The evolution of food safety and quality policies and practices in USA and UE. What's next?

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Abstract

The past forty years have seen a remarkable change in the regulatory environment in which the food industries operate: if the need of healthy and genuine food can be considered as old as manhood, food security is a relatively recent subject that has taken on increasing political, social and economic importance only in the last decades. The regulation of food safety has undergone major changes through both the public and private sector. Despite its recent history, food safety and quality are changing rapidly, becoming more stringent, both in developed and developing countries, through public and private quality control systems, in response to enhanced food safety problems. Private and public food safety regulations, standards and certification systems are responding to the consumer needs for safer foods throughout the whole farm to fork supply chain. In the meanwhile, food companies are seeking efficient means to assure food safety and quality in compliance with regulations across multiple countries. Despite all those efforts the global burden of food borne diseases is considerable: food recalls due to unsafe foods are growing every year (RAFSS, 2019; FDA, 2019), unsafe food containing harmful bacteria, viruses, parasites or chemical substances, still causes more than 200 different diseases and an estimated 600 million – almost 1 in 10 people in the world – fall ill after eating contaminated food and 420 000 die every year, resulting in the loss of 33 million healthy life years (WHO, 2015). Moreover, new treads, that are likely to increase in the future for many reasons such as the globalization of production, the increasing complexity of product formulas, and the closer monitoring by both firms and institutions (Berman, 1999; Chen, 2009), are mining the food supply chain: from malicious contamination of food for terrorist purposes, to deliberate acts of food sabotage, from GMO to Dioxins and polychlorinated biphenyls (PCBs) are toxic chemicals that persist in the environment and accumulate in the food chain. The aim of this paper is to retrace the main evolution stages of food safety, to understand how it has radically changed from its dawns to the present day and questions what changes are necessary or foreseeable in the near future.

Keywords — *Food Safety, Food Defence, Food Fraud, Public health protection.*

I. INTRODUCTION

The regulation of food safety has undergone major changes through both the public and private sector. If we think in historical perspective, it can be said that the law and food technologies have undergone not only an evolution but a radical reversal of objectives and motivations only in the last forty years.

Dating back to the dawn of the food safety, many of the known pathogens are the result of research occurred in the early twentieth century, when food microbiology developed in order to solve problems related to productivity and shelf life, rather than to meet a need for food safety. At that time, food poisoning had been known as "ptomaine poisoning" and ascribed to chemical changes in decomposing foodstuffs (1). From the early 1900, it came to be understood as being due to bacterial infection, causally associated with the consumption of animal foods, especially pork, beef and milk: in fact the early part of the past century, health of dairy animals and production, processing, and distribution practices were often poor and animal by and diary products ware the major vehicle for transmission to humans of diseases such as typhoid, diphtheria, septic sore throat, tuberculosis, and brucellosis (2).

Soon after its discovery, Salmonella represented a novel avenue for veterinary exploration, as the bacteria were thought to be the causative agent of hog cholera. But even after becoming the subject of worldwide attention from microbiologists, epidemiologists, and public health administrations, its connection to foodborne illness remained for long time a an unresolved conundrum and despite the frequent occurrence of cases of salmonellosis, active recognition of salmonellosis, or indeed of food poisoning in general, as a problem was slow to emerge. Almost the same destiny occurred to Listeria: when in 1924 E.G.D. Murray isolated Gram-positive pathogenic microorganisms, that couldn't be associated to any bacterial genus known at that time, the role of the agent called *Bacterium monocytogenes* was not realized until an epidemic of Listeriosis in newborns occurred in Germany in 1949. In the Institute of Pathology of the University of Halle a

peculiar entity was observed, hitherto unknown and called 'granulomatosis infantiseptica' (3). It was not until after World War II that as a result of technical advances in microbiology, which greatly facilitated the relating of case to cause, food poisoning had become a public health topic.

II. THE POST WAR FOOD LEGISLATION

During the post war years all the European Nations made efforts to improve food handling practices through regulation and education, where regulators combat food adulteration, fraud, and dangerous food. But mostly of the food law entered in force in the first after the European Community constitution was dictated by the desire to eliminate commercial obstacles within the European common market: the food legislative framework was conceived to facilitate the free movement of products and prevent distortions of competition, rather than in the interest of public health.

It is significant that the Treaty of Rome, establishing the European Economic Community, signed on 25 March 1957 together with the Treaty establishing the European Atomic Energy Community, does not even mention either public heath or food safety. Furthermore, no explicit reference to public heath was made until the adoption of the Single European Act (1986) and the Maastricht Treaty (1992).

The first interventions of EU food legislation are made up of nearly fifty "vertical" directives, aimed at defining composition standards for certain processed foods (the so-called "recipe rules"), laying down definitions and common rules in respect of the composition, manufacturing specifications, packaging and labeling of these products in order to ensure their free movement shaping many "euro-foods" and finding an agreement on common food quality requirements for "Euro-chocolate", "Euro-honey", "Euro-bread" and so on. The first of them, the Directive 73/241 / EEC on cocoa and chocolate products, had the declared purpose to remove the disparity between national laws which in fact hindered the free movement of cocoa products and may impose conditions of unfair competition on undertakings, directly affecting the establishment or functioning of the common market.

On one hand, national provisions on food were considered constituting trade obstacles; on the other hand, the Commission approach was based on the assumption that all specific requirements in national legislation of foodstuff already met all the essential public needs. Thus, the EC food law has initially been conceived as a set of rules prompted mainly by the desire to eliminate trade obstacles within the European internal market and having the force of law in all member states and, the legislative food law framework was designed primarily to answer economic rather than safety or public concerns. The harmonization approach was not dissimilar to the one adopted overseas at the same time.

In the USA, in the 70s, before the Congress 1906 Federal Food and Drugs Act, standards of identity were promulgated. They established the properties, characteristics and specific labeling requirements to which the various food products had to adapt in order to be identified with a specific legal name. Standards establish common or usual name and define nature of the food, generally in terms of types of ingredients that food must contain (i.e., mandatory ingredients), and those that it may contain (i.e., optional ingredients), the generally mandate how product is to be formulated or prepared, and sometimes specify how product must be prepared. According to FDCA§401: FDA may establish standard of identity for food to "promote honesty and fair dealing in the interest of consumers", and according to FMIA& PPIA (§§607(c), 457(b)): USDA may establish a definition and standard of identity or composition whenever "necessary for the protection of the public".

United States standards, both established by FDA or USDA, were aimed at preventing food fraud, and they were conceived as a trade promotion tool in the interest of consumers. Despite the fact that standards of identity were aimed to offer the necessary "public protection", this protection had few or nothing to do with public health and food safety, as a means to achieve a socially-desirable level of protection to human health.

The value protected by the standards was in fact the public trust, as well as the consumer's economic interest. In extreme summary, US Standards of Identity were primarily aimed at preventing "economic adulteration, by which less expensive ingredients were substituted so as to make the product inferior to that which the consumer expected to receive when purchasing a product with the name under which it was sold" (4).

Even when, in 1985, the European Commission abandoned the titanic effort to introduce a recipe for each category of food, embracing the so-called New Approach (5), in particular to those related to foodstuffs (6), based on the principle of mutual recognition formulated in the Cassis de Dijon judgment, its activity in the food sector was mainly oriented towards protecting the interests of the market.

III. THE TERRIBLE TWOS

To see the birth of the modern and formally regulated food safety both European Community and USA had to face two terrible foodborne outbreaks, dating back to the early 90s.

On January 12, 1993, a pediatric gastroenterologist notified the Washington State Department of Health of an increase in emergency department visits for bloody diarrhea and the hospitalization of three children with the hemolytic uremic syndrome. The first investigations suggested exposure at Jack In The

Box restaurants. Soon after, lab analysis confirmed E. coli was isolated from 11 lots of patties in Jack In The Box hamburgers in California, Nevada, and Idaho: a total of 732 people were affected by one of the most food poisoning outbreak in American history, that caused the death of four people, all of them children. At that time, most Americans had never even heard of E. coli, and even FDA was unprepared to face the outbreak. The outbreak "broke" the weekend of Bill Clinton's first Presidential inauguration, and it was one of the first exigencies to be faced by the new administration.

President Clinton called congressional hearings regarding the safety of the food supply, and the FDA raised recommendations on the internal temperature of cooked hamburgers to 155 degrees Fahrenheit. Immediately following the 1993 Jack-in-the-Box outbreak, the United States started to look for a more robust regulatory food safety system.

Soon after the Jack in the box outbreak, the British government had to face an unknown fatal human disease had appeared to be almost certainly linked to consuming Bovine Spongiform Encephalopathy (BSE) contaminated meat, as in late 1994 a number of people began to show symptoms of a neurological disease similar to Creutzfeldt-Jakob disease.

In Europe the outbreak eroded public trust in the food regulatory system, on the assumption that institutions had too often operated with conflicting policy objectives: the regulatory bodies and institution responsible for setting consumer protection standards were the same in charge of promoting trade and industry. Within the European Commission responsibility for regulating food safety was, for many years, located in Directorate-General III (DG-III), which initially had responsibility for promoting the interests of European industry. It was subsequently redesigned as having responsibility for the EU's internal market and enterprise.

Almost the same serious loss of public confidence in food safety policy-making institutions characterized the US: the fact that many food industries representatives had been appointed in the high ranking position of the USDA, shown that the financial pressures on the food industry were such that food hygiene was largely dependent upon external enforcement (7), compromising the independence of the regulatory process on food safety.

As a result, the E. coli and the BSE outbreaks clearly demonstrated the unsuitability of food systems conceived through the lens of the market and not focused on the protection of public health. There was increased interest on creating a more robust food safety system, by implementing of the Hazard Analysis Critical Control Point worldwide. Moreover, the institutions were forced to establish a new approach based on scientific assessments, aimed to guarantee effective and legitimate food safety policy and decision-making.

Following its adoption by the American FDA, elements of HACCP have also been integrated into the legislations of many European countries and made part of regulations at the European level through EU Directive 93/43, mandating five of the seven principles for parts of the food industry.

After this first move, the protection of public health become central in the food sector and took shape with the so-called "Hygiene package", the cornerstone of which is Regulation no. 178/2002, which finally endowed the Community with one of the most advanced food safety systems in the world that is still evolving.

IV. LATEST EVOLUTION KEYS

Despite the relatively recent history of food safety and its legal formalization, food safety and quality needs have changed rapidly The regulation of food safety has undergone major changes through both the public and private sector, as the need for an effective management of food quality and safety had become more and more evident among consumers.

Food safety norms have become more stringent, both in developed and developing countries, through public and private quality control systems, in response to enhanced food safety problems. Food companies are seeking efficient means to assure food safety and quality in compliance with regulations across multiple countries.

Notwithstanding all the efforts done, the global burden of food borne diseases is still considerable and new treads are mining food safety around the word. Food recalls due to unsafe foods are growing every year (RAFSS, 2019;) (8), unsafe food containing harmful bacteria, viruses, parasites or chemical substances, still causes more than 200 different diseases and an estimated 600 million – almost 1 in 10 people in the world – fall ill after eating contaminated food and 420 000 die every year, resulting in the loss of 33 million healthy life years (WHO, 2015).

It appears that the evolution of food safety has not yet reached its peak. Some key elements are often associated to the continuous evolution of food safety, both on the regulatory side, on the industrial, on the private and on the operational side.

First, reforms of food safety regulatory systems are still often led by consumers' real and/or perceived risks in food production, resulting out of a series of food safety crises and increasing consumer anxiety and distrust. In the last twenty years, in many cases, the stimulus for further innovations was triggered by new food scandals. Public concern on particular and brand new food safety issue, i.e dioxin contamination or Glifosate, increased public awareness, undermined the confidence of consumers in the capacity of the food industry (in its broadest sense) and the public authorities to ensure that their food is safe (9) and was itself the booster for new and more efficient regulations.

Secondly, many reasons such as the globalization of production, the increasing complexity of product formulas (10;11), new food tech and novel ingredients often rise the question If the traditional food security systems are still adequate to cope with today's complex and continuously evolving scenarios: global trade, economic growth, the structure of the agro-food supply chains, technological innovations, GMOs, novel foods, climate change, polychlorinated biphenyls (PCBs) are toxic chemicals that persist in the environment and accumulate in the food chain make the issue of food security increasingly complex and complexity is one of the worst enemies in the field of food security.

Third, new treads linked to deliberated contamination are likely to increase in the future from malicious contamination of food for terrorist purposes, to deliberate acts of food sabotage,

Fourth, responsibility for ensuring food safety has been devolved from the state towards the private sector. A variety of private entities is now involved in the establishment of voluntary standards including industry and trade organizations, professional societies, standards-setting membership organizations and industry consortia, which in some cases are coordinated by a public entity.

Fifth, food safety and quality, in addition to reducing risk, provide businesses with a basis for product differentiation, and become little by little part of companies' competitive strategies. In many cases food safety and quality company's policies are connected to a certain economic advantage, associated with origin, safety, environmental and social impact, etc.

Alongside the traditional distinction between "Food safety" and "Food security", it has combined and developed the most recent concepts of "Food Defence" and "Food Fraud Mitigation" which, together with the wider "Food Quality", constitute a range of tools aimed at promoting the safety and quality of food products.

Food Safety refers to handling, preparing and storing food to best reduce the risk safety related to "a biological, chemical, or physical agent" (BS EN ISO 22000; 2005;) (12;13).

According to the Food and Drug Administration (FDA), the term food defence is the effort to protect food from intentional acts of adulteration in cases where there is an intention to cause large-scale public health harm and economic disruption. Acts of intentional adulteration may take several forms like: acts of terrorism, acts of disgruntled employees, consumers, or competitors as well as economically motivated adulteration. The term food defence applies to the sum of actions and activities including Food defence measures taken to protect food from intentional acts of adulteration related to terrorism (14).

In this context of continuous evolution, EFSA recently announced the inclusion of sociologists in the scientific risk analysis process and the use of artificial intelligence for the study of complexity in the food chain. In the United States, in October 2019, the deputy commissioner of the FDA for food policy, in the wake of the law on the modernization of food safety, signed in 2011 by Barack Obama, presented the table on the "new era of food safety", defined Smarter Food Safety focuses on "much more than science and technology, but also on leadership and creativity, on simpler, more effective and modern approaches and processes."

Change is also necessary in industry, where to date the HACCP method is the main, if not the only, way to implement food safety risk management. Indeed, the identification and prioritization of hazards as a result of the first HACCP principle is limited to the risks of accidental chemical, physical and microbiological contamination and is often not sufficient to fully identify the hazards that during all phases of the production process contribute significantly and critically to food safety. This is how other branches dedicated to the prevention of intentional contamination and the mitigation of fraud risk have developed alongside food safety in the strict sense, dedicated to the prevention of risks from unintentional contamination.

The HACCP plan was associated with the preparation of the VACCP (Vulneranility Analysis Critical Control Points) and TACCP (Treats Analysis Critical Control Points) plans, which identify and aim to mitigate, respectively, the risks due to fraudulent alterations and intentional contamination of food products and for which food science often must be accompanied by additional skills, which mainly concern the sphere of behavioral sciences.

Furthermore, given the complexity of the supply chain, the activities traditionally relegated to the management of the supply chain, and therefore of the supplies and handling of goods, are often intimately connected with the safety of food in a broad sense and need to be reviewed with a view to protection of food integrity.

This is how the HACCP method has evolved, recently, in the USA, in the more complex HARPC (Hazard Analysis and Risk-Based Preventive Controls for Human or Animal Food), an instrument intended to comply with the requirements defined by the FSMA (Food Safety Modernization Act), necessary only for the Osas operating in the United States. Unlike HACCP, the HARPC system embodies the concept of prevention and evaluation not only of traditional physical, chemical and microbiological risks, which can be defined as conventional, but also the risks of technically unavoidable contamination (natural toxins, pesticides, pesticides, allergens, preservatives and dyes), those deriving from the dangers present in nature, those generated by unintentional behaviors related to the interaction between the human element

and the instruments, machinery, procedures, and those introduced by acts of contamination or intentional alterations, including acts of food bioterrorism and the mitigation of the risk of food fraud.

V. CONCLUSIONS

Although the adoption of a HARPC model is currently an exclusive prerogative of US operators, our food business operators, to keep up with the new and complex challenges, many companies around the word shall commit to adopt an increasingly multidisciplinary, holistic and systematic approach that requires employees, to extend their skills to the perfect understanding and knowledge of the organizational and decision-making process of the contract negotiation aspects, to include the in-depth knowledge of food law, social sciences and even criminology , without ever losing the science based approach.

The multidisciplinary approach, compatible and even complementary to the traditional approach, represents, for food producers and processors who can rely on it, a fundamental support tool for making informed 360° decisions, starting from the qualification and selection process of the suppliers, up to the communication and product marketing and from which the food technologist not only should not be excluded, but can draw a lot of relevant information and provide a reading key oriented towards achieving the goal of ensuring healthy, safe and genuine with a view to a complete food safety system.

Often, in the field of food safety, the expression "food safety management system" is heard, usually referred to a set of tools that include plans and good manufacturing practices, processes and procedures that are considered related, but of which rarely is a fundamental characteristic emphasized: the ability to influence each other.

On the contrary, the numerous activities and processes involving a food from the earth to the table are not only connected, but are capable of influencing each other (positively or negatively).

The positive influence and the creation of a real food safety system will occur not only if the food technologist is able to combine his scientific skills with the ability to understand and intervene in company organizational processes that are extraneous to the food sciences, but capable to impact on the safety of food, but also if other roles traditionally excluded from food safety training will acquire greater sensitivity and responsibility with a view to achieving the common and priority objective of guaranteeing the integrity of food.

One result of increasing public awareness about issues of responsibility in the processes of globalization is a proliferation of standards, codes of conduct, principles, and new reporting and monitoring systems throughout many industries. The emergence of global standards on issues of human and labor rights and environmental protection suggests that voluntary initiatives, where companies choose to participate, may be an attractive alternative to regulation or legislation.

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