From ‘Food to fraud’.
The continuous battle against dishonest practices in the food chain.

MSc Thesis

A comparative analysis between the European and the American (USA) food fraud control systems.

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From ‘food to fraud’: The continuous battle against dishonest practices in the food chain. A comparative analysis between the European and the American food fraud control systems.

Master Thesis

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Acknowledgments

I would like to express my gratitude to my supervisor Kai Purnhagen for his valuable comments and time while guiding me in the development of this thesis project. I also want to thank Prof. Bern van der Meulen for his suggestions and interest in my research.

It has been a rewarding and pleasant experience to work in the Food Law & Governance Department of Wageningen University.

Special thanks to my family, Joost Gieling and all my friends for their support and motivation at all time!

Abstract

Food fraud is an emerging problem that concerns not just the authorities but also the consumers all around the world because they could be exposed at any time, every day to the hidden risks in the food they purchase. Several recent cases, like the horsemeat scandal (2013) or the Melamine crisis (2008), had shown that food fraud is a current problem and strategies addressed to it shall be a priority. The objective of this research was to analyse the strategies carried out to combat food fraud in the main food safety legislations in Europe and the United States. Regulation (EC) 178/2002, also known as The General Food Law in Europe aims to provide the food policies that can assure a high level of protection of human health, within the limits of the free movement of goods; in this research every provision was carefully examined to determine until which extent and how food fraud is covered by them. In the United States, the Food Safety Modernization Act (2011) was created to modernize the food safety policies (Food, Drug & Cosmetic Act 1938) and turn the focus on prevention rather than intervention; this research focuses on the strategies that can include food fraud under their scope. A comparison was made between these legislations and two seafood fraud reports were included. The results showed that food fraud is slightly covered by a few food safety provisions and the lack of harmonisation in definitions, traceability system and enforcement of law seem to be the major challenges for the authorities when addressing this problem.

Key words: food fraud, economically motivated adulteration, legislation, food safety, Europe, United States, prevention, control.

List of abbreviations

CBP – Customs and Border Protections in US

DG SANCO - Directorate General (Health and Consumer Protection)

EC - European Commission

EP – European Parliament

EU – European Union

EFSA - European Food Safety Authority (also known as 'The Authority')

EFTA – European Free Trade Association

EMA – Economically Motivated Adulteration

FDA – U.S. Food and Drug Administration

FD&C Act – Food, Drug and Cosmetic Act (1938)

FSA – Food Standards Agency in the UK

FSAI – Food Safety Authority of Ireland

FSMA - Food Safety Modernization Act (2011)

FVO – Commission's Food and Veterinary Office

GAO –U.S. Government Accountability Office

GMP – Good Manufacturing Practices

GFL - General Food Law (Regulation (EC) No. 178/2002)

HACCP – Hazard Analysis and Critical Control Points

IFT – Institute of food technologies

JRC – Joint Research Centre (European Commission)

M.S. – Member States

OLAF – European Commission Anti-Fraud Office

ORA – FDA's Office of Regulatory Affairs

RASFF - Rapid Alert System for Food and Feed

UK – United Kingdom

U.S. - United States

U.S.A. – United States of America

U.S.D.A – U.S. Department of Agriculture

U.S.C. – U.S. Code

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1. Introduction and significance of research

Food is a basic necessity of life and consumers have the opportunity to choose which food best suits for their individual requirements. By the process of globalization including better communication methods, treaties and exchanges, consumers can purchase foods and products from all over the world, this could be very positive but it could also represent an open door for new health risks and hazards.

There exists different types of food risks[1], some could be unintentional like microorganisms that compromise the safety of the products or deterioration that can result in the loss of quality, or intentional that are usually motivated by economic gain or public harm.

The food risk matrix (figure 1) was created to clarify these concepts and differentiate them by action (unintentional or intentional) or motivation (economic gain or terror). [1]

Food risk matrix		
FOOD QUALITY	FOOD FRAUD	Motivation Gain: **Economic**
FOOD SAFETY	FOOD DEFENSE	**Harm** Public Health: Economic or terror
Unintentional	Intentional	
Action		

Figure 1. Food risk matrix (J. Spink)
Food fraud safety, defense and quality 2012.

For purposes of this thesis project, the main focus will be on “Food Fraud” which is an intentional practice in which food, ingredients or food products are adulterated, substituted, mislabelled, diluted or modified, usually, for economic gain (ACPPP 2012).[1]

Food fraud does not intend to cause harm to the consumer, but it has the potential to be a public health risk[1] because fraudulent operators do not follow good manufacturing and handling practices; so hidden substances, allergens or contaminants can be present in unknown levels and under any approval or scientific advice.

1. Retrieved at: http://www.youtube.com/watch?v=CGpOpfdcHRk Food fraud Video 2 of 3

Food fraud is not a new issue; recently, some cases have brought it into the public light (Shears, 2010). In 2008 in China, one of the biggest food fraud crisis of the 21st century took place when it was discovered that manufacturers were adulterating milk and infant formula with melamine, a compound used for plasticizers; this practice was made because the milk and infant formula were diluted and melamine appears to raise the protein content of this products. The consequences of this fraud affected almost 300,000 children who presented kidney damage, kidney stones or kidney failure and at least 6 deaths were reported. (Everstine, Spink & Kennedy 2013)

In Europe, the task of the government is to guarantee as much as possible, within the limits of the free movement of goods, that the food consumers are purchasing is safe to eat and it will not represent unacceptable risks; this is carried out by food regulations and policies. Food legislations are aimed to provide high levels of food safety which will be reflected in the promotion and protection of human health of the final consumer. (White paper of food safety, 2000)

Europe and United States are considered to have two of the safest food chains in the world.[2,3] Considering a high level of food safety as a priority[4], the last update of food safety laws in these regions have started to consider food fraud by alerting manufacturers and operators to follow GMP and avoid dishonest practices in the food chain.

The European food law, Regulation 178/2002 – 'The General Food Law' was built up with the creation of the "Farm to Fork" policy that considers the complete food chain as a whole from the raw materials to ended products.[5] The European Food Safety Authority was also created with the aim of providing scientific advice in terms of food safety, intervention in the rapid communication exchange in case of an emergency and communication with consumers about any risk related to food, besides this, new food safety measures were developed and new methods for operation and production.(Reg. (EC) 178/2002) Food fraud is considered in "Protection of Consumers' Interests" focused in prevention of deceptive practices, adulteration of food or any other practice that could mislead the consumers.[6]

2. Retrieved at: http://www.youtube.com/watch?v=U6v8eqEsoKY – Food fraud video 1 of 3
3. Retrieved at: http://europa.eu/rapid/press-release_IP-13-400_en.htm
4. Retrieved at: http://ec.europa.eu/food/food/foodlaw/index_en.htm
5. EU integrated approach to food safety
6. Article 8. Regulation (EC) 178/2002

In The United States, in 2011 The Food Safety Modernization Act was implemented, this is the last update since 1983 in food safety policies in the U.S. It aims to modernize the food safety system and focus on prevention. The main aspects of this Act are new food safety standards, preventive controls in food and food products produced and imported to the U.S., emergency management, science based standards, traceability, certifications, better communication with consumers and the prevention of intentional adulteration based on science and focusing on vulnerable points in the food chain.[7]

Food legislations seem to address food fraud in a limited way. Food fraud is a dishonest practice and is intended to avoid detection, thus it is not easy to have it under control; however several strategies and food safety standards can prevent the risks involved. Food fraud represents a big challenge; it is considered as a continuous risk and the government, food businesses and consumers must be aware of it.

The relevance of a legal framework analysis addressed to combat food fraud will show the improvements in food safety law and the strategies that are needed to prevent, intervene or respond to a food fraud incident. The significance of a comparison between Europe and United States will bring a clearer view of the measures intended to combat fraud and the most vulnerable points of the food chain.

2. Aim

This research aimed to compare the control measures for food fraud from 'The General Food Law' in Europe and The Food Safety Legislations in the United States, in order to determine the most important strategies to combat fraudulent practices in the food chain.

3. Thesis statement and research questions

Dishonest practices in the food chain are a continuous risk, they are intended to be undetected and that is what makes them more dangerous. Recently some large scale food fraud incidents have been present in developed countries and authorities should be aware to prevent this problem. A complete understanding of measures to prevent and detect food fraud is necessary.

7. Retrieved at: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm249243.htm

‘Fraudulent practice’ is a concept found in European legislation (Art. 8 Reg. 178/2002) and in the United States food fraud is considered as Economically Motivated Adulteration; this difference could have an impact on the regulatory framework and the strategies to control food fraud, so a clear understanding of definitions and legislation is needed. Together with this, a comparison between both legislations is required to determine the most important strategies to combat food fraud from each perspective. Figure 2 gives a schematic representation of the aim of this research.

Figure 2. Comparison between food safety legislations in Europe and United States regarding food fraud

To complete the aim of this research, the following research questions were formulated:

1. *How is the concept of food fraud considered in Europe? Is there a difference between this concept and economically motivated adulteration from USA?*

In USA, the concept of Economically Motivated Adulteration is defined, but who gives a definition for food fraud in Europe? Food fraud or fraudulent practices and EMA definitions need to be clarified to have a complete understanding of how food fraud is addressed by law and to provide legal consistency. If there are other reasons, more than economical to commit food fraud, legislation have to implement then decisions based on the causes. If regulatory framework is affected by the concept, then different sources and strategies will be needed.

2. *What is the place of food fraud in EU and US legislations? How do USA legislations and The General Food Law address this problem?*

Both legislations establish general food safety standards, but until which extent and how much detail is addressed to food fraud in these laws? A comparison of the different approaches will help to understand the different perspectives.

3. *How do food fraudulent practices fit into the concept of "unsafe food" by The General Food Law? Does U.S.A. have the same approach when considering a food as "unsafe"?*

The GFL states that *"Food shall not be placed on the market if it is unsafe."*[8] It is needed to understand what makes a fraudulent food as "unsafe", which description best suits for it and how it is comparable with the legislation in USA.The concept of "safe" or 'unsafe' food can have different perspectives in both regions.

4. *Are food inspections considered as a practice to prevent food fraud in these legislations? Until which extent and how inspections can have an impact in detection of food fraud?*

If inspections can be used as a tool to detect food fraud, legislation can implement specific checks to the most vulnerable points or products in the food chain and determine who will be in charge of carrying them out. Understanding until which extent can inspections prevent or detect fraudulent practices is of most importance.

5. *What similarities or differences does the section "Protection against intentional adulteration" from The FSMA have with article 8 "Protection of consumers' interests" from The GFL?*

In the last updates of food safety legislations for Europe and United States, "Protection of consumers" (general) is considered. In The General Food Law *article 8,* it is stated as "*Protection of consumer's interest*"[9] and in the FSMA section 106, it is stated as "*Protection against Intentional Adulteration*"[10], it is of most importance to clarify these statements and determine which are the major focuses in these sections and what is the relation between them, if any.

8. Article 14. Regulation (EC) 178/2002
9. Article 8. Regulation (EC) 178/2002. The
10. Title I. Section 106. Food Safety Modernization Act

6. *Which are the most relevant strategies to combat food fraud in the GFL and FSMA? Which other parties are involved in implementing these strategies?*

Strategies can be based on prevention, inspection, monitoring or others, so determining which ones are used in Europe and in United States will represent an overview of how the resources from each region help to combat fraudulent practices in the food chain and recognize which other parties or authorities are involved in their implementation.

4. Methods and limitations

This thesis project constitutes a description and comparison of food fraud control measures (or applicable) found in Regulation (EC) No. 178/2002 'The General Food Law' from the European Union and The Food Safety Modernization Act 2011 from The United States (considering it is founded on the Food, Drug and Cosmetic Act of 1938). This thesis was carried out in a period of 6 months based on desk research and analysis of sources of secondary law and two seafood fraud reports, one for each region. For the comparison, the common core method was used.

The common core method is based on the analysis of the present situation of the existing laws and its application in their social context. It provides an outline of the relevant elements of different legal systems identifying common features and showing the level at which diversities are occurring. (Mauro Bussani, 1998) The method is not intended to determine which situation is preferable than the other, but just to present the current situation in both legislations, equally.

Europe and United States were selected for this research because they are two of the most developed regions of the world and their food safety systems are considered as two of the safest ones.[11, 12] European legislation (GFL) was obtained from EUR-Lex website and the U.S. legislation (F,D&C Act and FSMA) were obtained from The Food and Drug Administration (FDA) website. Scholarly articles, online videos from public authorities, scientific publications and the proposal for Regulation 178/2002 (from Pre-Lex) were reviewed as well. Besides legislation, two seafood fraud reports were included to determine the similarities and differences in the decisions taken, while considering the influences from both perspectives.

11. Retrieved at: http://www.youtube.com/watch?v=U6v8eqEsoKY – Food fraud video 1 of 3
12. Retrieved at: http://europa.eu/rapid/press-release_IP-13-400_en.htm

For Europe, the seafood fraud report called ***"Deterring illegal activities in the fisheries sector"*** from JRC in 2011[13] was analysed; and for USA, the selected seafood fraud report was "*Oceana Study Reveals Seafood Fraud Nationwide*" from Oceana in 2013[14].

Seafood fraud reports were selected because this type of fraud is a growing concern worldwide; fish species substitution had been found in very high percentages from 25 up to 70% in USA (Oceana's report) and about 25% or more in Ireland and UK.[15] Seafood fraud represents a health risk for consumers by exposing them to unknown allergens, contaminants and/or toxins. It just not affect consumers' protection and information, but also affects the oceans, vulnerable fish populations, honest vendors and fisherman, among other parts of the food chain. Seafood fraud report in Europe was obtained from the Joint Research Centre (European Commission) website and the Seafood fraud report for USA was obtained from Oceana's website.

5. Food fraud: European perspective

5.1 The General Food Law & EFSA

Regulation 178/2002 (EC) of the European Parliament and of the Council, also known as 'The General food Law', is the legislation that provides the general principles and requirements of food law, measures and procedures related to food safety and establishes for the first time the European Food Safety Authority. It emerges from the necessity to have a unified and coherent approach to regulate the safety of the supply chain regarding foodstuffs in the EU.

The Regulation aims to provide food policies that can assure a high level of protection of human health and the free movement of goods, contributing, with this, to the EU welfare and its economic and social interests. Within its scope, the food supply chain shall be considered as a whole, covering all the stages of production, processing and distribution of food and feed[16], from raw materials coming from primary production - farm or river - to ended products; this is known as the '*farm to fork'* approach, where each member of the chain has the obligation to comply with the policies. Not just food, but also feed and feed businesses have to comply with this EU food law[17], because many animals are intended for human consumption and any risk related to their feed could represent a risk to the final consumers.

13. JRC Reference reports., JRC European Commission website
14. Oceana is an international organization focused solely on ocean conservation.
15. In a study carried out in Dublin, Ireland it was shown that up to 25% of cod and haddock products were identified as other species from those indicated on the labels, which is considered, mislabeled under EU regulations. (Miller and Mariani 2010
16. Article 1(3) Reg 178/2002
17. Article 1 (2) Reg 178/2002

Among the main objectives of this Regulation there are:

- The provision of harmonised definitions in order to prevent impediments or barriers between M.S. and allow the free movement of goods through the EU.
- Provide rules and principles regarding food safety of products that are intended to be placed on the internal market or for trade.
- Lay down responsibilities and obligations on food and feed businesses, making them responsible for the safety of their products.
- The creation of the European Food Safety Authority, also known as "EFSA", based on the necessity of reinforcing the scientific and technical support in the food safety system.

Within its principles and objectives, Regulation (EC) 178/2002, aiming to provide a high level of health protection and facilitate the free movement of goods, considers consumers interests' by preventing deceptive practices in the food chain and expanding the view of other policies related to labelling and advertising in foodstuffs placed in the internal market.

EFSA is an independent risk assessment body for food safety, it shall provide scientific advice and technical support for the EU's legislation and policies covering all fields which may have an impact in food or feed safety; it shall contribute to achieve a high level of protection for human life and health and work in close cooperation with competent bodies of the M.S. that carry out activities within this field. EFSA is divided in a scientific committee and scientific panels which are formed by independent scientists and experts in the field of food safety.[18]

Within the activities of EFSA, it is included[19] to provide scientific opinions to the EU and the M.S. when there is a reason to believe a food can pose a risk; coordinate the methodology to carry our risk assessments; provide scientific and technical support to the Commission when requested; collect and analyze data that allow the characterization of a risk that could have an impact on food safety; promote networking between European organizations and institutions and provide independent conclusions in matters of the detected risks for food safety. It is noticed that EFSA's tasks are focused in food safety, and food fraud may be included in its activities when it represents a food safety risk.

18. The Scientific panels cover the following fields: Food additives and nutrient sources added to food (ANS), Additives and products or substances used in animal feed, Plant protection products and their residues, Genetically modified organisms (GMO), Dietetic Products Nutrition and Allergies, Biological Hazards (BIOHAZ), Contaminants in the food chain (CONTAM), Animal health and welfare (AHAW), Plant health (PLH) and Food contact materials, enzymes, flavourings and processing aids. (CEF)
19. Article 23 Reg 178/2002

5.2 Food fraud in EU legislation

In European legislation there is no definition of "*food fraud*", according to Commissioner Borg[20] (2013) there is not a harmonised description for it, but it is considered as a category of criminal offence. Mr Eric Poudelet[21] (2013), stated that the Commission is looking forward to lay down a definition of food fraud at the EU legislation. In a document from the European Parliament called "*Fighting against food fraud*", he refers to food fraud as "*Intentional violation of food law – for profit",* including three types: deception and adulteration, counterfeiting, smuggling and prohibition (Poudelet, 2013). In an E-publication (2012) from the European Commission, John Dali[22] refers to food fraud as "*a significant problem driven by the lure of vast potential profits";* and also a definition for "food crime" was given as "*the production, processing, distribution or marketing of any counterfeit or sub-standard foodstuff"*[23].

In the Opinion made by the Economic and Social Committee on the 'Proposal of Regulation 178/2002' (The GFL) the Committee stated that not defining "misleading" or "adulteration" was a missed opportunity. When the proposal was amended by the European Parliament (2001), it was suggested to consider "*measures to combat food fraud*" [24] as part of the general objectives of food law[25]. The EP considered European Institutions were incapable of making an adequate response to the growing problem of food fraud and that it should be treated as a priority for EFSA[26]; despite this statement, the European Commission adopted the statement "*fair practices in food trade*" instead of "*food fraud*" in Article 5[27]. It is possible that food fraud was considered as just as one of the food crimes that exist and fair practices was a better way to allude to it. By the justification of the EP it seems that food fraud is still considered as a problem coming from "outside Europe" as the statement includes the term "*food trade*"(Art. 5 Reg. 178/2002); in addition it can be seen that when developing European legislation, the Commission "prefers" to provide statements in the matter of "do's" instead of "don'ts" (van der Meulen, 2013).

20. Tonio Borg, Member of the European Commission, responsible for Health
21. Mr Eric Poudelet, Director of the Safety of the Food Chain at DG SANCO
22. John Dali is the EU Commissioner for Health & Consumer Policy
23. Health and consumers voice 2012 (EC)
24. European Parliament (2001), Amendments on proposal of Reg. 178/2002 (EC).
25. Art. 5 (1) Reg. 178/2002
26. European Parliament (2001), Amendments on proposal of Reg. 178/2002 (EC).
27. Article 5 (1) states that: *Food law pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and environment.*

In the following chapters, an overview of how food fraud is addressed by the General Food Law is presented. The priorities in EU food law are directed to food safety problems, but some strategies and requirements may cover food fraud under certain circumstances. (See Annex 1 for a list of EU policies that may consider food fraud under their scope).

5.3 Definitions

For a better understanding of the topic, the definition of "*food or foodstuff"* stated in Article 2 of Reg. 178/2002 is provided as follows: "*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans". Food includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment."*

"Food 'shall' not include:

- *(a) Feed*
- *(b) Live animals unless they are prepared for placing on the market for human consumption* (i.e oysters)
- *(c) Plants prior to harvesting*
- *(d) Medicinal products*
- *(e) Cosmetics*
- *(f) Tobacco and tobacco products*
- *(g) Narcotic or psychotropic substances*
- *(h) Residues and contaminants*

Other definitions are: [28]

"Food business": any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food.

"Food business operators": natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

"Placing on the market": means the holding of food or feed, for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves.

28. Article 3. Reg. 178/2002 (EC)

"Final consumer": means the ultimate consumer of a foodstuff who will not use the food as a part of any business operation or activity.

5.4 Addressing food fraud: Protection of consumers' interests and Presentation of food

Protection of consumers' interests

Article 8, "*Protection of consumers' interests*" which referes to the prevention of fraudulent or deceptive practices, adulteration of food and "practices that may mislead the consumers seem to be a provision intended to the prevention of food fraud; it is stated as follows:

"Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim the prevention of fraudulent or deceptive practices, the adulteration of food and any other practices which may mislead the consumer".

This provision is part of the general principles of food law, which means it does not imply obligations. It seems like the Prevention of *"fraudulent or deceptive practices, adulteration or other practices which may mislead consumers"* are activities that should of concern for authorities more than for food businesses. The GFL leaves to interpretation the way to achieve the prevention of fraudulent activities. Regarding general requirements of food law, there is no imposition concerning the prohibition of counterfeit products in the market.

The phrase "*Consumers' interests*" can lead to several interpretations; for example, which kind of interests? 'Interests' could be: personal interests? Like tastes? Health status? Necessities? Or maybe as economic or financial interests? Social interests? Etc. By the statement "*Food law shall provide a basis for consumers to make informed choices"* it may be understood that the only interests aimed to be protected are those ones regarding not to be misled, but there are a lot more fraudulent activities like transhipping, theft or smuggling that should be also considered. According to these examples, it would also be important to determine at which point of the GFL, are the other parties (honest business, primary producers, and retailers) prevented from fraudulent practices, because if they are subject to food fraud, consequently their products will be too.

Authorities may want to give confidence to consumers making them to believe that they are being protected against fraudulent activities, but the way on how to do this and how to prevent

food fraud is not indicated in legislation. Every M.S. should take over its own rules concerning the Protection of Consumers Interests and Prevention of food fraud.

Presentation of food

The only statement, found in the General Requirements of food law, addressed to mislabelling and misbranding (two types of fraudulent activities) is to be found in Article 16 -Presentation. In the proposal for Reg. 178/2002, article 8 and article 16 were combined in one, but in the final version, '*Protection of consumers' interests"* was considered as part of the general principles of food law and 'Presentation' was considered as part of the general requirements, unfortunately both statements are described in a very general way and there are no definitions provided. Article 16 at the same time, reinforces Directive 2000/13/EC regarding labelling, presentation and advertising of foodstuffs and it covers food fraud by the prevention of fraudulent labelling or any false statement in the package that may mislead the consumers.

Article 16 states "*labelling, advertising and presentation of food and feed shall not mislead the consumers".* Food labels are the only source of food information for consumers when deciding to purchase food and food products; choices are based either in the individual tastes, the nutritional value of the food, the characteristics of certain food or ingredient, the necessities of certain life stage, the health or nutritional claims in the labels, certain medical conditions, etc.. The presentation of the product should not mislead consumers, it should not create a false impression or false attributes to the food. Some examples of fraudulent labelling are: misrepresentation of net content or weight, stating different country of origin, labelling inferior or low quality ingredients as superior ones, listing ingredients that are absent, omitting ingredients, labelling different animal species, labelling food as 'organic' when it is not, claiming false beneficial effects, modifying of the 'use by' or 'best before' dates or providing false information about the manufacturer. Consumers cannot determine if the information in the labels is true or false, normally consumers do not weight the content of a pre-packaged food by fully trusting in what it is stated in the labels; if a food label is misleading in certain way or there is any ingredient that is not listed, the only way consumers could notice is when getting ill after consuming it or maybe, they would never notice.

Article 16 is clear and it should not lead to different interpretations but it is important to highlight there is not a statement that dictates at which point of the food chain, labels and presentation should be verified for compliance with law; by this, fraudulent practitioners may place food with misleading statements in the market and they have the possibility of not being discovered or

maybe just after the food is placed in the market. It seems this is a critical point to consider for developing future EU law.

As for example, the horsemeat scandal in 2013; it was considered as a fraudulent labelling practice which was very close to become a food safety problem because of the possible levels of phenylbutazone in the meat; fortunately after the risks assessments carried out by EFSA it resulted that it did not pose a risk to human health. The measures taken to control it seemed to be temporary and only focused in the horsemeat[29], without considering there are a lot more animal species that can be mislabelled. The strategies were directed to prevent food safety issues related to the meat and the origin of the horses that can end up in the food supply chain and no provisions considering labelling or verification of labels. Some of the immediate actions taken were making extensive DNA testing for horsemeat and determine the levels of phenylbutazone. The DNA testing was imposed for one month with the possibility of extension to two months, but...Would that be enough? Would horsemeat just be mislabelled within the first and second month after the scandal? What will happen after those two months? What if not just horsemeat is being mislabelled, but any other animal species? The Commission adopted the posture that it was not a problem of the legislation by itself, but a problem in the **enforcement of legislation[30]**. Sadly but true, the horsemeat was discovered by a *"random*" inspection in Ireland, this could lead consumers to think authorities were "lucky" to find it. Decisions were made based in the *prevention of this particular case,* and not in future improvements of the law.

By any way, business operators should provide genuine, complete, proper and reliable statements in the labels, the advertisings and presentation of food shall not be intended to mislead consumers. These provisions are important for two main reasons, first to inform the consumers about the description, characteristics and attributes of the food they can find in the market and second to use them as a tool when risk management decisions, traceability and liability are needed in case of an incident.

29. What have EU done after the horsemeat scandal?
30. EP – video horsemeat scandal and measures

5.5 Food fraud as a food safety issue

Article 14 of Regulation 178/2002, as part of the general requirements of food law, states:

"*Food shall not be placed in the market if is it unsafe"*

1. *"Food shall be deemed to be unsafe if it is considered to be:*

a) Injurious to health

b) Unfit for human consumption (in such a way that it will not be expected according to its intended use)

When a food is deemed to be injurious to health or potentially injurious to health, the effects by acute, medium or long term exposure, including those that can affect future generations, are considered. People with specific health sensitiveness are taken into account when determining when a food is injurious to them, with the exception that when food is correctly labelled and any consumer with certain health condition, who does not follow medical recommendations, have an adverse health effect by the food choices he/she made (example. consequences of eating too many high cholesterol food products). When determining a food to be unfit for human consumption, it refers to food that is considered to be contaminated, spoiled, putrefied, deteriorated, damaged or any similar characteristic that makes it inappropriate for consumption according to its intended use. When unfit for human consumption, any reasons of contamination of an extraneous matter or any other way are included.

If food is committed into fraud, it acquires characteristics that can turn it into "*unsafe*". Any type of adulteration can result in a change of authenticity, quality and stability of the food; it can contain a mix of injurious and undeclared ingredients and severely affect the most susceptible groups such as vegetarians, pregnant women, children, elderly or people with an illness or allergies. Sometimes food fraud could even be more dangerous that food safety regular issues because contaminants or extraneous substances are unconventional and maybe not even authorised to be used in the food industry.

Some examples by which food fraud should be considered as *unsafe* are: food that has been adulterated with toxic or deleterious substances; food totally or partially substituted with constituents that are not authorised in the food industry; animals intended for human consumption that had been exposed to non-authorised drugs; animals that died from disease; omission of ingredients in the labels (specially posing a big risk to people with allergies);

modification of expiration date in the label or package of the food (the undesirable microbial load can pose a big risk to health); etc.

Unfortunately, the safety of a food committed into fraud cannot be determined by its only appearance (smell, colour, etc..), unless its regular characteristics are completely changed. If fraud is not detected before the food is placed in the market, safety risks will be discovered after consumers get the adverse effects from it. Several cases had shown that food fraud can represent a huge safety problem, here are presented some of them.

In 1981, a fatal food fraud case involved an industrial-grade rapeseed oil fraudulently and intentionally sold as olive oil (for human consumption) in Spain causing a huge intoxication affecting around 20,000 people and 330 deaths, some people who survived the intoxication are still carrying the life-threatening consequences[31]. In 2003, French authorities found dyes - normally used in the plastic and synthetic materials industry - in chili powder and chilli products, the Sudan dyes found are not authorised for their use in food, as they are considered to have genotoxic and carcinogenic effects (the dyes were used to enhance the colour of the products, as the price of chili powder is linked to the intensity of its colour[32)]. In 2005, in China more than 13 babies died of malnutrition after being fed with a diluted infant formulae with no nutritional value; the fraudulent practitioners supplied infant formula that contained less than 6% of the requirements of vitamins, minerals and protein for children, causing severe malnutrition and some fatalities. In 2008, China had a huge food fraud crisis known as 'The Melamine Crisis' when infant formulae was adulterated with melamine, a compound mainly used in the plasticizers industry to fraudulently rise the protein content in the nitrogen tests causing more than 300,000 hospitalizations and at least 6 deaths due to renal failure, kidney stones and kidney problems in babies and children. (Shears, 2010).

As seen in these cases, food fraud can have implications in food safety which may end up in harmful or fatal consequences, however not all food fraud cases turn out to be health risks; this can be shown by the "horsmeat scandal". Several discussions between representatives of the M.S. and the EU Commissiones took place[33] when determining if the horsemeat was a food safety issue or not; according to EFSA's report on phenylbutazone levels, the meat does not pose a health risk to consumers and Commissioner Borg adopted this posture, yet representatives from some M.S. considered food fraud as a type of crime that is not well covered nor enforced by EU law.

31. *Food Quality & Safety magazine,* June/July 2013
32. Questions & answers on sudan dyes. EC
33. EP – video horsemeat scandal and measures

It is clear that food fraud represents a food safety concern in many cases, but it is complicated to determine until which extent it can be injurious to health or unfit for human consumption; this can only be done after the risk assessment of the particular substances involved and the particular characteristics of the consumers.

In food fraud, the safety of the food mainly lies in the fraudulent practitioners because they are the only ones that know which substances are circulating into the food or which ingredient/s was/were omitted in the label. When food fraud represents a safety issue, the provisions in article 14 shall apply and it should be deemed as "*unsafe"*, but if it does not pose a health risk, it seems that food fraud receives less attention by the GFL, except when provisions regarding labelling should be considered.

5.6 Other provisions:

5.6.1 Responsibilities

Article 17 provides, to the food business operators, the legal responsibility to "*satisfy the requirements of food law which are relevant to their activities"*, which shall guarantee the products they are placing on the market meet all food law requirements; however no requirements regarding authenticity or quality are mentioned in the GFL. Unfortunately, in most of the cases, food business operators are the ones committing fraud, so it is their own responsibility to maintain honest practices within their business. The provision also attributes M.S. the responsibility to *enforce food legislation* by monitoring and verifying that relevant requirements of food law are met at all the stages of the food supply chain; they should also lay down measures and penalties applicable in case of infringement. It would be interesting to analyse if sanctions imposed to food fraud are higher that the profit that can be made from it.

These statements addressed to M.S. are reinforced by Regulation 882/2004 (EC) on official controls performed to ensure the verification of compliance with food law. M.S. may use the methods they consider more appropriate to carry out *official controls*. "Official control" is defined as: "*any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules"* [34].

34. Article 2 (1). Regulation 882/2004 (EC)

Several activities are aimed to detect non-compliances with food law; methods used to carry out official controls include monitoring, surveillance, verification, audits, inspections, sampling and analysis; however the way on how to accomplish them is not indicated. There is no obligation to keep records, no determination on how often official controls should be carried out and a very important statement: "*Member States shall maintain a system of official controls and other activities as appropriate to the circumstances"*, which allows every M.S. to determine their own *Relevant Circumstances*. This allows to M.S. to decide what to include within the official controls, so food fraud may not even be part of them or even worst, M.S. are not trained for it.

The lack of harmonisation on how to carry out official controls, the lack of specific techniques to use verification of compliance and the lack of attention in food authenticity may lead food fraud to be undetected or with very little chances to be detected; unfortunately there is no imposition to consider it under regular audits or inspections.

5.6.2 Traceability

Traceability is defined as *"the ability to trace and follow food, feed and ingredients through all stages of production, processing and distribution.*[35]*"* The implementation of a traceability system of food, feed and food producing animals at all the stages of production, processing and distribution is required[36]. The limitation is that food or feed business operators should at least identify the one step 'above' and the one step 'below' of whom they have supplied[37].

Food should be appropriately labelled or marked by codes (or other mechanism) and food business operators should keep the relevant documentation to facilitate its traceability. Operators also have the responsibility to know the businesses which they have supplied and where to identify the food (or ingredients) that were produced by their own responsibility [38] (food - or ingredients incorporated to a food- likely to be placed in the market). All the information regarding this system should be available to the competent authorities on demand[39].

35. Article 3 (15) Reg 178/2002
36. Article 18 Reg. 178/2002
37. Proposal of Reg 178/2002
38. Article 18 (2, 3) Reg 178/2002
39. Article 2 , 2nd paragraph art 18. Reg 178/2002

When a food fraud incident is of concern by the use a traceability system, the products should be able to be detected at any stage of the food supply chain, from primary production to retail level; and then risk management decisions can be implemented more efficiently (e.g. withdrawals from the market) or liability issues. The right and targeted identification of the origin of food is an essential part for the protection of consumers.

Traceability goes together with tracking. Tracking refers to the ability to follow the way of a food or feed from the beginning to the end of the food supply chain. Tracing refers to the ability to identify the origin of a food or feed through documents and records from the end to the beginning of the food supply chain. (See Fig 3.)

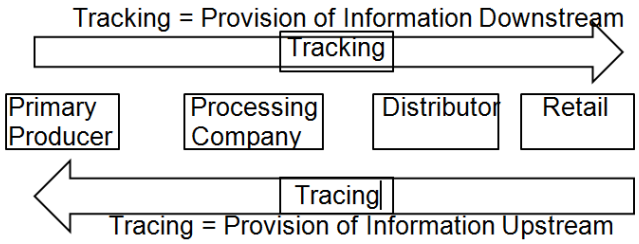

Fig 3. Tracking and tracing along the food supply chain [40] (adapted from F. Schwagele 2005/Traceability from a European perspective)

Traceability can also be used as a tool to identify at which point of the supply chain is food fraud occurring; however there are no requirements in EU food law to implement this or to identify facilities where fraud may be taking place. In addition there are no specifications on how to carry out traceability and there is no requirement to determine if it is being implemented in the right way. The most common form that food business operators use to perform traceability is by documents and certifications, yet these can also be subject to falsification[41] and there is no provision directed to the verification of authenticity for traceability documents.

40. This figure was adapted finishing the supply chain at retail level, because the requirement of traceability applies only to businesses and it is not extended to the consumer. (European Food Law Handbook Chap. 11)
41. Seafood fraud report JRC 2011

5.6.3 Precautionary principle

When there is a concern of an identified risk that may have harmful effects on health, but scientific uncertainty still persists, some temporary measures have to be taken in order to assure a high level of health protection until more information is available to carry out a complete risk assessment; this can done by the so called “precautionary principle” (article 7, Reg. 178/2002). The precautionary principle should not be a cause of unnecessary barriers in the free movement of goods or trade and it shall follows the principles of non-discrimination and proportionality (EC 2000). In the field of food fraud, the precautionary principle could also be used when a product is *suspected* to be committed into fraud and a risk to health is identified; risk managers should consider all the possible options, consult different sources of information and the opinion of experts in order to determine what an “acceptable level of risk” could be. Benefits of the measure taken also include the acceptance of it by the public, its efficacy and impact in the short and long term in the society.

5.6.4 Principles of transparency: Public information

When there exists any reason to suspect that any food or feed could constitute a risk – even for food safety or food fraud - to human life, health or animal welfare, depending on the seriousness of the matter, where does it come from and the danger it could represent, public authorities shall inform the general public (article 10 Reg. 178/2002). The public have the right to know if there is any food representing (or that could represent) a risk, the type of risk, what are the possible adverse health effects and the measures that are needed to avoid, minimize or eliminate it. Article 10 considers the rights of the general public to be informed *yet* the information and the way it is available will depend on the nature, seriousness and extent of the risk; this means the risk first need to be categorized and then, public authorities will decide how to communicate it. By providing access to information to EU citizens, the confidence of them in food law may be increased.

5.7 Control of food imports into the EU

Food and feed imported into the EU that is intended to be placed in the market or used for manufacturing food or feed for the internal market should comply with all specifications and requirements of EU food law (art. 11 Reg. 178/2002). If a food for import fails to comply with the EU food safety and labelling standards, then it will be rejected and not allowed to enter into the EU.

When food that is coming from a third country is rejected, the importer country should provide the exporter the reasons of rejection, which authorities were involved, the place of rejection, a description of the non-compliances, whether the whole or only a part of the consignment was refused to entry, etc. If any food is suspected to be committed into fraud before its entrance into the EU, then a temporary ban may be imposed until the suspicion is confirmed or declined (CAC 1997).

Food can be rejected by being found "*unsafe"* or "*unacceptable*" when subjected to examination and having any of the following characteristics (or other relevant) [42]:

- it does not cover the requirements of food law
- it has any type of defect
- it presents false statements in the labels
- it contains misleading documentation
- the contaminants or additives in it are exceeding the permitted levels
- it is presented in a decomposed or putrid form
- it contains not allowed substances
- there is contradiction between documentation and reports
- it is totally or partially damaged
- it presents any kind of biological, chemical or physical contamination
- false certificates are provided
- it is coming from a non-authorised establishment
- its label is altered or modified
- there is a suspect of adulteration
- it has a different quality than specified
- it is presented in bad condition
- Its package has signs of damage.
- others

Ideally, at border posts, authorities shall be aware of food fraud and include it in the ordinary inspections; unfortunately there is no imposition to consider fraud within their regular activities, a requirement which determines how much percentage of food should be inspected for fraud does not exist and there is no imposition that inspectors should be trained for fraud. It would be of most importance to include specific provisions directed to fraud in EU border inspections.

42. Imports of animals and food of animal origin from non-EU countries.

5.8 Could food fraud be considered as a defective product? Liability

Article 21 draws the provisions for liability to Council Directive 85/374/EEC concerning liability of defective products. According to this Directive, a "defective product" occurs when "*the product does not provide the safety which a person is entitled to expect including its presentation, expected use and the time when it was put into circulation"* (art. 2 Directive 85/374/EEC). The liability for a defective product lies in the producer; understanding the producer as the manufacturer of the final product, or the producer of raw materials or the manufacturer or the person who claims to present himself as the producer by a name or trading mark in the product (art. 3). If the consumer suffers a damage caused by a defective product, he/she has to prove the damage, the defect of the product and the relation between the defect and the damage. It is noticed that food law does not provide legal rights to the consumers, but it has a big influence on their rights by other foundations.

It is important to notice that "*if all provisions shall be without prejudice*" to Directive 85/374/EEC, then all definitions provided should apply as well and by this means "Food" should be considered as a "Product". By Article 2 of the Directive, a 'Product' means "*all movables even if incorporated into another movable or into an immovable; Product includes electricity".* This looks like a completely different perspective compared to the one given in Regulation 178/2002 in which food is defined as "*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans*.", so it could be understood that by this provision, food may be comparable to "*electricity*". It is noticed that regarding liability, EU food law transferred all the provisions to this Directive, even there are 17 years of difference between them and that by any way it is focused on food.

By article 6 of Directive 85/374/EEC, a "defective product" occurs when "*the product does not provide the safety which a person is entitled to expect"*; then a "defect" will be just considered as such based in the *safety* it provides; if food fraud does not represent a safety risk, it should not be considered as *defective*.

It is also mentioned that the injured person, in this case, the *consumer* has to prove the relation between the damage and the product (art. 4), but until which extent this could be possible? In EU food law, protection of consumers seems to be a priority, but in this statement it looks like law is protecting food businesses more than consumers, because how could a consumer prove a defect on the food? Do they have the right tools to do it? Do they have to send the food to analysis? Do they have to carry out the investigations? It is also stated that the injured person – consumer- is required to prove the damage he/she suffered (art. 4) and "damage" as defined

in Article 9, means, among others, a "*damage caused by death or personal injuries".* So consumers first should be victims and suffer consequences, even death, before they can prove there was a defect in the food. This approach does not seem to have any harmonisation with the General Provisions of food law.

Council Directive 85/374/EEC is not focused on food nor protection of consumers' health nor any other statement related to food law; consumers have to prove they suffer a damage and its relation to defective food, which seems to be quite complicated. Food law shall implement its own liability rules and follow the general principles it demands to have.

5.9 Tools for emergency/crisis

Tools for emergency or crisis refer to those provisions in legislation that should be met when food is already placed in the market and it is found to represent a risk for human life, health, animal welfare or environment; these measures are created to provide plans and steps to follow in case of an emergency or crisis. Tools for emergency/crisis in Regulation 178/2002 include: rapid alert system (art. 50), emergency measures (art. 53) and crisis management (art. 55).

5.9.1 Rapid Alert System

The Rapid Alert System for Food and Feed is a network for information exchange when a food or feed safety risk is identified. The parties involved in RASFF are the 27 Member states, the European Commission, EFSA, EFTA Surveillance authority and EFTA Member states.

M.S. should notify under RASFF of any risk identified in food or feed that is placed on the market or into a border point to The Commission, which is responsible for managing the network, and in turn will notify the other Member States, applicant countries, third countries, border posts and International Organisations. The risks will be characterised under "Alert" (risks that need immediate response), "Information" (risks that do not require immediate response) or "Border rejection" (food rejected for entrance into the EU because of an identified risk) . (See Fig. 4)

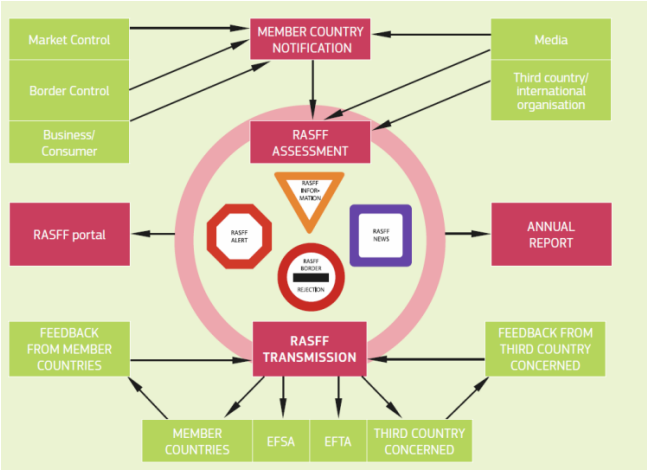

Figure 4. Schematic representation of the information flow of the RASFF (RASFF Annual Report 2011 p.8)

If a food fraud case is discovered and it poses a human health risk, then RASFF will be used; but if a food fraud incident is discovered and it does not pose a human health risk, then the use of the network would not apply. RASFF has demonstrated it works fine, but there are some food fraud incidents which are out of its scope; it has been suggested by representatives of some M.S. to create a network for information exchange specifically for food fraud cases. [43, 44]

5.9.2 Emergency measures

In case of an emergency; when food or feed is constituting a serious risk to human health, animal health or environment and it cannot be contained by measures taken; then the Commission should implement emergency measures (art. 53). Emergency measures include the *"suspension of the placing on the market or suspension of import"* and *"special conditions* and *appropriate interim measures".* It can be seen that these measures are intended to avoid that the food implicated in the risk is placed in the EU market, however it is not mentioned what to do when the food have already reached the consumers; and the other stages of the food supply chain are also not included in this statement. So what would happen if there is an emergency and the food implicated is still being produced by the industry? Should this be contained by the appropriate interim measures? Should the companies continue its production? Would its suspension on the market be enough? For how long it would be enough? Without clarity these can be subjected to a lot of interpretations.

43. European Parliament 2013. Draft report on food fraud
44. EP – video horsemeat scandal and measures

5.9.3 Crisis management

As another strategy, a 'general plan' for crisis management shall be created within the mandate of the Commission and the closely cooperation of EFSA and M.S (art. 55). The plan shall aim to establish the necessary steps to follow when a food or feed safety crisis takes place by having a good coordination and interaction with all the parties involved in risk management, including scientists and optimisation of all resources. When the Commission determines it, a crisis unit shall be established, which will be responsible of data collection concerning the risk, evaluation and identification of possible solutions to prevent, reduce or eliminate any risk to human life and health as quickly as possible. A key element in Article 55 is that a "*General Plan for Crisis Management in the field of the SAFETY of food and feed shall be drawn up*"; food crimes are not considered in EU food law and most of the measures to control risks are totally focused in food safety.

5.10 Conclusions: The General Food Law combating food fraud

The European food safety system is considered to be one of the safest in the world (Borg, 2013), but unfortunately due to the emerging food fraud incidents[45], consumers have lost confidence in it. There is a lack of approach to food fraud in EU legislation and recent cases have demonstrated that it represents a structural weakness in law.

When developing food legislation, the biggest concern was related to food safety and the risks to which consumers could be exposed; it is clear that food fraud was not a priority. The only way for GFL to focus on food fraud is when it represents a food safety risk. In addition, a harmonised definition and consistent terminology[46] for food fraud does not exist in EU and as a consequence, M.S. and regulatory agencies may take different approaches to address it, which may leads to barriers and divergencies among them.

5. 10. 1 The strategies

Protection of consumers'interests and presentation*:* There are two provisions intended to the "prevention" of food fraud found in the GFL: The first one is Protection of consumers'interests (art. 8), which is part of the general principles of food law and it does not imply obligations. The second is Presentation (art. 16), which intends to protect consumers of not being misled by the information provided in the labels; but unfortunately no provisions regarding authenticity of the labels (or products) are mentioned nor required.

45. Horsemeat scandal discovered in Ireland (2013), Melamine crisis from China affecting milk-based products in the EU market (2008), seafood fraud report by JRC (2011), chili powder contaminated with Sudan I dye detected in France (2003)
46. Common terminology used: 'fake', 'authentic', 'adulterated', 'counterfeited'

Several types of fraud[47] are out of the scope of food law, some examples are tax-avoidance, smuggling, addition of sugars (or others, as for example to mask poor-quality juices), dilution or addition of water / ice (to increase weight), etc..

Food safety requirements*:* It is a requirement of food law that just "*safe food shall be placed in the market*" (art. 14), whether determining if food committed into fraud is *safe or unsafe*, many conditions have to be taken into account, like the type of substances contained, type of modification, adverse health effects, level of toxicity of adulterants, intended consumers, level of dilution or substution, etc.

Responsibilities for food business operators: Unfortunately all the safety and authenticity of food lies in the business operators (art. 19), but at the same time they may be the responsibles for committing fraud. Some other operators that are involved in the food supply chain are not registered as such, which means they may not be subject to official controls for food law and here is no imposition nor training to business operators regading the prevention of fraudulent practices.

Responsibilities for food law enforcement: M.S. have the legal responsibility to verify that *relevant requirements* of food law are met by implementing a system of official controls (art. 17); so it can be understood that M.S. have to verify the authenticity of the information stated in the labels, if they consider it as relevant. The GFL does not especify which party has to implement them, or if they should they be carried out by Private organizations? Public authorities? Laboratories?. There is no requirement to keep records, it is not indicated at which part of the food chain controls must be implemented; this last condition is of most importance because once the food is placed in the market, consumers are already exposed to the risks implicated.

Traceability: Traceability is used as a strategy to follow a food through all the stages in the food supply chain until it reaches the final consumer, all food businesses shall implement a traceability system to identify the persons or business to whom they have supplied with a food (art. 18). It can be used to determine at which point of the food supply chain, fraud can occur; however traceability is mainly based in documents and certificates, which may be subject to falsification as well. In food law, there is no imposition to verify the authenticity of traceability documents and the way on how it is implemented depends on the food business operators.

47. Categories of types of fraud (table 3 In Moore, Spink, Lipp 2012)

Control of imports: The control of imports is also regulated by the GFL, by which all food imports shall comply with the relevant food law requirements to enter into the EU (art. 11), yet as food fraud is not considered as a priority, there is no imposition to include fraud in the regular controls at border inspections. There is no rule directed to the inspection of foreign facilities, unless M.S. have an agreement with the exporter country[48]; if there is an agreement, it is no specified if inspections and audits shall be carried out with or without previous notification. By the combination of all of these factors, it can be seen that there are very low chances that food fraud can be detected.

RASFF network: When a food risk has been identified, the RASFF network will be used as a tool for exchanging information among the M.S. The Commission, EFSA and other parties involved (art. 50), however it is directed to food safety issues and it is not created with the aim of communicating food fraud cases that do not pose a safety risk. RASFF has demonstrated to be a very useful communication tool, so it would be important to consider fraud cases within its scope; by now there is no other tool directed to alert about fraud incidents in the EU.

As final statement*, How can consumers' health be protected against fraud if most of the cases have been discovered when food is already placed in the market?.* Food fraud is partially covered by the GFL, strategies are not directed to it, EFSA tasks are not addressed to it, there is no prohibition to place counterfeit or adulterated products in the market and there are no requirements regarding the authencity of food, M.S. and business operators may not be trained to prevent, detect or combat it (either from local or imported food); the statistics or numbers that can reveal the extent on the problem in the EU are unkown. It is clear that food law focuses on safety issues; food fraud is not a new problem but it has demonstrated that the EU food system can be improved. It would be recommended that The Commission, EFSA and M.S. work in collaboration with Europol regarding the strategies that can be included in EU law to combat this problem.

48. Article 11 "*whether a specific agreement exists between the Community and the exporter country"*

6. Food fraud: American (USA) perspective

6.1 U.S. food legislation & FDA

Legislation in The United States is mainly contained in The U.S. Code, which has the general and permanent laws applicable to the whole country; The Code is divided by different subjects into 51 titles; Title 21 in the U.S.C is concerning about Food and Drugs, Chapter 9 contains The Federal Food, Drug and Cosmetic Act (sections 301-399d), Subchapter IV is directed to the food safety regulations. The F,D&C Act signed in 1938 is a set of laws that provides the Food and Drug Administration (FDA) the Authority to ensure food safety of the food circulating in the U.S., it has been amended by several times, the latest update is contained in Chapter 27 of Title 21 of the U.S.C. known as The Food Safety Modernization Act - FSMA (sections 2201-2252) which was signed by President Obama in 2011 with the aim to strengthen the safety of the food supply chain with a modern and preventive orientated approach and considering the complexity of the food chain due to globalization and the complex changes taking place in the international market[49].

FDA is the agency of the U.S. Federal Department of Health and Human services that has the responsibility of protect and promote public health including the regulation and monitoring of food, drugs and medical devices in The United States. Its responsibilities are divided through five product centres[50]:

- The Center for Biologics, Evaluation and Research (CBER) responsible for regulating and ensuring safeness and effectiveness of biologics for human use.
- The Center for Devices and Radiological Health (CDRH) responsible for regulating firms that manufacture medical devices and ensuring the compliance with safety standards in radiation-emitting products.
- The Center for Drug Evaluation and Research (CDER) responsible for regulating prescription drugs for human use.
- The Center for Food Safety and Applied Nutrition (CFSAN) responsible for ensuring the safety of food for human consumption, including dietary supplements, with the exception of meat, poultry and processed egg products which are regulated by the U.S. Department of Agriculture.
- The Center for Veterinary Medicine (CVM) responsible for regulating the feed, drugs and devices for animals.

49. More information available at http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm
50. www.fda.gov

These Centers have the task to monitor the safety of medical products and food, develop regulations and guidelines, conduct research and create communication networks with the industries and consumers. In addition, FDA's office of Regulatory Affairs (ORA) contribute to promote compliance with FDA's requirements and legislations, within its activities it is included the inspection of manufacturing facilities, testing products offered for import, analysis of samples and enforcement actions. The potential criminal violations of FDA's regulations, e.g. food fraud, are investigated at ORA's office of criminal investigations and some cases may be referred to The U.S. Department of Justice (GAO 2011).

6.2 Economically motivated adulteration (EMA)

In U.S. legislation there is not a definition for "food fraud", however in May 2009, a public meeting regarding this topic was carried out by FDA in which a working definition of "Economically Motivated Adulteration" was developed:

*"The fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production. i.e. for economic gain. EMA includes dilution of products with increased quantities of an already present substance to the extent that such dilution poses a known or possible health risk to consumers, as well as the addition or substitution of substances in order to mask dilution." (*GAO 2011)

This definition even not stated in law, is used when discussions and meetings regarding EMA are carried out; it is understood that EMA is considered as a type of intentional fraud which includes adulteration of certain component for economic profit and considers economic gain as the only motive for committing fraud. The working definition provided by FDA includes food and products as dietary supplements, tobacco, cosmetics, pharmaceuticals and medical devices (Everstine 2012). However, EMA is a subdivision of food fraud, because 'food fraud' is a broader term that encompasses EMA and other types of crimes as misbranding, theft, diversion, simulation, smuggling, counterfeiting, tax avoidance and transhipping (Spink, Moyer 2011).

EMA is not intended to cause public harm, but it definitely represents a health threat depending on the type of contaminant or substance introduced to the food. The type of damage will vary depending in the consumer, the amount of food consumed, the level and time of exposure, vulnerabilities of certain consumers, the type of adulteration committed, the toxicity of certain substances, etc.

Several strategies are being carried out by FDA to combat EMA. In 2011 FDA established a Working group named WEMA including experts from the 5 product centres and ORA in order

to create consecutive meetings, exchange information and discuss issues related to EMA, determine the best ways to address the problem and prevent the public health threats it can represent[51].

EMA is partially covered by U.S law, the F,D&C Act addresses EMA as part of the general strategies to combat 'adulteration' and 'misbranding', including efforts to regulate food safety and food imports. These strategies are reinforced by the FSMA by enabling the focus in prevention to food safety problems and providing new authority to FDA to help achieve higher levels of compliance with standards and to have a more coordinated response to problems, including stricter controls for food imports; an overview of these strategies is presented in this thesis.

6.3 Definitions: Adulteration and misbranding

F,D&C Act prohibits the introduction and circulation of adulterated or misbranded food into interstate commerce. For a better understanding, definitions provided by the F,D&C Act are provided as follows:

In section 341 of The F,D&C Act, *Food* is defined as follows: *"articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article"*[52] and by section 342 and 343, food shall be deemed to be adulterated or misbranded under the following conditions:

A food shall be deemed to be adulterated[53]:

1. *If it contains any poisonous, insanitary, etc., ingredients which may render it injurious to health. (i.e. pesticide chemical residue, food additives or new animal drugs that are considered as unsafe, diseased animals, prepared under unsanitary conditions, composed by filthy, subjected to radiation unless in conformity with regulation, etc..)*
2. *If any constituent has been abstracted, substituted or added (i.e. to increase its bulk, weight, reduce its quality, to cover damage or make appear a greater value than it is).*
3. *If it contains any color additive consider as unsafe under section 379(a) of F,D&C Act.*
4. *If it is confectionery and contains alcohol or a nonnutritive substance (except that this would not render the product injurious or hazardous to health).*
5. *If it is oleomargarine, margarine or butter containing filthy, putrid or decomposed substances or is unfit for food.*
6. *If it is a dietary supplement or ingredient that presents a significant or unreasonable risk of illness or injury*

51. GAO 2011. Apendix II comments of the department of health and human services. Meeting May 2009 FDA and EMA
52. FD&C Act Chapter 9, subchapter II. Section 321
53. F,D&C Act 1938, chapter 9, Title 21. Section 342

7. *If it is a dietary supplement that has been manufactured, packed or held under conditions that do not meet current GMPs regulations.*
8. *Reoffer of food previously denied admission for import (unless the manufacturer proves it complies with the applicable requirements)*
9. *Noncompliance with sanitary transportation practices*

A food shall be deemed to be misbranded[54]:

1. *If it presents a false or misleading label*
2. *If it is offer for sale under another name*
3. *If it is an imitation of another food (unless stated in the label)*
4. *If it container is made, formed or filled as to be misleading*
5. *If in package form (unless its label contains name and place of manufacturer and an accurate statement of the quantity of the contents in terms of weight, measure or numerical count.)*
6. *Prominence of information on label. If any word, statement or other information that is required to appear on the label or labelling is not prominently placed with conspicuousness. (according to the requirements)*
7. *Representation as to definition and standard of identity. If it purpots to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations and its definition and standard falls below such standard.*
8. *Representation as to standards of quality and fill of container. If it purpots to be a food which a standard of quality or fill of container has been prescribed and its quality falls below such standard (unless stated in the label).*
9. *Label where no representation as to definition and standard of identity. (unless the label states the common name of the food and in specific cases i.e. beverages, the total percentage of juice contained and each ingredient)*
10. *Representation for special dietary use. (unless it contains all the nutritional information required by regulations)*
11. *Artificial flavoring, artificial coloring, or chemical preservatives. (unless stated in the label)*
12. *Pesticide chemical on raw agricultural commodities (unless the shipping container of such commodity bears labeling which declares the presence of such chemical).*
13. *Color additives (unless the packaging and labeling are in conformity with such packaging and labelling requirements).*
14. *Packaging or labeling of drugs in violation of regulations*

54. F,D&C Act 1938, chapter 9, Title 21, Section 343

15. Nutrition information (unless it complies with regulation requirements)
16. Nutrition levels and health-related claims
17. Dietary supplements, if the label of labelling fails to list the name and quantity of each such ingredient and fails to meet the quality, purity or compositional specifications.
18. Catfish. If it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae.
19. Ginseng. If it purports to be or is represented as ginseng, unless it is an herb or herbal ingredient derived from a plant classified within the genus Panax.
20. Failure to label; health threat. If it fails to bear requirements under section 381 relating to food refused admission into the U.S. or if it is found that the food presents a threat of adverse health consequences or death to humans or animals.
21. Major food allergen labeling requirements. (unless stated in the label and in compliance with requirements)
22. Non-major food allergen labeling requirements (its presence shall be disclosed in a manner specified by regulation)
23. Dietary supplements. If it is marketed in the U.S., unless its label includes an address or information through which the responsible person may receive reports of adverse events related to it.

6.4 Adulterated food, a complicated but general term

In the F,D&C Act the term “adulterated” covers a wide range of specifications, more than the addition, substitution or omission of certain component(s) as stated in the definition of EMA (Spink, 2011). Adulteration of food includes all kind of insanitary conditions like food containing filthy, decomposed or putrid matter, diseased animals, noncompliance with GMPs or hygiene requirements or sanitary transportation practices; and the definition also covers the use of unsafe additives or chemical residues, so it is noticed that safety is somehow included in this definition, even no definition for “unsafe food”[55] is provided[56].

Food subjected to radiation is also considered as adulterated, unless it is in conformity with the regulation, it would be interesting to analyze why a radiated food shall be deemed to be adulterated, knowing that it is not the only process that can change the characteristics of food and food products.

55. Unsafe poisonous or deleterious substances defined in section 346, unsafe pesticide chemical residue defined in section 346(a), unsafe food additive defined in section 348, unsafe animal drug defined in section 360b
56. The term “safe” has reference to the health of man or animal as defined in section 321 (v) of the F,D&C Act

Dietary supplements are included in this category when they represent a significant risk of illness under their normal conditions of use and when they are not manufactured under the required standards; so not following Good Manufacturing Practices makes a dietary supplement adulterated.

It is interesting that oleomargarine, margarine and butter are considered in a separated category as it may be seen that these are special types of foods or maybe they are more likely to contain decomposed substances or filthy compared with any other type of food or fats. But then why not including milk, cheese or vegetable oils as well? Adulteration of these "margarines" is based in the filthy, putrid or decomposed substances they may contain, so it seems that it is a food safety issue more than a type of food fraud.

The statement "*which may render injurious to health*" refers that such substance or constituent of the food, should be considered as adulterated just when it represents a health threat, although if a substance is used to increase weight or mask dilution and is not directly representing a risk for health, the food shall also be deemed as adulterated, and it shall be forbidden to enter or circulate into the interstate commerce.

It seems that all kind of different categories are encompassed into this definition even some of them are not normally referred as "adulterated", but like "unsafe" under regular hygiene provisions (CAC 2003) and Good Manufacturing Practices. A few specific products (i.e. confectionery) are remarkable outstanding in the definition and it seems they require more attention than any other product, however even knowing there are a lot more new products involved in adulteration and misbranding, authorities should consider if more specific provisions, for products usually subjected to fraud, shall be included in law as well.

6.5 Misbranded food, a general but specific term

The definition of 'misbranded food' considers all specific requirements by law to be stated in the product labels, including the label itself, the name of the product, its content, package form, ingredient list and nutrition information additionally to pesticide chemicals, additives and colorants. If the label fails to mention the major and non-major allergen labelling requirements, the food shall also deemed to be misbranded; and dietary supplements shall contain information in which the responsible person can be contacted in case of a report or complain.

The definition for misbranding seems to be applicable to all kind of food, but there are two foods that seem to require special attention, catfish and ginseng; nowadays it is known that fish substitution and herbal plants substitution covers a wide range of species, maybe at the

time when this law was created, these products were the most likely to be misbranded, but it doesn't seem to be very useful anymore, especially because there are a lot of fish species and herbs circulating in the market and any of them could be subjected to substitution.

As a matter of example of this, in 2007[57] two people in Chicago developed the symptoms of tetrodotoxin poisoning, (tetrodotoxin is a neurotoxin that can cause paralysis and potentially death), after eating monkfish soup. FDA started an investigation which revealed the fish was not monkfish but Puffer fish (fish from the Tetraodontidae family). A revision of these cases – species substitution- should be considered for following amendments of the law.

6.6 Other provisions: Standards for food

Under Section 341 of the F,D&C Act, the Secretary of Human and Health Services shall promulgate "definitions" and "*standards of identity*", "*standards of quality*" and "*standards of fill of container*" for certain foods, when necessary under its judgment, so food under these categories should comply with the standards in order to protect consumers' interests. The exception for this rule applies to fresh and dried fruits, fresh and dried vegetables and butter; but it should apply for avocadoes, cantaloupes, citrus fruits, and melons, which definition and standard of identity should be related to their maturity and effects of freezing[58]. It is interesting that just these category of fruits shall be included when other soft fruits like mangos or strawberries are also subject to present changes in their physical form due to maturity and freezing.

Unfortunately, 'organic', 'false country of origin' or 'species substitution' are not considered in the definition of misbranding, yet they may still be subject to have a definition of standard of identity, quality or filled of container, if determined by the Secretary.

It would be of most importance that foods that have been implicated into EMA incidents shall be required to have a standard of identity. As an example, honey and natural sweeteners are products that are well known of being subjected to dilution and adulteration with several types of sugars (Everstine, Spink, Kennedy 2013). In 2003 a study carried out by honey packers reported about 70% of brands tested had been found to have adulterated honey[59], however nowadays the standard of identity for honey and honey products is not required by FDA.

57. Puffer fish imported to the U.S. is regulated by FDA and it can be sold under certain conditions: only meat, skin and testicles, prepared in an authorized facility and certified as safe, it can just be sold in restaurants belonging to the Torafogu Buyers Association. More info Cohen et al, 2009
58. F,D&C Act 1938, chapter 9, Title 21, Section 341 Definitions and standards for food.
59. The Honey Case Fairchild 2003

6.7 Intentional adulteration

In the U.S., there are three types of motives by which intentional adulteration can occur (GAO 2011): Adulteration by acts of terrorism; Adulteration by acts of disgruntled employees, consumers or competitors; and Economically Motivated Adulteration.

Adulteration by acts of terrorism includes those intentional acts intended to cause public health harm by adding harmful, toxic or lethal substances or components into the food; adulteration by acts of disgruntled employees, consumers or competitors are those intentional acts with the aim of harming the reputation of a company and trying to make consumers lose confidence in it (it may involve terrorist acts but its main purpose is more to affect the company than causing a health harm); economically motivated adulteration is the intentional act carried out for economic gain, it does not aim to cause a public health harm, but it has the potential to be a health risk depending on the type of substance or contaminant that may be introduced into the food and the population for which the products are targeted.

As some examples of intentional adulteration in the U.S., in 1984 *Salmonella* was intentionally added in food of a local restaurant of a religious commune to prevent public could vote for local elections (not economically motivated) (Torok 2997). And the well-known case in 2007 of pet-food adulterated with melamine shipped from China to fraudulent raise the nitrogen content in the protein tests (economically motivated) (FDA 2010). Any kind of intentional adulteration may result in unfortunate consequences like harm to health or death, loss of confidence by consumers, adverse economic impact, disruption in trade and exchanges, and public fear[60].

6.8 Protection against intentional adulteration

Section 350i of The F,D&C Act states provisions for Protection against Intentional Adulteration, by which, it is required that the Secretary shall:

a) *Conduct a vulnerability assessments of the food system*
b) *Consider the best available understanding of uncertainties, risks, costs and benefits associated with guarding against intentional adulteration of food at vulnerable points*
c) *Determine the best science-based mitigation strategies necessary to protect against the intentional adulteration of food.*

60. FDA Proposed rule on protecting food against intentional adulteration

It is of most importance to be very careful when determining strategies for intentional adulteration in general, as the different types – EMA, acts of terrorisms and acts of disgruntled employees, consumers or competitors - shall be approached from different perspectives.

The statements are given in a very general way providing the Secretary all the authority to carry out vulnerability assessments; it should be stated which kind of intentional adulteration shall be considered to carry out vulnerability assessments. These assessments can just be properly developed in collaboration with the industry, as the Secretary by itself cannot determine all the points at which the food could be susceptible to adulteration. Cooperation with industries that manufacture similar products will definitely be a good strategy to address the assessments.

The food chain of specific products could be very big and complex, and vulnerability assessments should consider all the stages of it, so it is very likely that divergences may occur between the different parties involved in the supply chain, as some people may have different perspectives and points of view of the problem. Without a harmonized, defined and singular approach, vulnerability assessments may not target all the intentional risks that can find their place in the food supply chain.

It can be noticed that these provisions, even intended for intentional adulteration are still not considering the different types of intentional adulteration that can take place in the food chain; regarding economically motivated adulteration, these type of vulnerability assessments could not go into too much detail within a company, because fraudulent manufacturers will intend to hide their non-compliances with the law, yet it can still be approached by several ways taking into account the following factors:

1. Analysis of previous incidents
2. Analysis of records in suspicious facilities
3. Determination of ingredients that are more likely to be adulterated
4. Determination of processes at which EMA is more likely to occur
5. Special attention to products with big prices variations
6. Special attention to products that requires high cost ingredients or processes
7. Inadequacies in testing results
8. Facilities presenting inadequacies in their records
9. History of complaints
10. Contaminants likely to be present in certain food
11. Availability of contaminants or adulterants
12. Products that go through a complex manufacturing process

13. Products appreciated for their special attributes
14. Manufacturers that refuses to stricter regulations or inspections
15. Analysis of records of compliance from business/country/manufacturer

Despite, when protecting against intentional adulteration, in any of the cases, the provisions stated in the F,D&C Act are directed as response measures. Vulnerability assessments may just be conducted after incidents or the study of well-known risks, as no vulnerability can be carried out when the vulnerable points of the food chain are unknown, this point would better suit for risks related to biological causes like microorganisms, but when determining it for EMA, many past incidents shall be analysed.

Considering the best available understanding including uncertainties, risks, benefits and costs of guarding and protecting against intentional adulteration may be difficult to understand because there is no imposition to carry out an action.

Determine the best science-based mitigation strategies for protection against intentional adulteration is a statement which does not consider the different types of adulteration. Does adulteration could really have a science-based strategy? Is it really a matter of science? Or a matter of a criminality?

The provisions in the F,D&C Act regarding intentional adulteration seem to cover a wide range of factors, however EMA is just partially covered by it. The statements are directed to responses after incidents, more than prevention. Intentional adulteration shall be covered from a different perspective than regular food safety problems. Food fraud may include a lot more crimes than just “adulteration or misbranding” as defined in The F,D,&C Act; as for examples, tax avoidance or transhipping. There are a lot of improvements that can be made in this statements.

6.9 Food safety modernization act (FSMA)

The FSMA is an amendment for the F,D&C Act; FSMA was signed in 2011 with the aim of providing a better control of the whole food supply chain, including imports and more stricter regulations to protect the food from any risk that it may represent. It has a preventive approach rather than reactive. By the FSMA, FDA is charged with new authority for monitoring the food supply chain, imports and improvement of the food safety system, including better controls and coordination regarding food imports. According to FDA from 10 to 15% of food consumed in the U.S. is imported and it is expected that this numbers will rise.

FSMA considers the creation of a system based on hazard analysis and risk based preventive controls in food facilities, in which science is used as a tool to develop strategies and prevent, mitigate or reduce any type of risk that may be present in the food. FSMA is divided into three main titles, each ones considering diverse strategies to improve the control of the food safety system.

Title1. Improving capacity to prevent food safety problems

Title 2. Improving capacity to detect and respond to food safety problems

Title 3. Improving the safety of imported food

6.9.1 Preventive strategies

By the F,D&C Act it is required that all facilities engaged in manufacturing, processing, packing or holding food for consumption in the U.S. shall be registered[61] and the FSMA, under section 101, provides authority to FDA to have access for inspection of records of such facilities. When there is determined or there is a suspect that food handled in the facility may cause adverse health effects or death to humans or animals – including any type of adulteration or misbranding - , the Secretary has the authority to suspend the registration of such facility.

It is required that the agents in charge of a facility shall carry out evaluation of the hazards that could affect the manufactured food, including those intentionally introduced, and implement preventive controls to minimize or avoid the occurrence of such hazards, (recordkeeping for 2 years is required). This strategy has the same basis as the HACCP analysis system, when hazards have to be determined and controls shall be implemented, FSMA also requires to include hazards that may be intentionally introduced.

Another requirements, under section 401 of FSMA is the development of contaminant specific and science based guidance documents and regulations. Contaminants that are likely to be intentionally introduced shall also be included; this will help to determine in a faster and effective way the level of risk coming from unexpected contaminants in food and the controls to minimize, prevent or avoid them.

61. F,D&C Act 1938, chapter 9, Title 21, Section 350(d). Registration of food facilities.

6.9.2 Protection against intentional adulteration in FSMA and food defense

Section 106 of FSMA reinforces the provisions stated in the F, D&C Act regarding protection against intentional adulteration and shifts the approach to facilities that are most likely to be vulnerable to it, rather than direct foods or hazards. It is required to conduct a vulnerability assessment of the food system and determine, in a written guidance document, the types of science based mitigation strategies or measures that are necessary to protect against the intentional adulteration of food. The rule covers domestic and foreign facilities subjected to registration under section 415 of the F, D&C Act.

A vulnerability assessment should consider all the stages in the food supply chain and all the parties involved in it, investigations and statistics shall be carried out when determining the most vulnerable point in the system, afterwards the science based mitigation strategies shall be developed by the collaboration of different bodies, agencies and experts in the field. However vulnerability assessments are directed to food safety problems like biological microorganisms and a vulnerability assessment for food fraud still does not exist (GAO 2011).

FDA has identified four key activities in the food chain that are most vulnerable to intentional adulteration. The activities are: bulk liquid receiving and loading; liquid storage and handling; secondary ingredient handling and mixing or similar activities. If facilities identify any of these activities under their system, the vulnerability assessment shall be carried out, by which steps in the process will require mitigation strategies to prevent or reduce intentional adulteration[62].

Food defense is part of the strategies to protect food from intentional adulteration or contamination, either for terrorism, economic gain or any other illegal reason with harmful meanings. Adulteration or contamination may include unconventional biological, chemical or radiological hazards. FDA has the task to promulgate regulations against intentional adulteration. Within this mandate, it is required the development of policies regarding hazards that may be intentionally introduced to the food considering preventive controls; another requirement is to establish science based standards for safe production of agricultural products and to carry out analysis of data regarding contaminants that are likely to be intentionally introduced and engage stakeholders to understand the benefits of these new implementations.

62. FDA Proposed rule on protecting food against intentional adulteration

Registered facilities are also required to develop a food defense plan that shall include actionable process steps for identifying vulnerability activities and processes, focused mitigation strategies at each actionable process to minimize or prevent the adulteration of food, monitoring of the mitigation strategies; corrective actions; verification to ensure the monitoring and corrective actions are being made; training for responsible persons to implement strategies and recordkeeping including all the steps mentioned above. The food defense plan acts as a strategy to verify the vulnerability assessments are carried out in the right way.

6.9.3 Detection and response to food safety problems

In order to better target inspection resources, high risk facilities and non-high risk facilities should be identified (Section 201 FSMA), it is required that FDA carries out more frequent inspection in high risk facilities; at least once in the first five years following enactment of the Act and afterwards, once every three years. For non-high risk facilities, the requirement is that they should be inspected at least once in the first seven years following enactment of FSMA and afterwards, once every five years. It is more likely that EMA can be detected under more frequent inspections of high risk and non-high risk facilities. Inspections are addressed to detect non-compliances with standards and intentional adulteration.

High risk facilities are those ones processing, packaging or holding foods that may have been implicated in outbreaks. When determining a facility as to be “high risk”, several factors have to be taken into account: the known safety risk factors of the food manufactured, processed, packed or held at the facility; data should include if the food has been implicated in recalls and/or outbreaks; compliance of facility with requirements and violation of standards; rigor and effectiveness of the hazard analysis and risk based preventive controls; whether the food or facility has received a certification for import or is part of the voluntary qualified importer program and any other criteria considered by FDA. When determining a facility as a high risk facility, the history of compliance can reveal any condition by which this facility can intentionally adulterate the food products.

Food may be subjected to analyses (Section 202 FSMA) under a specific requirement, a suspicion of a food problem or an admission for import or import alert. The Secretary shall establish a program for testing food and the analyses should be carried out by accredited and recognized laboratories. The Secretary shall also submit a report in implementing a national food emergency response laboratory network, by which accredited laboratories will have the task to analyse food that is involved in an emergency or crisis.

Tracking and tracing of the food is enhanced by section 204 of FSMA, it is required that a system to track and trace the food offered for import into the U.S. should be implemented; the Secretary, in contribution with the food industry, shall carry out pilots to rapidly identify recipients of food, this will help to identify, in an efficient way, any recipient when a threat of adverse health effects is identified. Recordkeeping should be maintained for no more than 2 years and it shall guarantee that the immediate previous source and the immediate subsequent recipient of the food are identified. Two pilots shall be developed including the industry of processed food and raw fruits and vegetables to reflect the diversity of the food supply chain; a final report on the findings regarding the pilots shall be developed and presented to the Congress.

For the first time, the voluntary recall authority is implemented (Section 206 FSMA); in case a food is detected to be or represent a health threat for humans or animals, the authority shall ask the responsible party to make a recall, but if this party refuses to do so, the Secretary may order such recall. In order to establish coherent and efficient communication during a recall, an incident command operation shall be established. Before the creation of FSMA, recalls were voluntary and FDA has no authority to carry them out when a food incident was detected; by this new rule, FDA has authority over food companies to recall a product if it can represent a risk to health or life for humans or animals.

Another strategy to better detect food safety problems is directed to the training of state, local, territorial and tribal food safety officials (Section 209). Training and educational programs for Employees of the state, local territorial and tribal food safety officials related to the responsibilities and policies established in the FSMA shall be provided, activities shall include examinations, testing and investigation for detecting compliance with the food safety requirements, including EMA.

6.9.4 Control of Food imports

A stricter foreign supplier verification program (Section 301 FSMA) is implemented by the FSMA; it is a program by which the Secretary shall provide guidance to importers to develop risk based programs, which shall include monitoring of records, checking compliance of all lots, annual inspections, hazard analysis, risks based preventive plans, testing and sampling with the aim to verify compliance with requirements and guarantee the food has not been adulterated or misbranded.

The voluntary qualified importer program (Section 302 FSMA) is a new implementation, by which voluntarily, importers may get a certification under the criteria of: compliance with the food safety standards, capability to ensure compliance with U.S. standards, compliance with importer requirements, recordkeeping, testing, inspections & audits of facilities and potential risks for intentional adulteration of the food.

FSMA provides FDA new authority to require import certifications for food or refuse admission (Section 303 FSMA) when it does not comply with the food safety requirements; factors that are considered for certification or refuse include the known safety risks associated to the food, country or territory, finding that the food safety systems in that country are inadequate. Food exporters need to prove the products they are supplying are safe and provide the same level of health protection as the products produced in U.S.

In order to have a better control of the food manufactured outside the U.S., FDA has the mandate to inspect foreign food facilities (Section 306); this should be developed by arrangements and agreements with foreign governments. If the foreign country refuse to permit entry of U.S. inspectors upon request, food shall be refused admission.

Another important strategy for control of imports is the accreditation of third-party auditors (Section 307 FSMA). Third party auditors shall be accredited by accreditation bodies when the applicable requirements are met.

A new approach for better control of imports is that audits shall be performed unannounced, which may allow the easier detection of non-compliances, including EMA.

6.10 Conclusions: Food Safety Modernization Act combating EMA

EMA is not easy to be prevented; the main reason for committing it is the economic gain involved by reducing costs of production or ingredients and making fraudulent profits from those actions. EMA is not a new issue, but is has being a problem nowadays and several incidents has been discovered recently. EMA may represent or may not represent a health risk but it has the potential to be a health threat by addition of dangerous or unconventional contaminants and substances into the food.

Unfortunately there are many fraudulent products circulating in the market that are still undiscovered. Some cases have shown that there is a lack of control in the supply chain by the current regulations, and some criminals have found the way to commercialize adulterated food and circumvent the law. For example, seafood fraud cases and species substitution has

been discovered by DNA testing, an expensive method which many food producers do not have access to. Seafood fraud has shown to be a big widespread problem in the U.S., in 2008 a study carried out by the University of Guelph demonstrated that about of the 26% of the fish samples were mislabeled and business were selling cheaper varieties of fish as expensive ones. This number just shows an example of how the problem of food fraud is present in the U.S.

FDA had tried to impose stricter regulations and better coordination with federal agencies to combat the problem of food fraud. Unfortunately, the F,D&C Act does not provide directed strategies to combat food fraud; the definition provided for "adulterated" and "misbranded" food include several factors including food safety and food quality, in which EMA could be partially covered but no other types of food fraud as tax-avoidance and transshipping. An example of transshipping is the case started in 2002[63], when China tried to export honey to the U.S. but it was banned because of the use of chloramphenicol in bees (that was not allowed for importing honey in U.S.), so Chinese companies sent the honey to other countries where it was re-labeled and then it was sent it back to the U.S. as coming from another country.

The FSMA provides FDA with more authority to have a stricter control of the food supply chain; it is required that companies should develop hazards analysis and risk-based preventive controls to have a better monitoring of the processes; however these types of strategies are addressed to the food safety control and not to food fraud.

FDA has the authority to inspect food facilities and records, which may aware the fraudulent practitioners to prevent food crimes, because if FDA determines there is a non-compliance with the regulatory frame, the business may lose its register[64].By the provisions stated in the FSMA regarding record inspections; inspection of facilities and risk-based preventive controls some incidents of EMA can be early detected.

63. Anti-counterfeiting and product protection program, Michigan state university. Video 1 of 3
64. Section 101 FSMA

FSMA requires that FDA develop guidelines and plans to produce safe products, including the training of people involved in the food supply chain and inspectors. A similar requisite is the development of a food defense strategy, an emergency plan considering communication channels between the federal agencies, companies and consumers and a plan for effective responses in case of an incident.

The FSMA reinforces the provisions contained in the F,D&C Act regarding protection against intentional adulteration, in which, based in the available information and previous cases, vulnerability assessments shall be carried out, however not all types of fraud are encompassed in the definition of ‘adulterated’ and ‘misbranded’; and vulnerability assessments shall also include food intentionally adulterated by act of terrorism.

It is clear that many of the EMA cases are coming from imports; this is why FSMA contains a chapter addressed to food for import into the U.S. FDA has the new task to verify foreign food facilities and importers have to verify internal suppliers. If any problem is detected at border inspections or a food is suspected to be adulterated or to be without compliance with the law, the food can be rejected or denied for entrance. However, food imported into the U.S. cannot be completely inspected, unfortunately many types of food fraud can easily go undetected because substances and contaminants normally do not pose special organoleptic characteristics and they are intended to be undetected by regular inspections and even worst, as there are no contaminant-specific testing methods, many of the adulterants may go unnoticed. The lack of simple and fast detection methods for verification authenticity of the food seem to be an opportunity to commit fraud, the chances of being discovered are small and the profit that can be made out of it is very big.

Inside a criminal mind, the lack of controls and lack of regulation is well studied and it represents an opportunity for committing deliberate acts; in the melamine crisis in China 2008, melamine was added to milk to rise the protein content because the test used for testing the protein content was not specific; melamine was not expected to be present in food and none of the regular tests was able to detect it.

FSMA provides stricter food safety regulations and higher control of imports; it provides FDA diverse tasks including more frequent inspection, detection of vulnerable points in the food supply chain and high risk facilities; however EMA is not directly addressed as not even an official definition is developed for it. There is no doubt that FSMA considers the changes due to globalization and it provides a modern perspective in the strategies aimed to combat food problems. It is of most important to detect the challenges that EMA represents and the vulnerable points of the food chain by which fraudsters can find an opportunity to commit fraud.

7. Analysis of two seafood fraud reports: European Union and United States

EUROPE

7.1 Illegal activities in the fisheries sector in Europe

In 2011, the European Union Joint Research Centre published a report (Martinsohn 2011) by which Illegal activities in the fisheries sector and its impacts were discussed. Illegal, unregulated and unreported fishing activities have led to undesired consequences like overexploited fish stocks, destruction of marine ecosystems, disturbance in marine habitats, unsustainable harvesting of fish stocks and distortion on economic development; they represent a health threat to consumers and obstruct their rights to be well informed leading to loss in consumers' confidence in the food supply chain as it happens with mislabelling and seafood fraud.

Species substitution and mislabelling are the most common and most reported seafood fraud incidents that not only cause economic and aquaculture consequences but also adverse effects on human health (Jacquet 2008). Due to the increasing numbers of food imports and complex food chain processes, the control of the fisheries sector represents a big challenge to governmental agencies, as more than 60% of the fish consumed in Europe is imported.

In Europe, The Common Fisheries Policy (CFP) is used as the main policy for the management of the fisheries sector, with a focus in ensuring sustainable exploitation of living aquatic resources; however illegal activities and overfishing have been a continuous problem and it now represents a crisis in the fisheries sector. Recently, to improve the CFP weak points, the EU has developed two legal tools to fight against illegal fishing activities, Council Regulation No.1005/2008 and Council Regulation No. 1224/2009 with an emphasis on detailed catch documentation and traceability of fishery products from all the way through the food supply chain. Traceability is considered as a strategy to support the monitoring, managing, control and law enforcement in the fisheries sector, yet it shall be accompanied by independent control measures to verify authenticity of information, as traceability is mainly based in certificates and labels which may be vulnerable to falsification.

The report conducted by the JRC describes the different analytical tools and molecular techniques that can be used to conduct traceability and better enforcement of legislation; these techniques should be able to determine the fish species, the place where the fish was caught and if it was derived from a wild or a farm catch.

The molecular techniques[65] are based on genetics, genomics, chemistry and forensics with the current slope lying down in DNA analysis as the most cost-effective method.

7.1.1 Efforts in EU legislation to combat seafood fraud

In EU, the main regulation in food safety and traceability applicable to the whole European Union is Regulation 178/2002; in the fisheries sector it is complemented by Regulation (EC) 104/2000 on the common organisation of the markets in fishery and aquaculture products; and Regulation 2065/2001 regarding information to consumers about fishery and aquaculture products, which states that commercial name, production method and origin of seafood shall be established in the labels. Other policies[66] are directed to prevention of illegal, unreported and unregulated fisheries activities; however the main focus of this discussion is directed to provisions stated in Regulation 178/2002 and traceability requirements.

All provisions in Regulation 178/2002 are applicable to all stages of the food supply chain until the product is delivered to the final consumer, which by definition is "*the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity" (*art 3. Reg 178/2002*);* this means all stages including primary production, storage, transport, sale or supply are subjected to comply with all the food law requirements (art. 4 Reg. 178/2002). Imports are included under the scope of the Regulation and food imported into the EU shall meet the same requirements of food law recognised by the EU (art. 11 Reg. 178/2002).

Traceability is defined as "*the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution."* (art. 3 Reg. 178/2002). Food business operators shall implement systems and procedures by which they will be able to identify any person and business from whom their products have been supplied and ensure this information is available for competent authorities on demand: "*Food placed in the Community shall be adequately labelled or identified to facilitate its traceability"* (art. 18 Reg. 178/2002). Traceability can be used as a strategy to follow all the processes which the food has been through and it may be useful to detect at which point of the supply chain the fraud is occurring; however being the seafood supply chain very big and complex, traceability may be vulnerable to fraud as well, as certificates and labels can be faked.

65. Techniques: fatty acid analysis, microchemistry and stable isotope analysis, genetic markers, mitochondrial DNA, repetitive DNA, single nucleotide polymorphisms, microarray, DNA sequencing, gene expression, analytical devices and forensic science.
66. Council Reg. No. 1224/2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy; Council Reg. No 1005/2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing; International Plan of Action to prevent, deter and eliminate illegal, unreported and unregulated fishing and Council Reg. 199/2008 concerning the establishment of a community framework for the collection, management and use of data in the fisheries sector and support for scientific advice regarding the Common Fisheries Policy.

The main objective of the JRC report about illegal fishing activities is to describe the available analytical tools and molecular techniques that can be used to verify the authenticity of the information stated on the labels. Unfortunately strategies to verify authenticity of species and origin are far away to be implemented in the current EU legislations. The law requires a traceability system to be implemented, but there is no requirement to verify if traceability documents and certifications are authentic and reliable.

By article 16, any form of food presentation or information presented in the labels "*shall not mislead the consumers"*; under this provision mislabelling of seafood, species substitution (selling seafood under another name) or modification of geographic origin is not allowed. Article 8 considers the prevention of fraudulent, deceptive practices and other practices that may mislead the consumer as part of the general principles of food law, but it does not imply obligations.

It has been studied that mislabelling occurs more frequently at distribution and retail stages (Jacquet 2008) and it may have several consequences; in addition to those ones related to health (i.e. allergens, contaminants and toxins), it also disturbs the marine ecosystems by compromising fish species vulnerable to extinction or species that are illegal for sale.

Seafood fraud is considered as an illegal act, it is intended to deceive consumer and it defrauds their interests as normally cheaper species are being sold as more expensive ones or farmed species are sold as wild caught that attributes them with a "false" higher value. Consumers do not have the appropriate tools to verify whether the seafood species they buy are the same as those indicated in the labels; the only thing they can do is to be aware that seafood fraud is a current problem and they should ask further information on the products they are purchasing.

Control of deceptive practices is a task that the government shall enforce with better strategies and verification of authenticity of information provided in the labels. Probably the tools needed to determine authenticity of information in the labels and species identification may be seen as too costly, but cost associated to fraud are also very high as they may involve loss of consumers' confidence, eco-label ineffectiveness and health risks (Jacquet 2008).

It is responsibility of the food business operators to comply with food law requirements at all stages of production, processing and distribution within the business under their control and Members States are responsible for the enforcement of food law, by maintaining a system of official controls covering all stages of food supply chain and establishing penalties in case of infringements (art. 17 Reg. 178/2002) . It is noticed that enforcement of food law is a

challenging task and by the seafood fraud reports it can be seen that there is a big chance for improvement in this area. There exists provisions regarding protection of consumers' interests (art. 8 Reg. 178/2002) and information in the labels (art. 16 Reg. 178/2002) ; however enforcement of them can be seen as not a priority for the EC as long as it does not endangers consumers' health.

The requirements in Regulation 178/2002 regarding food safety establish that "*Food shall not be placed in the market if it is unsafe"* (art. 14 Reg. 178/2002), by *unsafe food* it is meant to be: *"injurious to health or unfit for human consumption"*. When determining if seafood fraud can be considered as *injurious to health or unfit for human consumption*, some factors have to be taken into account depending on the type of fraudulent practice. If a seafood specie is substituted it may be deemed to be *injurious to health* when it is consumed by a person with a fish allergy, as allergens may vary in different species; it also may be *injurious to health* if it is a specie that contains high levels of mercury or toxins and may pose a health risk to young children or pregnant women. As an example, in the U.S. in 2007 two people developed the symptoms of intoxication when puffer fish was falsely labelled as monkfish (Cohen 2009); puffer fish is known to contain a deadly toxin and its process should be strictly controlled and prepared under high expertise.

When determining seafood fraud as *unfit for human consumption* different factors shall be considered; illegal fishing is a way of introducing prohibited and dangerous species to human consumption, another example may be presented when expiration dates on the labelling are changed deceiving consumers making them to believe the product is still fresh when it is not; by unreported and unregulated fishing, some seafood species containing deleterious contaminants or toxins may be illegally introduced in the EU market.

Conclusions

The EU is aware that seafood fraud is a current problem and fraudulent business take advantage of the weakness in law enforcement. It is clear that seafood fraud is an illegal act and several requirements regarding presentation, food safety and traceability could be violated. The JRC report on illegal activities in the fisheries sector addresses these weaknesses and provides an evaluation of the available molecular techniques to determine the authenticity of the fish species, the geographic origin and the type of catch from the seafood offered for sale and import. There is no doubt that these techniques and analyses can improve the traceability system in the food supply chain and by it, a higher level of health protection can be achieved.

Unfortunately in Europe, there is a very few data regarding the percentage of food fraud occurring in the seafood sector; in 2010 a study in Ireland revealed that cod and haddock were

mislabelled in 25% of the samples analysed (Miller, Mariani 2010). Similar numbers of seafood fraud are or may be occurring through the whole European Union; it may be seen as a great concern because more than 60% of the seafood consumed in Europe is imported and there is no data regarding the inspection addressed to fraud.

It seems that the major weakness for seafood fraud occurs during law enforcement, the financial profits can be very high and there are little chances, if any, to be detected. Inspection programs, especially on imports, shall be improved and molecular techniques shall be included by legislation as strategic tools to enforce traceability and to verify the authenticity of imported and locally produced seafood and seafood products. The JRC concluded that molecular DNA-based analysis are the most cost effective techniques to validate the traceability of the seafood species, and the field of genetics, genomics, chemistry and forensic can provide efficient support on the fisheries control.

UNITED STATES

7.2 Oceana's Seafood fraud report in the Unites States

From 2010 and 2012, Oceana, an international organization focused on ocean conservation, carried out one of the biggest seafood fraud investigations in the U.S., where 1,215 samples from 21 states were analysed by DNA methods to verify its correspondence with the specie that it claims to be, while sold. Samples were collected from retail outlets, restaurants, sushi venues, grocery stores and seafood markets. Samples were declared to be mislabelled if they did not comply with FDA seafood list guidelines[67]. Seafood fraud includes activities like mislabelling, species substitution, selling farmed fish as wild, or fish from the Pacific as from the Atlantic, or misrepresentation of any type of fish.

67. Seafood list is used to guide seafood labeling that contains the acceptable market names, scientific names and common names for the 1,700 seafood species recognized as commonly sold within the U.S.

The investigation concluded that seafood was mislabelled as often as 26 to 87% of the cases, an average of 1 of every 3 samples was mislabelled, snapper and tuna had the highest mislabelling rates and sushi venues presented the highest fraud levels, while grocery stores represented the lowest rates of fraud.

The seafood chain is normally very big and complex, including the catch, processing, transporting, wholesale level, retail or other practices involved, which makes difficult to determine at which point of it the fraud is taking place; yet the possibility that a specie is mislabelled because of human error, like ignorance, language translation mistakes or unawareness still can occur. In the U.S. more than 90% of the fish consumed is imported and unfortunately, less than 1% is inspected for fraud; as having almost 2,000 diverse fish species in the interstate commerce, seafood fraud seem to be a complete challenge for authorities.

Seafood fraud can represent a health threat, several population susceptible to allergies may be highly exposed to them when purchasing mislabelled fish, certain species contain very high numbers of mercury, contaminants or toxins that can endanger life of consumers; in addition to the health dangers involved, seafood fraud also defrauds consumers interests, honest vendors and fisherman, it represents a serious concern for vulnerable fish populations and disturbs the economic flow. Some fish species found in the investigation were not even allowed for sale in the U.S.

In 2004, FDA released an advice for pregnant, nursing women, and young children to avoid the consumption of swordfish, shark, tilefish and king mackerel because of the high levels of mercury they may contain. It is noticed that any species of fish can end up in the plate of susceptible people by a fraudulent labelling and endanger their health. Another example that can have health implications is the substitution of escolar as white tuna which may cause immediate digestive effects in some people.

7.2.1 Efforts in U.S. legislation to combat seafood fraud

FDA is aware that food fraud is a nationwide problem and it needs priority. FDA has developed *The Seafood List* that serves as a "*guide with acceptable market names for seafood sold in the interstate commerce",* it has been updated until 2013*.* The Seafood list contains a list of species that FDA has determined as sold or likely to be sold in interstate commerce and that are approved by law; it includes the acceptable market name, scientific name, common name and vernacular name (local or regional name) of seafood species. In Oceana's study, there were found some seafood species that did not belong to the species mentioned in the *Seafood*

List, which may represent a risk for consumers as they are not yet approved by FDA as acceptable for interstate commerce.

The policies for control of safety and quality for seafood are contained in the "seafood HACCP" and industries shall comply with the requirements stated in it; however it does not address seafood fraud. The provisions in the F, D&C Act apply to all facilities registered, except "*farms; restaurants; other retail food establishments; non-profit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels"*[68]. The term "farm" means "*a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both*[69]. The term Restaurant means *"a facility that prepares and sells food directly to consumers for immediate consumption*[69]*.* By this definitions it can be seen that the lack of regulation on farms and restaurants could be one of the main basis of the seafood fraud problems; as concluded in the investigation carried out by Oceana, the higher rates of seafood fraud occurs at sushi venues, that are considered as restaurants. The insufficient controls at farm level, where seafood raising can occur represents a big opportunity to commit fraud.

Seafood fraud, specifically seafood species substitution is prohibited under the F,D&C Act as "*misbranded food*":

"A food shall be deemed to be misbranded (Section 403 F,D&C Act):

- *If it presents a false or misleading label*
- *If it is offer for sale under another name*
- *Catfish. If it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae.*
- *Major food allergen labeling requirements. (unless stated in the label and in compliance with requirements)"*

By the statements regarding misbranding, seafood fraud shall be considered as an infringement of the law; species substitution is represented by a false or misleading labels, or a specie offered under another name or type, some examples are when cheaper species are sold as other expensive ones, the misrepresentation of seafood coming from wild catch when it is actually farmed or the commerce of illegal species under another name. Certain consumers are susceptible to allergies and allergens may vary depending on the fish species.

68. Registration of food facilities F,D&C Act 1938, title 21 (350d) C(1)
69. FDA 2012 Draft guidance for the industry. FDA Record Access authority

By legislation[70] it is required that the label of a food containing “a major food allergen”[71] declare its presence, so consumers can make informed choices. FDA considers “fish and crustacean shellfish” as part of the eight major allergens and its presence in a food must be declared. Undeclared fish or substitution of fish species may represent a big life threat to consumers with allergies. Unfortunately, there are not enough inspections to verify if labels are providing accurate and reliable information; expensive and complicated methods are required to verify species authenticity i.e. DNA testing; in addition most of the seafood products in the U.S. are imported[72] and fraud is not a priority on inspections[73].

Several provisions in U.S. law that address the problem of seafood fraud are contained in the FSMA. Preventive strategies include inspection of records from food facilities and suspension of registration of food facilities in case of a reasonable probability that food manufactured, processed, packed, received, or held in it may cause adverse health effects or death. If there is a reason to suspect that a facility which handle seafood is committing fraud, FDA has the authority to inspect records; by this it should be easier to determine whether the species are coming from – if a traceability system is implemented – how the species are being processed and how they are packed which may allow inspectors to determine any irregularity. If a facility is suspected or there are reasons to believe the products handled in it are being mislabelled, misrepresented or substituted, FDA may order the suspension of its registration.

Some strategies are intended to the detection of non-compliances with legislation, as seafood fraud is; domestic and foreign facilities shall be inspected with more frequency (Section 201 FSMA) and high risk facilities must be detected and be subjected to regular inspections. As most of the seafood products in U.S. are imported, inspection of foreign facilities is a strategy to have better control on imports; at least 600 foreign facilities shall be inspected in the first year after the amendment of the FSMA and the subsequent years, every 5 years the number shall increase at least to the double.

In order to detect the authenticity of seafood species, FDA shall establish a program for testing food by accredited laboratories (section 202 FSMA), with this, food tests shall provide accurate and appropriate information regarding the species purchased and detect facilities or retailers in which seafood fraud can occur.

70. Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004
71. Eight major allergens considered by FDA are: milk, eggs, fish (e.g., bass, flounder, cod), Crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, and soybeans.
72. About 90% of seafood consumed in US is imported
73. Less than 2% of products are tested for fraud in USA

Section 204 "*Enhancing tracking and tracing of food and recordkeeping"* on the FSMA, requires the establishment of pilot projects by FDA and USDA in coordination with food industries to evaluate technologies and methods for tracking and tracing of foods. A proposed rule to establish recordkeeping requirements for high risk foods must be published as well. Tracking and tracing seafood could be an essential strategy to reduce the occurrence of seafood fraud or to determine at which point of the chain the fraud is occurring.

Tracing a product involves documents regarding production and distribution chain of foods and to trace them back to the source. The implementation of a traceability system allows governmental agencies and industries to react efficiently and faster in case an incident is detected; products can be removed from the market and consumers can be notified when the product has already been purchased[74]. However, as it is a new strategy and pilots are carried out, the lack of track and trace of products is reflected by seafood fraud cases where it is almost impossible to detect the source of the fraud.

When seafood has been detected to be adulterated, misbranded or its use will cause health consequences to humans, the responsible parties are required to cease distribution and conduct a voluntary recall of the food in order to protect consumers health; however if the responsible party refuses to do so, FDA has the authority to carry out a mandatory recall under section 423 of FSMA.

Seafood imports may have the biggest implication in seafood species substitution cases, in a matter of prevention, the foreign supplier verification program shall be implemented[75]; every importer must carry out risk based foreign supplier verification activities for verifying compliance with requirements and to verify if food is not adulterated or misbranded under provisions in the F,D&C Act. FDA shall also create arrangements with foreign governments to allow the access to registered foreign facilities for inspection[76], with special emphasis in high risk food facilities, products or suppliers as identified by FDA.

74. Product Tracing requirements FDA website

75. Section 301 FSMA

76. Section 306 FSMA

Conclusions

Seafood fraud is a nationwide problem in the U.S., it may implicate health issues regarding allergens, toxins and certain compounds like mercury that may be deleterious for susceptible populations. Species substitution was the major founding by Oceana's report however there exist other types of seafood fraud, as for example, seafood may be deemed to be "adulterated", under section 342 of F,D&C Act when it "*contains ingredients which may render it injurious to health*" or "*if any constituent has been added (i.e. water) to increase its weight"* (section 342 F,D&C Act 1938). By the examples provided and species substitution rates it is clear that strategies to combat it are not well enforced.

It is prohibited by law that a food is adulterated or misbranded, but there are no effective or not enough detection methods to verify authenticity of the products. The FSMA provides regulations considering the complexity and growth of the modern food supply chain; increasing the frequency of facility inspections, verification of records and more control in imports; however the lack of a strong and efficient traceability system makes very difficult to determine at which point of the chain the food fraud is committed. FDA has the mandate to promulgate guidelines to the industries, yet it is still not clear how enforcement of legislation is carried out; it seems FDA has not developed a good communication network with agencies and parties that can combat the problem of food fraud. Policies and inspections are still directed to prevent food safety problems rather than fraud.

As noticed in the working definition, developed by FDA, of "*Economically motivated adulteration*: *The fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production. i.e. for economic gain."*, seafood fraud is not included within its scope, because species substitution does not involve addition or substitution of a substance to increase the apparent value of the food; but it may be considered as adulterated or misbranded under the definitions provided by the F,D&C Act. A clear and more complete description of EMA shall be developed, because without a coherent and comprehensible delimitation, strategies to combat it would never be effective.

FDA has developed strategies to combat food fraud, however there is a long way to go; it is of most importance that farms and restaurants shall be subjected to the same requirements as all the other food facilities. As long as there is no a clear definition for fraud and a focused approach, fraudsters will continue making profit from it and consumers will still be susceptible to its consequences.

8. Comparative analysis and discussion

8.1 Definitions for food and scope of legislations

There are some differences between the definition of food in EU and the US. EU provides more delimitations on what a food is, and it is defined as ""*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans" – not including feed - (art. 2 Reg. 178/2002),* while US gives a more limited[77] definition and is stated as: "*(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."* Section 201 F,D&C Act). It can be noticed that EU does not consider feed into the scope of the definition of food, while the US does. Feed is also subjected to requirements of the General Food Law in EU, but it is considered in a separated statement; provisions are directed to it as "feed" and not as food[78]. It is understood that the scope in the US is that pet food must meet the same requirements as food for humans or the other way around. Both definitions consider "another elements" that can be added to the food or that can be part of it (i.e. food additives or components of food); however EU clearly states that these elements are "*intended to be, or reasonably expected to be ingested by humans"*; in US definition, it is just mentioned that these *"articles are used as components of any such article"* so they could be likely to be for human or animal consumption without any distinction.

The scope of both legislations differs by the stages on which they apply, in EU the General Food Law applies to "*all stages of production, processing and distribution of food and feed",* with the exception of "*primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption"*; so it does not consider the food that has already reach the 'final consumer' for domestic preparation[79]. The domestic and foreign facilities subjected to registration and thus subjected to the provisions of US legislation are: "*any factory, warehouse or establishment (including for import) that manufactures, processes, packs or hold food",* it excludes: *farms, restaurants, other retail food establishments, non-profit food establishments in which food is prepared or served directly to the consumer, or fishing vessels"*[80]*.*

77. According to the Code of Federal Regulations, Title 21 Section 170. *"Food includes human food, substances migrating to food from food-contact articles, pet food, and animal feed"*
78. Article 1 (2). Regulation 178/2002: this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.
79. Article 3 (18). Reg 178/2002. Final consumer' means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.
80. Registration of food facilities F,D&C Act 1938, title 21 (350d) C(1)

The EU use the ‘farm to fork ‘approach by which all stages, including those ones involved in food for import, are required to comply with the requirements and in the US the requirements apply to domestic and foreign facilities, with some exceptions; however studies have shown that food crimes such as fraudulent practices are likely to occur at restaurants, retail levels or fishing vessels (species substitution); facilities which are out of the scope for the U.S.

8.2 Definition for food fraud

A legal concept of food fraud does not exist neither in EU or US. EU is looking forward to set down a definition (Poudelet, 2013); FDA has developed a working definition for Economically Motivated Adulteration (GAO 2011), which seems to be a category of food fraud.

The term used in the EU varies from each institution or agency, for example OLAF (EC’s anti-fraud office) defines food fraud as “*the deliberate act of deception intended for personal gain or to cause a loss to another party”*[81], Europol (law enforcement agency in EU) defines Counterfeiting as*: ““an infringement related to industrial property violation”*[82]*,* the definition by the Food Standards Agency in UK is “*food fraud is committed when food is deliberately placed on the market, for financial gain, with the intention of deceiving the consumer”*[83]*,* the Food Safety Authorities or Ireland refer to it as ““*food fraud is committed when food is deliberately placed on the market with the intention of deceiving the consumer, usually for financial gain”*[84]*.*

Even some of these definitions are related and connected between them, there is some variation; several other terms used in the EU when referring to food fraud are: deliberate contamination, adulteration, fraudulent practice, bad practice(85), deceptive practice, practice that may mislead the consumer(86, 87), infringement of food legislation.(88) dishonest practice, mislabelling, misbranding, labelling fraud and others.

81. OLAF’s website. . http://ec.europa.eu/anti_fraud/index_en.htm
82. https://www.europol.europa.eu/
83. FSA UK 2007 http://food.gov.uk/enforcement/enforcework/foodfraud/
84. Food Safety Authority of Ireland. 2012
85. Regulation 178/2002 (13)
86. Article 8 (1). Reg. 178/2002 (EC)
87. European Commission. Proposal for Reg 178/2002 presented in Nov 2000
88. Jos Chabert. The president of the Committee of the regions (2001)

In the other way around in the U.S., FDA has developed a working definition (not in legislation) for Economically Motivated Adulteration as: *"The fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production. i.e. for economic gain. EMA includes dilution of products with increased quantities of an already present substance to the extent that such dilution poses a known or possible health risk to consumers, as well as the addition or substitution of substances in order to mask dilution."* (GAO 2011); however this working definition does not consider other types of fraudulent practices like misbranding, smuggling, counterfeiting, tax-avoidance, etc. These other types of fraud need to be included in a legal and harmonised definition; by that way, the problem of food fraud would be better addressed.

The problem of not having a legal definition for food fraud is that agencies and authorities may develop different strategies to combat it which can lead to conflicts, maybe of interests, between the different states. In Europe, the definitions given by several agencies, as presented above, have some similarities with the working definition of EMA; most of them consider fraud as an infringement committed for financial gain, including the intention of deceiving the consumers. U.S. considers EMA as a substitution or addition of a substance which may render to possible health risks to consumer, so it can be noticed that EU have a focus on preventing consumers to not be defrauded or misled, as stated in article 8 of the GFL, and U.S. considers the safety issues and risks to health that can be involved through EMA, but within a very limited approach.

The definition of EMA includes the word "substance", but it is not clear what a substance is, maybe an additive? An approved substance? An unapproved substance? Just water? A toxic substance? Food fraud is more than the intentional addition or substitution of a substance, so this definition is referring to Adulteration. It can be understood that in the field of deceptive practices, adulteration is the most well-known type of fraud in the US; recently adulteration of pet food originates one of the biggest recalls in the history of the US, maybe it could be a reason for authorities to focus on this type of fraud.

8.3 Requirements for presentation and labelling

By EU's GFL it is required that "*labelling, advertising and presentation of food or feed…..shall not mislead the consumers"* (art. 16 Reg. 178/2002) and by the US' F, D&C Act, "*food shall be deemed to be misbranded if it presents a false or misleading label"* (section 343 F,D&C Act) *,* which is considered as a prohibited act by FD&C Act Chapter III: Prohibited Acts and Penalties.

The GFL prevents consumers from misleading practices regarding labelling, advertisement and presentation of food, and US addresses its provisions to prevent false or misleading labels.

So, what would be the difference between misleading and false labels in EU and US? FDA does not strictly consider the words "false or misleading" as untrue, in fact, the statements may be true, but the provisions are addressed to practices that are intended to deceive the consumers. FDA considers "*misleading" when "labeling is deceptive if it is such as to create or lead to a false impression in the mind of the reader"*[89] False impressions could be caused by failure in the information provided, and not only because of eccentric claims. It can be noticed that these statements are comparable to those provisions in EU food law, so both legislations aim to prevent consumers from deceptive practices regarding the appearance, packaging and information of food products.

The term misbranding in US seems broader than the term mislabelling in the EU; in US mislabelling is a type of misbranding. For deeming a food to be misbranded in US, the information contained in labels (i.e. name), the fill of container, package, prominence of information, representation for special dietary use, artificial flavouring, colour additives or chemicals, nutrition labelling, nutrition claims, dietary supplements, allergen labelling, etc. are considered. In EU provisions concerning food information, including identity, composition, properties, allergens, nutrition information and others are contained in Regulation 1169/2011 which also requires that food information shall not be misleading (art. 7); other requirements regarding nutrition and health claims are regulated under Regulation 1924/2006.

Deceiving consumers with false or misleading labels can have several consequences; their economic behavior can be directly affected and thus create unfair market competition. As an example, the horsemeat scandal in the EU; horsemeat is actually authorized to be sold as for human consumption, provided it complies with the safety requirements and certificates, however it was sold and labelled as "beef". Horse may be not part of a traditional food in several places and there exist people for which its consumption is forbidden by their religion or because it is considered as a "taboo". The information provided in the labels affected consumers' behavior; after the scandal was discovered, the economic consequences for the industry were a lot higher than the profit made by the substitution/adulteration, including arrests, suspension of license, loss of customers for some suppliers[90] and loss of consumers' confidence.

89. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/GeneralDeviceLabelingRequirements/ucm052190.htm
90. http://en.wikipedia.org/wiki/2013_meat_adulteration_scandal

Unfortunately there is not an adequate enforcement on law neither in EU or US to verify the authenticity of the information in the labels and some cases, (like the mislabeled horsemeat) are being discovered by a random inspection; this just means that there is a big possibility that there are other mislabeled products placed already in the markets. Should verification of labels be a priority for food law in these regions? Definitely!

8.4 Food safety vs. food fraud

Food legislations in EU and US are directed to food safety, yet they have some focus in food fraud. EU food law aims to guarantee a high level of human health and consumers' interests in relation to food and it addresses controls for risks with a direct or indirect impact in food safety (art. 1 Reg. 178/2002); while the FSMA requires science based preventive controls and strengthen the controls addressed to food safety[91]. It is noticed, in both regions, that food fraud is a concern when it poses a food safety risk and control and strategies to combat it shall apply; however when food fraud does not represent a safety risk, measures to combat it seem not to be a high priority.

In EU legal requirements like food safety, presentation, responsibilities and liability[92] may apply to food fraud, however EU does not lay down requirements regarding authenticity of food; it just stated that only safe food shall be placed on the market (art. 14 Reg. 178/2002), according to this, it can be understood that food committed into fraud that is not 'unsafe' can be placed on the market; the problem is whether to determine if food fraud is safe or not (see point 5.5). On the other hand, US prohibits the adulteration of food (section 342 F,D&C Act), which includes extraneous, insanitary or deleterious ingredients in the food, substitution of constituents, decomposed substances, supplements manufactured under GMP's and unsanitary conditions, food rejected for import, etc. It can be seen that the approach from the US is broader than the approach in the EU regarding adulteration of food. The US, also considers intentional adulteration of food (GAO 2011), by which three types are included: terrorism; disgruntled employees, consumers or competitors and economically motivated adulteration; the latter referring to a category of food fraud.

In the author's opinion, food fraud is not a priority, as long as it does not pose a food safety risk, in either legislations; it is indirectly covered and strategies are not directed to combat it.

91. http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm
92. Section 4. Reg 178/2002 General Requirements of food law

8.5 Traceability

In EU, the traceability of a food, animal or substance intended to be incorporated into a food shall be established at all stages of the food supply chain (ART. 18 Reg. 178/2002) and food business operators should implement their own traceability systems since the GFL came into force; in the US by the FSMA it is required that FDA develop pilot projects in cooperation with food industries to detect and analyse methods and appropriate technologies for rapid and effective tracking and tracing of foods, in addition a proposed rule-making for recordkeeping in high risk food facilities to help in tracing shall be published (section 204 FSMA).

The similarities between the two legislations is that they consider necessary the implementation of a traceability system, particularly for the rapid and accurate identification of a food when there is a risk of concern; however the requirements differ a bit between them. In EU the traceability is a responsibility of the food business operators and there is no imposition on which technologies should be used, which documents shall be developed, no requirements for record-keeping etc. which may lead to differences in terminology, legibility, formats, language, data analysis, code systems, etc. and it is also not defined which methods should be used by the M.S. to verify the accuracy and authenticity of documents. On the other hand, in US the tracking and tracing requirements seems to be a very new concept in the food field[93], FDA is looking forward to develop a national food tracing system, as in the present there is not a standardized system in place. By the requirements in the FSMA, the Institute of food technologists (IFT) under FDA's mandate, developed a report on the two pilot projects carried out; the report covers studies, pilot execution scenarios, available technologies, costs, domestic and foreign practices and provide some recommendations for developing a food tracing system[94].

EU considers "Traceability" as the ability to trace and follow a food through all stages in the food supply chain, in this statement the word "follow" seems to refer to "tracking"; in the US tracking and tracing are different terms, but they mainly refer to the system that helps to trace back a food to its common source or forward it through the distribution channels[95]. In the author's opinion, both legislations consider traceability as a system that allows authorities to efficiently react after an incident, however it is not intended to identify the points on which food fraud, or other crimes, can occur.

93. Before FSMA, traceability was just a requirement for medical devices (F,D&C Act)
94. http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm270851.htm
95. Frequently asked questions in product tracing

EU's perspective does not consider the complexity of the food supply chains neither the differences in company sizes, which allows a divergence between all the food businesses traceability systems. US is working on the implementation of a food traceability system considering record keeping and facilities' size, but the pilot projects were mainly based in products implicated in food safety outbreaks[96] and none in food fraud incidents. In addition, any of the legislations consider any analytical tool or technique to identify the authenticity of traceability documents.

8.6 Control of imports

In Europe, all products that are imported and intended to be placed in the internal market must meet the requirements of food law or meet the conditions agreed with the EU[97]. In the other hand in US, the FSMA strengthen the control of imports by foreign supplier verification programs (by which importers should carry out risk based foreign supplier verification activities for verifying compliance with law including that food is not adulterated or misbranded[98]**),** requirement of import certifications, voluntary qualified importer program, agreements with foreign governments, inspection of foreign food facilities, accreditation of third party auditors and introducing for the first time, controls for smuggled food[99].

US considers smuggled food into the provisions for imports; it could be considered as a type of fraud or food crime and it is defined as "*any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead"*[100]*.* By introducing food through fraudulent means, consumers can be exposed to several risks as food cannot be inspected nor checked for certificates or compliance with the requirements. FDA shall develop two strategies to detect smuggling food; this includes historical data analysis which will lead to the development of targeting rules and the development of a continuous post-operational analysis of data and subsequent enforcement actions[101]; while EU does not provide provisions regarding this topic. It is noticed that the US government is also trying to control smuggled food with the intention of causing public health harm or by terrorisms acts. After the incidents in September 2011, US have strengthened its controls including food[102], as there is a continuous fear that another attack can take place.

96. Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report
97. Article 11. Reg 178/2002
98. Section 301 FSMA
99. Section 211 FSMA
100. Section 309 FSMA
101. http://www.fda.gov/downloads/ForIndustry/ImportProgram/UCM261739.pdf
102. http://www.fda.gov/food/fooddefense/

In EU there is no imposition to include inspection of foreign facilities, nor percentage of food that should be inspected for fraud. In US inspection of foreign facilities is a requirement (section 306 FSMA) (upon agreements with exporter country) and if the third country does not allow inspections, the facility can lose its register. Unfortunately in US there is not an imposition of how much percentage of food should be inspected for fraud and studies have revealed that it is less than 2% (Oceana 2013). This could be one of the reasons why fraud cases are easily taking place, as fraudulent practitioners have very little chances to be detected; in addition to this, most of the inspections are directed to food safety.

In US, the Customs and Border Protection (CBP) controls and enforces the import requirements[103], (which may vary on the type of food, country of origin, etc.). Several agencies[104] are in charge of determining admissibility of food into the U.S. All foreign manufactures must register with FDA before exporting and all commercial imports require the filling of "*Prior Notice*[105]"; products from animal origin may require special permits and certificates (i.e. health). Once the products arrive in the US, FDA may inspect or collect samples before preceding the admittance of the shipment. If food is detected to have a violation with the law, it will be submitted to detention[106]

On the other hand, EU is considered as the world's biggest importer and exporter of foodstuffs [107]. Rules regarding food safety into the EU shall equally apply for imports; in addition EU works in close cooperation with international organisations and exporter countries to determine specific provisions intended to protect consumers' health[107]. Some requirements apply the same as in the U.S., some of them may vary depending in the country, region or establishment where it came from (only countries from the "Community list" are allowed to import food from animal origin into the EU) [108]. Food business operators should give notification before the arrival of the food; products of animal origin must be submitted to an import control and present relevant veterinary certificates, in certain cases, special conditions or restrictions may apply. EU also considers special conditions to control risks such as residues of veterinary medicines, pesticides, food additives, contaminants and GMO's.[109]

103. https://help.cbp.gov/app/answers/detail/a_id/83/~/importing-food-for-commercial-use-(resale)
104. The United States Department of Agriculture (USDA) Animal Plant Health Inspection Service (APHIS), Food Safety Inspection Service (FSIS), and/or the Department of Health and Human Services Food and Drug Administration (FDA)
105. Section 304 FSMA
106. Title III. Improving safety of imported food. FSMA
107. http://ec.europa.eu/food/animal/bips/special_imports_en.htm
108. Article 6 Reg 853/2004 obligations of importers
109. http://ec.europa.eu/food/international/trade/interpretation_imports.pdf

Imports are not subjected to inspection for fraud because there are other issues of concern for the authorities; the percentage of food inspected for fraud is less than 2% in US and there are no numbers regarding imports inspection for the EU. Many of the controls are based in past records for specific countries, but that does not mean that new incidents from different countries cannot occur. It has been discussed that many of the fraud incidents have entered to the countries by a third country. As long as food fraud is not a priority in border inspections, it will continue to be a continuous risk and a challenge.

8.7 Enforcement of legislation and responsibilities

In the EU, the Member States have the responsibility to enforce food law (art. 17, Reg. 178/2002) and in the US, FDA has the mandate to verify compliance with requirements[110]. In EU every M.S. shall develop its own strategies, which of course, may vary between them; by food law there is no imposition on the agencies that should cooperate to enforce legislation, every M.S. shall make use of its own resources and to verify what is considered as "relevant" (art. 17 Reg. 178/2002). In the other hand, in US, the FDA is responsible to regulate and verify food safety and compliance with requirements, which seems to be a more harmonised approach because enforcement shall be applied in the same way through all the states. The legal provisions that shall be enforced in the field of food fraud in EU are mainly food safety requirements, presentation and traceability; in the US are primarily those related to adulteration (which includes several types and safety issues) and misbranding, unfortunately a food traceability system in US is not implemented yet.

Due to the recent food fraud cases like seafood substitution, horsemeat scandal (2013) or melamine contaminated pet food (2008), it can be noticed that there is a weakness of enforcement in both legislations and that most of the food fraud cases have been discovered under conducting food safety activities (GAO 2011). In EU, there is not imposition to verify neither authenticity on labels nor authenticity of traceability documents. JRC had shown that traceability can be validated through DNA based molecular techniques[111], yet as a legal requirement is far away for being implemented. In the US it can be seen that inspections are not directed to verify accuracy and authenticity of information contained in the labels; molecular techniques are seen as an efficient tool to ensure species authenticity yet still as an expensive and complicated method. Traceability in the US is not yet implemented; FDA is still working on rule-making regarding the pilot projects carried out under the mandate of the FSMA[112].

110. http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm
111. JRC seafood fraud report
112. Section 204 FSMA

Law enforcement in EU should be carried out through a system of official controls (art. 17 Reg. 178/2002), however there is no harmonisation on how to implement it; every M.S. shall determine the relevant requirements to verify for compliance but it is not stated how they should carry out the activities (monitoring, inspection, etc.), size of facilities is not considered, there is neither an imposition on frequency for inspections nor record keeping. Contrary, in the U.S., requirements for inspection (including frequency, size of facilities, recordkeeping and number of facilities to be inspected) and sample analyses (including accreditation of laboratories) are very specific (section 201 & 202 FSMA). Inspection of foreign facilities is included under the US scope (section 306 FSMA), while for EU foreign facilities should be subjected to same official controls as the domestic ones (art. 11 Reg. 178/2002), yet their inspection is not mandatory.

It is of most importance that several agencies, like Europol, JRC and OLAF in Europe, or CBP and FDA in US, work in close cooperation sharing strategies to detect and combat the problem of food fraud in both regions. The lack of communication between the agencies can lead to deplete resources and overlap strategies ending up in an inefficient way to combat this problem.

9. Conclusion

1. How is the concept of food fraud considered in Europe? Is there a difference between this concept and economically motivated adulteration from USA?

In Europe, there is not a legal definition for food fraud; agencies and Member States differ in the terms they use for it. It is usually referred as an “infringement of law” or “deception” committed into the food for “financial gain” or to “deceive” the consumers. The Commission is considering laying down a definition for it.

In the United States, FDA developed the working definition of economically motivated adulteration as *“The fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production. i.e. for economic gain. EMA includes dilution of products with increased quantities of an already present substance to the extent that such dilution poses a known or possible health risk to consumers, as well as the addition or substitution of substances in order to mask dilution.”* (GAO 2011).

It cannot be said that there is or there is not a difference between EU and US; first of all EU does not have a definition for food fraud; second the definition of EMA specifically considers addition or substitution of a substance which leaves out many of the other types of fraud that exists like tax avoidance, misbranding, counterfeiting, species substitution, etc. If the

horsemeat scandal in EU wanted to be included into USA's "EMA concept", it would not meet the specifications of the description. It seems that US developed this concept after the melamine incidents with pet food and infant formula in China, but EMA should not be considered as a general term when referring to food fraud.

2. What is the place of food fraud in EU and US legislations? How do FSMA and GFL address this problem?

In EU food fraud goes indirectly covered by food safety provisions; legislations are not addressed to it. In the GFL it is a requirement that "Presentation of food shall not mislead the consumers" but there is no imposition to verify the accuracy of information contained in the labels. Traceability may also be seen as a strategy to follow a food product when it is of concern, but not as intended to detect at which point of the chain, fraud is occurring. Response strategies and communication network (RASFF) are directed to food safety concerns, and when food fraud does not pose a risk to human life or health, it seems to be a low priority issue.

In the US, adulteration and misbranding of food are prohibited acts; food safety is encompassed in these categories. Several acts of fraud as addition of deleterious or poisonous substances, abstraction or addition of constituents, unsafe additives, decomposed food, reoffering food when denied for import, presenting a misleading label, offered with another name or imitation of another food, containing undeclared pesticide or residues, incomplete nutritional information, etc. are covered under these categories. The FSMA reinforces the provisions in food safety matters and require stricter controls and identification of high risk facilities; by this food fraud can be more easily detected, yet provisions are not strictly directed to it.

3. How do food fraudulent practices fit into the concept of "unsafe food" by The General Food Law? Does U.S.A. have the same approach when considering a food as "unsafe"?

According to article 14 of the GFL, "*Food shall be deemed to be unsafe if it is considered to be: (a) injurious to health; (b) unfit for human consumption."* Fraudulent practices do not follow good manufacturing practices and are intended to mislead consumers, honest vendors and authorities; these type of practices have the potential to be injurious to health, even they are not intended for that. Food committed into fraud may contain contaminants, toxins, allergens, substances (not allowed for its use in the food industry) and thus represent a big risk to human health. Fraudulent practices could also (sometimes) not be injurious to health or unfit for human consumption, for example by declaring less content in the package, no direct risk to health is identified; so when determining if food committed into fraud is safe or unsafe, several

conditions shall be considered (the characteristics of the consumer, the type of fraud committed, the amount of food ingested, the type of added substance (if any), the interaction of the other ingredients and the substance in the food, the matrix of the food, etc.)

In the U.S., according to the Code of federal regulations, "safe" means that "*there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use*[302]*",* so the approach compared with the EU is very similar, as they both consider a substance that is not harmful or injurious; both perspectives take into account the cumulative effects of the substance of concern when determining it as safe or not. However US does not mention the term unsafe food under its food requirements.

4. Are food inspections considered as a practice to prevent food fraud in these legislations? Until which extent and how inspections can have an impact in detection of food fraud?

Inspections are intended to detect non compliances with food law, however they are directed to food safety issues more than food fraud. In these two legislations there is no imposition to consider fraud inspections as regular practices. In EU, as shown by the horsemeat scandal, the detection of horse in lasagne seemed to be found by a random inspection in Ireland and just after that case, the other M.S. (France, UK) detected it as well; unfortunately there are no numbers regarding the food that is being inspected for fraud in EU.

In the other hand, in the US, fraud is also not a requirement for inspections, by the FSMA high risks facilities shall be identified and more frequently inspected, however when determining an industry as high risk, just safety issues and past incidents were taken into account and fraud was out of this scope. By the recent seafood fraud report (Oceana) it was discovered that very high numbers of seafood were mislabelled, yet authorities have not implemented an inspection plan addressed to fraud or species substitution. The numbers regarding food fraud inspections in US are to be found directed for imports where less than 2% of food is checked for fraud.

5. What similarities or differences does the section "Protection against intentional adulteration" from The FSMA have with article 8 "Protection of consumers' interests" from The GFL?

Section 350i of The F, D&C Act regarding Protection against Intentional Adulteration requires the conduction of a vulnerability assessment of intentional adulteration in the food system; by a vulnerability assessment risks can be identified and prevented as well as focused mitigation strategies. US considers three types of intentional adulteration of food which are EMA, acts of terrorisms and acts of disgruntled employees, consumers or competitors, so vulnerability assessments shall be conducted for these three categories. When conducting a vulnerability assessment for EMA, several factors have to be analysed like previous incidents, records,

ingredients likely to be adulterated, high cost and complex processes, history of complaints, availability or adulterants, etc.

In the contrary, Protection of Consumers Interests in the GFL does not imply any requirement, it just mention that food law shall aim the prevention of fraudulent practices, adulteration of food or practices that may mislead the consumers, but the way on how to do it is not described and there is not imposition or obligation to analyse the vulnerable points of the food supply chain.

The only similarity between these provisions is that they are intended to protect consumers for intentional adulteration (US) or deceptive practices including adulteration (EU); however the approach in US requires action and the conduction of a vulnerability assessment, while EU does not. This could be explained because US considers several motives for committing adulteration including those that are intended to cause harm to the consumers, after the incidents in September 2011, US has strengthen its provisions in order to prevent any other type of terrorism attack. EU fortunately does not seem to have a fear like this, yet it should be more concise and precise within its food law provisions directed to the prevention of fraudulent practices, as nobody will conduct a vulnerability assessment if it is not required.

6. Which are the most relevant strategies to combat food fraud for GFL and Food legislations in USA? Which other parties are involved in implementing these strategies?

Relevant strategies, yet not totally directed to food fraud in the GFL are: Protection of consumer's interests, Presentation, Responsibilities of food business operators, Responsibilities of M.S, Food safety requirements, Traceability, Control of imports and under certain circumstances Rapid Alert System of Food and Feed. Food fraud seems to be a priority for EU law, just when it represents a food safety risk; however measures like responsibilities of M.S. and traceability can be used to detect it. The provisions are given in a very general way and open to interpretation, so it can be noticed that the way by which food fraud is combated will depend on every Member State in particular. Additionally, food fraud is not covered under EFSA's mandate. The Commission should work in collaboration with Europol and OLAF to develop new and efficient strategies to control it.

In the US, the strategies found in the F, D&C Act are those regarding adulteration, misbranding, standards for food (standards of identity", "standards of quality" and "standards of fill of container") and protection against intentional adulteration. The strategies presented in the FSMA, also addressed to food safety, covering food fraud in a certain way are: identification of high risk facilities; inspection of facilities; access to records; suspension of registrations;

mandatory recall authority; inspection of foreign facilities; development of preventive and science based standards; voluntary qualified importer program and traceability (even traceability is not implemented yet in the US). Despite the stricter regulations, it seems that FDA does not work in collaboration with other agencies to develop efficient strategies to combat the problem of food fraud.

Final comments

Food fraud is an opportunistic and intentional practice derived by economic gain which can threaten the integrity and safety of the food supply chain. Food safety regulations may not be enough to combat the problem and food authenticity requires attention.

The control of food fraud is a shared responsibility among all the parties in the food supply chain, including consumers. There is a need for collaboration with anti-crime organizations to provide better strategies and tools to detect food fraud.

10. Recommendations

Combining strategies to combat the problem of food fraud from European and American legislations:

1. Focus on food fraud
2. Better enforcement of food law
3. Implement surveillance system on food fraud
4. Demand safety and authenticity of food
5. Address official controls to food fraud
6. Use of DNA testing and molecular techniques for authentication
7. Standardize a traceability system considering all the stages of the food supply chain
8. Impose stricter and higher sanctions for fraudulent practitioners
9. Train food safety officials and authorities in food fraud
10. Inform consumers and make awareness of the problem

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ANNEX 1.

Regulatory framework in EU that could address food fraud

The regulatory framework in Europe tackling food fraud includes diverse perspectives, the main one for food safety is Regulation 178/2002, but some other legislations are also involved in the prevention of food fraud directly or indirectly. Here is a list of some legislations that may include food fraud within their scope:

1985 – Council Directive 85/374/EEC laws, regulations and administrative provisions of the Member States concerning liability for defective products

1993 – Council Regulation 315/93 laying down Community procedures for contaminants in food.

2000 - Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs

2002 – Regulation 178/2002 General Food Law

2004 – Regulation 854/2004 official controls on products of animal origin intended for human consumption

2004 – Regulation 882/2004 official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

2006 – Regulation 1924/2006 on nutrition and health claims made on foods

2006 – Council Regulation 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs

2007 – Council Regulation 834/2007 on organic production and labelling of organic products

2008 – Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings

2011 – Regulation 1169/2011 on the provision of food information to consumers

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