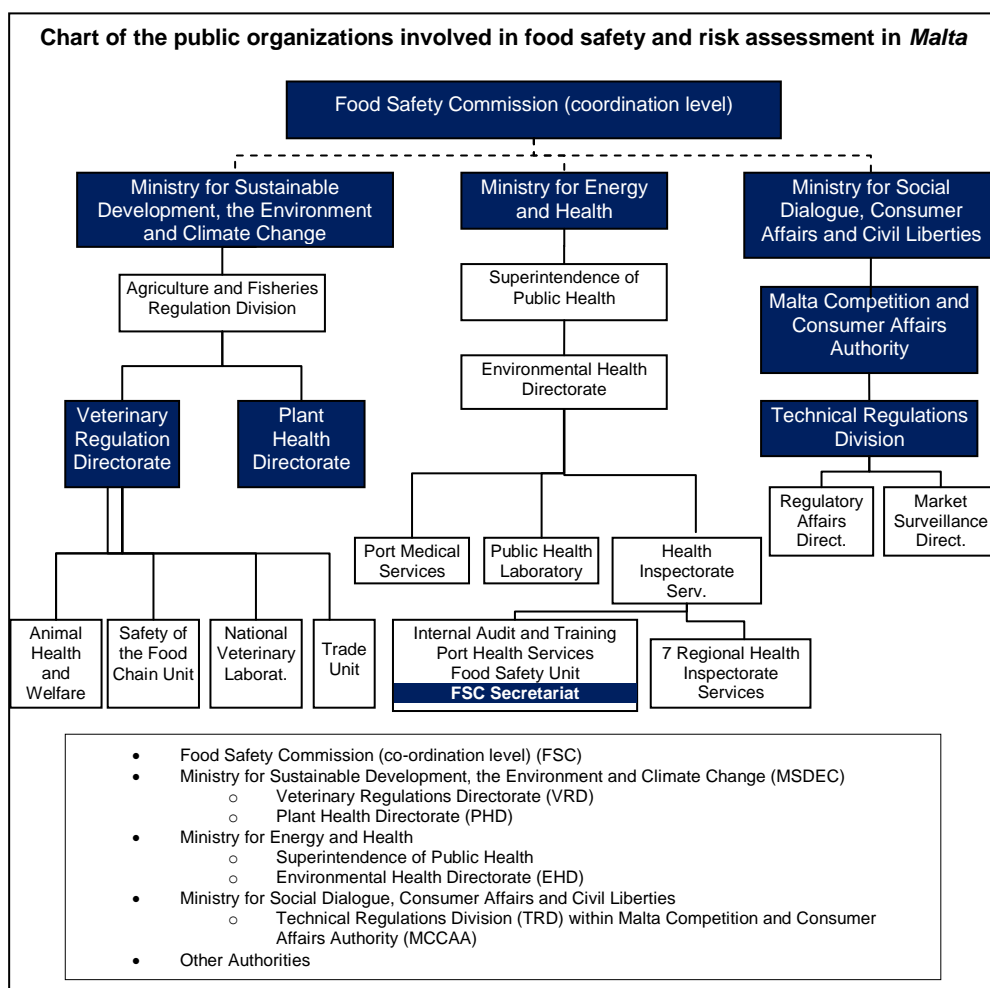
<sup>1</sup> AGROFOOD FACT BOOK, Investment Development Authority of Lebanon (IDAL), 2012.  
<http://investinlebanon.gov.lb/Content/uploads/SideBlock/131216042540287~Agrofood%20fact%20book.pdf>

# Country Profile: Malta<sup>i</sup>

## I – Key priorities for risk assessment

- Emerging risks
- European Union Member State cooperation for risk assessment: plant protection products, chemicals, botanicals in food supplements, novel foods, substances used in food contact materials and GMO varieties used for human consumption.
- Tools for risk assessment

## II – Major public actors involved in food safety (including risk assessment, management and communication)



Two Ministries have the main responsibilities for food safety, animal health, animal welfare and plant health in Malta

- the Ministry for Sustainable Development, the Environment and Climate Change (MSDEC) which includes the Veterinary Regulations Directorate and the Plant Health Directorate within the Agriculture and Fisheries Regulation Department.
- the Ministry for Energy and Health (MEH) which includes the Environmental Health Directorate (EHD) within the Superintendence of Public Health.

The Technical Regulations Division (TRD) within the Malta Competition and Consumer Affairs Authority (MCCAA) (under the portfolio of the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties) acts on behalf of MSDEC for plant protection products, and on behalf of the Ministry for Energy and Health for food risk assessment;

Co-ordination between these two Ministries on food safety issues takes place through the Food Safety Commission (FSC), which is an independent Government co-ordinating body established under the Food Safety Act of 2002. The FSC reports to and advises the Minister for Energy and Health.

Generally, Malta has a national centralised system. Due to the small scale of the services, the offices at central level are responsible not only for policy and co-ordination but also for direct implementation of controls.

#### Main public organisations involved in food safety and roles - Malta

Organisation	Main areas of remit (in term of risk assessment/ management/ communication)	Risk assessment	Risk management	Risk communication
<b>FSC</b> – Food Safety Commission	Co-ordinating function			x
Ministry for Social Dialogue, Consumer Affairs and Civil Liberties <b>MCCAA</b> – Competition and Consumer Affairs Division	Risk communication			x
Ministry for Social Dialogue, Consumer Affairs and Civil Liberties. <b>TRD</b> – Technical Regulations Division	Risk assessment	x		x
Ministry for Energy and Health. <b>EHD</b> – Environmental Health Directorate	Risk management		x	
Ministry for Energy and Health. Health Promotion and Disease Prevention Directorate				x
Ministry for Sustainable Development, the Environment and Climate Change <b>PHD</b> – Plant Health Directorate	Risk management		x	

## Main public organisations involved in food safety and roles - Malta

Organisation	Main areas of remit (in term of risk assessment/ management/ communication)	Risk assessment	Risk management	Risk communication
Ministry for Sustainable Development, the Environment and Climate Change. <b>VER</b> – Veterinary Regulation Directorate	Risk management		x	
Ministry for Sustainable Development, the Environment and Climate Change. Malta Environment and Planning Authority	Risk management		x	

Regulation (EC) No. 178/2002 is the central legal foundation for food legislation in Malta. In the case of infringements of food law, the courts decide on measures under the Food Safety Act (Chapter 449)

In Malta, there is institutional separation of risk assessment from risk management.

Risk assessments are not normally published.

Malta participates in the EU policy making processes and in the relevant European Agencies and Bodies.

Malta also participates in the work of Codex Alimentarius.

### **Food Safety Commission (FSC)**

**Website:** <https://www.gov.mt/en/Services-And-Information/Business-Areas/Health%20Services/Pages/Food-Safety-Commission.aspx>

The Food Safety Commission (FSC) is an independent statutory body, set up to co-ordinate the functions of all Competent Authorities responsible for food safety in Malta. The Commission is chaired by the Superintendent of Public Health within the Ministry for Energy and Health. Directors of Authorities responsible for food safety throughout the food chain and covering the areas of risk management, risk communication and risk assessment are represented within the FSC.

These include the Environmental Health Directorate (EHD), Veterinary Regulation Directorate (VRD), the Plant Health Directorate (PHD), the Technical Regulations Division (TRD) within the Malta Competition and Consumer Affairs Authority (MCCAA), the Malta Environment and Planning Authority (MEPA), and the Office for Consumer Affairs within the Malta Competition and Consumer Affairs Authority, and the Directorate of Health Promotion and Disease Prevention. Each competent authority has signed a Memorandum of understanding with the FSC.

The Food Safety Commission Secretariat (FSCS) organises the activities of the Food Safety Commission in order to satisfy its commitments as laid down by the Food Safety Act. The Food Safety Commission Secretariat co-ordinates the work of the FSC members regarding their obligations vis-à-vis the official control of foodstuffs. It acts as the link with local and international organisations, the food industry and individuals for the benefit of the consumer. The outcomes of FSC meetings are recorded and consensus is required before a decision is taken. The decisions or recommendations coming from these meetings are not legally binding for the competent authority. However, the FSC could advise the Minister of Health to take certain actions if necessary.

Competent authorities may organise *ad hoc* meetings with other authorities if and when needed, including Customs Services and Police Administrative Law Enforcement Section.

Due to the small scale of the services in Malta, the offices at central level are responsible not only for policy and co-ordination but also for direct implementation of controls (except EHD).

In summary, the FSC is responsible for monitoring, co-ordinating and reviewing all practices, operations and activities relating to food by:

- applying the precautionary principle on identifying risks to consumers;
- monitoring the enforcement of relevant legislation;
- administering the Rapid Alert System for Food and Feed (RASFF);
- formulating and implementing policies and strategies;
- providing advice to the Minister responsible for Public Health;
- carrying out studies, research and investigations;
- ensuring proper records and registers are kept;
- issuing guidelines as necessary.

### ***Veterinary Regulations Directorate (VRD)***

Belongs to the **Ministry for Sustainable Development, the Environment and Climate Change (MSDEC)**

**Website:** <http://vafd.gov.mt/home>

Within the Veterinary Regulations Directorate (VRD), the Heads of the Units report to the Director supervising the work of their sections. Manuals, standard operating procedures and guidelines are prepared by officers within the sections, reviewed and approved by the head of sections, unit or the Director. Internal and external training is prepared according to an internal procedure. Monthly management meeting are organised and minuted.

#### ***Food and feed***

The main objective of the Veterinary Regulation Directorate is to ensure that there is a comprehensive and integrated system of official controls from 'farm to fork' which contributes to protecting public and animal health and safeguarding consumer interests. The aim is that such a system contributes, in particular, to the following objectives:

- reduces food-borne illness;
- limits and monitors the risks to consumers from chemical contamination
- helps consumers make informed choices by running information campaigns
- protects consumers from food fraud and illegal practices
- improves collaboration with various competent authorities
- prepares national implementing legislation if and when required

These objectives are closely linked to specific key strategic and targets of the Directorate.

#### *Animal health and animal welfare*

The specific objectives of an effective system of official controls in the animal health and animal welfare sectors is to protect public and animal health, promote the welfare of animals, prevent, control and eradicate disease.

These objectives link closely with achieving specific key Directorate's strategic and business plans and targets.

### ***Plant Health Directorate (PHD)***

Belongs to the **Ministry for Sustainable Development, the Environment and Climate Change (MSDEC)**

**Website:** <http://www.agric.gov.mt/plant-health-dept-profile?l=1>

The Plant Protection Board (PPB) was set up in 2008 as a statutory advisory board and is constituted in terms of the Plant Quarantine Act (Cap. 433). All the various stakeholders are represented on this Board. Consultations and discussions on phytosanitary matters are taken care of by this Board. In addition the PHD may issue a consultation process to other relevant competent authorities and stakeholders not represented on the Board.

The main objectives of the Plant Health Directorate are

- to prevent the spread and introduction of primarily quarantine pests of plant material and plant products but also of pests and diseases affecting quality and to promote appropriate measures for their control;
- as the Maltese National Plant Protection Organization (NPPO), to co-ordinate and regulate activities to control the introduction and dispersion of major pests and diseases harmful to plant production and to encouraging the production of good quality and healthy plants, as foreseen in the International Plant Protection Convention (IPPC) and the European Union's legislative provisions;
- to monitor the market of propagation material in the Maltese territory with the aim of having available in circulation high quality propagation and planting material. This Directorate also deals with plant variety rights and the conservation of plant genetic resources;
- to prevent the entry of harmful organisms through examining imported consignments from third countries through identity and physical checks, and accompanying documentation;
- to monitor and carry out surveillance of intra-trade EU commodities (plant and plant products) and local production of plants and plant products to maintain the plant health status of Malta.

### ***Superintendence of Public Health: Environmental Health Directorate***

Belongs to **Ministry for Energy and Health (MEH)**

**Website:** <https://www.gov.mt/en/Services-And-Information/Business-Areas/Health%20Services/Pages/Environmental-Health-Unit.aspx>

Between EHD regional offices and units there is a direct line of command and co-ordination of activities. EHD provides regional offices and units with national plans, implementing rules and SOPs, guidelines and training. It also organises co-ordination meetings with management to

discuss general problems. In addition to this, EHD initiate monthly meetings with local units, and organise regular seminars.

The main objective of the Environmental Health Directorate is to promote and safeguard the well-being and health of the public from adverse environmental effects.

The Environmental Health Directorate strives to be the leader as an official control body in the fields of environmental health and food control. The aim is to have in place a workforce that:

- is aware of the needs of the Directorate's stakeholders
- has a sense of responsibility and belonging
- is accountable
- is able to work in a flexible and professional manner.

The Environmental Health Directorate leads programmes that promote the attainment of the highest standards of public health and hygiene by addressing risk factors associated with environmental hazards. The Directorate is responsible for safeguarding the health and well being of the public through the enforcement of legislation derived from the European Union, National and International legislation.

Functional units of Environmental Health Directorate include the Health Inspectorate Services, Public Health Laboratory, and Port Medical Services.

### ***Technical Regulations Division (TRD) within Malta Competition and Consumer Affairs Authority (MCCAA)***

Belongs to the **Ministry for Social Dialogue, Consumer Affairs and Civil Liberties**

**Website:** <http://mccaa.org.mt/en/regulatory-affairs-directorate>

The main objectives of the Malta Competition and Consumer Affairs Authority within the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties are the attainment and maintenance of well-functioning markets for the benefit of consumers and economic operators. Other objectives are:

- to promote and enhance competition;
- to safeguard consumers' interests and enhance their welfare;
- to promote voluntary standards and provide standardization related services;
- to promote the national metrology strategy;
- to promote the smooth transposition and adoption of technical regulations; and
- to perform such other function that may be assigned to it under this or any other law or regulations.

The Technical Regulatory Division within the Malta Competition and Consumer Affairs Authority (under the portfolio of the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties) acts on behalf of MSDEC for plant protection products, and on behalf of the Ministry for Energy and Health, for food risk assessment.

### ***Other authorities***

Other authorities with responsibilities in relation to food safety are:

- the **Office for Consumer Affairs** within the Malta Competition and Consumer Affairs Authority (Ministry for Social Dialogue, Consumer Affairs and Civil Liberties) - responsible for safeguarding consumer interests as envisaged by the provisions of the Consumer Affairs Act;
- the **Health Promotion and Disease Prevention Directorate** within Ministry for Energy and Health is responsible for food safety and nutrition policy in the context of health promotion;
- the **Environment Protection Department** within the Malta Environment and Planning Authority (MEPA) responsible for environmental issues (packaging waste, environmental impact of agricultural activity) and for genetically modified organisms.

### III – Food safety alerts management in Malta

1. Does the competent authority (or authorities) for food safety have an established mechanism to evaluate and react to food safety crises (crises management mechanism)?	<b>Yes</b>
2. If the reply to Q1 is yes, does this mechanism include a committee or a body with pre-determined representatives?	<b>Yes, a committee with pre-determined representatives exists and it can include additional members if needed for a specific crisis</b>
3. If there is an established mechanism for crisis management (the reply to Q1 is Yes):	
3a. Do actors with risk assessment capacity participate directly in this mechanism?	-
3b. Do actors with risk management capacity participate directly in this mechanism?	-
3c. Do actors with risk communication capacity participate directly in this mechanism?	-

#### ***Mechanism to evaluate and react to a food safety crisis***

This mechanism is in virtue of Article 13 of Regulation (EC) 882/2004 with respect to crisis management and the implementation of a contingency for feed and food, and the measures to be taken especially with respect to the channels and procedures for sharing information between the relevant parties as required by paragraph 2(c). A list of the administrative authorities to be engaged as required by article 13, 2(a) and their powers and responsibilities as required by article 13, 2(b) is also attached as annex 6.

#### ***Top Down approach***

When information of a national crisis is received from a Head of Department, Political figure or any other high ranking official within the Public Service, the information is normally passed on to one of the National Crisis Coordinators. Action taken is dependent on the urgency and nature of



the crisis. If the crisis is within the remit of the entity represented by the national crisis coordinator, action is taken and limited within that entity. Should the crisis involve more than one entity, the national crisis coordinator communicates with the other national crisis coordinators and together decide on a way forward. If the crisis is widespread and requires that an urgent meeting of the Food Safety Commission be convened in order to discuss and decide on any action required, the secretary of the Food Safety Commission is contacted and a meeting convened at a very short notice, even within the same day. The Food Safety Commission can and will invite any other entity to be present for such a meeting.

### ***Bottom Up approach***

If information of a national crisis is received at a regional office, either through EHOs within regions or within any other regional office of the various entities scattered around the island, the officer receiving the information will inform his immediate superior and the information is passed up the chain of command until one of the national crisis coordinators is informed. Action taken will follow the procedure mentioned for the top down approach.

### ***Contingencies arising after office hours***

The Health Inspectorate Services within the Environmental Health Directorate implements a round the clock, 24/7 On-Call Duty roster covering the whole of Malta as well as Gozo. With such an on call system, 13 Environmental Health Officers are kept on standby duty after office hours should a contingency arise. Officers normally perform on call duty on a weekly basis and a copy of the On Call Duty Roster is sent to operator of Mater Dei Hospital. Once Mater Dei Hospital is alerted with a food related contingency, the Senior Environmental Health Practitioner on call duty is immediately informed who in turn informs the Director for Environmental Health. Action taken is commensurate with the extent of the contingency and the procedure adopted for the top down approach is then implemented.

Also included on the on call duty roster is an official who has 24/7 access to the Rapid Alert System on Food and Feed (RASFF). Should a contingency develop via RASFF, the official on call duty informs the Director for Environmental Health and action taken is again commensurate with the urgency of the case. The official on call duty on RASFF will inform RASFF should a local contingency involve other member states.

## **IV – Characteristics of the food sector in Malta**

The number of food premises that are registered with the Food Safety Commission is 8126.

### **Number of enterprises:**

**% of the industrial sector:** N/A

**% of the industrial workforce:** N/A

**% of industrial turnover:** N/A

### **Top subsectors (in terms of number of enterprises):**

The top 5 food categories (no. of establishments) are:

1. Catering Establishment - 2930
2. Retailers - 2430
3. Miscellaneous - 1494 (Importers first seller, wholesalers, food transport, temperature controlled vehicles, cold stores, stores, reception halls, vending machines)
4. Hawkers - 762
5. Manufacturing - 459

The top 5 sub-categories are:

1. Snack bar/cafeteria/takeaway - 1103
2. Restaurant - 728
3. Grocery includes self-service, mini market etc. - 773
4. Temperature controlled vehicle – 518
5. Bar – 462

The number of registered Food Handlers having non-expired cards (licenses) is 36388.

**Top subsectors (in terms of turnover):** N/A

## **V – Civil Society Organisations**

### ***Consumers' Association Malta***

**Website:** <http://www.camalta.org.mt/site/home.php>

In Malta there exists one consumer association (Consumers' Association Malta; CA Malta). This association acts as a representative for the local consumers on several national boards, amongst them, the Malta Competition and Consumer Affairs Authority (MCCAA), the Medicines Committee and the Consumers' Affairs Council which is a national board whose primary focus is to advise the Minister responsible for consumer affairs on policy and legislation. CA-Malta also represents consumers on other boards mainly the Users' Boards of Public Utilities as well as representing the local consumers in international fora especially at EU level.

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<sup>i</sup> **Country profile elaborated by:**  
**Flavia ZAMMIT**

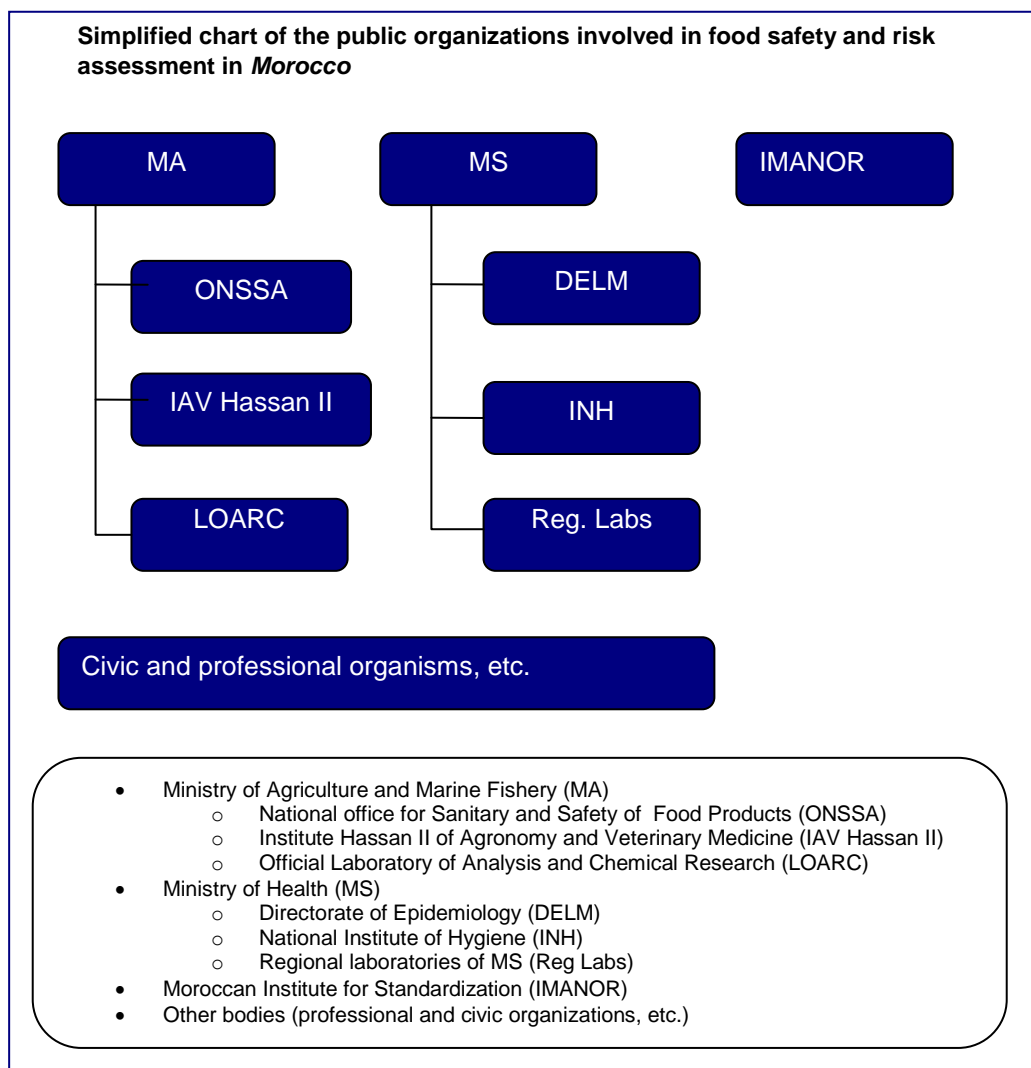
*Regulatory Affairs Directorate, Technical Regulations Division  
Malta Competition and Consumer Affairs Authority, MCCAA  
E-mail: [flavia.zammit@mccaa.org.mt](mailto:flavia.zammit@mccaa.org.mt)*

# Country Profile: Morocco<sup>i</sup>

## I – Key priorities for risk assessment

- Emerging foodborne pathogens
- Risk assessment of food contaminants (pesticides, mycotoxins) and additives
- Tools for risk assessment

## II – Major public actors involved in food safety (including risk assessment, management and communication)



## Main public organisations involved in food safety and roles – Morocco

Organisation	Main areas of remit	Risk assessment	Risk management	Risk communication
<b>MA</b> – Ministry of Agriculture and Marine Fishery	Plant health, animal health – Fishery, agricultural products, animal feeds	x	x	x
<b>ONSSA</b> – National office for Sanitary and Safety of Food Products	Animal health, food safety	x	x	x
<b>LOARC</b> – Official Laboratory of Analysis and Chemical Research	Food safety	x		
<b>IAV Hassan II</b> – Institute of Agronomy and Veterinary Medicine (IAV Hassan II)	Training- Food safety, animal health, research & cooperation	x		
<b>MS</b> – Ministry of Health	Human health, food safety, environmental health	x	x	x
<b>DELM</b> – Directorate of Epidemiology	Human health, food safety, environmental health	x	x	x
<b>INH</b> – National Institute of Hygiene	Training, food safety, environmental health- research & cooperation	x		
<b>Reg Labs</b> – Regional Laboratories for Environmental Health	Food safety, environmental health	x		
<b>IMANOR</b> – Moroccan Institute for Standardization	Production of standards, certification, training	x		

### **National legislation**

- Law N° 25-08 on the creation of the National Office of Food Safety products (ONSSA)
- Law No. 12-06 on the standardization, certification and accreditation, law creating the IMANOR
- Law No. 28-07 on the safety of food products. The principal objectives of this law are:
  - o Establishment of the general principles of food safety in Morocco,
  - o Determination of the conditions under which food and feed should be developed, produced and marketed to be called safe product,
  - o Indication of mandatory consumer information rules, via labeling of food and feed.

### **Ministry of Agriculture and Marine Fishery (MA)**

#### **Tasks of MA:**

- General agricultural policy
- Food and plant health
- Risk assessment
- Risk management
- Risk communication

**Website:** <http://www.agriculture.gov.ma>

MA of Morocco has the charge to define and implement the Government's policy in the field of agricultural development. It carries out studies and research for the development of agriculture at regional and national levels. It is in charge to develop legal and regulatory texts relating to agricultural activities; it also collect, analyze and disseminate statistics and agricultural information. MA conducts also all prospective studies on research opportunities for profitable crop and livestock production. MA develops government policy on the safety of plants, animals and food products throughout the country and at border posts.

### ***National office for Sanitary and Safety of Food Products (ONSSA)***

#### **Tasks of ONSSA:**

- Plant health
- Animal health
- Food safety
- Codex Alimentarius Focal Point
- Legislation

**Website:** <http://www.onssa.gov.ma>

ONSSA was created in 2008. It is in charge to implement the government policy on safety of plants, animals and food products from raw materials to the final consumer, including foods intended for animal feed. ONSSA is responsible for the health protection of animals and plants against diseases, protect public health by reducing the risk of diseases, ensure the safety of food products for sale including products of fisheries and aquaculture; improve sanitary and phytosanitary supervision; ensure the safety and quality and product compliance of food import and export regulations. Finally ONSSA implements the legal environment encouraging investment in the agro-industrial sector. Nowadays, ONSSA is composed of 3 national laboratories and 14 regional laboratories. ONSSA ensures the permanent secretariat of several national and technical Committees (CIPCARF, etc.), and it is the focal point of the National Committee of Codex Alimentarius.

### ***Institute of Agronomy and Veterinary Medicine (IAV Hassan II)***

#### **Tasks of IAV Hassan II:**

- Training
- Research
- Cooperation

**Website:** <http://www.iav.ac.ma>

IAV Hassan II Institute is a Polytechnic center of multidisciplinary expertise, it provides training in agricultural and life sciences and technologies (Engineers, Veterinary Doctors and Doctors in Agricultural Sciences). It actively contributes to the effort to modernize agriculture through the conduct of innovative research programs that meet the expectations and needs of changing world agriculture. Skills IAV extend the following areas:

- Agriculture and agricultural resources
- Rural development and spatial planning
- Environment and natural resources management
- Agro-industrial processing
- Plant, animal and microbial biotechnologies
- Veterinary Public Health
- Services associated with agricultural production, distribution and marketing.

## ***Official Laboratory of Analysis and Chemical Research (LOARC)***

### **Tasks of LOARC:**

- Food analysis (food composition, food additives and chemical contaminants)
- Quality control
- Fertilizers control
- Pesticides control

**Website:** [www.loarc.org](http://www.loarc.org)

LOARC was founded since 1914. The Laboratory was accredited according to COFRAC standards since 1999. LOARC is responsible for controlling the marketability of agricultural products (foodstuffs, fertilizers and pesticides). It conducts operations expertise in chemical and physico-chemical analyzes in accordance with the enabling legislation for this purpose.

In this context, the LOARC handles over 20,000 samples of food matrix annually in terms of composition and quality control of product safety, including research and quantification of food additives and contaminants (heavy metals , pesticide residues , mycotoxins, PAHs , PCBs , etc.), and detection of fraud and forgery .

## ***Ministry of Health (MS)***

### **Tasks of MS:**

- Global Health Policy
- Risk management
- Risk communication
- Risk assessment

**Website:** [www.sante.gov.ma](http://www.sante.gov.ma)

The MS is responsible for the development and implementation of government policy on population health. It works in conjunction with relevant departments, to promote the physical, mental and social well -being of the inhabitants. The MS harmonizes and coordinates policy objectives and actions or measures that contribute to raising the level of health in the country and works to ensure, at national level, a better allocation of resources for prevention, care curative or assistance.

## ***Directorate of epidemiology (DELM)***

### **Tasks of DELM:**

- Epidemiological studies
- Risk management
- Risk assessment
- Risk communication

**Website:** [www.sante.gov.ma](http://www.sante.gov.ma)

DELM is a central Directorate of the MS. It is in charge to ensure the epidemiological surveillance of the population and hold a central epidemiological file. DELM assess the epidemiological characteristics of the population. It performs all surveys and studies in epidemiology. DELM is in charge to design and implement programs to fight against diseases, contributing to the surveillance, monitoring and control as well as monitoring in the environment and ensuring the sanitary control of foodstuffs. Recently a new committee on risk assessment of chemical contaminants in foodstuffs has been set by the MS. This committee is coordinated by the DELM.

## ***National Institute of Hygiene (INH)***

### **Tasks of INH:**

- Training, research and cooperation
- Quality control
- Analytical and technical support
- Epidemiological surveillance based on laboratory data
- Risk assessment

**Website:** [www.sante.gov.ma/INH](http://www.sante.gov.ma/INH)

INH was created in 1930, it is the Moroccan national reference center of MS. INH is composed of several departments with different expertises especially in environmental health (microbiology, chemistry and toxicology). It has several missions: analytical and technical support of the programs of MS, training, research and cooperation. INH was implicated in different investigations and risk assessment studies especially for food-borne outbreaks and environmental contamination of the environment such as botulism crisis during 2000, food poisoning due to pesticides residues, air pollution, etc.

## ***Regional laboratories of MS (Reg Labs)***

### **Tasks of Reg Labs:**

- Training
- Quality control
- Analytical and technical support
- Epidemiological surveillance

**Website:** [www.sante.gov.ma](http://www.sante.gov.ma)

Reg Labs of the MS are in charge of epidemiological surveillance of the environment at the local and regional level by detection of sources and factors of contamination. Reg labs are in charge to collect information about microbiological and chemical hazards both of drinking water and foodstuffs.

## ***Moroccan Institute for Standardization (IMANOR)***

### **Tasks of IMANO:**

- Production of standards
- Certification of private and public organisms
- Training

**Website:** <http://www.imanor.ma>

IMANOR is the Moroccan official body responsible for standardization and was created in 2010. Through its new status as an organization with administrative and financial autonomy, IMANOR aims both to contribute to increasing the competitiveness of Moroccan firms and secondly, to provide support to public policies establishing conditions of economic competition, consumer protection, preservation of the environment and improvement of living conditions.

To achieve its objectives, IMANOR is responsible for:

- The production of Moroccan standards
- Certification of compliance with reference standards
- Publication and dissemination of standards and related products
- Training on technical standards and their implementation;
- Representation of Morocco to the international and regional standards organizations.

### III – Food safety alerts management in Morocco

1. Does the competent authority (or authorities) for food safety have an established mechanism to evaluate and react to food safety crises (crises management mechanism)?	<b>Yes</b>
2. If the reply to Q1 is yes, does this mechanism include a committee or a body with pre-determined representatives?	<b>Yes</b> ( a committee with pre-determined representatives exists and it can include additional members if needed for a specific crisis)
3. If there is an established mechanism for crisis management (the reply to Q1 is Yes):	
3a. Do actors with risk assessment capacity participate directly in this mechanism?	<b>Yes</b>
3b. Do actors with risk management capacity participate directly in this mechanism?	<b>Yes</b>
3c. Do actors with risk communication capacity participate directly in this mechanism?	<b>Yes</b>

### IV – Characteristics of the food sector in Morocco

**Number of enterprises<sup>1</sup>:** 2093 enterprises in 2011

**% of the industrial sector:** 26%

**% of the industrial workforce:** 22%

**% of industrial turnover:** The food industry sector generated in 2011 a value of about 29 billion MAD, or 29% of industrial GDP.

**Top subsectors (in terms of number of enterprises):** the fishing industries and exploitation of seafood sector is composed of 414 the enterprises.

**Top subsectors (in terms of turnover):** Mainly oriented towards export, the fishing industries and exploitation of seafood sector generates a turnover of MAD 14.8 billion, which represents nearly 50% of food exports, 10% of total exports of the country and around 2.5% of National GDP.

With a total cultivable agricultural land near 8.7 million hectares, Morocco has 16 regions, offering diverse opportunities with high added value. To develop a sector which represents 19% of national GDP<sup>1</sup>, Morocco put a new strategy in agriculture called the Green Morocco Plan (PMV). This plan was built with the objective to achieve an agricultural GDP of more than 100 billion dirhams (around 10 billion €) in 2020.

The leading products for export are from the processing of fruit and vegetables (46% of food exports, 30% towards the European Union), olive oil (and especially extra virgin olive oil,

<sup>1</sup> A. AMARA Ministre de l'Industrie, du commerce. Entretien avec le magazine LES ÉCO SUPPLÉMENTS – AGROALIMENTAIRE : Un secteur en ordre de marche VENDREDI 26 JUILLET 2013. Available at : <http://www.leseco.ma/images/stories/932/Speciale-Agroalimentaire.pdf>

<sup>2</sup> Focus sur l'agro-alimentaire au Maroc. EuroMed@Change Mai. 2013



Morocco is the 4<sup>th</sup> largest producer, with 10.6% share market), Argan oil, citrus (including 32.5% of production is destined for export markets), spices, medicinal and aromatic plants and essential oils (doubling exports between 2004 and 2009). Morocco has also an important fisheries industry, which represents today 2-3% of GDP, and not less than 12% of total exports<sup>2</sup>.

Around 95% of Moroccan companies in the food sector are SMEs, while a growing number of large companies as well as several food groups are being resized nationally. Recently, the multinational companies are increasing their presence in the Moroccan agro-industrial sector including the dairy industry and the non alcoholic beverages industry (juices).

## V – Civil Society Organisations (examples)

- **Professional association: FENAGRI.**  
Website : <http://www.fenagri.org>
- **Food safety association: Moroccan Society for Mycotoxicology MSM.**  
Website: [www.msm.org.ma](http://www.msm.org.ma)  
Email: [msm.maroc@yahoo.fr](mailto:msm.maroc@yahoo.fr)

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<sup>i</sup> **Country profile elaborated by:**

**Abdellah ZINEDINE**

*Département de Biologie, Faculté des Sciences*

*Université Chouaïb Doukkali*

*E-mail: [zinedineab@yahoo.fr](mailto:zinedineab@yahoo.fr)*

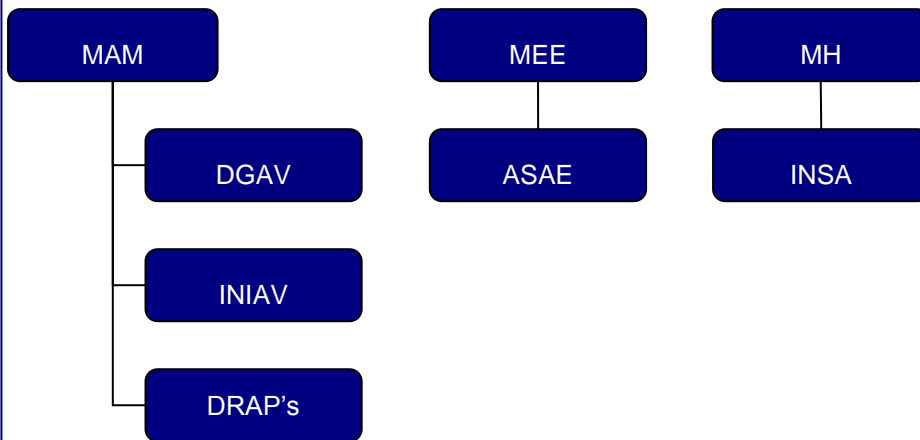
# Country Profile: Portugal<sup>i</sup>

## I – Key priorities for risk assessment

- Reliable databases on food safety.
- Better Laboratory results, better risk assessment authorities' decisions.
- Role of consumer organizations in decision process.

## II – Major public actors involved in food safety (including risk assessment, management and communication)

**Simplified chart of the public organizations involved in food safety and risk assessment in *Portugal***



- Ministry of Agriculture and Sea (MAM)
  - General Direction of Food and Veterinary (DGAV)
  - National Institute of Agrarian and Veterinary Research (INIAV)
  - Regional Directions of Agriculture and Fishing (DRAP's)
- Ministry of Economics and Employment (MEE)
  - Food Safety and Economics Authority(ASAE)
- Ministry of Health (MH)

## Main public organisations involved in food safety and roles – Portugal

Organisation	Main areas of remit (in term of risk assessment/ management/ communication)			
		Risk assessment	Risk management	Risk communication
<b>MAM</b> – Ministry of Agriculture and Sea	Food and feed Animal and plant health Contaminants Food contact materials GMO's	x	x	x
<b>DGAV</b> – General Direction of Food and Veterinary	Food and Feed Animal and plant health Contaminants Food contact materials GMO's	x	x	x
<b>INIAV</b> – National Institute of Agrarian and Veterinary Research	Food and Feed Animal and plant health GMO's		x	x
<b>MEE</b> – Ministry of Economics and Employment	Function of the market, consumer policy	x	x	x
<b>ASAE</b> – Food Safety and Economics Authority	Surveillance and prevention of economic activity legislation	x	x	x
<b>MH</b> – Ministry of Health	Health policy	x	x	x
<b>INSA</b> – Health National Institute	Additives and contaminants in food		x	x

### ***Ministry of Agriculture and Sea (MAM)***

#### **Tasks of MAM:**

- Agriculture policy
- Risk assessment, management and communication

**Website:** [www.portugal.gov.pt/pt/os-ministerios/ministerio-da-agricultura-e-do-mar.aspx](http://www.portugal.gov.pt/pt/os-ministerios/ministerio-da-agricultura-e-do-mar.aspx)

Ensure the enhancement, protection, quality and safety of agro-food primary production

### ***General Direction of Food and Veterinary (DGAV)***

#### **Tasks of DGAV:**

- Food and feed safety competent authority
- Risk assessment, management and communication
- RASFF contact Point

**Website:** [www.dgv.min-agricultura.pt](http://www.dgv.min-agricultura.pt)

Define and coordinate strategies to promote food safety, food for animals and materials in contact with foodstuffs in conjunction with the Food Safety and Economics Authority, as well as plant health and protection and health of animals.

Develop , coordinate and evaluate the implementation of plans of official control on the production and processing foodstuffs, the respective raw materials, ingredients and additives, materials in contact with foodstuffs and animal byproducts and feed.

Develop, coordinate and evaluate the implementation of plans of official control within the plant and waste pesticides, as well as official control plans relating to the protection and animal health, including actions hygiene and health inspection of animal products and implementation of prevention and control programs relating the animal or zoonotic nature of diseases.

Coordinate and audit the implementation of the various plans of official control by regional directions of agriculture and fisheries within their competence.

Coordinate the technical and regulatory activities relating the control and certification of propagation material plants, including the cultivation of plant varieties GM.

### ***National Institute of Agrarian and Veterinary Research (INIAV)***

#### **Tasks of INIAV:**

- Food and feed safety National Reference and Official Plans Laboratories
- Risk management and communication

**Website:** [www.iniaiv.pt](http://www.iniaiv.pt)

Develop the scientific and technological bases support the definition of sector policies.

Promote research activities, experimentation and demonstration, in line with the defined policies for the respective sectors, ensuring technical support and contributing to scientific development and innovation, improving competitiveness in agro-forestry areas, crop protection, food production, animal and plant health food security as well as to food technology and biotechnology application in those areas.

Ensuring the functions of the National Reference Laboratory particularly in the areas of food security, animal and plant health.

Cooperate with scientific and technological, national or international related institutions, and participate in scientific and technology activities, particularly in consortium networks and other ways of joint work, and promote exchange and transfer of knowledge with national or international public and private entities, in particular through the establishment of agreements and protocols of cooperation.

Participate in the preparation of official control plans in the areas of animal and plant health and food safety.

Perform laboratory analysis for the official control plans coordinated by MAM, within their areas of competence, namely, through the networking of accredited laboratories.

## ***Ministry of Economics and Employment (MEE)***

### **Tasks of MEE:**

- Promoting the rights of consumers
- Ensure a system of open, but balanced, economic competition

**Website:** [www.portugal.gov.pt/pt/os-ministerios/ministerio-da-economia-e-do-emprego.aspx](http://www.portugal.gov.pt/pt/os-ministerios/ministerio-da-economia-e-do-emprego.aspx)

## ***Food Safety and Economics Authority (ASAE)***

### **Tasks of ASAE:**

- Inspection of food chain
- Risk assessment, management and communication

**Website:** [www.asae.pt/](http://www.asae.pt/)

The Food Safety Authority and Economics, abbreviated as ASAE, whose mission is the inspection and prevention of the compliance of regulating legislation for the trade conduct in food and non-food sectors, as well as assessment, management and communication of risks in the food chain, being national liaison body with their bodies counterparts at European and international level;

It also characterizes and assesses the risks impact in food security, collaborating in the area of their responsibility with the European Safety Food Authority;

Supervise all places where there should be any industrial activity, tourism, trade, agriculture, fishing or services.

## ***Ministry of Health (MH)***

### **Tasks of MH:**

- Health policy

**Website:** [www.portugal.gov.pt/pt/os-ministerios/ministerio-da-saude.aspx](http://www.portugal.gov.pt/pt/os-ministerios/ministerio-da-saude.aspx)

## ***Health National Institute (INSA)***

### **Tasks of INSA:**

- Food safety and nutrition
- Risk management and communication

**Website:** [www.insa.pt/](http://www.insa.pt/)

INSA is active in the areas of food security and nutrition, with the vision to achieve gains in public health through the in-depth study of the situation of the country in the areas of food and human nutrition, health promotion, prevention of forborne illness and the improvement of the nutritional status of the population through research and development, surveillance, reference, providing differentiated services, training, information and advice.

Collaborates with similar institutions and other national and international organizations, including the World Health Organization (WHO), the Organization for Food and Agriculture of the United Nations (FAO) and the European Authority for Food Safety Authority (EFSA), participating in National and International Programs and Plans.

### III – Food safety alerts management in Portugal

1. Does the competent authority (or authorities) for food safety have an established mechanism to evaluate and react to food safety crises (crises management mechanism)?	<b>Yes</b>
2. If the reply to Q1 is yes, does this mechanism include a committee or a body with pre-determined representatives?	<b>No</b> , no committees are formed specifically for crisis management
3. If there is an established mechanism for crisis management (the reply to Q1 is Yes):	
3a. Do actors with risk assessment capacity participate directly in this mechanism?	-
3b. Do actors with risk management capacity participate directly in this mechanism?	-
3c. Do actors with risk communication capacity participate directly in this mechanism?	-

### IV – Characteristics of the food sector in Portugal

**Number of enterprises:** 13 098 (2013)

**% of the industrial sector:** 11 % of the enterprises

**% of the industrial workforce:** 21%

**% of industrial turnover:** 24%

**Top subsectors (in terms of number of enterprises):** Beverages, Flour and bakery products, Meat, Fats and oils, Dairy (2012)

**Top subsectors (in terms of turnover):** Beverages, Meat, Flour and bakery products, Dairy, Animal feeds (2012)

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<sup>i</sup> **Country profile elaborated by:**

**Jorge BARBOSA**

*Instituto Nacional de Investigação Agrária e Veterinária, I.P.*

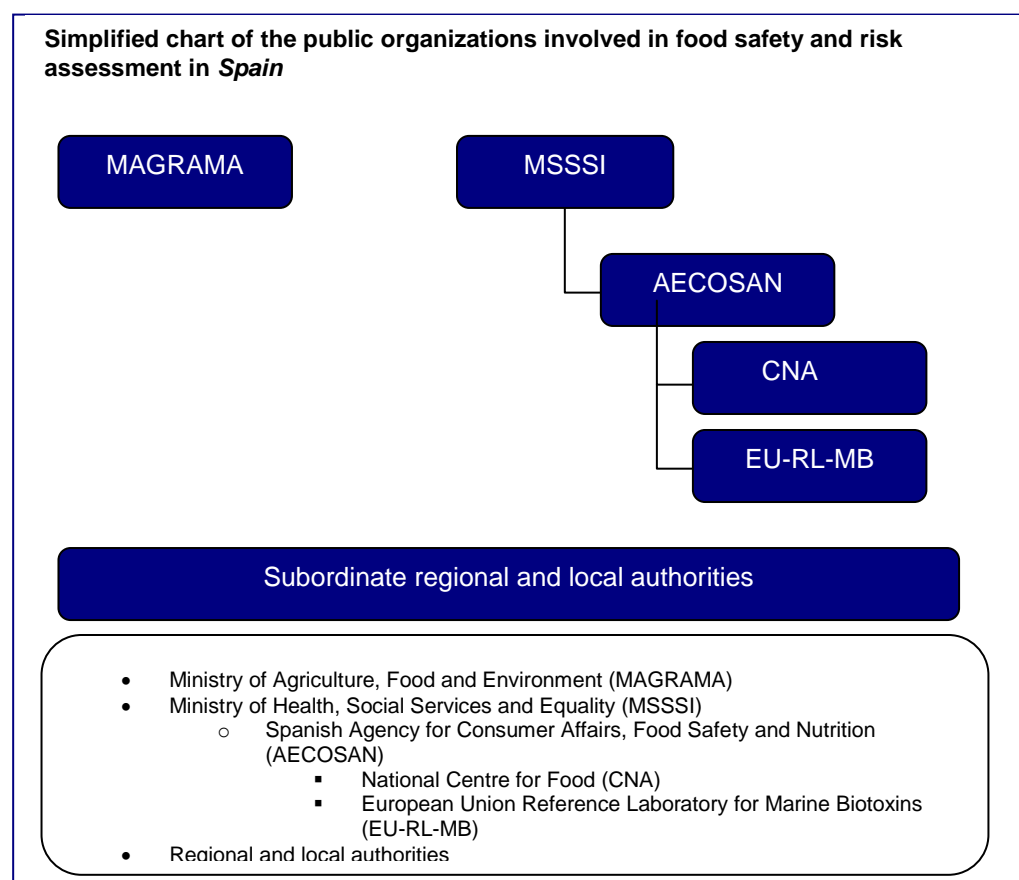
*E-mail: jorge.barbosa@iniav.pt*

# Country Profile: Spain<sup>i</sup>

## I – Key priorities for risk assessment

Risk assessment in regard to food safety and nutrition is done by AECOSAN's scientific committee, with the scientific and technical support of the Area of Risk Assessment. The reports are prepared to meet the risk management needs (fit-to-purpose).

## II – Major public actors involved in food safety (including risk assessment, management and communication)



## Main public organisations involved in food safety and roles – Spain

Organisation	Main areas of remit	Risk assessment	Risk management	Risk communication
<b>MAGRAMA</b> – Ministry of Agriculture, Food and Environment	Plant health, plant protection products, feed, mineral water, novel foods, genetic engineering, residues of veterinary medicinal products, zoonoses, contaminants	x	x	
<b>MSSSI</b> – Ministry of Health, Social Services and Equality	Plant protection products, control and inspection of food of animal and plant origin at border inspection posts	x	x	
<b>AECOSAN</b> – Spanish Agency for Consumer Affairs, Food Safety and Nutrition	Mineral waters, drinking water, food supplements, novel foods, residues of veterinary medicinal products, zoonoses, contaminants, nutrition	x	x	x
<b>CNA</b> – National Centre for Food	Residues in live animals and products, zoonosis, mycotoxins, PAHs, plant protection products, biocontam.	x		
<b>EU-RL-MB</b> – European Union Reference Laboratory for Marine Biotoxins	Marine biotoxins	x		
<b>Regional and local authorities</b>	Implementation of feed and food official controls		x	x

Regulation (EC) No. 178/2002 is the central foundation for food legislation in Spain. Infringement of food regulations can lead to measures under criminal law and consumer damage claims under civil law, whereby the final decision rests with the courts. Government measures with regard to food safety are often based on scientific risk assessment. However, the final decision on the legality of governmental measures rests with the courts.

In Spain there is no institutional separation of risk assessment and risk management. Risk assessments are published on the Internet unless there are statutory provisions that prohibit this.

The decentralized political organization of Spain distributes competences in food safety. The Autonomous Communities are the principal official control authorities and the central Administration deals with most of the foreign duties and are the contact point for EU and international organizations. In addition the central and regional competences are separated between primary and post-primary production.

### ***Ministry of Agriculture, Food and Environment (MAGRAMA)***

#### **Tasks of MAGRAMA:**

- Agricultural policy, food safety



- Risk assessment
- Risk management

**Website:** <http://www.magrama.gob.es>

MAGRAMA deals with agricultural policy, feed safety and the safety of food of animal and plant origin during primary production. MAGRAMA prepares draft legislation and is responsible for the coordination of state food inspections in this area. It is also responsible for the preparation of risk assessments with regards to residues of plant protection products and animal feed and it is the regulatory authority for plant protection products and pesticides.

The area of work of MAGRAMA extends beyond food safety to plant health, animal health and animal welfare.

### ***Ministry of Health, Social Services and Equality (MSSSI)***

#### **Tasks of MSSSI**

- Health policy, food safety
- Risk management

**Website:** <http://www.msssi.gob.es>

MSSSI deals with health policy and food safety. It also prepares draft legislation in the field of food (secondary food production) and is responsible for the coordination of state food inspections in this area. It is in charge of control and inspection of food of animal and plant origin during import, export and transit. MSSSI is also responsible for the control and monitoring of residues of plant protection products in food of animal origin. The regulatory authority for veterinary medicinal products is the Spanish Agency for Medicines and Health Products, a subordinate agency of MSSSI.

### ***Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN)***

#### **Tasks of AECOSAN**

- Risk assessment
- Risk communication
- Risk management
- Codex Contact Point
- EFSA Focal Point
- RASFF/ INFOSAN Contact Point

**Website:** <http://www.aecosan.msssi.gob.es/>

AECOSAN is a subordinate specialist authority within the portfolio of MSSSI. AECOSAN is the competent authority for all legislative projects with regards to safety of food available in Spain; this includes incorporation of EU directives into national law as well as new national regulations. As a scientific institution that enjoys independence in terms of the results of its opinions, AECOSAN prepares expert reports on risk assessment, particularly in conjunction with novel foods, residues of veterinary medicinal products, food supplements, zoonoses and mineral waters, drinking water. AECOSAN prepares recommendations for risk reduction and identifies new health risks. AECOSAN is also responsible for the risk management of GMOs (food). Other main areas of AECOSAN are research and transparent communication with the public at large, science and other involved or interested circles. AECOSAN is also involved in the coordination

of state food inspections. The area of work of AECOSAN extends beyond food safety to nutrition.

### ***National Centre for Food (CNA)***

**Website:** <http://aesan.msssi.gob.es/CNA/web/home.shtml>

The National Centre for Food carries out tasks of scientific and technical support and laboratory analytical control.

It is the National Reference Laboratory for the cases established in the community legislation: detection of residues in live animals and animal products, food-borne zoonosis, control of mycotoxins in foodstuffs, control of polycyclic aromatic hydrocarbon (PAH) residues in foodstuffs, control of plant-protection product residues in foodstuffs, analysis of milk and milk products, control of bacteriological and viral contamination of bivalve mollusks. It is also an approved laboratory by the USA Department of Agriculture for research of *Listeria monocytogenes*, *Salmonella* spp. and veterinary medicinal products residues, pesticides, heavy metals, species identification, etc. in meat and meat products for exporting to the USA. Furthermore the National Food Centre is accredited by the Spanish National Accreditation Entity for tests No. 178/LE 397 and 178/LE 905. The CNA is part of the ENGL network of the European Commission (Enforcement National GMO Laboratories).

### ***European Union Reference Laboratory for Marine Biotoxins (EU-RL-MB)***

**Website:** <http://aesan.msssi.gob.es/en/CRLMB/web/home.shtml>

The **EURLMB** is the **European Union Reference Laboratory for Marine Biotoxins**. As such, it coordinates the activities of a network of National Reference Laboratories (NRL), established in each EU Member State, regarding the methodologies applied to control marine biotoxins in shellfish, in order to protect public health and guarantee a maximum level of food safety.

The Marine Biotoxins Laboratory in Vigo (Spain) was designated as EURLMB in 1993. Since 2004, the EURLMB is under the Spanish Ministry of Health, Social Services and Equality.

### ***Regional and local authorities***

The regional and local levels in Spain consist of 17 autonomous regions, two autonomous cities (Ceuta and Melilla) and 52 provinces. They are the competent authorities responsible for the implementation of feed and food official controls.

### III – Food safety alerts management in Spain

1. Does the competent authority (or authorities) for food safety have an established mechanism to evaluate and react to food safety crises (crises management mechanism)?	<b>Yes</b>
2. If the reply to Q1 is yes, does this mechanism include a committee or a body with pre-determined representatives?	<b>Yes</b> , a committee with pre-determined representatives exists and it can include additional members if needed for a specific crisis
3. If there is an established mechanism for crisis management (the reply to Q1 is Yes):	
3a. Do actors with risk assessment capacity participate directly in this mechanism?	<b>Yes</b>
3b. Do actors with risk management capacity participate directly in this mechanism?	<b>Yes</b>
3c. Do actors with risk communication capacity participate directly in this mechanism?	<b>Yes</b>

### IV – Characteristics of the food sector in Spain

**Number of enterprises<sup>1</sup>:** approx. 30,000. 96.2% are SMEs (<50 employees)

**% of the industrial sector:** 17.4%

**% of the industrial workforce:** 20%

**% of industrial turnover:** 86,298 million Euros (2012). 14% of total industrial net sales and 7.6% of Spanish GDP.

**Top subsectors (in terms of number of enterprises):** (Data from 2011; from highest to lowest) Meat industries; alcoholic beverages; dairy industries.

**Top subsectors (in terms of turnover):** (Data from 2011; from highest to lowest): flour, starch and starchy products; beverages; meat industries. beverages, meat industries,

### V – Civil Society Organisations

In Spain there are several CSOs with relevance to the food sector. Some focus on consumer rights and consumer protection (not necessarily specific on the food sector), while others relate with food security. Finally there are several NGOs with ecological/conservationist interests, which actively participate in the civil society.

Amongst those, the consumer associations engage in the public dialogue for new legislation or market regulation regarding foodstuffs representing the interest of the consumers. For example,

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<sup>1</sup> Data obtained from the Federation of Enterprises of Food and Beverages, excluded primary production: [http://www.fiab.es/archivos/documentoMenu/documentomenu\\_20130510124729.pdf](http://www.fiab.es/archivos/documentoMenu/documentomenu_20130510124729.pdf)

they are represented at AECOSAN via the Institutional Commission and the Advisory Board, both collegiate organs of the Agency.

Other institutions, such as the MAGRAMA and the MSSSI, have a public space for consultation. The consulted topics vary (draft legislation, plans, programs and strategies, environmental assessments, notification of GMOs deliberate releases and contained use, etc.). There are approximately 11 consumer associations with nation-wide coverage.

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<sup>i</sup> **Country profile elaborated by:**

**Ana CANALS CABALLERO, Cristina ALONSO ANDICOBERRY**

*Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN)*

*Ministry of Health, Social Services and Equality*

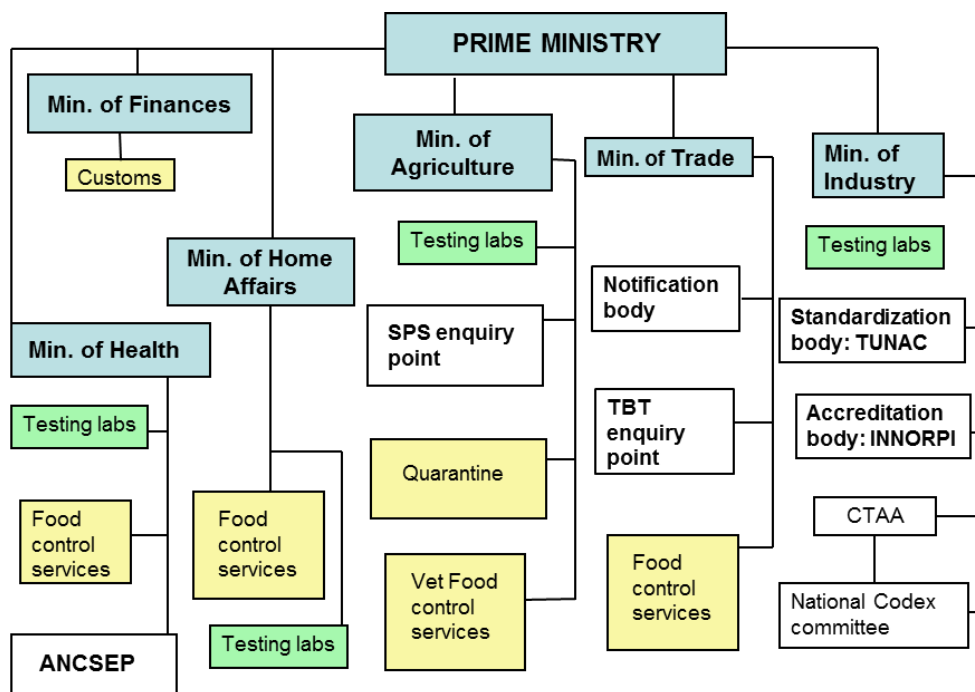
*E-mail: [acanals@msssi.es](mailto:acanals@msssi.es)*

# Country Profile: Tunisia<sup>i</sup>

## I – Key priorities for risk assessment

- A food law with the new principles related to food safety (risk analysis approach, transparency, precautionary principle, responsibilities, etc.).
- A consumption database.
- Training about qualitative and quantitative risk assessment methodologies.
- Training about risk based control approach.

## II – Major public actors involved in food safety (including risk assessment, management and communication)



## Main public organisations involved in food safety and roles – Tunisia

Organisation	Main areas of remit (in term of risk assessment/ management/ communication)	Risk assessment	Risk management	Risk communication
Ministry of Agriculture	Plant health, animal health – incl. aquaculture, agricultural products, feed; overview of food issues	x	x	x
Ministry of Trade	Quality and safety control of all products, fraud repression		x	x
Home Affairs Ministry	264 existing municipalities, food hygiene		x	
Ministry of Health	Hygiene services for food control activities	x	x	x
Ministry of Industry	Horizontal commissions that gives agreements to industries to export and open special food factories		x	
Ministry of Finance	The customs are involved in boarding control		x	
Ministry of Tourism	Food control activity		x	

### Components of the Food Control System

<sup>1</sup>**ANCSEP**: National Agency for coordination between all controllers in the fields of 10 defined products (food, feed, drugs, drinking water, hazardous chemicals ...) (see more information in Appendix V).

<sup>2</sup>**CTAA**: technical center of food industries (supports the national programmes to promote food industries).

**National Codex Committee** created in 2000 comes under the Ministry of Industry and its secretariat comes under CTAA.

**Testing laboratories** involved in food control:

- Under the Ministry of Health: 22 regional hygiene labs, Pasteur Institute lab (national Salmonella reference) and lab of the National Institute of Nutrition and Food Technology. Pasteur Institute food and water lab and two regional labs are involved in an accreditation process.
- Under the Ministry of Home Affairs: Tunis Municipality food lab (accredited).
- Under the Ministry of Agriculture: lab of the National Veterinarian Institute (involved in an accreditation process) and Lab of Quarantine.
- Under the Ministry of Industry: LCAE3 (the main control lab in Tunisia) which is accredited in chemical and microbiological analysis on water but in process for accreditation in microbiological food analysis. They are also accredited in metrology.

<sup>1</sup> Agence Nationale de Contrôle Sanitaire et Environnemental des Produits

<sup>2</sup> Centre Technique de l'Agro-Alimentaire

- Private sector: some food labs exist and some are accredited for some analysis; they are mainly used by factories for their home control.

### **Food control services:**

All of them (except those of the Ministry of Home Affairs) are built with a central department (coordination, national programmes) and 24 regional services; one in each regional administrative department –governorate– under which they are involved in addition to their head Ministry. All of them have to control many areas, not only food.

- Under the Ministry of Agriculture:
  - The veterinarian services are the “competent authority” regarding EU fishery trade.
  - Quarantine and other plant control services
- Under the Ministry of trade:
  - They play the coordinators role according to the Consumer Protection Act.
  - The metrology services are also under the Ministry of Trade.
- At the Home Affairs Ministry, the control services are included in the 264 existing municipalities and have only local authority. The municipalities have an important role in food hygiene by the control of public establishments (Organic Municipalities Act<sup>4</sup>). But specialized services exist only for the big towns.
- Under the Ministry of Health, the hygiene services are set up everywhere but they play more the role of technical advisors and educational staff than controllers. But, more and more the role of controller is well established. They are mainly technicians, physicians and engineers. They are also the main managers of the food born diseases surveillance.
- Under the Ministry of Industry: There are no control services under this ministry but they are head of some horizontal commissions that gives agreements to industries to export and open special food factories. Even all the ministries involved in control are represented in these commissions; the management is conducted by the Ministry of Industry which is according to its organic text, is a technical advisor and booster of enterprises.
- Under the Ministry of Finance, the customs are involved in boarding control and all the parties have to cooperate with them, but they don't have a technical role, only an administrative one. They are very well organized.
- Under the Ministry of Tourism: the food control activity is more a home control than an official one. In fact they have some prerogatives regarding hotels and restaurants, but they aren't named by the consumer protection Act.

### ***Other components of the Food control system***

#### **Consumer Protection Act<sup>5</sup>**

It's a harmonised text and a horizontal one. This law dates from 1992 and has the aim to cover all kind of goods including food. It has introduced in our country the responsibility of the buyer (producer or trader) and the obligation to protect and inform the consumer (guarantee). Then the law introduced home control and preventive way in general. The Consumer Protection Act is

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<sup>3</sup> Laboratoire Central d'Analyses et d'Essais

<sup>4</sup> Law number 75-33 March 1975

<sup>5</sup> Law n° 92-117 - December 1992

also based on national and international regulations as references to evaluate facts without discrimination between local, imported or exported goods. This law defines the 4 types of controllers that are involved in: controllers from the ministries of Trade, Agriculture, Home Affairs and Health.

The major lacking for this law is that it isn't food specific.

There are some applying texts of this act; one of the more recent is a decree concerning food packaging<sup>6</sup>, which is the same as EU directory. But our regulations oblige producers and importers to have a sanitary authorisation to use specific packaging for specific food.

### **Standard Body (INNORPI<sup>7</sup>)**

The new standardization act law n° 2009-38 (June 30th 2009) permit activities of standard building, product and system certification with industrial property. The technical committees are well defined and work according to rigorous procedures; they have an ambitious programme to harmonize all standards, especially food ones with codex, ISO and EU. We have all kinds of food standards even they aren't all updated. The new law doesn't permit to make mandatory standards, and encourages specialized departments to produce the appropriate technical regulation with a deadline in 2015.

INNORPI ([www.innorpi.tn](http://www.innorpi.tn)), is a non-administrative public institution operating under the supervision of the Ministry of Industry, Energy and Small and Medium-sized enterprises. It is in charge of standardization, product and quality systems certification, quality promotion and protection of industrial property.

### **Accreditation Body (TUNAC)**

Created in 1994<sup>8</sup>, TUNAC, the Tunisian Accreditation Council (Conseil National d'Accreditation, CNA) (<http://www.tunac.tn>) is now recognized by ILAC, IAF and is in charge of the accreditation of laboratories and of conformity assessment bodies. It has accredited more than 100 laboratories.

TUNAC is a non-administrative public institution operating under the supervision of the Ministry of Industry.

### **Food born illnesses surveillance system**

The notification of food illness is mandatory<sup>9</sup> and specialized departments are trying to make it active under IHR2005 by creating a national food alert system connected to the WHO system (INFOSAN).

### **Regarding the WTO structures**

The Ministry of Trade is the body, which most involved in the WTO agreements; they have a directorate of relationship with the WTO and they are the managers of the national commission that discusses the WTO affairs. They also are **the notification body** and some notifications were issued.

**There is a TBT enquiry point and a SPS enquiry point** (they aren't working mainly by the interactive methods but only by diplomatic routes).

As it was said, still there is no specific law for food and we may use a general law (law n°117 – 1992) also called consumer protection act to deal with risks related to food, nevertheless, Tunisia has its own experience in the field of risk analysis approach related to food.

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<sup>6</sup> Decree n° 1718 August 2003.

<sup>7</sup> Institut national de la NORmalisation et de la Propriété Industrielle

<sup>8</sup> Modified by Law 92-2005, octobre 3rd 2005

<sup>9</sup> law number 92-71 dated on 27 July 1992



### III - Food safety alerts management in Tunisia

1. Does the competent authority (or authorities) for food safety have an established mechanism to evaluate and react to food safety crises (crises management mechanism)?	<b>Not really</b> , but into the food law project crises management is set up
2. If the reply to Q1 is yes, does this mechanism include a committee or a body with pre-determined representatives?	No, <b>committee/committees</b> are formed <b>ad hoc</b> , depending on the needs of the crises"
3. If there is an established mechanism for crisis management (the reply to Q1 is Yes):	
3a. Do actors with risk assessment capacity participate directly in this mechanism?	<b>No</b>
3b. Do actors with risk management capacity participate directly in this mechanism?	<b>Yes</b>
3c. Do actors with risk communication capacity participate directly in this mechanism?	<b>Yes</b>

ANCSEP is setting to study to implement national food alert system

### IV - Civil Society Organisations

**Consumer protection association** is an NGO, which plays an important role into the SPS infrastructure but isn't really involved in the control system; it's an interface of it.

Other new consumer organisations NGO were created newly

**Maghrebine association for food safety:** AMSSA Tunisia, it was created to improve food safety and consumer protection. AMSSA's commitment is to provide objective and independent science-based advice and clear communication grounded in the most up-to-date scientific information and knowledge regarding risks in the food chain.

## Appendix - Tunisian Experience with Risk Analysis System<sup>10</sup>

The experience began with a policy decision: the creation of the ANCSEP [National Agency of the Sanitary and Environmental Control of Products]. The creation of the agency was announced in a speech by the President of the Republic in 1999. This announcement was made within the context of a meeting of the High Council of Export, thus it was a strong signal for the international harmonization of the trade in products. In fact, it is in the specific context of international crises, particularly food-related, at the end of the 20th century, that the Western countries first began to examine their national systems for control and prevention and hastened to create authorities capable of controlling the risk connected with consumption, as well as the risks connected with the environment. Beginning with conviction, the creation of a national institution permitting the “sustainable” protection of the consumer was essential in Tunisia as in other countries [1].

Conceived as an authority for coordinating controls and placed under the jurisdiction of the Ministry of Public Health in order to ensure its independence with regard to politics and the economy, the ANCSEP has continued to evolve in its activities and its missions, adapting along the way to the expectations of its partners (specifically the national control authorities), to the evolution of the international situation (specifically the partnership agreements and other technical cooperation programs), but also by remaining attentive to scientific developments and strategic concepts.

That is how, from coordinator of controls, its role has evolved “evaluator of health risks”, propelled in this direction by the logic of a historic progression whose stages we will attempt to analyze [2].

### *The initial period*

In fact, among the first studies conducted by the ANCSEP, as early as 2001, is an evaluation of a food safety system in Tunisia in the form of three preliminary studies carried out by experts and concerning, respectively, the legal framework, the control system and the analytical capacities for food products. This evaluation has made it possible to demonstrate the gaps and the insufficiencies at different levels, basically connected with control and prevention processes, the complexity of product circuits, the multiplicity of participants and the absence of a harmonized and multi-disciplinary approach.

Following this report, in 2002 the agency began to develop an overall strategy defining the general directions and the specific objectives for establishing a national harmonized food product control system. The project promoters wanted to use a participative method in the form of PIPO (Planning of Interventions by Objective<sup>11</sup>) with which all of the participants had been associated and represented [5]. However, this proposal to update the sector had no indication as regards its application.

The agency learned from this relative failure as coordinator and thus as “unified voice” of the different departments involved in control to make itself available to them and to respond to their needs (consisting for the most part in requests for assessment of problems posed by products<sup>12</sup>) as well as doing its utmost to continue to advance in its mission of implementing a national food safety strategy.

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<sup>10</sup> Paper presented at “Sharing an Understanding of Food Safety Regulatory Systems: United States, Middle East and North Africa.” Cairo, September 20-22, 2010.

<sup>11</sup> Manual for the application of “PLANNING OF INTERVENTIONS BY OBJECTIVES (PIPO)” General Administration for Development Cooperation, Brussels, March 1991, 2<sup>nd</sup> edition.

<sup>12</sup> Which, in fact, constitutes a request for assistance in the decision for risk (complicated or new) management.

## ***The second period***

The next milestone in this evolution was a second important policy decision made by the Minister of Public Health on a proposal from the ANCSEP. The agency had been given the opportunity during its participation in the regional FAO/OMS conference on food safety in Africa in Zimbabwe (October 2005). It is, in fact, following the work of this conference that a five-year strategic report and food safety action plan for the African region was adopted. This African consensus report was sent to the various Tunisian structures concerned, after having been confirmed by the Minister of Public Health, validating the adoption of the Risk Analysis (RA) approach as the basis for organizing a national food safety system for Tunisia.

This position-taking was in full harmony with the general policy of opening up the country; it specifically made it possible to be “in compliance” with agreements with the WTO13 as well as with the agreements on the application of sanitary and phytosanitary measures (SPS) and those on the technical barriers to trade (TBT), as well as with international requirements, specifically those of the CODEX Alimentarius, the OIE and the IPPC, organizations with which Tunisia is strongly involved. It is in this way that the approach recommended by the Codex and the OIE safety code, for the prevention of food safety and animal disease risks, is based on the three parts of the Risk Analysis:

- Evaluation of risks or Risk Assessment ( R Asst) ,
- Risk Management (RM),
- Risk Communication

These three sections, although distinct, are intimately connected and need to be reexamined in an ongoing manner, in the light of new scientific data and data from the field, in order to be able to adapt the strategy for intervention in new circumstances.

The ANCSEP has continued to work on the RA concept and the terms and conditions for its implementation, both on the national and international level.

On the international level, for example, the agency actively participated (as a member of the Tunisian delegation) in the development of the draft CODEX directive devoted to the application of the RA concept to the scale of countries, a directive which was adopted by the Codex

Commission in 2007 under reference CAC/GL 62-2007: “WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY INTENDED TO BE APPLIED BY GOVERNMENTS” [8]. Note also that since 2005 the ANCSEP had been a designated focal point of the INFOSAN international network of authorities in food safety developed by the WHO in cooperation with the FAO and that it has been a member of its “advisory group” since its creation in 2006.

On the national level, the ANCSEP proposed a draft strategic plan as part of the contribution to the preparation of the 11th national development plan (2007-2011) and which was supposed to accompany the implementation of a main component of the same plan, i.e. the food law, fruit of a policy decision announced in the 2004-2009 presidential program. This is a law equivalent to the European “food law” (EC Regulation no. 178/2002)<sup>14</sup> intended to replace/complete law 92-117 on consumer protection (law dated December 7, 1992) which organizes the control of products based on an approach that is preventive but not food-specific.

This strategic plan has thus been in effect since 2007. It is built on a global and consensual approach of harmonization with international concepts of food safety, while ensuring the adherence of all of the departments participating in food safety control in Tunisia and is developed on three main components:

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<sup>13</sup> Tunisia was a very early member of the GATT discussions; it became a member of the WTO in 1995.

<sup>14</sup> Component under the responsibility of the Ministry of Commerce, main actor in market control and coordinator in the application of the consumer protection law (law 92/117)

## **Evaluation of the impact of the implementation of the Risk Analysis approach at the national level**

This consists of studying by means of an “international expert report” the assessment of the impact of the implementation of the “Risk Analysis” (RA) approach on the current technical-administrative organization with regard to food safety in Tunisia. The study made it possible to describe the current reform of the food policy in Tunisia and to define the significance and the impact of the European legislation, the basis of the reform, on the administrative organization of this policy. The principle of RA symbolizes the main problem posed by this reform: how to create the coordination between the actors who are historically specialized and working independently on distinct legal bases?

This action bears the name of its author: the “DEMORTAIN Study”. It was conducted in May 2007 by organizing brainstorming sessions bringing together the representatives of the different ministries, interviewing top management to analyze the implications of adopting this approach on the articulation processes for assessment and control as well as the elements necessary for the positioning of the ANCSEP in the national landscape with a view towards adapting to the circumstances of each country, while complying with the international rules and requirements. It confirmed the positioning of the agency as an independent Risk Assessment organ [4].

## **Consolidation of the food control system in Tunisia (Consensual Approach for the strengthening of food control capacities)**

The project had adopted FAO-WHO participative methodology<sup>15</sup> developed in 2006, called step- by-step, permitting the capitalization of results at each stage in order to help the countries to identify and assess their needs for strengthening the capacities of national food control systems [9]. The action consisted in determining the needs for strengthening national Risk Management capacities connected with food and the proposal of a relevant consensual organization following a detailed bibliographic study. This management system (official control) was capable in fact of being designed as a whole (unitary system managed by a single structure), but this possibility having been set aside (at least for the short-term) by the majority of the protagonists, a shared organization was adopted, which entails the definition of an effective and complementary distribution between the different participants, i.e. a matrix of areas of responsibility clearly specifying the role of each participant in such a way so as to cover the food chain in a more exhaustive and complementary way by avoiding the overlapping of responsibility. The action was conducted from January to July 2008 [6].

## **Implementation of a national warning system for food safety**

As an “INFOSAN” focal point in Tunisia, the ANCSEP launched a study to implement a national warning system for food safety in synergy with international trends, specifically the joint initiative of the three international organizations, FAO, WHO and OIE, in order to link and coordinate the pre-existing warning and response systems and improve the early warning capabilities for threats caused by animal diseases and food contamination in relation to the health of the population (GLEWS Early warning and rapid response system) [7].

## **Summary**

To summarize, the effective implementation of the three strategic plan components makes it possible to update the national food safety system which is the objective to be obtained. The results of this work have been utilized in order to develop the draft national law on food safety. But, it must be noted, these results were generated by a “historic evolution” which we may diagram according to the engineering research methodology of stages [3] and which explains the result of concrete and adapted solutions. In order to do so a research approach [10] which is similar to Research-Action (an empirical analysis of a situation), but which is distinguished from

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<sup>15</sup> [www.fao.org/ag/agn/index\\_en.stm](http://www.fao.org/ag/agn/index_en.stm)

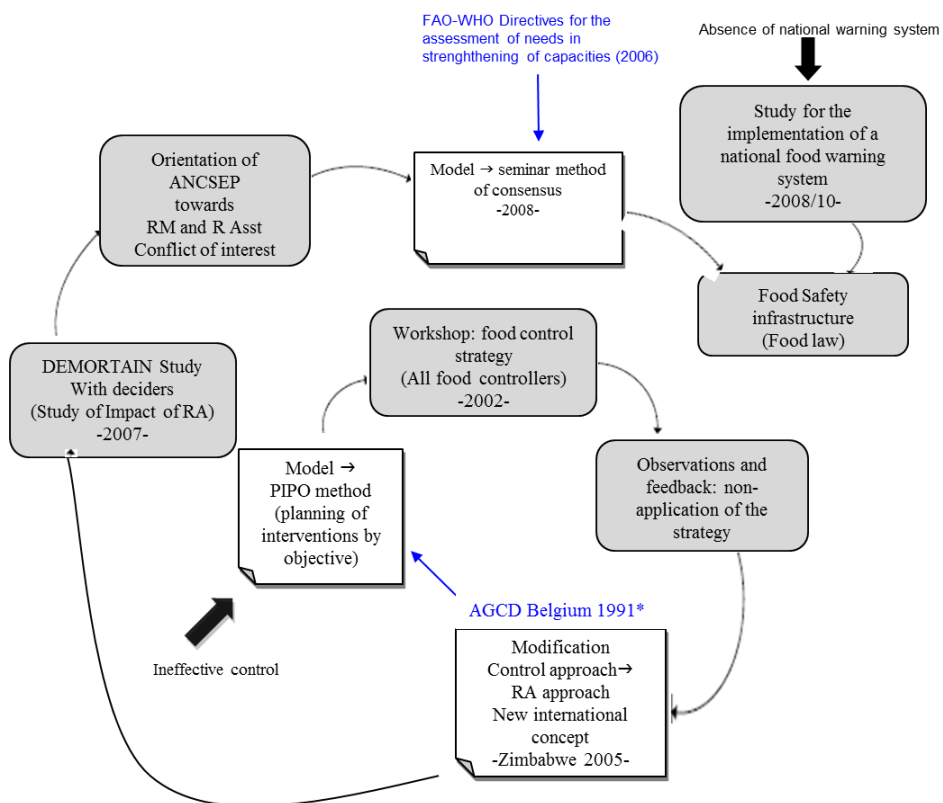
the classical method insofar as “the researcher is also going to be an engineer who, during a research process which loops back on itself designs a tool, builds it, implements it in the field, and evaluates it in order to create both representations of the situation useful to the action, and theoretical knowledge (progressively) generalizable to other situations” (Suchman, 1987) [11].

### Perspectives

The current stage, the implementation of the new food law and its consequences, specifically the texts redefining the position and the missions of the agency as Risk Evaluator, will have to be confirmed by a policy decision. This new legislation (to emerge) has opted to base the national system on the concept of RA with two independent entities, one for Risk Management (A coordinators of controls) and one for Risk Assessment (ANCSEP as refunded).

But the national food safety system [SSA] thus built stone by stone, will not cease to evolve under the impetus of feedback from the field and new knowledge, with the same ever-changing movement which permitted its implementation. It may perhaps be necessary to specifically take into account for the evaluation of risks:

- The notion of risk/benefit instead of focusing primarily on the negative health impact.
- The notion of combined risk instead of doing assessments per individual risk as is done currently.



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<sup>i</sup> **Country profile elaborated by:**

**Leila CHEKIR**

Laboratory of Cellular and Molecular Biology

Faculty of Dental Medicine

University of Monastir

E-mail: leila.chekir@laposte.net

# Country Profile: Turkey<sup>i</sup>

## I – Key priorities for risk assessment

- Strengthening of infrastructure of risk assessment body
- Methods and tools for risk assessment
- Collection and collation of data
- International cooperation for risk assessment
- Emerging risks
- Cooperation and communication with other national authorities

## II – Major public actors involved in food safety (including risk assessment, management and communication)

In Turkey, food safety, veterinary services and plant health is currently regulated by the following basic laws and their secondary legislation:

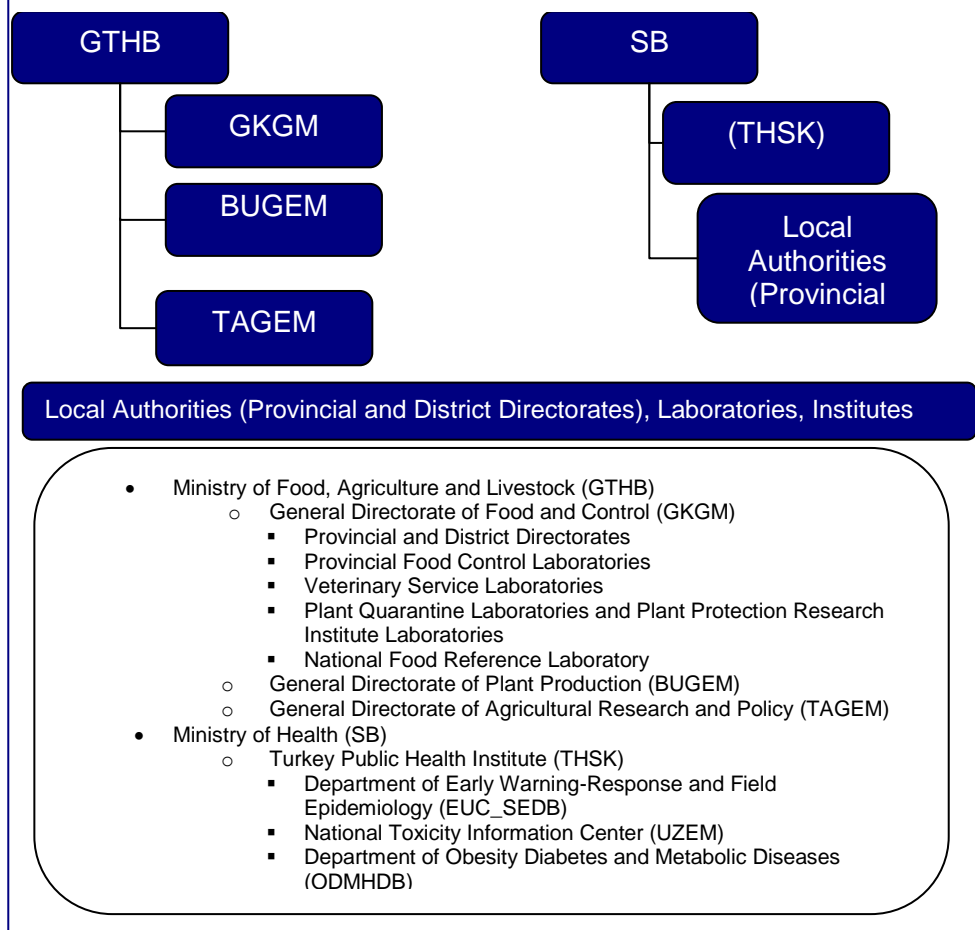
- Law on Veterinary Services, Plant Health, Food and Feed (No. 5996)
- National Biosafety Law (No.5997)
- Law no.1380 on Fisheries
- Law no. 5553 on Seeds

The Law no.5996 titled “Veterinary Services, Plant Health, Food and Feed” covers the provisions of Regulations no.178/2002/EC, 852/2004/EC, 853/2004/EC, 854/2004/EC, 882/2004/EC as well as relevant provisions of various EU legislations on not only food and feed safety but also veterinary and phytosanitary issues. The Law establishes a framework for veterinary services, zootechnics, plant health, food safety, feed, hygiene and official controls, while leaving the details to secondary legislation.

In Turkey, there is Department of Risk Assessment under the GKGM together with risk management departments. Therefore, there is not an institutional separation of risk assessment from risk management. There is not a risk assessment published, yet.

Turkey participates in the work of Codex Alimentarius, World Organisation for Animal Health (OIE) and European and Mediterranean Plant Protection Organization (EPPO) and some of EFSA network meetings as an observer country.

**Simplified chart of the public organizations involved in food safety and risk assessment in Turkey**



**Main public organisations involved in food safety and roles – Turkey**

Organisation	Main areas of remit (in term of risk assessment/ management/ communication)	Risk assessment	Risk management	Risk communication
<b>GTHB</b> – Ministry of Food, Agriculture and Livestock	Food and feed safety , veterinary and phytosanitary tasks incl. aquaculture,	x	x	x



Organisation	Main areas of remit (in term of risk assessment/ management/ communication)	Risk assessment	Risk management	Risk communication
	agricultural products			
<b>SB</b> – Ministry of Health	Health policy, foodborne outbreaks, inspection and control of the quality of water intended for human consumption, natural mineral water, dietary foods for special medical purposes for babies and adults	x	x	x
<b>GKGM</b> – General Directorate of Food and Control	Food and feed safety, animal health, animal welfare and plant health	x	x	x
<b>BUGEM</b> – General Directorate of Plant Production	Organic production of agricultural products		x	x
<b>TAGEM</b> – General Directorate of Agricultural Research and Policy	Research in the field of plant health, animal health, food and feed safety, animal husbandry, fishery, horticulture and field crops	x		x
<b>Laboratories</b>	Analyses of foodstuffs		x	
<b>EUC_SEDB</b> – Department of Early Warning-Response and Field Epidemiology	The early warning and response activities including foodborne outbreaks.	x		x
<b>UZEM</b> – National Toxicity Information Center	The call center that gives advices and provides antidote nationwide		x	
<b>ODMHDB</b> – Department of Obesity Diabetes and Metabolic Diseases	Responsible for adequate and balanced nutrition; Participate in food codex commission of GTHB		x	

### ***Ministry of Food, Agriculture and Livestock (GTHB)***

#### **Tasks of GTHB<sup>1</sup>:**

- Agricultural policy, food and feed safety, veterinary and phytosanitary tasks
- Risk assessment
- Risk management
- Risk communication

**Website:** <http://www.tarim.gov.tr>

<sup>1</sup>Partial list including those tasks with relevance to food safety and risk assessment/ management/ communication

The GTHB is responsible for food and feed safety, including veterinary and phytosanitary aspects. The GTHB aims to protect public health, plant and animal health, animal welfare and consumer interests taking into consideration the protection of the environment. The GTHB is responsible for official control and inspection at all stages of the food and feed chain.

To protect human and animal health, the GTHB cooperates with the Ministry of Health and other relevant institutions with regard to the monitoring of certain zoonotic diseases and agents and antimicrobial resistance. Another reason for the GTHB cooperation with other institutions is to jointly conduct epidemiological research projects to investigate foodborne zoonotic diseases.

### ***Ministry of Health (SB)***

#### **Tasks of SB<sup>1</sup>:**

- Health policy, foodborne outbreaks
- Food safety
- Risk assessment
- Risk management
- Risk communication

**Website:** <http://www.saglik.gov.tr>

The SB is responsible for specific aspects in the area of food safety. The SB prepares the legislation and is responsible for inspection and control of the quality of water intended for human consumption, natural mineral water (swimming pool, spa and bathing water), dietary foods for special medical purposes for babies and adults respectively, as well as products which do not require prescription but have been scientifically and clinically proven to be used as drugs, including enteral nutritional products. The SB is represented by Provincial Health Directorates (PHD) in provinces.

Laboratory confirmations of clinical and non clinic samples are done either at the selected provincial public health laboratories or by the national reference laboratory of SB. Moreover, AMR and nosocomial infection control programs are also monitored by SB.

Provincial Health Directorates are the main responsible bodies at peripheral level.

### ***General Directorate of Food and Control (GKGM)***

#### **Tasks of GKGM<sup>1</sup>:**

- Food and feed safety
- Risk assessment
- Risk communication
- Risk management
- Codex Alimentarius Contact Point
- OIE Contact Point
- EFSA Focal Point
- RASFF Contact Point

**Website:** <http://www.tarim.gov.tr/GKGM>

The GKGM is a unit of the GTHB and responsible for developing policies and preparing legislation, as well as the subsequent enforcement, control and inspection of food and feed safety, animal health, animal welfare and plant health at the central level. The GKGM is the regulatory authority for pesticides and veterinary drugs.

Laboratory services for animal health, plant health as well as food and feed safety are provided

by 8 veterinary control and research institutes, 8 plant protection research institutes, 4 quarantine laboratories, 39 provincial control laboratories, 1 food control and central research institute, and 1 national food reference laboratory under the supervision of the GKGM. There are also 84 private laboratories operating with the authorisation of the GKGM. Most of the practical implementation and enforcement activities are carried out by 81 Provincial Food, Agriculture and Livestock Directorates (PADs) and 914 District Food, Agriculture and Livestock Directorates (DADs) with a vertical chain of command between the two.

Department of Risk Assessment, under the General Directorate of Food and Control, covers food and feed safety, plant health and animal health and welfare. In this context, the Department shall provide scientific advice, scientific and technical support to risk managers in GTHB. It conducts these tasks through Scientific Commissions and the Scientific Committee and provides secretarial service for them.

### ***General Directorate of Plant Production (BUGEM)***

#### **Tasks of BUGEM<sup>1</sup>:**

- Organic production of agricultural products
- Risk management
- Risk communication

**Website:** <http://www.tarim.gov.tr/BUGEM>

BUGEM is a unit of the GTHB and responsible for determination and inspection of standards and the convenience of use of the agricultural inputs and the production technologies such as the organic production of agricultural products.

### ***General Directorate of Agricultural Research and Policy (TAGEM)***

#### **Tasks of TAGEM<sup>1</sup>:**

- Agricultural research
- Risk assessment
- Risk communication

**Website:** <http://www.tarim.gov.tr/TAGEM>

TAGEM is a unit of the GTHB and involved in agricultural research in the field of plant health, animal health, food and feed safety, animal husbandry, fishery, horticulture and field crops to identify the priorities and strategies of agricultural research and development taking into account the national development plans and to prepare and implement in those areas.

Some specific areas such as issues with regard to residues of plant protection products and veterinary drugs, heavy metals and other contaminants, mycotoxins, additives, microbiological criteria are studied in research institutions and laboratories, such as the Plant Protection Central Research Institute and the Veterinarian Central Research and Control Institute.

Some of the laboratories associated with TAGEM carry out laboratory analysis of samples collected during food, feed, animal disease and phytosanitary controls and inspections under GKGM supervision. TAGEM is also secretariat of the Biosafety Board which is responsible for the authorisation of GMOs for food and feed use and also secretariat of its Scientific Commissions which are responsible for risk assessment.

### III – Food safety alerts management in Turkey

1. Does the competent authority (or authorities) for food safety have an established mechanism to evaluate and react to food safety crises (crises management mechanism)?	<b>Yes</b>
2. If the reply to Q1 is yes, does this mechanism include a committee or a body with pre-determined representatives?	<b>No</b>
3. If there is an established mechanism for crisis management (the reply to Q1 is Yes):	
3a. Do actors with risk assessment capacity participate directly in this mechanism?	<b>Yes</b>
3b. Do actors with risk management capacity participate directly in this mechanism?	<b>Yes</b>
3c. Do actors with risk communication capacity participate directly in this mechanism?	<b>Yes</b>

#### ***Additional explanations on alert management in Turkey***

Issues related to official controls, sampling, administrative sanctions and determination of contact persons in food-borne cases and outbreaks are regulated by "Procedure for Official Controls on Foodborne Infections and Poisoning". According to the procedure, a permanent and a substitute persons are determined at all of the 81 Provincial Food, Agriculture and Livestock Directorate, 40 official food control laboratories and 81 Provincial Public Health Directorate as the poisoning contact points. Ministry of Food, Agriculture and Livestock (GTHB) and the Ministry of Health (SB) operates control activities jointly during the cases and outbreaks.

### IV – Characteristics of the food sector in Turkey

**Number of enterprises<sup>2 3</sup>:** 35631

**% of the industrial sector<sup>2</sup>:** 11,65

**% of the industrial workforce<sup>2</sup>:** 12,38

**% of industrial turnover<sup>2</sup>:** 13,40

**Top subsectors (in terms of number of enterprises):** Bakery products, grain products and starch, dairy products, processed and preserved fruit and vegetables, cocoa, confectionery and chocolate, beverages, vegetable oils, meat and meat products *(in descending order)*

**Top subsectors (in terms of turnover):** processed and preserved fruit and vegetables, dairy products, grain products and starch, meat and meat products, Bakery products, vegetable oils, beverages, cocoa, confectionery and chocolate *(in descending order)*

### V – Civil Society Organisations

In Turkey, there are several CSOs with relevance to the food sector. Some focus on consumer

<sup>2</sup> Source: Federation of Food and Drink Industry Associations of Turkey, Inventory-2012 (Based on the data of 2010).

<sup>3</sup> Current number: 80245 (April, 2014).

rights and consumer protection, some others work directly or indirectly towards food security (food aid; within their mission objectives) while some are for sectorial cooperation and development. These CSOs for sectorial cooperation and development are involved in building up a new legislation or market regulation. Consumer associations act as information suppliers towards consumers, help to strengthen consumer demand for quality food products while operating within the framework of ethical values. They aim to train, inform and make aware consumers so that they demand safe food. Besides, they carry out activities to develop cooperation with related local and international bodies.

Besides associations, there are also professional chambers that engage in the public dialogue for new legislation or market regulation regarding foodstuffs representing the interest of the consumers, too. There are also federations comprising of associations and in some cases companies.

Currently, there are more than 100 food/consumer related civic organizations, including regional and national coverage.

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<sup>i</sup> **Country profile elaborated by:**

**Serap HANCI**

*Ministry of Food Agriculture and Livestock*

*General Directorate of Food Control, Department for Risk Assessment*

*E-mail: Serap.hanci@tarim.gov.tr*

# List of participants

## **ALBANIA**

### **Afrim BAKAJ**

General Director  
National Food Authority (NFA)  
Muhamet Gjollështa, 56  
Tirana  
ALBANIA  
afrim.bakaj@aku.gov.al

### **Besnik JAKAJ**

Director of Risk Assessment and  
Communication  
National Food Authority (NFA)  
Muhamet Gjollështa, 56  
Tirana  
ALBANIA  
Besnik.Jakaj@aku.gov.al

### **Pamela RADOVANI**

Inter-Institutional Relations NFA  
National Food Authority (NFA)  
Muhamet Gjollështa, 56  
Tirana  
ALBANIA  
Pamela.Radovani@aku.gov.al

## **FRANCE**

### **Sandrine BLANCHEMANCHE**

INRA - Unité Economie Publique  
16, rue Claude Bernard  
75231 Paris Cedex 05  
FRANCE  
sandrine.blanchemanche@grignon.inra.fr

### **Hélène ILBERT**

Institut Agronomique Méditerranéen de  
Montpellier (IAMM-CIHEAM)  
3191 route de Mende,  
34093 Montpellier cedex 5  
FRANCE  
ilbert@iamm.fr

### **Moez SANAA**

Agence Nationale de Sécurité Sanitaire  
Direction Evaluation des Risques  
27-31, avenue du Général Leclerc  
94701 Maisons-Alfort Cedex  
FRANCE  
moez.sanaa@anses.fr

## **GREECE**

### **Gorgias GAROFALAKIS**

Dpt. Nutrition Policy & Research  
Hellenic Food Authority  
124 Kifissias Av. & 2 Iatridou Str.  
11526 Athens  
GREECE  
ggarofalakis@efet.gr

### **Antonis KAMBANIS**

Scientific Committee  
Hellenic Federation of Food Industries  
(SEVT)  
340 Kifissias Ave.  
15451 Athens (N. Psychiko)  
GREECE  
antonis.kambanis@gr.nestle.com

### **Panagiotis SKANDAMIS**

Assistant Professor  
Laboratory of Food Quality Control &  
Hygiene  
Department of Food Science & Technology  
Agricultural University of Athens  
Iera Odos 75, 118 55  
Athens  
GREECE  
pskan@aua.gr, pskan@otenet.gr

### **George TSAMIS**

Agricultural Policy Division  
Ministry of Rural Development and Food  
GREECE  
ax5u035@minagric.gr

## **ITALY**

### **Umberto AGRIMI**

Dept. Food Safety and Veterinary Public Health  
Istituto Superiore di Sanità - National Health Institute  
Viale Regina Elena, 299  
00161 Rome  
ITALY  
umberto.agrimi@iss.it

### **Antonia RICCI**

OIE/National Reference Laboratory for Salmonellosis  
Istituto Zooprofilattico Sperimentale delle Venezie  
Viale dell'Università, 10  
35020 Legnaro (Padova)  
ITALY  
aricci@izsvenezie.it

### **Giuseppe RU**

Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta  
BEAR - Biostatistica Epidemiologia e Analisi del Rischio  
Via Bologna, 148  
10154 Torino  
ITALY  
giuseppe.ru@izsto.it

### **Aida TURRINI**

Centro di Ricerca per gli Alimenti e la Nutrizione  
via Ardeatina, 546  
00178 Rome  
ITALY  
aida.turrini@entecra.it

## **LEBANON**

### **Khalil Amine EL-HELOU**

Department of Nutrition, Faculty of Pharmacy  
Medical Sciences Campus  
Saint-Joseph University  
Damascus Road  
Beirut  
LEBANON  
khalil.helou@usj.edu.lb

## **MALTA**

### **Flavia ZAMMIT**

Regulatory Affairs Directorate  
Technical Regulations Division  
Malta Competition and Consumer Affairs Authority (MCCAA)  
Mizzi House, National Road,  
Blata I-Bajda, HMR 9010  
MALTA  
flavia.zammit@mccaa.org.mt

## **MOROCCO**

### **Abdelaziz CHOUKRI**

Chef de Division Vétérinaire de l'Hygiène Alimentaire  
Office National de Sécurité Sanitaire des Produits Alimentaires (ONSSA)  
Rue Hadj Ahmed Cherkaoui  
Agdal, Rabat  
MOROCCO  
abdelaziz.choukri@gmail.com

### **Abdellah ZINEDINE**

Département de Biologie, Faculté des Sciences  
Université Chouaïb Doukkali  
BP 20 El Jadida, 24000  
MOROCCO  
zinedineab@yahoo.fr

## **PORTUGAL**

### **Jorge BARBOSA**

Instituto Nacional de Investigação Agrária e Veterinária, I.P.  
Av. da República, Quinta do Marquês  
2784-505 Oeiras  
PORTUGAL  
jorge.barbosa@iniav.pt

### **Fernando Jorge DOS RAMOS**

Centro de Estudos Farmaceuticos  
Faculdade de Farmácia, Universidade de Coimbra  
Azenhaga de Santa Comba  
3000-295 Coimbra  
PORTUGAL  
fjramos@ci.uc.pt, fframes@ff.uc.pt

**Lubélia Maria MARTINS DA SILVA**  
Departamento de Riscos Alimentares e  
Laboratoriais (DRAL)  
Instituto de Apoio às Pequenas e Médias  
Empresas  
e à Inovação (IAPMEI)  
Edifício F - Estrada do Paço do Lumiar  
1649-038 Lisboa 22  
PORTUGAL  
Immsilva@asae.pt

## **SPAIN**

**Agustín ARIÑO**  
Facultad de Veterinaria  
Universidad de Zaragoza  
Calle Miguel Servet, 177  
50013 Zaragoza  
SPAIN  
aarino@unizar.es

**Alejandro BARRANCO**  
Unidad de Investigación Alimentaria  
AZTI Tecnalia  
Astondo bidea, 609 eraikina  
48160 Derio (Bizkaia)  
SPAIN  
abarranco@azti.es

**Ana CANALS**  
Spanish Agency for Consumer Affairs,  
Food Safety and Nutrition (AECOSAN)  
Ministry of Health, Social Services and  
Equality  
Alcalá, 56  
28071 Madrid  
SPAIN  
acanals@msssi.es

**José María GARCÍA ÁLVAREZ-COQUE**  
Escuela Técnica Superior de Ingeniería  
Agronómica y del Medio Natural  
Universitat Politècnica de València  
Camino de Vera, s/n  
46022 Valencia  
SPAIN  
jmgarcia@upvnet.upv.es

**Vicente SANCHÍS**  
Applied Mycology Unit  
Food Technology Department  
University of Lleida  
Avda. Rovira Roure, 191  
25198 Lleida  
SPAIN  
vsanchis@tecal.udl.cat

**Antonio VALERO**  
Department of Food Science and  
Technology  
Faculty of Veterinary  
University of Cordoba  
Campus de Rabanales s/n  
Edif Darwin-Anexo  
Ctra Madrid-Cádiz Km 396-A  
14014 Córdoba  
SPAIN  
bt2vadia@uco.es

**M<sup>a</sup> Carmen VARELA**  
Centro Nacional de Epidemiología  
Instituto de Salud Carlos III  
Avda Monforte de Lemos, 5  
28029 Madrid  
SPAIN  
mvarelam@isciii.es

## **TUNISIA**

**Thouraya ANNABI- ATTIA**  
Agence Nationale de Contrôle Sanitaire et  
Environnemental des Produits (ANCSEP)  
Ministry of Public Health  
2, Rue Ibn Nadim Montplaisir  
1073 Tunis  
TUNISIA  
thouraya.attia@rns.tn

**Leila CHEKIR**  
Laboratory of Cellular and Molecular  
Biology  
Faculty of Dental Medicine  
University of Monastir  
Rue Avicenne  
Monastir, 5000  
TUNISIA  
leila.chekir@laposte.net



**Sabeur MANSOUR**

Department of Control of Products for  
Animal Feed  
Agence Nationale de Contrôle Sanitaire et  
Environnemental des Produits (ANCSEP)  
2, Rue Ibn Nadim Montplaisir  
1073 Tunis  
TUNISIA  
sabeur.mansour@laposte.net

**TURKEY****Hanife AYAN**

Department of Food Control and  
Laboratories  
Ministry of Food Agriculture and Livestock  
Eskişehir Yolu km 9  
Lodumlu/ Ankara  
TURKEY  
hanife.ayan@tarim.gov.tr

**Nihal BABALIOĞLU**

Ministry of Health  
Türkiye Halk Sağlığı Kurumu  
Refik Saydam Yerleşkesi D Blok  
Sağlık Mah. Adnan Saygun Cad. No:55  
06100 Sıhhiye/Ankara  
TURKEY  
nbabalioglu@gmail.com

**Serap HANCI**

Ministry of Food Agriculture and Livestock  
General Directorate of Food Control  
Department for Risk Assessment  
Eskişehir Yolu km. 9  
Lodumlu/ Ankara  
TURKEY  
Serap.hanci@tarim.gov.tr

**EFSA****Mary GILSENAN**

Evidence Management (DATA) Unit  
European Food Safety Authority (EFSA)  
Via Carlo Magno, 1 A  
I-43126 Parma  
ITALY  
Mary.GILSENAN@efsa.europa.eu

**Ernesto LIÉBANA**

European Food Safety Authority (EFSA)  
Scientific Unit on Biological Hazards  
Vi Carlo Magno, 1 A  
I-43126 Parma  
ITALY  
ernesto.liebana@efsa.europa.eu

**Finn SHEYE**

Pre-Accession and ENP Coordinator  
Advisory Forum and Scientific Cooperation  
Unit  
European Food Safety Authority (EFSA)  
Via Carlo Magno, 1 A  
I-43126 Parma  
ITALY  
finn.sheye@efsa.europa.eu

**IAEA****Najat MOKHTAR**

International Atomic Energy Agency (IAEA)  
Nutritional and Health-Related  
Environmental Studies Section  
Division of Human Health  
Department of Nuclear Sciences and  
Applications  
P.O. Box 100  
Wagramer Strasse, 5  
A-1400 Viena  
AUSTRIA  
n.mokhtar@iaea.org

**OIE****Rachid BOUGUEDOUR**

World Organisation for Animal  
Health/Organisation Mondiale de la Santé  
Animale (OIE)  
Représentant Afrique du Nord  
17 Avenue d'Afrique-El Menzah V  
2091-Tunis  
TUNISIA  
r.bouguedour@oie.int

**IAMZ- CIHEAM****Dunixi GABIÑA**

Instituto Agronómico Mediterráneo de  
Zaragoza (IAMZ)  
Av. Montañana, 1005  
50059 Zaragoza  
SPAIN  
iamz@iamz.ciheam.org

**Antonio LÓPEZ-FRANCOS**

Instituto Agronómico Mediterráneo de  
Zaragoza (IAMZ)  
Av. Montañana, 1005  
50059 Zaragoza  
SPAIN  
iamz@iamz.ciheam.org

**Ignacio ROMAGOSA**

Instituto Agronómico Mediterráneo de  
Zaragoza (IAMZ) Av. Montañana, 1005  
50059 Zaragoza  
SPAIN  
iamz@iamz.ciheam.org