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An international perspective on vulnerable personas protection in agri-food legislation

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Desidero dedicare la mia tesi ai miei amatissimi genitori, Corrado e Concetta, a mia nonna Iolanda, e al mio fidanzato Alberto.

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Chapter I

Agri-food market in Italy and its relationship with Europe

1.1. The principle of primacy of the EU Law

According to Article 11 of the Italian Constitution, Italy rejects the war as an instrument of aggression against the freedom of other people and agrees, on conditions of equality with other States, to the limitations of sovereignty that may be necessary to a world order ensuring peace and justice among the Nations[1]. Article 11 of the Constitution has a primary role of importance inasmuch states the legal basis upon which Italy have built its international relations, the Article has as well legitimized the entry of Italy in the United Nations and the signing of the founding Treaties of the European Union. European Union's construction has developed over time, from the Treaty of Rome of 25 March 1957 to the Treaty of Lisbon of 13 December 2007. The Treaty of Lisbon entered into force in December 2009, amending the Treaties of Rome and Maastricht, it augmented the powers of the European Parliament and provided for innovations to adapt the European institutions to the enlargement of the EU. The Lisbon Treaty is composed of the Treaty on European Union, TEU, and the Treaty on the Functioning of the European Union, TFEU, it highlights matters which fall within the competence of the Member States and matters in which decisions are taken directly by the European institutions, in particular the European Parliament and the Council, and it also increases the democratic accountability of the Union, strengthening the Charter of Fundamental Rights and consolidating the rule of law[2]. The European Union has legal personality and as such its own legal order which is separate from international law. European Union law has direct or indirect effect on the laws of its Member States and becomes part of the legal system of each Member State, moreover EU sources of law are divided into primary legislation such as the Treaties and general legal principles, secondary legislation, based on the Treaties, and supplementary law. The Treaties and the general principles, together with the Charter of Fundamental Rights of the European Union, are the most important sources of law, are also known as primary legislation. International

[1] https://www.senato.it/documenti/repository/istituzione/costituzione_inglese.pdf
[2] https://www.europarl.europa.eu/italy/it/scoprire-l-europa/il-trattato-di-lisbona

agreements stipulated by the EU are subordinate to primary legislation, secondary legislation is the following in terms of importance and is valid only if it consistent with the acts and agreements which have precedence over it. As regards EU's secondary legislation, there are several types thereof, among which there are Regulations, Directives, Decisions, recommendations and opinions, it is of interest to briefly describe each of them. Regulations are of general application, binding in their entirety and directly applicable as soon as they enter into force, they require full compliance by those to whom they apply and do not need to be transposed into national law. They are designed to ensure the uniform application of Union law in all the Member States and supersede national laws incompatible with their substantive provisions. Directives are binding, as the result to be achieved, upon any or all the Member States to whom they are addressed to but leave to the national authorities the choice of form and methods. National legislators must adopt a transposing act or national implementing measure to transpose directives and bring national law in line with their objectives, citizens are given rights and bounds by the legal act only once the transposing act has been adopted[3]. Member States guarantee the effectiveness of EU law in transposing directives, as well as ensure that the transposition is effected with the period laid down in the directive. Decisions are binding in their entirety, to those they are addressed are stipulated, they can be directly applicable on the same basis as directives. Recommendations and opinions do not confer any rights or obligations on those to whom they are addressed but provide guidance as to the interpretation and content of Union law. The Italian and European legal systems have then been relating to each other, a form of primacy and harmonization have been implemented. As the main sources and scope of European Union law have been revised, it is of interest to recall the principle of primacy of the European Law with respect to the Member States. The general rule assigns the primacy of the European Law on the member States' one and assures that regulations and directives shall be fully effective without laws of reception and adaptation[4]. The principle of distribution of competences (Article 5 of the Treaty of the European Union- TEU) combines with the

[3] https://www.europarl.europa.eu/factsheets/en/sheet/6/fonti-e-campo-di-applicazione-del-diritto-dell-unione-europea

[4] A. GERMANÒ- M. PIA RAGIONIERI - E. ROOK BASILE, Diritto agroalimentare, Torino, 2019, p.9.

principle of primacy and in the case in which the internal law is in contrast with the European one, the first loses its effectiveness, according to the above-mentioned principle.

1.2. CAP

After the entry into force of the Single European Act, particularly during the 90s, the reform of the Common Agricultural Policy (CAP) has begun[5]. The entire system has been reformed, four specific changes has been made, and the aforementioned amendments have been introduced in order to align the EU norms to the principles and rules of the World Trade Organization. The first has been the abolition of fixed book pricing on agricultural products and the provision of direct aids to farmers, the fixed book pricing has been cancelled, so a sort of protection to the farmers has been denied, but they benefit from financing for the activity they carry out[6]. The second concerns the need of clarifying the separation of the first pillar, regarding the agricultural production and the financing of farmers, to the second pillar, which refers to the rural development for which specific measures and specific financing are foreseen. In all the measures contemplated for the two pillars a specific attention has been paid to the sustainability and the attention to the environment. The third regards the protection of high-quality typical and traditional products, this norm is of special importance for Italy both in terms of support for Italian agriculture and in term of promotion of top-class products[7]. Some examples are the products that are Protected Designation of Origin (DOP) or the Protected Geographical Indications (IGP) that are recognized at European level, preventing the competition on prices on row materials in Italy, which would cease the production in loco because uncompetitive[8]. CAP is regarded as a partnership between agriculture and European society, its main aims are to support farmers and increase their productivity, assuring a stable supply of affordable food; safeguard European Union farmers to make a reasonable living; increase the sustainable management of natural

[5] https://ec.europa.eu/info/food-farming-fisheries/key-policies/common-agricultural-policy/cap-glance_it#thecapafter2020

[6] F. CAPELLI, La tutela dei prodotti agroalimentari di qualità in Italia e in Europa, Napoli, 2018, p. 34.

[7] F. CAPELLI, Valorizzazione dei prodotti agro-alimentari italiani tipici e tradizionali, Napoli, 2014, p. 487.

[8] A. MATTIACCI- C. VIGNALI, The typical products within food "glocalization": The makings of a twenty-first-century industry, in British Food Journal, 2004, pag. 710.

resources; maintain rural areas and natural landscapes across Europe; keep the rural economy alive by promoting jobs in farming, agri-food industries and associated sectors.
A set of measures called the Common Organization of the Market (CMO) have been constituting a fundamental element of the PAC since its creation, they have been providing a structure for market support schemes in numerous agricultural sectors. CMOs have been created to practically implement the objectives of the CAP (Article 40 TFEU), particularly to stabilize markets, ensure a fair standard of living to farmers, increase agricultural productivity by means of mechanisms governing the production and commercialization of agricultural products in the EU[9]. CMOs have been several distinct entities, 21 precisely, each regulating specific agricultural products, until the implementation in 2007 of the Council Regulation EC number 1234/2007, which embedded all the rules and measures in one single CMO.

1.2.1 Exclusive and not exclusive competences in terms of agriculture and nutrition

The treaty of Lisbon has been enriched, in occasion of the formulation of the actual article 38 of TFEU, by a subparagraph to the paragraph 1 that proclaims that the Union shall define and implement a common agricultural and fishery Policy, not dictating a list of common policies to respect anymore. Moreover, article 2 of TFEU acquires essential importance since it clarifies that when Treaties attribute to the Union a concurrent jurisdiction with respect to a Member State in a specific matter, the Union and Member States might legislate, elucidating that the Member States can exercise their legal competence to the extent that the EU has not exercised its own or ceased to do so[10]. The Italian Constitution takes into consideration the matter of alimentation in the Article 117, not mentioned into the Treaty of Lisbon, even if feed has a close relationship with public health and consumer protection, both mentioned in the Article 4 of the TFUE[11]. European Union has implemented the construction of an extensive legal framework concerning the agri-food law. The security and healthiness of aliments has been called back by the European Union, in terms of competences, in 2002 with

[9] https://www.europarl.europa.eu/factsheets/en/sheet/108/il-primo-pilastro-della-pac-i-l-organizzazione-comune-dei-mercati-ocm-dei-prodot
[10] A. GERMANÒ- M. PIA RAGIONIERI - E. ROOK BASILE, op. cit., p.13.
[11] F. ALBISINNI, Strumentario di diritto alimentare europeo, Torino, 2015, p. 23.

the Regulation 178/2002. The aforementioned Regulation has its legal bases the Articles 43 on agriculture, 168 on health, 133 on the Community trade policy and 114 on the approximation of the laws. Thereby, the reference to the legal basis of "agriculture" suggests that the dispositions on food and feed, on ingredients, on adjuvants, on solvents, preservatives, sweeteners, allergenic substances, on GMOs contained in food and food hygiene pertain to European competences, according to Article 38 TFUE, which govern agriculture, fishing and commerce of agricultural products.

1.2.2. Guidelines of agricultural production for human consumption

All the aliments are of agricultural origin, the legal discipline that relates to them is the framework for agricultural production and the trade of safe and healthy products intended for human consumption is the core principle that inspired the EU legislation. The European law refers both explicitly and implicitly to aliments as agricultural products intended for human consumption. The agri-food law is comprehensive of beverages and includes primary production, intending all the stages of breeding and cultivation of natural fruits; secondary production, the processing of basic agricultural products in aliments; and the commercialization, the allocation of both natural and transformed agricultural products in the market[12].

1.3. Aliment

The basis of human nutrition are aliments, an important distinction to be done regards the difference between them in scientific terms and in legal terms. An aliment is scientifically a part of the macro nutrients such as proteins, fats, carbohydrates, minerals and vitamins, which are fundamental for humans to perform life functions[13]. The definition of aliment has been characterized by slightly differential traits from country to country in the European Union before 2002. *Exempli gratia* the Italian law, before the put in place of the EU law 178/2002, regarded as the most important trait of aliments their edibility. The European Union perceived the need of assuring a common approach towards food safety among all the

[12] A. GERMANÒ- M. PIA RAGIONIERI - E. ROOK BASILE, op. cit., p.16.
[13] http://www.treccani.it/vocabolario/alimento/

adhering countries and hence committed its efforts to produce guidelines and laws to be applied. In Europe, the ruling law is the num. 178/2002 and defines an aliment as:" Any substance either processed product, partially processed or not processed, reasonably intended to be eaten by humans"[14]. The most important trait on the aliment definition, according to European legislation, hence is the reasonability of ingestion thereof, this characteristic includes chewing gums, potable water and any of the substances deployed in the production or preservation of the aliment. The facets that are covered by the definitions of aliment are multiple, they comprise not-processed plant foods, for example fresh fruit and vegetables, and aliments subject to industrial processes before they are positioned on a supermarket shelf. The row materials deployed for the production of industrial foods are subject to processes that rely on improvement agents such as food enzymes, additives, flavorings, adjuvants and in the latest years, in some circumstances, brought by the enhancement of technology, also by GMOs, new foods, supplements, and nano-engineered aliments. The European Union established conditions of use for improvement agents and redacted a series of legal acts termed "food improvement agents' package", FIAP, in order to increase the harmonization among the Union to permit the free movement of goods in safety. The European Commission established as food improvement agents' additives, enzymes, flavorings and solvents. Food additives are substances that are not normally consumed as food itself but are added to food intentionally for a technological purpose, such as the preservation of food, and other natural source material that are intended to have a technological effect in the final food and which are obtained by selective extraction of constituents (e.g. pigments) relative to the nutritive or aromatic constituents. European Union set the rules on food additives in the Regulation EC 1333/2008, the norm dictates the principles of food adjuvants as well. Technological adjuvants are chemical substances that improve and facilitate the food production process, *exempli gratia* to extract natural flavors from roots, barks, leaves, fruits or flowers. An adjuvant differs from a food additive because it runs out during food processing in a way that its presence or the presence of its by-products in the final product is negligible or absent, as attributable to inevitable technological residuals; if the residuals are absent or negligible it is not mandatory to include

[14] D. PISANIELLO, Guida alla legislazione alimentare, Roma, 2020, p. 119.

the presence of the adjuvant in the label. Enzymes are protein molecules present in all living organisms, they exert a fundamental role in accelerating and catalyzing chemical reactions, such as the conversion of starch into sugar, and are obtained from extraction from plants or animals or fermentation of micro-organisms. The EU prescribes the Regulation on enzymes in the EC 1332/2008, however, it has still not been adopted by the Community in year 2018 entrusting the distinct national norms, compatible with the EC Regulation, to rule. Flavorings are products that are added to food in order to impart or modify odor or taste, EU legislation defines: flavoring substances, flavoring preparations, thermal process flavorings, smoke flavorings, flavor precursors, other flavorings[15]. Since 2011 the legislation on flavorings is included in the CE Regulation 1334/2008, the Annex I include a list of approved flavorings and source materials. Solvent is defined, according to CE Regulation 2009/32, as:" Any substance for dissolving a foodstuff or any component thereof, including any contaminant present in or on that foodstuff", moreover the Regulation sets the maximum limits of residual in the food or in its ingredient per each single solvent used[16]. The technological development in the Twentieth Century opened opportunities for new niches of business, changed some others and still forced others to change their way of doing business to remain competitive in the market. The competition incremented since the trade agreements among states and nations stabilized. One of the business sectors that have been challenged by technological novelties has been agriculture. Since the birth of the first Genetically Engineered Organism in 1973[17], the attention on development of technologies and practices to increase the fields of application of GMOs in the world grow. Each Nation has different laws on GMOs, blatant discrepancies are noted, for example, between United States and Italy in terms of adoption of the technology and in public opinion. This dissertation would cover, in the third chapter, the salient traits of the debate of GMOs and the differences between USA and Italy. A common set of Regulations discipline the matter of GMOs in European Union, in fact, stringent rules on GMOs have been established since 2003 because the free trade of goods forced adhering Countries to stipulate a common set of laws. The Genetically Modified Organisms for food

[15] https://ec.europa.eu/food/safety/food_improvement_agents/flavourings_en
[16] https://ec.europa.eu/food/safety/food_improvement_agents/extraction-solvents_en
[17] Rangel, G., 2015. *From Corgis to Corn: A Brief Look At The Long History Of GMO Technology - Science In The News*. [online] Science in the News. Available at: http://sitn.hms.harvard.edu/flash/2015/from-corgis-to-corn-a-brief-look-at-the-long-history-of-gmo-technology/

and feed are subject to the EC Regulation 1829/2003 and to EC Regulation 1830/2003 regarding the traceability and labelling of GMOs and the traceability of food and feed obtained from GMOs. The cultivation of GMOs is ruled by the EC Regulation 2001/18/CE on the deliberate release of GMOs in the environment, the transboundary movement of GMOs is disciplined by the EC Regulation 1946/2003 and the CE Regulation 2009/41 regards the usage of genetically modified microorganisms. The trade in food or feed containing GMOs must be authorized in advance, on the basis of the EC Regulation 1829/2003, by the Commission after a thorough analysis on the risks for human and environmental health by the European Food Safety Authority. European Union requires, similarly for the aforementioned category, a pre-market authorization for novel foods, approximately definable as the foodstuff that has not been significantly consumed in EU before 15th May 1997. A Novel food can be newly developed, innovative food, food produced using new technologies or production processes, as well as food that has been traditionally eaten outside the EU[18]. Some examples of novel foods are vitamin K, extracts of Antarctic Krill oil and chia seeds. European Union pretend novel foods to be safe, well described in the label and have to be approved by the Commission. The EU Parliament introduced a centralized assessment and authorization procedure, with the Regulation EU 2015/2283, in order to simplify the analysis on novel foods, and since January 2018 the Commission is responsible for the admission thereof. The European Food Safety Authority (EFSA) is in charge of the risks assessment procedures to establish the safety of any incoming novel foods. Novel foods Regulations determine the rules also for nano-engineered aliments, aliments that are manipulated at the nanoscale, in the molecules, in order to ensure specific properties. Nanotechnology offers substantial prospects for the development of innovative products and applications in many industrial sectors, including agricultural production, animal feed and treatment, food processing and food contact materials [19] . The applications of the aforementioned are partially marketed as well as currently under research, the main expected benefits include increased efficacy of agrochemicals through nano-encapsulation, enhanced bioavailability of nutrients and more secure packaging material through microbial

[18] https://ec.europa.eu/food/safety/novel_food_en
[19] https://ec.europa.eu/jrc/en/news/nano-food-and-agriculture-regulations-require-collaboration-ensure-safety

particles. *Exempli gratia* nano-capsules with prolonged-release of iron that will allow the iron-fortification of certain foods, to cure people affected by iron deficiency. Nano-engineered aliments are subject to risk assessments for consumers' health from European Food Safety Authority in Europe, Switzerland have been the only other forerunner country that introduced regulatory frameworks for dealing with safety of the nanotechnologies in agri-food and feed. The last category, treated in this dissertation, under the definition of aliment is the supplements one. Supplements are defined as foodstuff intended to supplement the normal diet and which constitute concentrated sources of nutrients, or other substances, with a nutritional or physiological effect both single and multi-nutrient that can be marketed in pills, tablets, capsules, liquids and other dosage. The European Union harmonized the discipline for those products with the Directive 2002/46/EC, such harmonization is considered partial since it regulates the list of vitamins and minerals admitted in the composition of supplements and their chemical composition, but not the maximum levels of single components inside the supplement[20]. National legislators of each country of the Union have to implement the Directive and prescribe the maximum levels of components in each supplement. The Italian Ministry of Health adopted regularly updated guidelines on the daily vitamins and minerals intake with the Ministry of Health Decree 10th August 2018.

1.3.1. The principle of Mutual Recognition or "Cassis de Dijon"

The fact that today the agri-food market must be considered not in a national but in a European perspective is mainly referable to the principle of Mutual Recognition, which is based on the elaboration carried out by the European Court of Justice. The European Union's agri-food legislation is characterized by a multiplicity of objectives and legal instruments, while somehow suffering from the difficulty of giving a systemic order to a sector rich in cross-cutting tensions, it expresses in a peculiar way the creation of rules in which European, national, regional, international sources intersect, with the objective of bringing public and private responsibilities to coherence through cooperation, testing and establishing models

[20] D. PISANIELLO, op. cit., p.155.

and tools, that became relevant components of the European legal experience[21]. European Union has a central role in relation to national legislation as regards the agri-food regulatory framework, the Principle of Mutual Recognition is the result of the relevance and primary role that the European Union has in relation to national legislation. The principle "Cassis De Dijon ", enshrined by the European Court of Justice, is based on the equivalence of the prescriptions on production applicable national and establishes that the products that are legally admitted in the trade of a Member State can be marketable in all the other European States. The principle of Mutual Recognition derives from a sentence of the European Court of Justice in 1979. The German federal administration was forbidding the commercialization of a French liquor called "Cassis de Dijon", with alcoholic content of 15-20%, because the definition of liquor in Germany was exclusively for beverages with more than 25% of alcoholic volume. The Court abolished the German import ban on the French liquor and the same case law continued also for many other products. *Exempli gratia* Italian law reserved the term "vinegar" for wine vinegar, instead, in other member States, the word vinegar has been attributed also to apple cider vinegar; the word "beer", that the German legislation pretended to be free of adjuvants, in contrast to other states' law; the term "pasta" that for Italian law could be produced only with durum wheat flour, in other States of the Union it can be made from the common wheat semolina. The judgement of the Court of Justice has been assuring the positive result of the free circulation of goods within the Union, with the legal nomenclature assigned in the country of production. The same name, however, might correspond to a product of diverse quality and composition in the importing state, hence, trivializing the legal name[22]. The main drawback of the unrestrained implementation of the system has been the extraterritorial dilation of the legal rules, that has brought out a competition among both products and legal regulations, a phenomenon called "law shopping", consequently forcing the legislators to lower the original quality of a product in order to grant to national entrepreneurs the same advantages of other countries' ones[23].

[21] L. SCAFFARDI- V.Z. ZENCOVICH, Cibo e Diritto una prospettiva comparata, Roma, 2020, p.194.
[22] A. GERMANÒ- M. PIA RAGIONIERI - E. ROOK BASILE, op. cit., p.36.
[23] A. GERMANÒ- M. PIA RAGIONIERI - E. ROOK BASILE, op. cit., p.36.

1.4. Agri food market in Italy

Italy is well known globally for the historical and cultural heritage as well as for the quality of agri-food products. This section of the dissertation will display some numbers regarding the agri-food sector in Italy from year 2017 to 2019, according to the ISTAT databases. In terms of agricultural economy in Italy, 2017 registered a sharp increase in added value in terms of agriculture, forestry and fishing, precisely of 3.9% at current prices and a simultaneous decline in terms of volume (-4.4%)[24]. The prices for agricultural products to the public registered a considerable increase (+6.2%), meanwhile the growth of prices of purchased agricultural products have recorded a much less pronounced increment (+1.6%), hence registering higher margins with respect to the previous year[25]. Year 2018 recorded a weak recovery in volume, the production of 0.6% and value added of 0.9%[26]. The total value of the agricultural economy in Italy during 2018 accounted for 59,3 billion euro with an increase in total volume of 1.8%[27]. 2019 has been represented by a bending in the production of agricultural products both in terms of volume (-0.8%) and in terms of value added (-1.6%)[28]. The total volume of production of agriculture, forestry and fishing accounted for 61.6 billion euro in Italy[29]. Italy is the first State in Europe for the total number of high-quality products, certified with the IGP, DOP and STG since 2008, according to ISTAT databases [30].

The Italian agriculture configured a particularly difficult scenario in 2020, the Covid-19 pandemic worsened the deficiencies of a 2019 closed in decline because of the adverse weather conditions. Global exchanges slowed down, the effects of export in United Kingdom are not yet predictable, since Brexit occurred in the fourth trimester of 2019 and not enough time elapsed, and lastly the eventual effects driven by a new tariff imposition for the Italian products in US market[31]. The Coronavirus outbreak not only impacted on the numbers of the agri-food sector but established the conditions for a major crisis in the population identity and ideals. Among the difficulties of the agri-food sector certainly the measures adopted by

[24] https://www.istat.it/it/files//2018/05/Andamento.economia.agricola.2017-1.pdf
[25] https://www.istat.it/it/archivio/215285
[26] https://www.istat.it/it/archivio/230458
[27] https://www.istat.it/it/files//2019/05/Andamento-economia-agricola-2018.pdf
[28] https://www.istat.it/it/archivio/243183
[29] https://www.istat.it/it/files//2020/05/Andamento-economia-agricola-2019.pdf
[30] https://www.istat.it/it/archivio/224608
[31] http://www.ismeamercati.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/10277

states to limit the spread of Covid-19 infections, such as the close of national borders, have negatively influenced the food traffic between European countries. Another relevant situation that threatens the Italian agri-food sector is the drastic reduction in tourism, in fact the food consumption of tourists in Italy is worth 12 billion euros per year[32]. The prospective of a global crisis resulting from a pandemic has not been something predictable and changed people's habits, routines if not life and priorities. The impact of these changes has been reflected also in the food choices, with positive and negative sides. The lockdown in Italy has created a situation of poverty among groups of population to the extent that not everyone had the economic capabilities to satisfy the family needs in terms of grocery shopping, forcing them to rely on solidarity associations. Moreover, the agri-food supply chains have been challenged by the lack of workers, especially by the shortage of farm workers, that are crucial to assure the overall functioning of the chain itself. The positive sides that resulted from the problems have been the increase in solidarity and cooperation actions to help the vulnerable, the rediscovery of traditions and the pleasure of sharing food, albeit in some cases poor and simple, with the family. Food, apart from being a primary necessity, has an important social and unity function, is a means to demonstrate a person's feelings and has an evocative power of memories. Italy has rediscovered the importance of valuing the agri-food supply chain as the core of its social and economic system, and even if the current scenario prospects many difficulties, the need would be to take them as opportunities to improve.

1.5. Italian agri-food supply chain

A well-organized supply chain in the agri-food sector is the asset that provides the highest value to the market as a whole, it allows food to be properly cultivated, processed, transported and safely consumed. The definition of food supply chain, according to Saccomandi, is: "… food supply chain means the set of economic, administrative, political agents that directly or indirectly delimit the path that an agricultural product has to go through, from the initial stage of production to reach the final stage of use, and all the

[32] https://www.ilsole24ore.com/art/export-agroalimentare-e-coronavirus-ordini-ci-sono-ora-vanno-limitati-danni-ADf31tC#

interactions of activities performed by agents that determine the process[33]". The actors that directly or indirectly are part of the agri-food supply chain are defined as internal when they operate in the food supply chain and external as professionals that entertain an economic relationship with the chain, even not being part of it. Among internal actors are counted the producers of raw materials and fresh products, the agriculture, and food processing industry, together with the distributors and traders. The distribution and trade are carried out at three diverse levels: wholesale of agricultural products and foodstuff; retails sales for domestic consumption, *exempli gratia* butchers and greengroceries; and restaurants, bars, canteens and catering. A food-supply chain is made of several phases as well as actors that operate thereof. In the first phase of the food-supply chain companies that produce capital goods are involved, such as the ones that produce the agricultural machinery, fishing vessels, infrastructures as well as companies involved in animal breeding, agricultural production, fishing and aquaculture. It is of interest to note that the activities set out in Article 2135 of the Italian Civil Code, defined as typical objects of the agricultural enterprise, are cultivation of the soil, forestry and animal husbandry. These activities are directed to the care and development of a biological cycle or of a necessary phase thereof, regarding both vegetables and animals, which might use the soil, the forest, brackish or marine waters. Another form of agricultural enterprise, namely the social agricultural enterprise is defined by the Italian Law 141/2015, extends the object of the activities to services of general utility, expression of the multifunctionality of the agricultural enterprise, aimed at the development of interventions and social services, socio-sanitary, educational and socio-occupational integration, in order to facilitate adequate and uniform access to essential services for persons, families and local communities throughout the national territory and in particular, in rural and disadvantaged areas. Another important figure, that has to be mentioned is the entrepreneur in the fishing industry and is defines as the holder of a fishing license who carries out, professionally and in a single, associate or corporate form, the professional fishing activity and related activities. Fishing cooperatives and their consortia are also considered to be entrepreneurs in the fish industry when they predominantly use product

[33] A. ZAGHI-P. BONO, La distribuzione del valore nella Filiera agroalimentare italiana, 2011, in https://agriregionieuropa.univpm.it/en/content/article/31/27/la-distribuzione-del-valore-nella-filiera-agroalimentare-italiana

of their members meaning that they provide mainly the same goods and services needed for performing activities, as well as the aquaculture entrepreneur carrying out the activity in a single or associated form[34]. The second phase consists on the transformation of raw materials and involves food processing and production industries, *exempli gratia* collectors of horticultural products, cow milking farms, cattle slaughter, production of jams. Companies that work in packaging and labelling industry are part of the third phase of the supply chain. In the last phase, the distribution, both transportation companies and distributors play a crucial role, together with insurance companies, banks, special credit institutions in agriculture, consulting companies and warehouses. Therefore, it is important to consider that the agri-food supply chain develops not only in the agricultural activity itself but in all the instrumental and connected activities in the entire chain. In fact, related or ancillary activities, that have not been regarded as separate, are a subject to which specific and progressively increasing attention has been devoted, as they are likely to complement the production cycle. Ancillary or related activities are identified as the farm, the handling, the storage, processing, marketing of products, leaving to secondary legislation the possibility of widening this list, thus allowing to consider the evolution of production and technology[35]. Other activities identified as related activities are also those carried out in the services for agriculture and fisheries, including those of information technology, research, experimental nature, energy saving and industrial processing of agri-food waste. An important consideration regards the agricultural entrepreneurial activity, as defined by law 2135 of the Italian Civil Code, which is concrete in the exercise of related activities, meaning for this activities, exercised by the same farmer, directed to handling, preservation, transformation, marketing and valorization of products derived primarily from the cultivation of the soil, or of the forest or from the rearing of animals, and activities directed to the supply of goods or services through the predominant use of the company's equipment or resources normally used in the agricultural activity carried out, including activities to enhance the territory and the rural and forestry heritage, meaning reception and hospitality activities. The same applies to the entrepreneurial activity in the fish industry, for which the reference

[34]P. MASI, *Impresa ittica e attività connesse*, in *Dir. agroal.*, 2016, pag. 419.
[35]G.L. TREQUATTRINI, *Commento all'art. 43 t.u.b.*, in *Commentario* Capriglione, I, Padova, 2001, pag. 330.

framework typifies categories of activities which are variously linked to the main activity: activities aimed at handling, conservation, processing, marketing, promotion and enhancement of products are identified; based on the model of agritourism, recreational fishing, fishing tourism, the supply of goods and services related to aquaculture, including for hospitality, recreational, educational, cultural purposes; active management interventions, aimed at the valorization of production, sustainable use of aquatic ecosystems an the protection of the coastal environment[36]. Lastly, as far as social agricultural enterprises are concerned, are considered as related activities those consisting of recreational, didactic and formative services realized through the utilization of the material and immaterial resources of agriculture[37]. The aforesaid premise allows to understand the scale and complexity of an agri-food supply chain, which would thereafter be described both in terms of actors and activities that have a role within it.

1.5.1. Food Business Operators

The aforementioned stages of the chain involve a series of actors that the Regulation EC 178/2002 terms as *food businesses*, and are specifically defined as "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". A category of professionals, of primary importance, operating in the food business are Food Business Operators, European Union legislation defines in Art. 3 of Regulation EC number 178/2002 Food Business Operators, FBOs, as "the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control". According to this definition, whether FBO is a juridical or physical persona is indifferent as long as it possesses the decision-making capability, its responsibility would concern decisions on processes, structures and actions of the company where it works. European agri-food legislation attributes the responsibility for safety and legal compliance of the product to FBOs and establishes, according to Art. 17.1 of the Regulation EC 178/2002, that: " Food and feed business operators at all stages of production, processing and distribution within the

[36]P. MASI, op. cit. p. 424.
[37]I. CANFORA, *L'agricoltura come strumento di* welfare*. Le nuove frontiere dei servizi dell'agricoltura sociale*, in *Dir. agroal.*, 2017, pag. 15.

businesses under their control shall ensure that foods and feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met". In this context, the role of official control focuses on market surveillance, the responsibilisation of FBOs is concretized in the obligation of compliance with qualified standards, together with the assurance of protection of human health and the correctness of information. The conferral of a cumbersome obligation of conformity to private operators has to be coordinated with the differentiation of functions performed by operators along the agri-food production chain. FBOs and food businesses might be differentiated according to the peculiarity of their activities within the agri-food supply chain in primary actors, post-primary producers and distributors. Each of the aforesaid categories have to cooperate, in their respective activity, in order to assure security and compliance of agri-food products, as Article 17.1 of the Regulation EC 178/2002 elucidates, thus to moderate the risk final consumers and companies might bear[38].

1.5.2. Primary Operators

The distinction between primary and post-primary operators is substantial in terms of hygiene requirements and obligations and financial costs for official controls. The activities of primary operators are subject to compliance to Annex I of Regulation EC number 852/2004 and to Regulation EC 853/2004, specifically they enter into force in the discipline primary products of animal origin (untreated milk, honey, eggs, fishery products, and so on). Another difference between the above-mentioned actors resides in the fact that there is no obligation to conduct the business according to HACCP for primary operators' activity, for post-primary it is mandatory[39]. A primary operator is intended an actor that is involved in the production, breed or cultivation of agricultural products and positions himself in the primary production sector of the market, indeed primary production is defined[40] as "the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products". Primary products, according to the European legislation,

[38] D. PISANIELLO, op. cit., p.239.
[39] Art. 5 Regulation EC num. 852/2004.
[40] Art. 3 number 17 of Regulation EC 178/2002.

comprise thus vegetable products such as cereals, fruit, herbs, mushrooms and spouted seeds; products of animal origin such as eggs, untreated milk, honey, fishery products, live bivalve mollusks; wild harvested products of plant or animal origin. The primary operator has to register as an FBO for the purpose of the Regulation EC 852/2004. According to the Italian law in terms of hygiene of foodstuff, the collection of mushrooms, truffle, berries and wild snails, their transportation to the processing plant, as well as the production and snail farming and their eventual transportation and commercialization is enclosed in the concept of primary activity. Operations related to or associated with the primary production are subject to the same legal regimen, *exempli gratia*: the transportation, the storage and handling of primary products at the production site, provided that this does not alter their nature; the transportation of live animals; the transportation for the delivery of primary vegetable products, the nature of which has not yet been modified from the production site to a plant. All the operations aimed at ensuring a better presentation such as packaging, the washing, fruit selection, cereals drying, slaughter, exsanguination, evisceration, cut of fins, refrigeration and packaging of fish and the centrifugation of honey are included as well[41].
All the operations of the agricultural enterprise cease to be defined primary or related to primary whenever they alter the products or present new possible risks for aliments, for instance the peeling of potatoes or cheese production even if is performed in the same firm.

1.5.3. Post-Primary Operators

Post-primary operators might be: a manufacturing company, that realizes semi-finished products, ingredients and other components used in the food processing; this includes both the *real producer*, the producer of the finished product intended for sale, and the *apparent producer,* the one that affixes the label or bears the responsibility to market the final product. Post-primary producers take responsibility on the following obligations:" the registration or, in the case of products of animal origin, the granting of the activity; the compliance with the applicable hygiene and health requirements; the compulsion of hygienic conduction according to HACCP; the obligation to cooperate with official supervisory authorities; the compulsory compliance with legislation on the disclosure of information on food; payment

[41] D. PISANIELLO, op. cit., p.240.

of official control fees". The professional operator and producer, when purchasing a component intended for human consumption is obliged to adopt proportional measures, depending on the characteristics of the product and its intended use, verifying that the procured ingredient meets the safety requirements also through genuinity controls by sampling, before further use it as a part or ingredient in the preparation of a food distributed on an industrial scale[42]. Both the Italian and European legislation do not impose to disclose the identity of the legal entity that actually manufactured the food (real producer); it is sufficient to communicate the legal persona whom undertakes the responsibility to release the foodstuff on the market, possibly being the real producer, the apparent producer, the sales manager or the importer in EU[43]. The above-mentioned distinctions gain significance in the identification of the legally responsible entity in case of infringement of laws regulating the foods' disclosure of information.

1.5.4. Secondary actors in the supply chain

The secondary actors in the supply chain, also called stakeholders, supply producers with indispensable goods and services for the development of the supply chain, and they indirectly affect aliments' final price, since the cost of procurement of indispensable goods impact producers' financial position[44]. Secondary actors in the chain are, for example, companies that produce fertilizers, additives, suppliers of water, electricity and machinery.

1.5.5. Distributors

The distributors have to contribute in order to ensuring safety and compliance, as foreseen in Art 17 of EC Regulation 178/2002, however both European and Italian law highlight the difference in their role, exempting them from certain mandatory provisions that are in force for other Operators. In the European Union, the Regulation 178/2002 is an example of the differences in responsibilities is explicated in Article 19, it regards the distributors' set aside

[42]G. VACCARO, Il principio di precauzione e la responsabilità delle imprese nella filiera alimentare, in Riv. dir. alim., 2015, pag.55.
[43] D. PISANIELLO, op. cit., p.242.
[44] A. ZAGHI-P. BONO, La distribuzione del valore nella Filiera agroalimentare italiana, 2011, in https://agriregionieuropa.univpm.it/en/content/article/31/27/la-distribuzione-del-valore-nella-filiera-agroalimentare-italiana

obligation, and it states:" A food business operator responsible for retail or distribution activities which do not affect the packaging, the labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities". The above-mentioned approach to the aside obligation has been adopted also by Italian legislators, whom, in providing for administrative sanctions for aside obligations' non-compliance, establishes significantly reduced penalty frameworks for distributors. Distributors' role is cited in the definition of "Retail", in of Art 3 comma 7 of EC Regulation 178/2002, as such:" Retail means the handling and/ or processing of food and storage at the point of sale or delivery to the final consumer, and includes *distribution terminals*, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centers and wholesale outlets". Therefore, it would seem to exist a partly different treatment for retailers and distributors, compared to the one applied to other Primary Operators, in terms of food safety and compliance assurance, however the Court of Justice sought to substantiate that security debt that could be derived from Article 17 in several legal cases.

1.5.6. Distribution

The last phase of the agri-food supply chain is the distribution, it entails the handling and storage of the product at the point of sale or direct delivery thereof to the final consumer. This dissertation will successively elaborate on aliment logistics, both in terms of packaged and cold chain products. The actors taken into consideration at this stage are large-scale retail trade, retail trade and Ho-Re-Ca channels, briefly mentioning food delivery businesses. Retail trade is concretized both in the case of operators working in their shop, the case of traditional retail and large-scale retail-trade, and store-less agents whom carry on their business by means of itinerant sellers, street vendors, vending machines and online marketplaces. Large scale retail-trade is defined as a type of agri-food retail, not of mass consumption, implemented through the concentration of stores in large areas (not less than 200 m2 and reaching over 4000 m2) and managed by commercial chains belonging to the

same holding[45]. The above mentioned network of supermarkets have replaced, over time, the traditional shops for diverse reasons, among which: they have taken advantage of the economies of scale in purchases of stocks, given their considerable bargaining power; have obtained favorable rental condition of premises; possess an easily recognizable brand for consumers; have built consumer loyalty through private labelling of products; possess capabilities to invest on marketing campaigns; have a broader product portfolio at a lower, competitive price. The large-scale retail trade however has been applying market logic to commodities such as food, seeking for greater efficiency, higher profit margins and lower prices for consumers, soon becoming able to impose quality and quantitative standards as well as prices and delivery times on suppliers, leveraging on their very strong bargaining power. Traditional retail usually possesses the following characteristics: a single plant in an only location; coincidence of ownership and control; family-run business with small size; limited but often specialized assortment and a shop that has a usable area of less than 100 m2. The traditional retail trade has been challenged by huge groups of supermarkets in Italy, however some company of excellence have resisted carrying on the attention to products and the food-supply chain behind them, focusing on the respect of the environment, aliments' seasonality and ethics. The traditional retail not only has regained value in terms of quality for local communities but also would possibly revamp through the synergy of its characteristics and the possibilities provided by internet to reach a much broader clientele. Such possibilities provided by the internet concretize in food-deliveries and dedicated e-commerce platforms, shortening the distance between the final consumer and the food through the adoption of innovation. There exists also business to business retail in agri-food sector, a relevant case is the one of Farmers Markets which are only open to agricultural producers, those are widespread in all Italian regions and are organized with a monthly or weekly frequency, having the producers guarantee the provenance, traceability and healthiness of products. The consumers' advantage is the money saving, the seasonality and also the pleasure to help small business, however coping with the disadvantage of choosing greenery among a small assortment. The Ministry of Agriculture has dictated, in the MIPAAF Decree 10/20/2007, the guidelines for the implementation of markets reserved for direct

[45] http://www.treccani.it/enciclopedia/gdo_%28Lessico-del-XXI-Secolo%29/

sales of products by farmers, identified in the Civil Code in Art.2135. The above-mentioned Decree has no regulatory nature, since the exclusive legislative competence in matters of trade and agriculture is reserved to the Regions, as Art. 117 of the Italian Constitution declares. The last category of distributors this dissertation would briefly consider is summarized by the acronym Ho-Re-Ca, which means Hotellerie, Restaurants and Catering three categories that supply food and drink to final consumers. Ho-Re-Ca channel contains and involve many product categories and subcategories of the above mentioned, *exempli gratia* some facilities that are included in the *Hospitality* are hotels, B&Bs, camping, hostels, refuges, residence; in *Restaurant* business are included bars, pubs, bistro, bakeries, ice-cream shops, canteens; and *Catering* involves companies that produce, distribute and supply of food, beverages, disposables, preparation of kitchens with temporary catering services whenever there are no suitable facilities for the preparation of food.

1.5.7. Types of supply chains

Agri-food Supply chains are many and vary in characteristics, one is the so called "length", it might be defined short or long on the basis of the number of the actors involved in the realization of the final product. The shortest food-supply chain, also defined as direct sale, occurs when the producer of horticultural products sells directly to the consumer, avoiding intermediaries. A KM0 products is defined as such when come from a production or processing of agricultural raw material location placed at a distance not exceeding 70 km from the place of sale[46]. A product that derives from a short agricultural supply chain is defined as such if its trade is characterized by the absence of intermediaries or by the presence of a single intermediary. Short food supply chains have the plus of enhancing the nutritional properties and characteristics of the food linked to its place of origin, the sustainability of biodiversity and the support for small businesses. As the supply chain is shortened, the producer has the advantage of gaining a higher margin on sales and the consumer purchases a high-quality product at a lower price, both increasing the respect for the environment and diminishing he amount of CO2 emissions[47]. The nutritional properties

[46] https://www.camera.it/temiap/documentazione/temi/pdf/1130954.pdf?_1540196781108
[47] F. GIARÈ- S. GIUCA, Agricoltori e filiera corta. Profili giuridici e dinamiche socio-economiche, in INEA, Roma, 2010.

of fresh fruits and vegetables can serve as a nutrition education for the consumers that are interested in having a healthy lifestyle and respect the seasonality, territoriality and the typicality thereof. A long chain would instead involve, *exempli gratia*, the producer of greengroceries, the processing industry, the purchasing groups, the supermarkets and the final consumer. Long food-supply chains, usually comprehensive of industrialized phases, has allowed the placing on the market of standard quality products, detached by seasonality and territory, impoverishing their nutritional and organoleptic characteristics. European Union promotes short food supply chains since this mechanism enhances local sensing and dynamism, when the type of production, its geographical location and the ability of locals to consume all the production allows so. EU recognizes the importance of the link between short food supply chains with agroecology, whose aim is approximate the producer to the environment in which operates, preserving, or restoring the complexity and richness of the agri-eco-socio-system.

1.5.8. Food waste legislation

Food supply chains, and their shape, are directly correlated to a relevant and contemporary problem, which is food waste. Italian Ministry of the Environment established the National Day again food waste on 5 February in order to raise awareness on an unfortunate paradox: the actual production of food would feed the entire globe, yet hunger remains a serious problem for many. Every year 1.6 billion tons of food, estimated to be worth about 1200 billion dollars are lost or wasted, not considering the wastage of soil, energy, labor and water involved[48]. This is a problem with considerable environmental, social, economic and ethical consequences in fact United Nations, in their UN Sustainable Development Goals Agenda for 2030, laid down a series of objectives aiming to terminate it[49]. Among the causes that determine food waste overproduction is one of the main, the model of society of abundance and hyper consumerism affects, buying more than what is needed and be consumed, the last stage of the agri-food supply chain. However, there are several sorts of waste that take place at different times on the journey made by the food along the supply chain: *food waste* results

[48] http://www.fao.org/publications/sofa/en/
[49] https://unric.org/it/agenda-2030/

from the misbehavior of resellers and consumers and food loss, which takes place in the early stages of the production processes, collection, processing, transport and sale. According to the State of Food and Agriculture 2019, about 14% of the food globally is lost or wasted after harvest during the operations in food businesses, before reaching retail, at the phase of storage and during transport[50]. Food waste globally reaches at least 44% of the calories produced considering waste, overfeeding and livestock farming associated with an ecological footprint that consumes at least 32% of natural resources generated each year[51]. Even if Italian numbers register a food waste share of 63% consuming at least 50% of resources, largely generated in other countries and imported, for the first time in the last 10 years domestic food waste is decreasing: 2020 registered a 25% reduction with respect to 2019, corresponding to an annual saving of 1.5 billion euros[52]. A brief mention to a research carried on by an Italian Institute for Environmental Protection and Research's researcher that discovered, studying the Italian market, that short, organic and local supply chains cut loss levels from 60% to 25% at all stages of the chain prior to final consumption[53]. Small scale agroecology reduces waste of one third compared to that of the industrial food system, the Italian Slow Food[54] has always supported, and as IIEPR[55] and FAO[56] suggest, local food networks, solidarity, small scale and ecological businesses protecting rural agriculture and agroecology. European Union legislation have not provided member States with a clear definition of food waste and hence the establishment of a comprehensive and coordinated framework for prevention and food surplus collection is difficult to delineate at the moment. European Commission, with the EC Communication number 398/2014, proposed that:" Member States develop national food-waste prevention strategies and endeavor to ensure that food waste in the manufacturing, retail/distribution, food service/hospitality sectors and households is reduced by at least 30 % by 2025". This proposal regards the obligation for member States to adopt specific plans, in function of a target, for the prevention of food

[50] http://www.fao.org/3/ca6030en/ca6030en.pdf
[51] https://www.slowfood.it/giornata-nazionale-spreco-alimentare-la-filiera-corta-e-la-soluzione/
[52] https://www.ansa.it/canale_terraegusto/notizie/in_breve/2020/02/04/le-famiglie-sprecano-meno-cibo-nel-2020-calo-del-25_5dd17734-9949-4ba8-8c57-bf66c4578880.html
[53] https://www.slowfood.it/giornata-nazionale-spreco-alimentare-la-filiera-corta-e-la-soluzione/
[54] Is a large international non-profit association committed to restoring the value of food, in respect of those who produce, in harmony with the environment and ecosystems.
[55] The Italian Institute for Environmental Protection and Research.
[56] Food and Agriculture Organization of the United Nations.

waste along the entire supply chain, excluding Primary production. European Commission have also issued a Communication, EC Communication number 571/2011, encouraging member States to include a solution to the problem of food waste in their national waste prevention plans (to be adopted no later than 13th December 2013) and set the objective of halving the disposal of the edible fraction of food waste in EU within 2020[57]. A virtuous example of agri-food waste problem solving has been observed in one of the European Union member States, Italy. Italy is the first State in the world that adopted a law, law number 166 of 19th August 2016 (known as "*Legge Gadda*") presenting a strategic approach to the problem of food waste while being a perfect example of application of *subsidiary principle*[58]. Gadda law was born from the shared work of all the actors involved in the process of recovery and redistribution of food surpluses. The law is based on incentives and on the valorization of good practices, on the ability to create lasting relationships between the involved subjects that consider the mutual necessities and capabilities. In this way it will be increasingly possible to develop virtuous networks of collection and use of surpluses avoiding formal obligations and constraints that risk overloading, with discontinuous flows of food, the management of non-profit organization. Before the entry into force of the Gadda law companies and distribution chains could freely donate surplus food up to a value of 5 thousand euros, after the implementation the threshold has been raised to 15 thousand euros for those who want to donate surplus food to non-profit and charitable institutions while those who want to destroy it, they must respect the specific dictates of the law. The main points characterizing Gadda law for its uniqueness are: the creation of a regulatory framework within which incorporating the existing rules on fiscal benefits (L. 460/97, L. 133/99), the civil liability (L. 155/03) and procedures for health and hygiene safety procedures (L. 147/13); the provision of a clear definition of food business operators, transferors, food surpluses, food waste, donation, minimum durability and expiry date, etc.; possibility for authorities to donate confiscated food to non-profit organizations; administrative concessions for donors through the simplification of donation procedures

[57] https://ec.europa.eu/environment/enveco/resource_efficiency/pdf/studies/Task%203-Food%20waste.pdf

[58] In accordance with *subsidiary principle*, in areas of non-exclusive Union competence, it shall act only if and to the extent that the objectives of the proposed action cannot be sufficiently achieved by the Member States and can be better achieved at European Union level.

with respect to the destruction of foodstuff; promotion of the priority value of food recovery for human consumption to avoid destruction, insofar human usage is not possible, it enhances the recovery for zootechnician or energetic use; recognition of the MIPAAF Coordination Table for the consultation of all the actors involved in the fight against food waste and poverty; 2 million euros increase in the 2016 National Fund for the distribution of food to poor people, devoted for the purchase of food for indigents; planning of communication campaigns on national television encouraging corporate donations and raising consumer awareness about waste; encouragement of relations with agricultural business for harvesting in the field; introduction of the possibility for municipalities to encourage those who donate to non-profit organizations by reducing the waste tax.

1.5.9. Logistics

Agro-alimentary logistics is subdivided into the following categories, depending on the type of food preservation and on the need for speed in distribution and delivery of operations: fresh, ultra-fresh, frozen and products that do not need cold technologies[59]. The complexity of handling fresh, ultra-fresh and frozen products is very high and is regarded as "temperature controlled" and "cold chain" logistics. The logistic complexity results from the complexity of: network, as a series of actors involved in the procurement, production and distribution of a given product; logistic process, management of physical flows and related information from the acquisition of the row materials and distribution of the finished product to the final consumer; product, including components and raw materials necessary for the realization of the final product destined to the consumers[60]. Moreover, food industry intrinsically presents elements of complexity that reverberate on logistics: high distances between production and consumption site, low added value, perishability, the need to ensure continuous monitoring of quality and traceability, the respect of seasonality and the need to reduce the stocks along the distribution channel. The complexity at network level is mainly due to the geographical dispersion of the actors involved. The complicated points in the process derive from the timing and manner of supply, production and distribution

[59] F. IANNONE, Sistemi di Logistica e Trasporto per il Settore Agroalimentare in Italia, Napoli, 2009, pag. 36.
[60] O. OMTA- J. BIJMAN- J. TRIENEKENS- J. WIJNANDS- E. WUBBEN, International agrifood chains and networks: Management and organization, The Netherlands, 2009, p.139.

operations, one example includes the need for rationalization of fluxes required by GDO imposing frequent deliveries of foodstuff *just in time* but in small batches. Perishability of products is one of the critical points that link process complexity to product's complexity, it establishes both maximum *lead times*[61] of the product and the *shelf life*[62] of ultra-fresh aliments (24-48 hours) or fresh aliments (some weeks). The maintenance of quality standards required for an agri-food product during transportation and storage is ensured by constant monitoring of: temperature, humidity, atmosphere, handling and packaging[63]. Foods' temperature control during transportation and storage is crucial in order to respect health and hygiene regulations, moreover each macro-category of products require an *ad hoc* supply-chain on the basis of the degree of urgency they have to be distributed to the final consumer. The use of cold chain in food storage and transportation has the advantage of preserving a food without altering its biological, nutritional and sensory values. Cold chain presupposes a constant preservation of aliment's temperature along all the way from production to sale, including transportation, storage and display in order to ensure integrity, hygiene standards, food safety and the best conservation. The techniques used to preserve a food through the cold chain are: refrigeration, adopted in the transportation of fruit and ready meals (Temperatures ranging from 0° to +4°C); freezing, the food is subject to negative temperatures (-15° C/-20° C) with consequent crystallization of water and solidification of the product; quick-freezing applies the just-mentioned technique with the only difference that the product's cooling and solidification occur in a very short time span[64]. The transfer is crucial for aliments' cold chain continuum and is concretized through the adoption of means of transportation equipped with instruments capable of monitoring air temperature in the transport compartment and guarantee a product's isothermal condition[65]. Vehicles used for the transport of perishable foodstuffs, under controlled temperature conditions, must comply with standards issued both by the Italian Ministry of Health and by the Ministry of Transport, to ensure a better protection of the products in order to safeguard consumers'

[61] Lead time is the amount of time that passes from the start of a process until its conclusion.
[62] The length of time that a product, especially food, can be kept in a shop before it comes too old to be sold or used.
[63] F. IANNONE, op. cit., p.37.
[64] http://www.salute.gov.it/imgs/C_17_pagineAree_1187_listaFile_itemName_10_file.pdf
[65] https://www.istitutosurgelati.it/la-catena-del-freddo/

health. Vehicles must comply with the Italian Law number 264/1977 for the characteristics of vans and temperature control systems, also known as A.T.P.[66], a United Nations regulation regarding temperature-controlled refrigerated transport of perishable goods intended for human consumption[67]. The necessary equipment of warehouses devoted to food storage, apart from shelves and pallets, includes refrigerators and freezers. The cold chain methodology is used mainly for ultra-fresh, fresh and frozen aliments, other aliment that are not included on the above-mentioned categories would be referred as packaged food in this section of the dissertation. There is not a specific regulation for the transportation, at European and at Italian level, of packaged food, however the respect of the norms dictated by the HACCP Manual for the transport of fresh and packaged food at European level is mandatory. The HACCP for the transport of packaged foods is a certification that attests the compliance of the transporters with all the obligatory hygienic conditions. This important certification, created to ensure food safety and prevent risks related to it, is in fact also required for those who transport the various foods from one place to another, both in Italy and abroad. The dissertation would further discuss about food certifications, HACCP included, in the second chapter.

[66] Accord Transport Perissable.
[67] https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XI-B-22&chapter=11&clang=_en

Chapter II

Protection of the vulnerable personas in the agri-food market

2.1. Protection of the vulnerable personas

The issue related to the protection of the vulnerable entity in the economic-private relationships has been identified a long time ago. The contract in fact has always been considered the point of encounter between subjects that, with their own ambitions, objectives, abilities and acquaintances give life to the operation of mediation in the opposing interests, that leads to the creation of a legally binding agreement[68]. The negotiation therefore assumes the connotation of an ideal moment of "battleground" in which every contender tries to achieve the best result. However, the strengthening of situations of imbalance of opposing negotiation forces has made it clear, in modern times, that the related law provisions were likely not to consider the disproportionality of the forces involved. All these elements have contributed to consider the idea that "the neutrality of the contract hides profound injustices"[69]. In this context, the rigidity of the definition of consumer, which has raised widespread discontent in the doctrine, would have monopolized the attention of the interpreters with regard to the protection of the weak contractor because, given its transversality, is applicable in any market segment where a trader is opposed to a consumer[70]. It is important to point out that the most careful doctrine has indicated that the category of consumer does not include in itself the one of the weak or vulnerable contractor. In fact, there are often situations in which a person defined as "consumer" does not appear to be absolutely weak compared to the counterpart as well as others in which, on the contrary, the person who does not meet the specific characteristics of the "consumer", is in a real situation of vulnerability[71]. It should be noted that, not neglecting some exceptions, the consumerist discipline has flattened the concept of weak contractor on subjective characteristics that do not always reflect the actual problems that the individual contractor

[68] G. BERTI DE MARINIS, La tutela del cliente 'vulnerabile', in Banca, borsa, tit. cred., 2018, I, pag. 651.
[69] MARINELLI, La tutela civile dei soggetti deboli, in Giust. Civ., 1994, II, pag. 159.
[70] G. BERTI DE MARINIS, op. cit., p.652.
[71] P. PERLINGIERI, La tutela del consumatore tra liberismo e solidarismo, in Riv. Giur. Molise e Sannio, 1995, p.99.

manifests in a negotiation. Is therefore clear that the concept of weak contractor is extremely volatile as it is directly dependent on a multitude of factors, which interacting, modulate the vulnerability of the entity, making it more in need of protection than the average consumer[72]. A specification on the assumption at the basis of the above-described approach has to be provided in order to clarify the scenario of vulnerable personas protection. Historically, private law has perceived the position of the vulnerable entity by first analyzing its status at the moment of negotiation, although if peculiar, because it presupposed the physical involvement of the vulnerable in the execution of the negotiation. In more recent times, the consideration for the vulnerability has turned again to the market, with the pointed attention towards an entity considered weak in structural sense[73]. It has been therefore possible to abandon the need to distinguish the socio-economic dimension from the existential weakness of the persona in a private law point of view and hence, the union of the two dimensions, has resulted in the identification of the entity as a "person" who brings his vulnerabilities in the market. The vulnerable "person" shall not only be identified as the natural person or consumer, but in a broader perspective, and in certain circumstances, also in industry professionals and entrepreneurs[74]. This latest perspective is confirmed by the EC Regulation 178/2002, which does not make any explicit reference to the consumer as a natural person as the only possible consumer, preferring a diverse distinctive criterion that expands the field of protection from the mere pair consumer/professional-entrepreneur to the duo final consumer/Food Business Operator, considering important that the entrepreneurial or professional activity falls within the food sector or is in any case connected to it[75]. The discipline of protection of the vulnerable entity is characterized by a remarkable width and is declined in several shades, among which is included the vulnerable consumer protection.

[72] G. BERTI DE MARINIS, op. cit., p.653.
[73] D. POLETTI, Soggetti deboli, in Enc. dir., Annali, VII, Milano, 2014, p.965.
[74] D. POLETTI, op. cit., p.978.
[75] G. SPOTO, Tutela del consumatore, etichette a semaforo e informazioni "negative", in Riv. dir. alim., 2018, pag. 30.

2.2. Consumer protection

2.2.1. Identification of consumers and vulnerable consumers

The notion of consumer is a crucial concept delimiting the application of consumer protection rules, however there is not a consistent and uniform definition at European level, there are instead divergences amongst the Member States. The consumer is defined in Italian jurisdiction at the article 3 of Consumer Code as:" the natural person acting for purposes other than the business, commercial, craft or professional activities carried out". Even if the definitions are phrased in different ways in each Member State, however, the vast majority include a common core for the notion of 'consumer', accordingly a consumer is a *natural person*, who is acting outside the scope of an economic activity (trade, business, craft, liberal profession)[76]. A further clarification is essential for the interest of this dissertation, Article 3 point 18 of EC Regulation 178/2002 defines the *final consumer* as "the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity", hence discerning the classification of final consumer and consumer, considering that this latter might utilize food in an intermediate stage of the food supply chain. A substantial difference has to be considered, for the purpose of this dissertation, namely the distinction between average consumers and vulnerable consumers in the agri-food legislation. The EC Directive 2005/29 relies on the principle of proportionality to protect consumers from unfair commercial practices, specifically it discerns average and vulnerable consumer protection. This Directive takes as a benchmark the *average consumer,* who is reasonably well-informed and reasonably observant and circumspect, considering social, cultural and linguistic factors, as interpreted by the Court of Justice, but also contains provisions aimed at preventing the exploitation of *consumers* whose characteristics make them particularly *vulnerable* to unfair commercial practices because of their mental or physical infirmity, age or credulity in a way which he trader could reasonably expect to foresee. Considering the Directive on unfair commercial practices, the European Court of Justice clarified, from the point of view of regulatory sources, that the concept of average consumer should not be considered with a statistical approach and that the courts and national authorities should

[76] https://www.europarl.europa.eu/RegData/bibliotheque/briefing/2013/130477/LDM_BRI(2013)130477_REV1_EN.pdf

consider the case-law of the Court itself to determine a description of an average consumer's typical reaction[77]. The concept of average consumer, which has become a criterion for assessing the lawfulness of all business practices, is however, the result of a hermeneutic process which moves in abstractions and which disregards a fundamental consideration: consumers in different Member States are not all identical, but differ in linguistic, cultural and social, habits, interests and tastes. The notion of average consumer cannot therefore be applied in absolute terms, not only because, as the Community legislation itself pointed out, there may be consumers who are particularly vulnerable because of their age, illness, or lack of adequate education, so in such situations it should be ensured to the weakest and most exposed consumer group a "higher" level of protection or in any case a protection articulated differently with respect to the average. The European Parliament and Council aim to protect, with directive EU 609/2013, several further groups of vulnerable consumers: infants and young children, people with peculiar medical conditions (i.e. diabetics, allergic, celiac) and people undertaking energy-restricted diets to lose weight.

2.2.2. Italian and European laws on consumers' protection

The consumers' right to be informed is included in the objectives towards which the Union is directing its policies. The information asymmetry between the Operators and consumers in the agri-food sector is corrected by regulatory interventions aimed at ensuring a minimum set of information that will allow more informed choices. In fact, information asymmetry not only determines an imbalance in the individual relationship but has potentially wider repercussions from a systemic point of view. The elimination or reduction of information asymmetry barriers, through the fulfillment of specific obligations, considered by the legislator essential for producers, allows to switch from a selective protection of consumption to a more general one, more efficient and advantageous for all consumers and producers concerned. The protection of the economic interests of a consumer appears among the General Principles of agri-food law stated in Article 8 of EC Regulation number 178/2002, which recognizes that food law aims to protect the interests of consumers and to

[77] G. SPOTO, op. cit., p. 29.

build a basis for them to make informed choices in relation to the food they consume[78]. Is of the interest of this dissertation to reference Article 8 of EC Regulation number 178/2002 in order to pose foundations to the treatment of following subjects, it specifically states as such:" 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 at the prevention of: fraudulent or deceptive practices; the adulteration of food; and any other practices which may mislead the consumer". The issue of consumers' protection is included also in Article 16 of the aforementioned law, it regards the presentation of foodstuff declaring as such: " Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers". As article 16 concerns, it is regarded as a general requirement of agri-food law, its compliance is already within the scope of activities subject to the official control of Regulation EC 882/2004, which stipulated that the scope of official food control should not be limited to the prevention of risks unacceptable to human health, but also included the task of preserving and protecting the market from unfair competition among entrepreneurs in particular in the food and feed sector, as well as the protection of the consumer from illegal labels, illicit communication and unlawful practices. The above-mentioned Regulation has been even more explicated with the new Regulation EC 2017/625 on official controls. Notwithstanding innovations brought by the digital revolution, food labelling is the primary means of communication between the producer and seller of food on one hand and the purchaser and consumer of the other, as Food and Agriculture Organization of the United Nations declares in the Codex Alimentarius[79]. The European approach in the Regulation on food information, EC Regulation 1169/2011, sought to overcome the regulatory gap with new forms of digital communication and marketing, balancing the interests pertaining to the free movement of goods and the level of protection of consumers. The primary source of norms at European level in relation to consumer

[78] D. PISANIELLO, op. cit., p.104.
[79] http://www.fao.org/3/a-y2770e.pdf

protection is the EC Regulation 1169/2011, alongside Community derived standards Italian scenario in terms of alimentation, as established in Article 117 of Italian Constitution, is among the subjects in which the legislative function is carried out in concurrent way between the State and the Regions[80]. The consumer protection in agri-food sector is also guaranteed by the recognized responsibility of the producer for the damage resulting from a defective product, the Directive 1999/34/ EC unified responsibility of all producers, agricultural and non-agricultural, by introducing the principle of objective liability. The defect in a foodstuff must be assessed according to the safety requirements drafted in EC Regulation 178/2002 and referred to salubrity of production places, storage or processing. However, within the meaning of the Article 117 in Legislative Decree 205/2006 of Italian Legislation, a product is defective when it does not offer the assurance that it can be legitimately expected, taking into account all the circumstances, including: the manner in which the product has been put in circulation, its presentation, its obvious characteristics, instructions and the warnings provided; the use for which the product may reasonably be intended and the behavior which, in relation to it, can reasonably be expected; the time during which the product was put into circulation. Article 123 of the aforementioned law establishes that the damage caused by death or personal injury and the destruction or deterioration of anything other than the defective product, provided that it is of a type normally intended for private use or consumption and thus principally used by the injured person, shall also be compensated. Consumer protection legislation encompasses several different disciplines, concretizing through the vast majority of aspects related to aliments, inter alia labelling, the veracity of information, compulsory information, avoidance of unfair commercial practices, consumer damage due to defective product and so on. The dissertation would, in this chapter, describe consumer protection in terms of safety, food security, aliments' labels, food information and quality of aliments.

80 http://www.diritto24.ilsole24ore.com/art/dirittoCivile/2016-03-24/la-tutela-consumatore-diritto-agroalimentare-114934.php

2.3. Safety

2.3.1. Food security

European Union's food safety policy has been reformed in the early 2000s after several human food and animal feed crises, such as bovine spongiform encephalopathy (BSE). European Union seeks to ensure: food and animal feed are safe and nutritious; there are high standards of animal health and welfare, as well as plant protection (e.g. safe use of pesticides); information is clear about the content (e.g. additives or preservatives), origin (traceability) and use of food (e.g. special diets). European Union food safety policy is mainly governed by Articles 168, on public health, and 169, on consumer protection, of the Treaty of the Functioning of the European Union, moreover EU law covers the entire food chain -- from "farm" to "fork" -- such as aspects ranging from labelling, through packaging to hygiene, using an integrated approach. The European Community, from 90s onward, has performed an intense activity of harmonization of control systems resulting in the introduction of an obligatory procedure for companies and personas of self-control for specific agri-food products, the most important have been fishery products, meat products and milk[81]. After the entry into force of the EC Directive 89/397, now repealed and replaced by EU Regulation 2017/625, on foodstuff's official control and considering the self-monitoring systems introduced for the products mentioned above, the Community ultimately adopted Directive 93/43 on food hygiene, now repealed by EC Regulation 852/2004, which generalizes the system of self-monitoring and makes it compulsory for all Food Business Operators. The general food safety requirements are set out in Article 14 of EC Regulation 178/2002, non-compliance with these define a food as an *unsafe food*, definition of which is divided in two categories: unsafe food and unfit food. Unsafe and unfit food are two separate cases which are also relevant for the different obligations required to manage the withdrawal of non-compliant products. As a preliminary point, it should be recalled that food safety requirements are established in the General Framework for product safety hence it's appropriate to mention the latter in order to clarify the relationship between the two regulatory areas. The consumer protection has assumed an important role since the Treaty of Maastricht, resulting in the inclusion of the obligation to market only safe products, it is

[81] F. CAPELLI, op. cit., p.346.

stated in the EC Directive 2001/95/CE. The Directive imposes on economic operators, producers and traders, obligations to prevent risks related to the use of products and by providing a series of duties on the authorities responsible for market surveillance. It is important to state the definitions of dangerous and safe product, a dangerous product:" shall mean any product that does not meet the definition of '*safe product*'" instead a safe product:" shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular: the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance; the effect on other products where it is reasonably foreseeable that it will be used with other products; the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product; the categories of consumers at risk when using the product, in particular children and elderly". Private operators bear high risks in the design, sales and after sales phase, they have the obligation of constantly updating the risks related to their products, as well as the duty to take appropriate action in cases of withdrawal and recall. The above-mentioned obligations are governed by a series of types of offences punishable by contraventions, except if the assumptions are more serious, according to Italian law's Article 112 of Consumer Code. The most serious criminal act, provided for Article 411 of the Penal Code, murder punishable also in the culpable form. The relationship and difference between the General Framework on products safety and the food safety requirements can now be clarified. The EC Directive 2001/95/CE is intended to be a supplementary discipline which is to be applied in cases where there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned. Therefore, shall not apply to those products insofar as concerns the risks or categories of risks covered by the specific legislation. The above-mentioned Directive could then, in theory, also be applied to foodstuff; indirect confirmation is drawn from Article 59 of EC Regulation 178/2002, according to which the discipline of the EC Directive 2001/95 "includes food and industrial products but not feed" and that the requirements of public health protection, which underlie

food production, require the establishment of an early warning system, 'better and wider' than RAPEX[82]. In this sense, the Italian transposition of the Directive, which excludes from the scope "food products covered by Regulation 178/2002" would not appear to be fully in conformity. Practically, abstracting the Italian implementation, food safety requirements are set as *lex specialis* such as to entail the substantial erosion of possible scopes for application of the Directive, unless substantial situation involving a risk that cannot be managed under food law are found.

2.3.2. European Food Safety Authority

European Food Safety Authority, EFSA, is a European Agency funded by the European Union that operates independently of the European legislative and executive institutions (Commission, Council, Parliament) and EU Member States. EFSA was set up in 2002, under General Food Law 178/2002, following a series of food crises in the late 1990s to be a source of scientific advice and communication on risks associated with the food chain[83].

Being EFSA the EU's independent agency that produces scientific opinions in remit of food and feed safety, nutrition, animal health and welfare, plant protection, plant health and the possible impact of food chain on the biodiversity of plant and animal habitats it also forms the basis for the European policies and Legislation. The core values that guide EFSA's activities are the scienfic excellence, independence, openness, innovation and cooperation[84]. The communication and involvement of stakeholders, citizens in primis, is one of the founding values of European Food Safety Authority, of equal importance to the independence of the risk assessment process, as established in the founding regulation EC number 178/2002. Some articles of the aforementioned Regulation enable an informed debate on delicate and important scientific issues related to EFSA's mandate, *exempli gratia*: Article 42 explain that EFSA shall develop effective contacts with consumers' representatives, producer representatives, processors and any other interested party; Article 38 regards transparency and in particular transparency in agenda setting, opinion of scientific authorities, annual declarations of interest, the results of scientific studies, the

[82] D. PISANIELLO, op. cit., p.248.
[83] https://www.efsa.europa.eu/en/aboutefsa
[84] https://www.efsa.europa.eu/en/about/values

annual report of its activities, requests of scientific opinions from Member States, the European Parliament or the Commission; Article 40 concerns EFSA's way of communicating its initiatives, the information to the general public in a rapid, objective and reliable way, communicate with the Commission and the Member States to promote the necessary coherence in risk communication process, shall publish all its opinions, in accordance with Article 38, shall ensure appropriate cooperation with the competent bodies in Member States with regard to public information campaigns.

2.3.3. The principle of precaution

The concept of the precautionary principle has been first set out in a European Commission Communication adopted in February 2000 in which it defined the concept and envisaged the possible way of application. The precautionary principle is detailed in Article 191 of the Treaty on the Functioning of the European Union (TFEU). It relates to an approach to risk management whereby if there's the possibility that a given policy or action might cause harm to the public or the environment and if there is still no scientific consensus on the issue, the policy or action in question should not be pursued. The General Food Law Regulation, EC number 178/2002, is based on the precautionary principle, and the principle may be invoked only in the event of potential risk and may never justify arbitrary decisions. The risk management attitude of the European Union concerning world-wide problems of production and trade of products intended for human and animal nutrition is different with respect to other countries in the world, insofar as in these last after public authorities' risk assessment, risk management is of responsibility of entrepreneurs and consumers, European Community instead assumes all the responsibility for control and prevention actions adopting the principle of precaution [85]. In general, related to the concept of protection, the dissertation would subsequently specify what has already been mentioned in the first chapter, namely the health and hygiene requirements that an Operator has to respect.

[85] A. GERMANÒ-E. ROOK BASILE, Il diritto alimentare tra comunicazione e sicurezza dei prodotti, Torino, 2005, pag. 306.

2.3.4. Health and hygiene requirements

This dissertation has already covered the laws governing health and hygiene standards in the Chapter One, however it is of interest thereof to mention Hazard Analysis and Critical Control Points, HACCP, and the rules applied to materials in contact with foodstuff. The agri-food Operator, here regarded as an entrepreneur, must self-check and self-certify the hygiene of his production and marketing by analyzing the risks and controlling the critical points of his production process through the preparation of a manual consisting on a set of principles: identifying any hazards that must be prevented, eliminated or reduced to acceptable levels; identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels; establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; establishing and implementing effective monitoring procedures at critical control points; establishing corrective actions when monitoring indicates that a critical control point is not under control; establishing procedures, which shall be carried out regularly, to verify that measures outlined in subparagraphs (a) to (e) are working effectively; and establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f). The phases considered by the HACCP system concern all stages of the agri-food supply chain, from preparation to the supply of food to the final consumer, so that all operators dealing with food in the distribution circuit are required to follow the HACCP procedures.

2.3.5. Food Contact Materials

Food come into contact with many materials during its production, processing, storage, preparation and serving before its consumption, such materials are called Food Contact Materials, FCMs. FCMs are either intended to be brought into contact with food, are already in contact with food, or can reasonably be brought into contact with food or transfer their constituents to the food under normal or foreseeable use, *exempli gratia* containers for transporting food, machinery to process food, packaging materials, kitchenware and

tableware not including public or private water supply equipment[86]. Food Contact Materials should be sufficiently inert so that their constituents neither adversely affect consumer health nor influence the quality of the food, in order to ensure safety of FCMs and quality of goods EU provides binding rules that business Operators must comply with. The safety of FCMs is evaluated by the European Food Safety Authority, the testing methods are studied by the EURL-FCM[87], the safety is as well tested by business Operators placing FCMs on the market, and by the competent authorities of the Member States during official controls.

2.3.6. The rapid alarm system and its application on food products and feed for animals: The Regulation EU 16/ 2011 of European commission

The European Union has one of the highest food safety standards in the world thanks to the substantial legislation in place, that assures that food is safe for consumers, moreover a key instrument adopted to ensure the flow of information to enable swift reaction when risk to public health are detected in the food chain is RASFF- the Rapid Alert System for Food and Feed. RASFF enables to share information efficiently, providing a full-time service to process urgent notifications effectively, indeed many food safety risks had been adverted before they could have been harmful to European consumers[88]. RASFF provide food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed, it helps European countries to act rapidly and in a coordinated manner in response to a health threat caused by food or feed. The types of RASFF notifications are differentiated according to the degree of urgency they bear, the one that identifies a serious health risk for consumers is the *alert*, the information is used when a risk has been determined but Member States do not need to take rapid action, the *border rejection* concerns a food coming from outside the European Union and bears a risk, it is used to ensure that the rejected product does not re-enter the EU through another border, and all the other information related to food and feed that can be interesting for control authorities is transmitted in the form of *news*.

[86] https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en
[87] European Reference Laboratory for Food Contact Materials.
[88] https://ec.europa.eu/food/safety/rasff_en

2.4. Tutelage of the veracity regarding the information provided to the consumer

2.4.1. Label and Food's Information

Throughout the past fifty years mandatory food labelling requirements have increased in number and complexity, the most important Regulation that has integrated and modified the rules on products' labelling in all EU Member States is the EU Regulation 1169/2011. As a matter of fact, according to the above-mentioned regulation, a label is defined as "any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to the packaging or container of food" and the act of labelling "means any words, particulars, trademarks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food". Is of interest of this dissertation to briefly mention that in Italian jurisdiction the food communication is governed by two normative sets: one based on EU Regulation1169/2011 and the other, generally applicable to all commercial communications regarding: the rule of unfair competition (art. 2598 of the Civil Code), the rules on misleading and comparative advertising regarding Business to Business relationship, in Legislative Decree 145/2007, and consumer-oriented communication on unfair commercial practices, in Consumer Code art. 18[89]. The EU Regulation 1169/2011 translates on the communication side of the product the objective of food legislation: protecting the consumer while ensuring the proper functioning of the internal market by accomplishing free movement of foodstuff legally produced and marketed within the Union, considering, where appropriate, the need to protect the legitimate interests of producers and to promote quality products. The eventual existence of information barriers or different rules would make it impossible to acknowledge alternative and consequently would preclude consumers' freedom of choice. The EU Regulation 1169/2011 defines the principles, requirements and responsibilities relating to food information, bringing together in a single legislative act previously separated regulatory areas: horizontal regulation (Directive 2000/13/ CE), nutrition labelling (Directive 90/496/ CEE) as well as other sectorial disciplines. The new Regulation has a very wide scope, is applicable in all cases in which a food is made available to the consumer, no longer prepackaged products sold to the

[89] D. PISANIELLO, op. cit., p.282.

final consumer and products sold to the general public only, but also consumer consumption in caterings[90]. The Regulation 1169/2011 introduces innovations in the discipline such as: details of attribution of non-conformities and the responsible personas thereof; extension of the nutrition declaration requirement; new regulatory framework on origin and provenance; obligations on food allergens; layout requirements and a number of additional indications. The Regulation 1169/2011 has had an important impact on the division of responsibilities between European Union and Member States, in this sense Article 38 thereof prohibits Member States from adopting and maintaining national provisions on matters expressly harmonized by the Regulation, unless authorized by the European Union law[91]. In this regard, it must be pointed out, according to Article 38.2 of the Regulation, that Member States may adopt national measures concerning matters not specifically harmonized by the Regulation provided that they do not prohibit, impede or restrict the free movement of goods that are in conformity with this Regulation and, according to Article 39.1 thereof, that in addition to the mandatory particulars Member States may adopt measures requiring additional mandatory particulars for specific types or categories of food, justified on grounds of at least one of the following: protection of public health; the protection of consumers; the prevention of fraud; the protection of industrial and commercial property rights, registered designations of origin and the prevention of unfair competition. The national legislators however have an important role, the scope of intervention thereof certainly concerns non-prepacked foods: food offered for sale to the final consumer or mass caterers without pre-packaging or packaged in places of sale at consumer's request or pre-packed for direct sale, except for the provision of information on the presence of allergens, always mandatory although regulated at national level, indeed the Regulation explicitly notes that although in such cases the consumer demand for other information is limited, information on potential allergens is considered very important. Evidence suggests that most food allergy incidents can be traced back to non-prepacked food therefore, information on potential allergens should always be provided to the consumer. Before proceeding is of interest of this dissertation to consider that the discipline of Regulation 1169/2011 distinguishes different

[90] BERND M.J.V.D. MEULEN, The structure of European Food Law, in Laws, 2013, pag. 83.
[91] D. PISANIELLO, op. cit., p.295.

regimes of information provision depending both on food type and the stage along the supply chain: prepackaged products offered to the consumer; non-prepackaged products; where prepacked food is intended for the final consumer prior to sale to the final consumer and where sale to a mass caterer is not involved at that stage; where prepacked food is intended for supply to mass caterers for preparation, processing, splitting or cutting up; Food Business Operators that supply to other FBOs food not intended for the final consumer or to mass caterers shall ensure that those other Food Business Operators are provided with sufficient information to enable them, where appropriate, to meet their obligations. The legislation for pre-packaged products offered to the final consumer is harmonized at European level, with the exception of interventions granted by Article 38, instead for non-prepackaged foods European law is without prejudice to national competence, excluding allergen information guarantees and requirements on fair information[92]. The EU Regulation 1169/2011, as already anticipated, disciplines the provision of *food information*, this locution entails "all the information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication". This implies that all commercial communication is subject to several requirements: no longer only food labels, advertising material, web pages, but also the content of company pages on social networks, information transmitted through QR code or via smartphone apps, up to and including verbal communications, such as the ones of product line promoters, such as food supplements or sports food. The Regulation shall apply to food business operators at all stages of the food chain, where their activities concern the provision of food information to consumers. It shall apply to all foods intended for the final consumer, including foods delivered by mass caterers, and foods intended for supply to mass caterers.

2.4.2. Behavioral psychology and Nutri-scores

In regards of conscious consumption choices implemented by means of the label, there are theories of behavioral psychology, one of which is proposed by Gerd Gigerenzer which assert that ignoring a part of the information in the act of making a choice can lead to a more

[92] D. PISANIELLO, op. cit., p.297.

accurate and informed outcome. Therefore, according to these theories, a high amount of information in the foods' label distracts the attention of the consumer from the most important information for the buying decision[93]. These studies come to opposite conclusions with respect to the theories considering useful to provide as much information as possible to the consumer and help to demonstrate that not all consumption habits respond to the same logic, especially confirming that agri-food legislation is complex and has to be considered from multiple perspectives. Such arguments are also invoked by those who are in favor of the usage of Nutri-score labels, in which the fundamental indications on ingredients considered less healthy are provided through different colors, thus having the advantage of making the consumers immediately understand the characteristics of the food in question[94]. The Italian legal doctrine, however, has raised doubts about the real effectiveness of Nutri-scores, which have been instead adopted in France and Spain after a debate involving the Ministries of Health and Agriculture as well as consumer associations and representatives of the food industry. The point that concerns the doctrine against the use of Nutri-scores regards that some countries of the Union chose different paths with respect to other Member States, considering that their totality should pursue common policies, acting in accordance with the same objectives of harmonization and consumer protection[95]. The European Union legislation does not allow Member States to unilaterally impose their own food labelling system, the countries can only recommend methods thereof. The Nutri-score has been officially recommended by health authorities in France, Spain, Luxembourg, Belgium, Germany and Netherlands. The position of the European Union legislation on labelling would be presented in the following sections of the dissertation.

2.4.3. General requirements for the provision of food information

It is necessary to distinguish between general and specific requirements in food information's discipline. General requisites are enunciated in Regulation 1169/2011 in Chapter III from Article 6 to Article 8, specific requirements are disciplined from Article 9 to

[93] G. GIGERENZER, Decisioni intuitive. Quando si sceglie senza pensarci troppo, Milano, 2009.
[94] B. MURPHY- J. SANDERSON, Soft law, responsibility and the biopolitics of front-of-pack food labels, in Griffith Law Review, 2018, pag. 377.
[95] G. SPOTO, op. cit., p. 34.

Article 35 and regard the mandatory information and the respective provision thereof. Article 6 explicitly states "Any food intended for supply to the final consumer or to mass caterers shall be accompanied by food information in accordance with this Regulation."
The amplitude of the aforementioned provision, concerning all foods and not just the pre-packaged ones, stands also in the assonance with EC Regulation 178/2002, confirming that compliance with food law must be understood as comprehensive also of the aspects related to the correct information of the consumer and fair competition between professional operators[96].

2.4.4. Fair information practices

Article 7 of Regulation 1169/2011 contains the second general requirement that Food Business Operators have to pay attention on when providing food information and is based on the principle of loyalty, specifically "1. Food information shall not be misleading, particularly: as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production; by attributing to the food effects or properties which it does not possess; by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasizing the presence or absence of certain ingredients or nutrients; by suggesting by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally used in that food has been substituted with a different component or a different ingredient;
2. Food information shall be accurate, clear and easy to understand for the consumer;
3. Subject to derogations provided for by Union law applicable to natural mineral waters and foods for particular nutritional uses, food information shall not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties;
4. Paragraphs 1,2 and 3 shall also apply to: advertising; the presentation of foods, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed".

[96] D. PISANIELLO, op. cit., p.301.

2.4.5. Mandatory and voluntary information

The list of mandatory particulars for all foodstuff is included in Article 9 of the EU Regulation 1169/2011 and the compulsory are: the name of the food; the list of ingredients; any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerance used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; the quantity of certain ingredients or categories of ingredients; the net quantity of the food; the date of minimum durability or the 'use by' date; any special storage conditions and/or conditions of use; the name or business name and address of the food business operator referred to in Article 8(1); the country of origin or place of provenance where provided for in Article 26; instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions; with respect to beverages containing more than 1,2% by volume of alcohol, the actual alcoholic strength by volume; a nutrition declaration[97]. It is of interest to briefly describe the difference and peculiarities between the country of origin or place of provenance. The country of origin is, in accordance with Articles 23 to 26 of Regulation EEC number 2913/92, identified with the country of the last substantial transformation, if a product is obtained in two or more countries, that concept refers to the country in which the products have undergone their last substantial and economically justified processing or working. The place of provenance means instead any place where a food is indicated to come from; the name, business name or address of the food business operator on the label shall not constitute an indication of the country of origin or place of provenance of food. Again, focusing to more general obligations provided by EU Regulation 1169/2011, Article 18 defines that the ingredients shall be designated by their specific name and have to be included in descending order of weight, as recorded at the time of their use in the manufacture of the food. Additives and enzymes are respectively regulated by EC Regulation 1333/2008 and EC Regulation 1332/2008, in particular is important to take into consideration that additives are marked in the label with the letter "E" followed by a number in order to distinguish dyes (from E100 to E199), preservatives (from E200 to E299) and

[97]A. MAHY- N. CONTE-SALINAS, European Food Labelling Law, in International Food Law and Policy. Springer, 2016, pag.507.

antioxidants (from E300 to E399)[98]. Additives and enzymes used as processing aids are excluded, according to the scope of EU Regulation 1169/2011, from the list of mandatory label information. With regards to the way the information is displayed in the label, the EU Regulation 1169/2011specifies respectively in articles 22 and 23 how the quantitative indication of the ingredients and how the net quantity of the food should be expressed. In the case of certain special characteristics or for specific types of foods, the additional mandatory particulars must be added according to Article 10 and annex III of the above-mentioned legislation[99]. Article 12 of the aforesaid Regulation clarifies that mandatory food information shall be available and shall be easily accessible for all foods, in the case of prepacked food, mandatory food information shall appear directly on the package or on a label attached thereto. In regard of legibility, it is defined by the Regulation as the physical appearance of information, by means of which the information is visually accessible to the general population and which is determined by various elements, inter alia, font size, letter spacing, spacing between lines, stroke width, type color, typeface, width-height ratio of the letters, the surface of the material and significant contrast between the print and the background. The Regulation clarifies in Article 13.1 that "mandatory food information shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible; it shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter of any other intervening material" and this statement could lead to a reshaping of communication spaces in the label, often calibrated for the benefit of images and voluntary indications[100]. The mandatory information, according to Article 15 of the Regulation shall appear in a language easily understood by the consumers of the Member States where a food is marketed, except in the use of pictograms or symbols authorized by an act of the Commission. The intent of Regulation 1169/2011 is to provide a systematic structure for the aliment's information, guaranteeing consumer's right to be informed, consumers must be able to undertake cognizant choices and acquire relevant information regarding both the protection of their health as much as to environmental, social, religious and ethical considerations that are

[98] A. GERMANÒ- M. PIA RAGIONIERI - E. ROOK BASILE, op. cit., p.85.
[99] D. PISANIELLO, op. cit., p.305.
[100] A. MAHY- N. CONTE-SALINAS, op. cit., p.508.

significant for them. For this purpose, Regulation 1169/2011 in Article 4 includes the various mandatory information in three specific categories:

(a) Information on the *identity* and *composition*, properties or other characteristics of the food;

(b) Information on the *protection of consumers' health* and the safe use of a food, in particular it shall concern information on: compositional attributes that may be harmful to the health of certain groups of consumers; durability, storage and safe use; the health impact, including the risks and consequences related to harmful and hazardous consumption of a food;

(c) Information on *nutritional characteristics* so as to enable consumers, including those with special dietary requirements, to make informed choices.

In this label's mandatory information summary of categories, three main aspects have to be refocused, namely, the product's i*dentity*, the indication of the *expiry date* of a product and the information on the *safe use of a food*. The *product identity* is given by its product name and, specifically, a product's legal name means the name of a food prescribed in the Union provisions applicable to it or, in the absence of such Union provisions, the name provided for in the laws, regulations and administrative provisions applicable in the Member State in which the food is sold to the final consumer or to mass caterers. The *expiry date* means the date by which the food is to be consumed, so that the sale or cession of the product is prohibited after that date, since the food is microbiologically perishable and could constitute danger for human health[101]. Expiry date differs from date of minimum durability since the latter means the date until which the food retains its specific properties when correctly stored. The absence of information on the safe use of a food makes the product 'defective' and appoints the producer responsible for the damage caused by its use.

2.4.6. Voluntary food information

The 2011 legislator's initial consideration on voluntary food information seems to be moved by a meticulous need to regulate them, it is coherent with the sentence in Regulation 1169/2011, stating "Experience shows that in many cases voluntary food information is

[101]A. GERMANÒ- M. PIA RAGIONIERI - E. ROOK BASILE, op. cit., p.88.

provided to the detriment of the clarity of the mandatory information; therefore, criteria should be provided to help food business operators and enforcement authorities to strike a balance between the provision of mandatory and voluntary food information". The Regulation 1169/2011 establishes a grid of requirements and obligations for the protection of the final consumer, which would indicate a balance between mandatory and voluntary food information, which distinguish between non-regulated and regulated by means of vertical regulatory acts. Article 37 of the above-mentioned Regulation clarifies that "voluntary food information shall not be displayed to the detriment of the space available for mandatory food information". Non-regulated voluntary information may relate to elements related to mandatory information, such as additional details on a nutrient, and in this case the information shall be expressed in accordance with the concerned articles of the law in order not to incur in a fine, or also, the voluntary information might not refer to a mandatory one, *exempli gratia* the reference to a product's environmental impact[102]. Article 36 of Regulation 1169/2011 regard the applicable requirements on food voluntary information provision and states as follows:" Food information provided on a voluntary basis shall meet the following requirements: it shall not mislead the consumer, as referred to in Article 7; it shall not be ambiguous or confusing for the consumer; and it shall, where appropriate, be based on the relevant scientific data. The Commission shall adopt implementing acts on the application of the requirements referred to in paragraph 2 (the aforementioned) to the following voluntary food information: information on the possible and unintentional presence in food of substances or products causing allergies or intolerances; information related to suitability of a food for vegetarians or vegans and the indication of reference intakes for specific population groups. Article 43 specifies the matter of voluntary indication of reference intakes for specific population groups, the Regulation provides that "Pending the adoption of the Union provisions referred to in point (c) of Article 36(3), Member States may adopt national measures on the voluntary indication of reference intakes for specific population groups; Member States shall communicate to the Commission the text of those measures without delay". To the categories of voluntary information defined as *regulated*,

[102] D. PISANIELLO, op. cit., p.352.

insofar as harmonized and pertaining to consumer protection, belong: nutritional claims, health claims and claims on the absence of gluten or on the presence to a limited extent.

2.4.7. Nutrition and health claims made on foods

The voluntary provision of information pertaining to energy, nutrition facts or information of other nature are governed by the requirements of EC Regulation 1924/2006, on nutrition and health claims made on foods. The European rules on nutrition and health claims serve to confirm the limits of the unfair commercial practice which, in this sector, may sometimes call into questions situations likely to endanger the health and safety of the adult consumer and child consumer. Specifically, according to Article 21 commas 3 and 4 of the Italian Consumer Code, a commercial practice concerning products which are liable to endanger the health and safety of the consumers, fails to inform consumers in such a way as to induce consumers to disregard the normal rules of prudence and vigilance, is considered to be unfair; and it is considered unfair the commercial practice which, as it is likely to reach children and adolescents, may, even indirectly, threaten their safety. The Regulation 1924/2006 shall apply to all indications used voluntarily in the context of commercial communications, whether in the labelling, presentation or advertising of foodstuff supplied to the final consumer, moreover should be included in the scope of the Regulation any food intended for hospitals, restaurants, schools, canteens and similar collective catering services excluding, under specified conditions, prepackaged aliments[103]. As regard general principles for all claims, in Article 3 of Regulation 1924/2006, the use of nutrition and health claims shall not: be false, ambiguous or misleading; give rise to doubt about the safety and/or the nutritional adequacy of other foods; encourage or condone excess consumption of a food; state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. Derogations in the case of nutrients for which sufficient quantities cannot be provided by a balanced and varied diet, including the conditions for their application, may be adopted in accordance with the procedure referred in Article 24 (2), taking into account the special conditions present in Member States; refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or

[103] D. PISANIELLO, op. cit., p.354.

through pictorial, graphic or symbolic representations. A peculiar attention should be reserved to comparative nutritional claims, in which information is given on the difference in the amount of a nutrient or in the energy value, *exempli gratia* the term *energy-reduced* or *light.* A comparison may only be made between foods of the same category[104], taking into consideration a range of foods of that category; the difference in the quantity of a nutrient and/ or energy value shall be states and the comparison shall relate to the same quantity of food. Comparative nutritional claims shall compare the composition of the food in question with a range of foods of the same category, which do not have a composition which allows them to bear a claim, including foods of other brands. Health claims refer to any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and heath and shall only be permitted if the following information is included in the labelling, if no such labelling exists, in the presentation and advertising: a statement indicating the importance of a varied and balanced diet and healthy lifestyle; the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect; where appropriate, a statement addressed to persons who should avoid using the food; and an appropriate warning for products that are likely to present a health risk if consumed to excess.

2.4.8. Labels and aliments' traceability

The label explicates an informative function towards consumers, who usually draw most of the necessary information for their product's choice[105]. Traceability is a crucial matter and it is of interest of this dissertation to briefly account for the difference of traceability related to a product made of a single ingredient and composition, that will be the former treated, and the compound foods, either made by already stocked products or made by the mix of several primary products. Although traceability cannot be confused with product labelling insofar as the latter is aimed exclusively at consumers and the former is aimed exclusively at companies and food inspectorates, however the label, has a function related to traceability that carries out each time it is necessary to withdraw a food at risk from the market.

[104] May refer to the nutritional content which must be homogeneous or to the occasions of consumption that have to be overlapping, it would be wrong to compare nutritional claims pertaining to butter and milk.
[105] A. GERMANÒ- M. PIA RAGIONIERI - E. ROOK BASILE, op. cit., p.210.

Traceability facilitates the immediate identification of those responsible, on the one hand it determines the unification of the various stages involved in the production of the single food, and on the other it is an element of differentiation, for the purposes of responsibility, of individual operators, allowing the single final product to be traced back to different sources of production [106]. Traceability of compound foods is ensured by invoices and bills accompanying the products and the label compulsorily presents, according to EU Directive 2011/91, the lot to which the foodstuff belongs.

2.5. The quality

2.5.1. Identification of the meaning of quality and protection thereof

The term quality has a relative meaning, this is noticeable in the ISO definition: "The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs"[107]. In simpler words it is possible to perceive a product's good quality when it "complies with the requirements specified by the consumer"[108]. Is of interest of this dissertation to preface a comment on the semantic value of the expressions "*Legal protection of the quality of agri-food products*" with respect to "*protection of the quality*". When referring to the quality of an agri-food product, the average consumer thinks [109] of its quality characteristics which, depending on his degree of knowledge of the category of the product concerned, may include: both the physical and organoleptic characteristics of the product (size, appearance, composition, taste, perfume) and its connection with the territory of production or processing, and, finally, the methods used to produce it (type of farming, processing techniques, seasonality, packaging system)[110]. As can be understood, the quality, so considered, refers to the intrinsic quality characteristics of an agri-food product that, being perceived and to some extent evaluated and appreciated, are able to enhance it in the eyes of the *average consumer.* Consequently, to protect the quality of an agri-food product, in the sense just indicated, means ensuring that most appropriate conditions are created so that all the criteria of agricultural cultivation and production and all the craft and industrial

[106] A. GERMANÒ- M. PIA RAGIONIERI - E. ROOK BASILE, op. cit., p.210.
[107] https://stats.oecd.org/glossary/detail.asp?ID=5150
[108] http://www.fao.org/3/W7295E/w7295e03.htm
[109] As results from numerous opinion pools and specific market research.
[110] F. CAPELLI, op. cit., p.269.

processing criteria are respected enabling a product to be properly produced with the above-mentioned quality characteristics and that the average consumer is able to appreciate. The legal protection of the quality of a foodstuff means, in fact, the protection of the indication used by the producer to describe its quality characteristics, be it the trademark registered by the producer himself, or the collective mark registered by the consortium of operators whose the producer is a member, either by the sales denomination imposed by national law or, finally, by the legally registered designation of origin or geographical indication[111]. The mark, either a trademark or collective mark, serve for the producer as a mean to identify its product with respect to the competitor's one and for the consumer, whom purchases a product relying thereof, the mark hence constitutes the attestation of the intrinsic qualitative characteristics described above, with the consequence that by legally protecting the mark also the qualitative characteristics attested by it are protected. In conclusion, therefore, by legally protecting the mark or the protected designations, the quality of the product bearing that mark is protected.

2.5.2. Marks and collective mark

A brief mention to EU Directive 2015/2436, governing marks and collective marks is due for the sake of the second chapter's clarity. A guarantee or certification mark, according to Article 27 of the aforementioned Directive, means " a trade mark which is described as such when the mark is applied for and is capable of distinguishing goods or services which are certified by the proprietor of the mark in respect of material, mode of manufacture of goods or performance of services, quality, accuracy or other characteristics, from goods and services which are not so certified;" whereas a collective mark means "a trade mark which is described as such when the mark is applied for and is capable of distinguishing the goods or services of the members of an association which is the proprietor of the mark from the goods or services of other undertakings".

[111] F. CAPELLI, op. cit., p.269.

2.5.3. European voluntary quality indications

According to the Green Paper and to International Organization for Standardization, quality is about meeting consumer expectations. The agricultural product qualities addressed in this Green Paper are the product characteristics, such as farming methods used, place of farming, that a farmer wants to be better known and a consumer wants to know. Quality is an issue for every farmer and every buyer, whether they are dealing with commodities produced to baseline standards or with high-hand quality products in which Europe excels. The context in which the problem of food quality is the market, precisely the means of determining the victory of one competitor over the others, it is necessary to imagine alongside an attractive price, other singular requirements, that by being appreciated by consumers, confer a commercial advantage on the producer of the product possessing them, with respect to other producers that do not. It is therefore understood that these requirements, that the manufacturer offers, must be communicated to have competitive value, they must indicate the prestige of the aliment, and as a consequence, if the quality is to be used to win the competition in the market, the *real quality* requirements must be additional to those that all products must have by law. In other words, quality requirements should be requirements that go beyond the fact that the final product has been obtained in a hygienic manner and in compliance with food safety rules, which designate the characteristics of an aliment and its tradability in the European market, according to Regulation 178/2002 on food safety. Consumers must be informed of the quality indications' presence. The indications must be voluntarily communicated on the label. In the market for agri-food products, Community approved "symbols" are used to attest the quality of a product, they either indicate a particular connection of the product with the territory or a specific production technique, the "symbols" PDO, PGI, TSG and Mountain Products are the most relevant[112]. Such indications shall be expressed as symbols, after the producer groups[113] have determined the respective specifications, have them recognized by the Union, and have them accredited in a dedicate register. PDO, PGI, TSG and Organic are voluntary indications whose requirements are however identified and prescribed with their registration by the European Union, hence,

[112] A. GERMANÒ- M. PIA RAGIONIERI - E. ROOK BASILE, op. cit., p.129.

[113] Groups means any association, irrespective of its legal form, mainly comprised of producers or processors working with the same product, according to Article 3.1 n.2 of the EU Regulation 1151/2012.

in other words, such indications are voluntary concerning the use, but are regulated in terms of content, it is proper to name them *Community indications of quality*.

2.5.4. Agri-food quality schemes: PDO, PGI, TSG and Mountain products

The EU Regulation number 1151/2012 establishes so-called quality schemes, sets of rules for the identification and protection of names and indications designating agricultural products or agri-food by reason of their specific characteristics or properties due to the production method or place of production[114]. Is not the aim of this dissertation to deepen the details on quality schemes because the amplitude of the subject precludes such a possibility however, it is of its interest to include the general rules defining each European voluntary quality scheme. According to Regulation 1151/2012, 'Protected Designation of Origin' is a name which identifies a product: "originating in a specific place, region or, in exceptional cases, a country; whose quality or characteristics are essentially or exclusive due to a particular geographical environment with its inherent natural and human factors; and the production steps of which all take place in the defined geographical area"; for the purpose of this Regulation, 'Protected Geographical Indication' is a name which identifies a product:" originating in a specific place, region or country; whose given quality, reputation or other characteristic is essentially attributable to its geographical origin; and at least one of the production steps of which take place in the defined geographical area". A salient diversity in the definition of PDO and PGI regards the mention to the territory, in particular as regards PDOs all the production phases of the product and ingredients used must necessarily originate in the declared territory, *exempli gratia* 'Prosciutto di Parma PDO'; for PGI products, the territory gives, through certain stages or components of the processing, its particular characteristics but not all the ingredients of production belong to the declared territory, *exempli gratia* 'Bresaola della Valtellina PGI' is obtained from animals not reared in Valtellina but following traditional production methods of that area and taking advantage of the favorable climate conditions for maturation[115]. The qualifying feature of a PDO or PGI is that the right to use the "protected name" is reserved exclusively to operators located in a

[114] D. PISANIELLO, op. cit., p.168.

[115] https://ec.europa.eu/info/food-farming-fisheries/food-safety-and-quality/certification/quality-labels/geographical-indications-register/#

specified area who undergo a control and certification system under the supervision of competent authorities[116]. The registration of a product as a PDO or PGI, according to Article 13 of EU Regulation 1151/2012, ensures its protection against :"Any direct or indirect commercial use of a registered name in respect of products not covered by the registration where those products are comparable to the products registered under that name or where using the name exploits the reputation of the protected name, including when those products are used as an ingredient; any misuse, imitation or evocation, even if the true origin of the products or services is indicated or if the protected name is translated or accompanied by an expression such as 'style', 'type', 'method', 'as produced in', 'imitation', or similar, including when those products are used as an ingredient; any other false or misleading indication as to the provenance, origin, nature or essential qualities of the product that is used on the inner or outer packaging, advertising material or documents relating to the product concerned, and the packing of the product in a container liable to convey a false impression as to its origin; any other practice liable to mislead the consumer as to the true origin of the product". The term *Traditional Specialities Guaranteed*, according to Article 17 of the aforementioned Regulation, refer to:" A scheme for Traditional Specialities Guaranteed is established to safeguard traditional methods of production and recipes by helping producers of traditional product in marketing and communicating the value-adding attributes of their traditional recipes and products to consumers". TSG is a European quality mark intended to protect products which are characterized by the specificity of traditional composition or product method, but without a geographical reference area. Mountain Product has, instead, been established as an optional quality term, it shall only be used to describe products intended for human consumption in respect of which:" both the raw materials and the feedstuff for farm animals come essentially from mountain areas; in the case of processed products, the processing also takes place in mountain areas". It is relevant to state that, according to Article 31 of the EU Regulation 1151/2012, mountain areas are those delimited pursuant to Article 18(1) of Regulation EC number 1257/1999.

[116] D. PISANIELLO, op. cit., p.171.

2.5.5. Italian PGI, STG, PDO

From the point of view of the Italian legislation, the PGI, STG and PDO belong to all the regulated agri-food products covered by the Ministerial Decree of 16th February 2012. Italy is the European country with the highest number of agri-food products with a designation of origin and a geographical indication, namely 299, recognized by the European Union, in fact Italian agri-food excellences are inevitably binded to their territory of origin[117]. The European Geographical Indication system favors the economy of the territory, protects the ecosystems and biodiversity to preserve the territory of origin, supports the social cohesion of the entire Community, while providing greater guarantees to consumers through a high level of traceability and food safety, with respect to other products.

2.5.6. Ethics and religion

In order to complete the examination of voluntary quality indications indicating the value of the food allocated to the market, mention should also be made of those signs which, in a now multi-ethnic Europe, meet the religious needs of certain categories of consumers, which are assured by the presence of a certain indication on the food label. For example, in order to reach customers of Muslim religion, food producers have an interest to indicate on the label the species of meat that constitutes the product and the method of slaughter of the animals used. Categories of consumers could be induced to purchase the food by the notion in the label that has been produced in accordance with the rules of the Fair-Trade market, or in accordance with provisions prohibiting the exploitation of women or children: these indications are voluntary as well and can be used as long as they are true and not deceptive[118].

[117] https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/396
[118] A. GERMANÒ- M. PIA RAGIONIERI - E. ROOK BASILE, op. cit., p.134.

Chapter III

The animal protection and the impact of the usage of hormones in the market: a comparison of Chinese, United States' and European law

3.1. Consumer Protection

The initial consideration of this chapter concerns a mention on the diverse legislative approach countries, namely United States of America, China and Europe, adopt towards the consumer protection issue and their respective legal systems. European point of view in regards of consumer protection legislation has been extensively treated in the previous chapters of the dissertation, hence it is reasonable for the interest of the treatise to adopt it as a reference point.

3.1.1. Consumer protection legislation in the United States of America

United States of America provide consumers with a series of rights in order to protect thereof, specifically: *the right to safety*, to be protected against the marketing of products and services that are hazardous to health or to life; *the right to be informed*, to be protected against fraudulent, deceitful or misleading information, advertising, labelling, or other practices, and to be given the facts needed to make informed choices; *the right to choose,* to have available a variety of products and services at competitive prices; *the right to be heard*, to be assured that consumers interests will receive full and sympathetic consideration in making government policy, both through the laws passed by legislatures and through regulations passed through administrative bodies; *the right to education*, to have access to programs and information that help consumers to make better marketplace decisions; *the right to redress*, to work with established mechanisms to have problems corrected and to receive compensation for poor service or for products that do not function properly[119]. United States of America are part of the common law system Countries, common law, also referred as "case law", heavily relies on court precedents in formal adjudications rather than

[119] https://www.mass.gov/service-details/consumer-bill-of-rights

on codes, these last used in the European Union countries[120]. United States' regulatory framework arises from several levels of government namely state, federal and local, inevitably placing the need to establish a priority between the three levels. Federal law dominates the regulation of food safety in the USA but there is a close interrelationship with state and local authorities, as well as an expanding role and impact of International food standards [121]. The two U.S. federal agencies with primary responsibility for food safety are the Food and Drug Administration, FDA, and the Food Safety and Inspection Service, FSIS.

U.S. policy on consumer protection is inclined to not directly regulate consumers, it is assumed to be a consumer's responsibility to decide what to eat, but to foster public policies aiming at enabling consumers to make informed decisions. The steps that are considered crucial in order to do so are: *educate consumers* so to allow them to assess their situation in terms of nutrition and food safety; provide *specific product informatio*n to consumers on the label focusing on nutrition, allergies, quantity, ingredients and business contact information; and somewhat *regulate advertising and discretionary information* on labels in order to inform and educate consumers, to assure the information is accurate, not misleading nor claiming inappropriate information about the product[122]. European and U.S.A.'s legal systems are different, the former is based on codes providing rules for deciding on specific disputes while the latter relies on court antecedents in formal judgements, hence, an unbiased comparison on consumer protection legislation is complex to provide.

3.1.2. Consumer protection legislation in China

People's Republic of China, PRC, legal system is defined by the government a "socialist legal system", although China's legal system is primarily based on the Civil law paradigm[123].

Consumers rights in China are safeguarded by" People's Republic of China Law on Protection of the Rights and Interests of Consumers", first adopted in 1993 and last amended in 2013[124]. The section dedicated to consumer rights is named "Chapter II", the concerned articles are from the seventh to the fifteenth, particularly: Article 7 establishes that consumers should

[120] https://www.lexisnexis.com/en-us/lawschool/pre-law/intro-to-american-legal-system.page
[121] https://www.ag.ndsu.edu/foodlaw/overview/keypoints
[122] https://www.ag.ndsu.edu/foodlaw/safe-408-608/retailfoodservice-consumers
[123] https://www.loc.gov/law/help/legal-research-guide/china.php#sources
[124] https://www.chinalawtranslate.com/consumer-protection-law-including-2013-amendments/?lang=en

not suffer injury to their person or property when purchasing or using goods or receiving services, hence having the right to require that goods meet the requirement of safety for their person and property; Article 8 determine that consumers have the right to know the circumstances (intended as price, place of production, manufacturers, usage, performance, standard, principle components, date of production, expiration period, certificate of inspection, instruction for use and services of goods or services) of goods they purchase or use, or services they receive; Article 9 stipulates that consumers can independently select goods or services, having the right to conduct a comparison; Article 10 outlines that consumers have the right to fair transactions, thus have the right to refuse coercive trading behavior by business operators; Article 11 sets the right of consumers to receive a compensation, in accordance with the law, in the case in which they suffer harm to their person or property from their purchase of a good or receipt of services; Article 12 points out that consumers can form social organizations to protect their lawful rights and interests; Article 13 specifies that consumers have the right to gain knowledge regarding consumption and protection of their rights and interests; Article 14 establishes the consumer's right of personal dignity when they purchase or use or receive services, it consists of having their ethnic customs respected and their personal information protected; Article 15 determine consumers' right to conduct oversight over goods, services and the effort to protect consumer rights and interests, they can report and make accusation on conduct infringing upon consumer rights and interests and illegal actions or failure to perform duties of state organs or their employees and have the right to make criticism and recommendation regarding the protection of consumer rights and interests. The notion of consumer protection in China with respect to Europe, hence, appears to be common in essence but divergent in substance, European regulatory framework is structured in an organic way, allowing for clear and objective interpretation of consumers rights, the Chinese set of rules seems, to be ambiguous, probably because of the linguistic barrier and translation. It is clear that also the cultural differences and the socio-economic context contribute to the differences in legislations, however the aspect that have to be emphasized is the dialogue between cultures as a form of growth and improvement which lead a Regime to include in its regulatory framework some rules to protect consumers.

3.2. Legislation on the usage of hormones in animals

3.2.1. Usage of hormones in Europe

European Union has adopted a precautionary principle approach, since 1981, with Directive 81/602/EEC prohibiting the use of substances having a hormonal action for growth promotion in farm animals, examples of this kind or growth promoters are oestradiol 17β, testosterone, progesterone, zeranol, trenbolone, acetate and melengestrol acetate (MGA)[125]. The prohibition applies to Member States and imports from third countries alike. The legal instrument in force since 1996, concerning the prohibition on the use of stock farming of certain substances having a hormonal or thyrostatic action and of β-agonists, is the Directive 96/22/EC as amended by Directive 2003/74/EC. The goal of the Directive 96/22/EC is to protect consumer's health and preserve the quality of food by controlling the use of hormones in animals. The Directive prohibits the administration of certain substances to farm animals to promote growth, the substances are: thyrostatic substances; stilbenes, stilbene derivatives, their salts and esters; oestradiol 17β and its ester-like derivatives; beta-agonists; substances with an oestrogenic, other than oestradiol 17β and its ester-like derivatives, androgenic or gestagenic action. A brief definition of the above-mentioned substances is needed to clarify the meaning of the following discussion. Tyrostatic are medicines that reduce, or stabilize, the production of thyroid hormones; oestrogenic are hormones that stimulate the development of female secondary sex characteristics (for example, lighter muscling and weight of cows than bulls), exert systemic effects such as growth and maturation of long bones and promote oestrus (i.e. regularly occurring period of sexual receptivity) in female mammals; androgenic are hormones that control the development and maintenance of masculine characteristics; gestagenic are hormones that produce progestational (i.e. favoring gestation) effects in the uterus; beta-agonist are drugs that relax muscles (for example when giving birth) by stimulating beta-adrenoceptors. The Directive 96/22/EC prohibits: the placing on the market of the substances listed above where they are to be administered to animals intended for human consumption (not including therapeutical and zootechnical exceptions); the placing on the market and slaughter of animals containing these substances or residues of these substances; the placing

[125] https://ec.europa.eu/food/safety/chemical_safety/meat_hormones_en

on the market of meats or products od animal origin containing these substances or residues of these substances; the holding of these substances on a farm. The EU prohibits the import of animals, meat or products of animal origin from non-EU countries that authorize the administration of these substances for growth promotion. However, the EU prohibition does not apply where these countries are able to offer an equivalent guarantee for exports such as a segregated breeding system. Directive 2003/74/EC has amended Directive 96/22/ EC, confirming the prohibition of hormones for growth promotion in animals, it also reduced substantially the circumstances under which oestradiol 17β could be administered for other purposes to food-producing animals. Directive 2008/97/EC amended Directive 96/22/EC and its limits only to food-producing animals, withdrawing prohibitions for pet animals. Oestradiol represents a potential risk for human health and hence is completely prohibited for use in food-producing animals. The Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) re-evaluated the risks to human health from hormone residues in bovine meat and meat products treated with six hormones for growth promotion. In 1999 this independent scientific advisory body concluded that no acceptable daily intake (ADI) could be established for any of these hormones. For oestradiol 17β SCVPH concluded that there is a substantial body of evidence suggesting that oestradiol 17β has to be considered as a complete carcinogen (exerts both tumor initiating and tumor promoting effects) and having examined additional scientific data, confirmed its opinion in 2000 and 2002[126]. Based on this scientific opinion, the Commission proposed to the European Parliament and to the Council to amend Directive 96/22/EC, prohibiting the use in stockfarming of certain substances having a hormonal or thyrostatic action, through the adoption of Directive 2003/74/EC[127]. As amended, Directive 96/22/EC confirms the prohibition of substances having a hormonal action for growth promotion in farm animals. Moreover, it drastically reduces the circumstances under which oestradiol 17β may be administered for other purposes to food producing animals. European Union has implemented a Directive, in 1996, for monitoring substances having a hormonal action and other substances in animals and animal products, namely Directive 96/23/EC, now repealed and replaced by Regulation EU

[126] https://ec.europa.eu/food/safety/chemical_safety/meat_hormones_en
[127] https://ec.europa.eu/food/safety/chemical_safety/meat_hormones_en

2017/625, enacted in order to monitor substances and residuals having an anabolic effect, unauthorized substances and veterinary drugs and contaminants. The key points of Directive 96/23/EC regarded national monitoring plans for the above-mentioned substances, EU countries have been assigning to a central public department or body the task of drawing up plans to monitor the detection of residues or substances in live animals, their excrement, tissue and animal products, animal feed and drinking water. Moreover, third country surveillance plans have been established with the Commission Decision 2004/432/CE, on the approval of residue monitoring plans submitted by third countries in accordance with Directive 96/23/EC.

3.2.2. European Regulatory Framework and International scenario

The approach European Union decided to adopt regarding hormones in meat and the Regulations thereof elicited international reactions, especially from the United States and Canada. The United States and Canada have indeed contested the prohibition of the use of hormones as growth promoters in food producing animals, and in 1997 a panel of the World Trade Organization ruled that the EU measure was not in line with the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), U.S.A. and Canada obtained an authorization by the WTO to impose trade sanctions on products from the EU, the value of which is USD 116,8 million per year[128]. The European Union appealed against this ruling and, in 1998, the WTO Appellate Body reversed most of the findings on the panel, whom only upheld the finding that prohibition of imports of meat from hormone-treated animals to the EU did not comply with the requirement that such a measure should be based on a relevant assessment on the risks to human health[129]. In reaction to these findings, the EU mandated a new assessment of the risks to human health from hormone residues in bovine meat and meat products treated with six hormones used for growth promotion. Subsequently the EU amended Directive 96/22/EC by adoption of Directive 2003/74/EC and thus implemented its international obligations in the context of WTO. The Directive enacted in 2003 legitimated Community restrictions on the usage of hormones in livestock farming and the ban on

[128] https://ec.europa.eu/food/safety/chemical_safety/meat_hormones_en
[129] S. CHARNOVITZ, Rethinking WTO Trade Sanctions, in The American Journal of International Law, 2001.

imports of meat treated with hormones, the European Union then notified WTO of the above-mentioned decision, immediately triggering a rejection from United States and Canada of the evidence provided by the Union and the maintenance of sanctions towards it. In 2008 a Special Group of the WTO has issued a ruling against the sanctions imposed by the U.S.A. and Canada on European exports, in retaliation for the restrictions applied by the EU on imports of meat treated with hormones[130]. The EU has been criticizing the fact that Canada and the United States of America unilaterally maintained these measures although the Union has, in the meantime, carried out a new scientific risk assessment, to demonstrate that hormone-treated meat presented unacceptable risks. The Special Group has noted that the U.S.A. and Canada have maintained retaliation measures, although the Union has adopted new rules on import of meat treated with hormones, in response to the previous accusations of these two countries. The Special Group has then agreed with the European Union on the fact that United States of America and Canada, maintaining the sanctions without consulting WTO, have breached the Regulatory framework of the WTO and therefore the U.S.A. would have needed to review its measures. In 2009, the EU and the U.S.A. concluded a Memorandum of Understanding, revised in 2014, to resolve the long-standing dispute within the World Trade Organization over the use of certain growth hormones in meat production[131]. Under the agreement the European Union had opened up a quota of 45,000 tonnes of beef not treated with hormones to suppliers complying with the requirements, including the United States. The European Union and the United States of America signed an agreement, fully compliant with WTO rules, in 2019 to revise the functioning of the quota for the import of hormone-free beef in the EU. The agreement, ending the "*tariff war*" on hormone-treated meat, stipulates that 35,000 tonnes, in a total of 40,000, of the aforementioned quota would henceforth be allocated on a time span of 7 years to the United States, whose meat will comply with strict quality and safety European standards.

130 https://www.ilpuntocoldiretti.it/attualita/carne-trattata-agli-ormoni-lomc-si-esprime-contro-le-ritorsioni-di-stati-uniti-e-canada/

131 https://ec.europa.eu/commission/presscorner/detail/it/IP_19_5010

3.2.3. Usage of hormones in United States of America

It is of interest of the dissertation, given the topics covered earlier, to review the United States of America's legislative approach toward the usage of hormones in food and specifically in meat production. In 1938 the Congress of United States of America passed a set of laws called Food, Drug and Cosmetic Act establishing that the authority responsible for the safety of food, drugs, medical devices and cosmetics was the U.S. Food and Drug Administration, FDA. The Food and Drug Administration is a federal agency of the Department of Health and Human Services and is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of U.S.A.'s food supply, cosmetics and products that emit radiation[132]. The FDA is, amongst others, responsible for the Regulation of animal drugs, from approval to the usage thereof. As a matter of fact, according to the Regulation of animal drugs, the term "drug" means articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United Stated or official National Formulary; articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles other than food intended to affect the structure or any function of the body of man or other animals, including also articles intended for use as a component of a drug[133]. FDA have established, according to The Generic Animal Drug and Patent Restoration Act of 1988, a publicly available list of approved animal drug products called the Green Book, which is updated every month. Among the drugs regulated and approved by the FDA, it is of interest of this dissertation to focus on hormones used for growth in animals. Since the 1950s the FDA has approved a number of steroid hormone drugs for use in beef cattle and sheep, including natural estrogen, progesterone, testosterone, and their synthetic versions, which increase the animals' growth rate and the efficiency by which they convert the fed they eat into meat[134]. The FDA approves these drugs only after information and/ or studies have shown that the food from the treated animals is safe for people to eat, and that the drugs do not harms the

[132] https://www.fda.gov/about-fda/what-we-do
[133] https://www.fda.gov/animal-veterinary/resources-you/fda-regulation-animal-drugs
[134] https://www.fda.gov/animal-veterinary/product-safety-information/steroid-hormone-implants-used-growth-food-producing-animals

treated animals or the environment. For each approved product, the FDA discloses all the details to the general public through a specific website, namely Freedom of Information Summary, in which all the information used to determine that the drug is safe for the treated animals, the animal products (edible tissues such as meat), are safe for humans to eat, and that the product is effective. These steroid hormone drugs are typically formulated as pellets or "implants" that are placed under the skin on the back side of the animal's ear, the implant dissolve under the skin, not requiring removal, and at slaughter the ears of treated animals are not used for human food. Using scientific data, FDA establishes the acceptable safe limits for hormones in meat, a safe level for human consumption is a level of drug that would be expected to have no harmful effect in humans based on extensive scientific study and review. The FDA report distinguishes "naturally-occurring hormones" and "synthetic hormones", the firsts are described as naturally produced throughout life in animals and are necessary for normal development growth and reproduction, for example estradiol, progesterone and testosterone. FDA, regarding naturally-occurring hormones, affirm that "people are not at risk from eating food from animals treated with these drugs because the amount of additional hormone following drug treatment is very small compared with the amount of natural hormones that are normally found in the meat of untreated animals and that are naturally produced in the human body"[135]. Synthetic Hormones are synthetic versions of natural hormones, such as trenbolone acetate and zeranol, and FDA requires information and/or toxicological testing in laboratory animals to determine safe levels, a level which would be expected to have no harmful effect in humans, in animals' edible tissues intended to final consumers. As seen, the approach United States of America adopt towards drugs, and specifically hormones, is completely diverse from the European one, the former approves new drugs and before the prohibition of a substance, it must be proved to be dangerous; the latter, according to the principle of precaution, admits a substance only if it is shown that it does not endanger health. The United States of America make extensive use of hormones in animal breeding because it allows to have economic advantages, at the apparent expense of population's health. Moreover, according to the FDA's Act called "Steroid hormone implants

[135] https://www.fda.gov/animal-veterinary/product-safety-information/steroid-hormone-implants-used-growth-food-producing-animals

used for growth in food-producing animals" there are several references to terms related to the usage of hormones such as "scientific studies", "studies shows that food from the treated animals is safe" and so on, but the bibliography, link or any other reference is not included. The FDA's report, in regards of both naturally-occurring and synthetic hormones, refers to "safe level" thereof in animals' edible tissues as "a level which *would be expected to* have no harmful effect in humans", posing the eventuality or not giving the certainty that this should necessarily happen. A world power country that changed, in 2020, its strict policy for imports of meat from the United States have been China, as is reported by the U.S. Meat Export Federation, because even if the zero-tolerance policy for growth hormones, apart from ractopamine[136], is not in force anymore, still China has approved the maximum residue limits of hormones in meat recognized by the Codex Alimentarius Commission, not allowing a hormone-blind import of meat[137]. China has previously had zero tolerance for any residue of growth hormones, which has restricted the amount of beef it could import from the United States where those drugs are widely used. China is the world's top importer of meat, making the U.S.' meat eligible for import signed a trade deal with respect to the past decades and a possible future scenario of import increase thereof[138].

3.2.4. Hormones in China

People's Republic of China policy regarding hormones usage is not included in an individual regulation, mentions thereof appear in the Regulation on Veterinary Drug Administration (2016) and in the Decision of the State Council on Amending the Regulations on Administration on animal feed and feed additives (2001). The Regulation on Veterinary Drug Administration indicates as responsible for compiling and publishing a catalogue of varieties of medicated feed additives permitted to be added in animal feeds the Administrative Department for Veterinary Medicine of the State Council [139]. In Article 41 of the aforementioned Regulation its clearly stated that: "It is prohibited to add in animal feed or

[136] Is an additive used in animal feed to grow them larger, leaner and to increase food conversion efficiency in livestock.
[137] https://www.usmef.org/international-markets/china/
[138] https://www.reuters.com/article/us-usa-china-trade-beef/china-proposes-standards-on-hormone-residues-in-beef-after-u-s-trade-deal-idUSKBN20Z31W
[139] https://www.fmprc.gov.cn/mfa_eng/wjb_663304/zzjg_663340/jks_665232/jkxw_665234/t209904.shtml

drinking water any hormonal drug or other prohibited drugs specified by the administrative department for veterinary medicine of the State Council, directly adding a bulk drug in animal feed or drinking water or directly administering such a drug to animals is prohibited[140]." Moreover, the same article mandates that no veterinary drug that might be added in animal feed with approval may be added therein before being made into medicated feed additives by a veterinary drug manufacturer; specifying that using drugs for human beings to animals is prohibited. Article 68 of the aforementioned Regulation establishes the pecuniary sanctions and punishments for the breach of law, hence in the case an entity adds in animal feed or drinking water, or administers, any hormonal drug or other prohibited drugs specified by the administrative department for veterinary medicine of the State Council. The latter source of rules, the Decision of the State Council on Amending the Regulations on Administration on animal feed and feed additives, specify in Article 19 that:" It is prohibited from adding any hormonal medicine or any other medicine the use of which is prohibited by the competent agricultural administrative department of the State Council to animal feed or drinking water for animals"[141]. It is unequivocal that the availability, in terms of quantity and quality, of information related to the usage of hormones in Chinese regulatory framework does not qualify as sufficient. The material appears to be scattered and basing the research on reliable sources such as the Food and Agriculture Organization of the United Nations legislation database is arduous since the majority of animals and livestock Regulations are only available in Chinese. Moreover, the ambiguity of the two provisions quoted above leaves ample room for interpretations that could jeopardize the validity of the laws. This section, dedicated to a general display of the regulatory frameworks of Europe, United States of America and China in regards of the usage of hormones in meat products and production, elucidates that the European legislation is the one that mostly protects consumers and their health, providing accurate scientific reports to support its approach to the matter. The next section of this dissertation would cover the comparison of the legislations regarding livestock law, animal protection during breeding, transportation, slaughter and culling in Europe, United States of America and China.

[140] https://www.fmprc.gov.cn/mfa_eng/wjb_663304/zzjg_663340/jks_665232/jkxw_665234/t209904.shtml
[141] http://www.lawinfochina.com/display.aspx?id=12961&lib=law

3.3. European Union protection of animals kept for farming purposes

European Union, with the Council Directive 98/58/EC, lays down general rules for the protection of animals kept for farming purposes, irrespective of the species, such as animals destined for the production of foodstuff, wool, skin or fur, or for other farming purposes, including fish, reptiles and amphibians. All the Member States of the European Union have ratified the European Convention for the Protection of animals kept for farming purposes, which disciplines the appropriate provision of housing for animals, feed and care to the needs of the animals[142]. European countries must adopt rules to guarantee that the owners or keepers of animals look after the welfare of their livestock, making sure that animals are not caused any unnecessary pain, suffering or injury. The rearing conditions relate to several aspects, particularly: the *staff* that look after animals have to be proportionate in number with respect to the livestock's magnitude and have to have appropriate professional skills and competence; the *inspections* on animals kept in husbandry systems have to be done at least once a day, making sure that the ill or injured animals are isolated and treated properly; *records* of any medical treatment done on animals have to be kept by the owner or keeper for at least three years; all the animals have to be granted the *freedom of movement* without unnecessary suffering or injury; the *buildings and accommodations* have to be made with easy-to-clean and disinfect materials, parameters such as air circulation, dust levels, temperature and humidity have to be kept in acceptable limits and the animals must not be kept in permanent darkness or constant exposure to artificial lighting; *automatic or mechanical equipment* essential for the health of the animals must be inspected at least once a day; pending the adoption of specific provisions for *mutilations*, national provisions in accordance with the Treaty apply thereof; rearing methods that cause suffering or injury must not be used unless their impact is minimal, brief or explicitly allowed by national authorities, emphasizing that no animal should be kept on a farm if it's harmful to its health or welfare.

[142] https://www.coe.int/it/web/conventions/full-list/-/conventions/treaty/087

3.3.1. Protection of animals at the time of the killing

The European Regulation EC 1099/2009 governs the protection of animals at the time of killing, it introduces welfare rules for the killing or slaughter of animals kept for the production of food and products such as fur and leather and covers killing of animals on farms in the context of disease control situations. The key points of the aforementioned underline that animals must be spared any avoidable pain, distress or suffering during their killing, as well as that businesses such as slaughterhouse operators, at all times of the year, must ensure that animals: are provided physical comfort and protection, kept clean, protected from injury and handled and housed taking into account normal behavior; do not show signs of avoidable pain or fear or abnormal behavior; do not suffer from prolonged withdrawal of feed or water; are protected from avoidable interaction with other animals that could harm their welfare. The Regulation provides details about restraining and stunning animals, different animals are treated with diverse methods, and it particularly specifies that stunned animals must remain unconscious until death, unless subject to particular methods prescribed by religious rites. The killing and related operations can only be carried out by persons with a certain level of competence, for instance: the handling and care of animals before they are restrained; the restraint of animals for purposes of stunning or killing; the stunning of animals and the assessment thereof; the shackling or hoisting or bleeding of live animals and the slaughtering in accordance with religious practices. The Regulation includes provision for slaughterhouses, there are detailed rules for the construction, the equipment and operations thereof, procedures must be constantly monitored by operators together with Animal Welfare Officers in order to ensure compliance, the banned methods of restraints include: suspending or hoisting conscious animals and mechanical clamping or tying of the legs or feet. All the additional details on methods and tools that have to be used for killing are comprised in the Annexes of the Regulation, as well as other specific measures not included in this dissertation. In regard of emergency killing or depopulation the Regulation provides specific rules and, also in that case, the owner has to comply thereof. The respect of the provisions of Regulation EC 1099/2009 is mandatory, in the case of non-compliance penalties must be effective, proportionate and dissuasive.

3.3.2. Animal welfare during transport

The last Regulation, namely Regulation EC 1/2005, treated in this section of the dissertation concerning European Union regards animal welfare during transportation. The aim thereof is to regulate the transport of live animals between European countries, including controls on animals entering or leaving the Community, while ensuring that any injury or unnecessary suffering to the animals is prevented. The Regulation establishes a set of mandatory requirements, in particular: transport arrangements must be made in advance to minimize the length of the journey and meet animals' needs; the animals must be fit to travel; the means of transport and loading and unloading facilities, must be designed, constructed, maintained and operated so as to avoid injury and suffering and ensure animals' safety; people handling the animals must be properly trained and may not use any form of violence; transportation to destination must take place without delay and involve regular checks on the animals' welfare; sufficient height and floor space must be available for the animals; water, feed and rest must be provided when needed; transporters must be authorized for journeys longer than 65km, provide detailed documentation on animals' origin and ownership, destination and journey time and ensure an attendant accompanies the animals, unless they are in containers with sufficient feed and water; national authorities must inspect and approve means of transportation before they are used; keepers and operators must ensure the rules and welfare standards are followed at the various points of departure, transfer of destination. Moreover, the Regulation specifies also that National authorities must require transporters to be based in a European country; demonstrate they have sufficient and appropriate staff and equipment as well as have no record of serious breaches of EU or national animal protection rules during the previous 3 years. Provisions for long journeys within and outside the borders of the European Union are also included. The transporters in long journeys between European countries and to destinations outside EU have to, according to the Regulation, have to carry the necessary documentation, authorization, satellite navigation and plans for the emergency as well as have to be ready to be checked by national authorities at the point of departure and on random basis thereafter. Considering that a general and not specific overview on European legislation in terms of livestock law has been provided, it is of interest of the dissertation to provide a broader perspective in regards of animal welfare legislation outlining a comparison among European,

United States' and Chinese point of view. Since the aim of this section of the dissertation is to provide a comparison, in terms of animal welfare legislation, among the European, United States' and Chinese legislative frameworks, it is important to introduce a means, namely the Animal Protection Index, that will be used for an impartial parallel of the respective legislations.

3.4. Animal Protection Index

API is an index of 50 countries worldwide, raking the commitment to protecting animals, assessing the animal welfare policy and legislation thereof, it has been made by a global organization named World Animal Protection active in the field since more than 50 years[143]. The API purposes are to put issues of protecting animals on the global agenda, establish benchmarks to improve the welfare of animals worldwide providing a dialogue platform for countries. The index ranks 50 countries according to animal welfare legislation and policy, the countries are assessed on 10 indicators and receive a letter grade ranging from A, the highest score, to G, the weakest score, for each indicator as well as an overall grade[144].

The 10 indicators used are:

1. Animal sentience is formally recognized in legislation
2. There are animal protection laws that prohibit causing animal suffering either by a deliberate act of cruelty or by a failure to act
3. There are laws that apply to animals used in farming including rearing, transport and slaughter
4. There are laws that apply to animals in captivity
5. Companion animals
6. Animals used for draught and recreation
7. There are laws that apply to animal used in scientific research
8. There are laws that apply to wild animals
9. The Government has assigned responsibility and accountability for improving animal protection at a high government level and has provided resources

[143] https://ec.europa.eu/food/sites/food/files/animals/docs/aw_platform_20190617_pres-12.pdf
[144] https://api.worldanimalprotection.org/methodology

10. The Government has incorporated the OIE's guiding principles for animal welfare and its animal welfare standards into policy and legislation.

3.5. Comparison of European, United States' and Chinese legislation of animal welfare

3.5.1. European Legislation of animal welfare

A preliminary clarification on the comparison is due, since the API index compares countries and the European Union is not definable as such, Italy has been chosen as the reference country to rank European Legislation, still all the mentions to Italian legislation would not be taken into consideration. Moreover, it is not interest of this dissertation to display the indicators of the API index, one by one, for each country, but instead provide a general overview of the respective legislations. In the previous section of this chapter, some EU legislations in regard of animal welfare have been analyzed, namely the Council Directive 98/58/EC, the Regulation 1099/2009/EC and the Regulation EC 1/2005. According to the API index, the wording of Council directive 98/58/ EC is general and does not consider species-specific needs, compared to other Directives; regarding Regulation 1099/2009/EC it is considered positive since it mandates stunning prior to slaughter and concerning Council Directive EC 1/2005, it is reputed positive since it states that the transport of animals over long journeys should be limited as far as possible. According to API index, apart from the already mentioned Regulations in regards of animal welfare, it is important to mention: Directive 1999/22/EC that establishes the requirements for keeping animals in zoos, including ensuring the well-being of animals, providing sufficient space for and environmental enrichment and avoidance of stress; Directive 2010/63/EU regarding the protection of animals used for scientific purposes, the European Convention on the Protection of Pets[145]. European Union recognizes, in the Lisbon Treaty, that animals are sentient beings and has created Reference Centers for Animal Welfare, which are meant to improve the enforcement of the legislation on animal welfare, disseminate good practices by studying methods for improving and assessing the welfare of animals[146]. European Union has created a Platform for Animal Welfare in order to increase businesses' voluntary

[145] https://api.worldanimalprotection.org/country/italy
[146] https://ec.europa.eu/food/animals/welfare/eu-ref-centre_en

commitments in the matter, promote welfare standards to valorize Union's products at global level and involve stakeholders[147]. The European Commission, in order to promote animal welfare standards, has developed several international activities with its partners to raise animal welfare awareness and to promote European model and principles worldwide. In particular the international activities are divided in three different levels of action according to partnerships: *Multilateral activities* are pursued through cooperation of World Organization for Animal Health (OIE) and the Food and Agriculture Organization of the United Nations (FAO), with the aim of supporting the dissemination of EU Standards in non-European countries; *Bilateral activities* with non-European commercial partners aiming at the inclusion of animal welfare clauses in trade agreements; Training and technical assistance to improve knowledge and support local workers[148].

3.5.1. United States of America legislation of animal welfare

The United States of America has a few key pieces of animal welfare legislation applicable at the federal level: The Animal Welfare Act, 1966, sets general standards for the humane care and treatment that must be provided for certain animals bred for commercial sale, exhibited to the public, used in biomedical research, or transported commercially; The Horse Protection Act, 1970, prohibits sored horses from participating in shows, exhibitions, sales or auctions; the Humane Slaughter Act, 1978, mandates humane slaughter for certain species; the Preventing Animal Cruelty and Torture Act (PACT) establishes a federal crime to engage in animal crushing; there is federal legislation to protect farm animals, with the exception of poultry and fish, during transport and slaughter[149]. In regards of the Humane Slaughter Act, it requires cattle, calves, horses, mules, sheep and swine to be handled and slaughtered in a humane way by rendering the animals "insensible to pain by a single blow or gunshot or an electrical, chemical or other means that is rapid and effective, before being shackled, hoisted, thrown, cast or cut, with exemptions for religious slaughter." Most US animal welfare laws are enacted at the state level, in this regards it is worth to mention that California passed a Proposition in 2018, considered one of the most progressive pieces of

[147] https://ec.europa.eu/food/animals/welfare/eu-platform-animal-welfare_en
[148] https://ec.europa.eu/food/animals/welfare/international-activities_en
[149] https://api.worldanimalprotection.org/country/usa

animal welfare legislation in the world, that specifies minimum space requirements for animals raised for food, effectively banning cages for laying hens, sow stalls and crates foe calves. Moreover, California implemented the Circus Cruelty Prevention Act, outlawing the use of wild animals in circuses; it became the first state to prohibit the sale of fur products (entering into force in 2023); passed a legislation prohibiting pet stores from sourcing animals from commercial breeders. Another positive example of legislation has been implemented in Massachusetts, with the Protect Animal Welfare Act and Safety: the first in 2014 establishing an animal welfare task force and the second, PAWS II, aiming at reporting animal cruelty to law enforcement agencies, preventing automatic euthanasia of animals confiscated from the animal fighting industry and modernizing prohibitions against animal sexual abuse. Focusing the attention to the US' federal law, API asserts that there is a lack of federal protection for animals: the Animal Welfare Act does not apply to farm animals, birds, rats and mice used for research; there is not a federal legislation protecting farm animals during the rearing phase; the Humane Slaughter Act does not apply to poultry or fish; the access to information related to the number of animals kept by research laboratories, companies, zoos, circuses and animal transporters, and whether those animals are being treated humanely in accordance with Animal Welfare Act, is not public[150]. The US Department of Agriculture is responsible to promulgate laws and regulations pertaining animal welfare on a limited number of issues, its subsidiary, the Animal Plant Health Inspection Service (APHIS) is responsible for enforcing the Animal Welfare Act, implemented by the APHIS Animal Care and Veterinary Units. It is important to mention that, beyond legislation, most livestock production industries have developed and implemented science-based animal care guidelines in response to consumer concerns with regard to animal welfare, assurances that animals are being raised according to these guidelines are provided through voluntary third-party audits rather than legislation. API in conclusion, basing on an extensive body of scientific evidence, recommends to the US Government to define in legislation, at minimum, all vertebrates, cephalopods[151] and decapod crustaceans[152] as sentient.

[150] https://api.worldanimalprotection.org/country/usa
[151] Is any member of molluscan class, such as squid, octopus or nautilus.
[152] Any crustacean, such as lobsters or crabs.

3.5.2. Chinese legislation of animal welfare

An overall piece of legislation solely focused on animal welfare protection is still missing, the main relevant legislations for animal welfare in China are the Animal Husbandry Law of the People's Republic of China, amended in 2015, which is only applicable to livestock and poultry production standardization, and the Law of the People's Republic of China on the Protection of Wildlife, which focuses on conserving endangered wildlife endangered species[153]. Animal sentience is not formally recognized in Chinese legislation. The Husbandry Law contains minimal welfare requirements, mandating that livestock and poultry farms provide suitable conditions for the breeding, survival and growth of the animals. Animal cruelty is not banned by a stand-alone law, rather animals receive limited protection in terms of being considered a food source, through penalties related to property damage or food poisoning. The Wildlife Protection Law allows for the commercial breeding of endangered wildlife, through a permit system, since the law focuses on species protection, individual wild animals may still be consumed and traded. Several categories of animals in China still lack legal protection, such as stray animals, draught animals and those used for recreational purposes, moreover it is still compulsory for some imported products to be tested on animals before being given licenses for sale in the country. In regards of laws against animal suffering, the first comprehensive animal welfare legislation, the animal protection law of the People's Republic of China was drafted in September 2009 but was never passed into law or enacted. Article 29 of Regulations for the Administration of Laboratorial Animals requires that those involved in laboratory animal work must love and protect animals and shall not disrespect or abuse thereof; Article 2 of a Guidance for the aforementioned Regulation provides that kindness to animals means to take effective measures to avoid unnecessary harm, hunger, discomfort, fear, torture, disease or pain during the process of rearing or using laboratory animals. As concerns protection of animals used in farming, the Government has enacted some legislation regarding aspects of farm animal rearing, transport and slaughter, which is based on food safety concerns, but which contains elements relevant to animal welfare protection. The Chinese Veterinary Medical Association, under instruction by the Ministry of

[153] https://api.worldanimalprotection.org/country/china

Agriculture, is drafting non-binding guidelines on the welfare of various categories of animals, including farm animals and will include infrastructure, feeding environment and health; these guidelines have been approved by the appointed National Committee but are still under review by the Ministry of Agriculture. The Ministry of Agriculture issued a series of supplementing documents on slaughter, encouraging stunning before slaughter even if stunning is not required.There is not a law to ban animal fights. In relation to the protection of wild animals' welfare, China reformed in 2017 the Protection of Wildlife, the legislation is concerned with conservation of endangered species and with the use of wildlife as natural resources for humans, rather than with the welfare of individual animals[154]. In early 2020, to combat the spread of Covid-19, the Law of the People's Republic of China on the Protection of Wildlife and other relevant laws were amended to strictly prohibit the hunting, trade, transport and captive-breeding of terrestrial wildlife for the purpose of consumption. As is evident from the display of three different Regulatory frameworks related to animal welfare, European and United States' ones are far more advanced compared to the Chinese. From a human point of view, the lack of legislations to protect animals in China creates a feeling of uneasiness and sorrow, accompanied by a tendency to condemn the approach the Chinese have towards the issue. It not the intention of this dissertation to excuse or to judge Chinese approach, but to underline that the animal welfare is also somehow related to culture and tradition.

3.5.3. Wet markets in China

The definition of wet market is: "a market for the sale of fresh meat, fish, vegetables, seafood, herbs and spices", the traditional wet markets sell meat that is freshly slaughtered[155].Those markets are defined "wet" sometimes referring to their difference compared to traditional markets or sometimes because the ice used to preserve the fresh food melts and the floors are usually humid. Wet markets are open-air and represent an everyday destination for many Chinese people, constituting an important routine and moment for social life. Some wet markets stock live fish and poultry, even if many Chinese provinces have banned the sale

[154] https://api.worldanimalprotection.org/country/china
[155] https://www.oxfordlearnersdictionaries.com/definition/english/wet-market

thereof after avian flu outbreaks in the late 90s, still the target for health experts are markets in which wildlife is sold. Numerous infectious diseases, including HIV and Ebola, have their origins in close contact between humans and live animals, especially if animals are kept in dirty conditions, like market cages, and can easily spread to sellers or customers through body fluids, this appears to be the case for Covid-19[156]. The virus is thought to have originated in bats, which may have passed to an intermediary species that then passed it to humans at the Huanan market[157]. The Seafood Wholesale Market of Wuhan was selling wild animals like wolf pups, snakes, bamboo rats, porcupines, badgers and many others, moreover a stall thereof was offering in its menu online around a hundred varieties of live animals ranging from foxes to peacocks to masked palm civets. Demands by United States' officials and by many other authorities in the globe in January 2020 have been raised to shut down the wet markets, not considering that they represent fundamental sources of food for many Chinese. The Chinese Authorities have placed a temporary ban on the sale of wild animals for consumption and closed the Wuhan market in January 2020, however some worrying reports have been published documenting that other markets in the southern China have begun to reopen, selling bats, lizards, cats, dogs and many other animals[158]. The issue of cultural differences poses a barrier to properly and impartially assess the problem. For Chinese cultural reasons in fact, in many regions, people pretend to see the specific animals they are buying be slaughtered in front of them, so that they know that they are receiving the products they pay for. Banning the consumption of wild meat in China affects also many aspects of Chinese tradition, for example traditional medicine is extensively based on wild animal products. Consuming wild animals' meat has also sociological implications for Chinese, since they view food as their primary need, starving is still a big problem, even if a person has not economic problems, eating rare animals or organs has become a measure of identity. It is crucial to refer that breeding and selling wild animals was, until recent times, promoted by the Chinese government as an essential tool for rural development and poverty alleviation. China's wild-meat industry is valued at $7.1 billion industry, the value of the

[156] https://www.weforum.org/agenda/2020/04/china-wet-markets-covid19-coronavirus-explained/
[157] https://www.businessinsider.com/china-bans-wildlife-trade-consumption-coronavirus-2020-2?IR=T
[158] https://www.weforum.org/agenda/2020/04/china-wet-markets-covid19-coronavirus-explained/

larger wildlife-farming industry, in 2017, accounted for $74 billion[159]. Since the Covid-19 outbreak, Chinese authorities have shut down 20,000 farms raising peacocks, civet cats, porcupines, ostriches and wild geese, many experts support this approach to help prevent the spread of viruses. Wildlife trade and consumption represents a menace to animals and a serious public-health risk because the physical propinquity of buyers and sellers to live and dead animals, especially in wet markets, creates a nurturing environment for zoonotic diseases.

[159] https://www.businessinsider.com/china-bans-wildlife-trade-consumption-coronavirus-2020-2?IR=T

Chapter IV

Intolerant personas or bearers of pathologies and their tutelage

"A man is what he eats" a philosopher named Feuerbach said. Not every person has the privilege to eat, nor to eat what he would crave for. Many people are affected by allergies, intolerances or pathologies that restrict the range of their edible aliments. It is an important issue to take into consideration because of its direct relationship to health and welfare of human beings, this chapter of the dissertation would analyze the issue of intolerant personas or bearers of pathologies and their tutelage.

4.1. Intolerant persona or bearer of pathologies and its tutelage

The fact that some population groups suffer from pathologies, allergies or intolerances associated with diverse types of aliments require that specific rules to assure them a proper protection are implemented, because of their vulnerability with respect to the rest of the population. The instrument that allows the protection for vulnerable personas to materialize is legislation, the dissertation would elaborate on the matter after having provided a general overview of some of the pathologies involved. Lactose intolerance consists on the inability to digest lactose, a type of sugar found in milk and other dairy products, this differs from the allergy insofar as does not involve the immune system[160]. Celiac disease is an autoimmune disorder that occurs in genetically predisposed people where the ingestion of gluten leads to an immune response that attacks the small intestine, resulting in a damage of the villi[161] which are responsible of nutrients absorption, thus if left untreated it can lead to serious health problems[162]. Diabetes is a chronic, metabolic disease characterized by elevated levels of blood glucose, a sugar, which leads over time to serious damage to the heart, blood vessels, kidneys and nerves [163]. Obesity is a chronic, relapsing, multifactorial, neurobehavioral disease, wherein an increase in body fat promotes adipose tissue dysfunction and abnormal

[160] https://www.medicinenet.com/common_food_allergy_triggers_pictures_slideshow/article.htm
[161] Characteristic formations of the mucosa of the small intestine, formed by small protrusions, thanks to their presence the surface of the mucosa fulfills the function of intestinal absorption.
[162] https://celiac.org/about-celiac-disease/what-is-celiac-disease/
[163] https://www.who.int/health-topics/diabetes#tab=tab_1

fat mass physical forces, resulting in adverse metabolic, biomechanical, and psychosocial health consequences [164]. As aforementioned, some among the totality, of vulnerable personas' pathologies have been briefly explained, however it is significant to mention, as an introduction to the European legislation, also other general categories of vulnerable groups of population, such as infants and young children and people in need of food for special medical purposes. The European Union has adopted a Regulation, namely Regulation EU 609/2013, in order to protect specific vulnerable groups of consumers, infants and young children, people with specific medical conditions and people undertaking energy-restricted diets to lose weight, by regulating the content and the marketing of foods products specifically created for and marketed to them. The protection thereof is ensured through strict provisions on foods, compositional and labelling rules and by means of the simplification of the regulatory framework, excluding contradictory laws [165]. The EU Regulation 609/2013 has strengthened provisions on foods for vulnerable population groups, such as infants and young children, overweight or obese people and people with specific medical conditions, and delegated responsibility to the European Commission to adopt through delegated acts, specific compositional and labelling rules for: infant and follow-on formulae, processed cereal-based foods and other baby foods, special medical purposes and total diet replacement for weight control. In order to be precise, gluten-free and very low gluten foods have been furtherly governed by EU Regulation 1169/2011, on the provision of food information to consumers, and meal replacement for weight control by EC Regulation 1924/2006. It is of interest of the dissertation to briefly review each of the aforementioned food for specific groups legislation and then to focus on food information law and subsequently on the regulations regarding allergens.

4.1.1. Food for infants and young children

Infants are children under the age of 12 months while young children are babies aged between 1 and 3 years, they have specific nutritional requirements in order to grow healthy, in fact specific formulations are peculiar for each stage of growth*: infant formulae* are used

[164] https://obesitymedicine.org/definition-of-obesity/
[165] https://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food_en

during the first months of life and satisfy by themselves the nutritional requirements; *follow-on formulae* are used when appropriate complementary feeding is introduced and constitute the principal liquid element in a progressively diversified diet; *processed cereal baby-food and baby foods* is food intended for infants when they are weaned and for young children as a supplement to their diet and/ or for their progressive adaptation to ordinary food[166]. The infant and follow-on formulae are currently covered by Commission Directive 2006/141/ EC, which establishes the requirements for the composition, including energy, proteins, vitamins, minerals and more, as well as labelling of the formulae. According to the aforementioned Directive, infant and follow-on formulae have to respect European legislation on hygiene, the use of food additives, the presence of contaminants and the use of contact materials. EU Regulation 2016/127, in force from 2020, is meant to supplement EU Regulation 609/2013 in regards of compositional and information requirements for formulae and child feeding. Infant and follow-on formulae must not contain detectable levels of pesticide residues, not more than 0.01 milligrams per kilo, and very toxic pesticides are prohibited in their production, according to EU Regulation 609/2013.

4.1.2. Food for weight reduction

Foods for weight reduction are either total diet replacement products for weight control or meal replacement products for weight control, the compositional and labelling requirements for foods used in energy restricted diets are governed by Commission Directive 96/8/EC and have been adapted to EC Regulation 1924/2006[167]. The compositional criteria regard energy, protein and fat quality and quantity, fibre, vitamins and minerals. The Regulation on food for weight reduction sets comprehensive compositional and labelling rules for diet replacing products for weight control, requires the Commission, through delegated act, to specify compositional rules for total diet replacement products for weight control.

[166] https://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/children_en
[167] https://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/weight_reduction_en

4.1.3. Food for special medical purposes

The rules for the composition and labelling of foods intended for dietary management of individuals affected by disorders, diseases or medical conditions have been established by Directive 1996/21/EC and are now included in EU Regulation 609/2013. These foods are intended for the exclusive or partial feeding of people whose nutritional requirements cannot be met by normal foods, the Directive establishes the guidelines for composition and level of vitamins and minerals thereof[168]. The new Regulation, namely EU Regulation 609/2013, in terms of food for special medical purposes sets generic composition and labelling rules; requires the Commission to adopt, through delegated act, specific compositional and labelling rules for foods for special medical purposes; prohibits to make nutrition and health claims thereof; extends to food for special medical purposes intended for infants all rules on labelling, presentation, advertising, limitation of pesticides and marketing applicable to infant formulae in order to avoid misclassification of products.

4.1.4. Gluten-free food

The Commission Implementing Regulation EU 828/2014 defines harmonized conditions under which foods might be labelled as "gluten-free" or" very-low gluten", it applies also to non-pre-packed foods such as the ones served in restaurants and sets the guidelines for operators on how they should inform intolerant consumers about the difference between foods naturally free of gluten and products specially formulated for them[169]. Before the implementation of EU Regulation 609/2013, the labelling and composition of people suitable for people intolerant to gluten was regulated by EC Commission Regulation 41/2009. The new Regulation on food for specific groups from 2016 onwards, namely the EU Regulation 609/2013, required the Commission to transfer its rules under the framework of EU Regulation 1169/2011, on the provision of food information to consumers. EU Regulation 1169/2011 lays down rules requiring the mandatory labelling for all foods of ingredients such as gluten-containing ingredients. In order to ensure clarity and consistency, European Union decided to incorporate all the rules applying to gluten in the same piece of legislation,

[168] https://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/medical_en
[169] https://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/gluten_en

through EU Regulation 609/2013 the Union incorporated in the EU Regulation 1169/2011 the framework of rules related to information on the absence of gluten in food.

4.1.5. Food for diabetics

In 2008 the European Commission produced a report on the desirability of special provisions for foods intended for people suffering from diabetes, the report concluded that there was no scientific basis on which to produce specific EU legislation covering compositional requirement for this group of foods, food for diabetics have thus been excluded from the scope of EU Regulation 609/2013[170].

4.2. Provision of food information to consumers

Vulnerable consumers are defended by the European legislation, as is clear from the vast framework of laws described formerly, devoted to each category of bearer of pathologies, infants and young children as well as intolerant personas. The legislation on the food devoted to specific groups of population is strictly correlated to the discipline of provision of food information to consumers, since the information itself is one of the most important means used to allow consumers' conscious and careful choices. In regard of the provision of food information to consumer, the European Union has adopted EU Regulation 1169/2011.

The dissertation, in Chapter II, has analyzed EU Regulation 1169/2011 in terms of: its range of application, the label, its aims of ensuring consumer protection while assuring free movement of foodstuff in the Union, the division of responsibility between The EU and Member States, the different regimes of information depending on food type and their stage along the supply chain, general requirements for the provision of food information, fair information practices and mandatory and voluntary information. It is still interesting in this context to recall EU Regulation 1169/2011 in order to analyze its impact with respect to allergens, ingredients and substances that cause allergies or intolerances and requirements for restaurants.

[170] https://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/diabetics_en

4.3. Relationship between EU and Member States on norms on allergens

It is of interest of the dissertation to recall the relationship between the EU and Member States, with a focus on Italy, according to EU Regulation 1169/2011, on the norms related to allergens. In this context, the Union clarified that the majority of food-allergy incidents can be traced back to non-prepacked food. Non-prepacked food means foods offered for sale to the final consumer or mass caterers without pre-packaging or at the place of sale at consumers' request or prepared for the direct sale. The division of responsibilities is concretized through this aspect: the scope of greater intervention of each Member States' national legislator concerns non-prepacked food, except for the provision of food information regarding allergens, which is mandatory according to European law and has to be always provided, even if according to national level modes.

4.3.1. Italian norms on allergens

In the case of the non-prepacked foods, European law shall be without prejudice to national competence, except for guarantees on allergen information and requirements on fair information[171]. It is of interest to review the Italian legislation on the issue. The Italian legislative provisions in terms of non-prepacked food are contained in Article 19 (8) of Legislative Decree 231/2017, specifically stating that "in the case of non-prepacked aliments […] the indication of the substances or products referred to in the Annex II of EU Regulation 1169/2011 is mandatory; this claim should be provided, in a way so that it can be traced back to each food, before it is served to the final consumer by the mass caterers and must be placed on the menu or registry or the equivalent system, even digital, so that it is well kept in view. In the case of adoption of digital systems, the provided information must also appear in written documentation, easily accessible for both the competent authority and the final consumer. Alternatively, a notice on the possible presence of the same substances or products that might cause allergies or intolerances on the menu may be given, on the register or on a special sign referring to request the necessary information to the staff, information must result from written documentation and easily available for both the competent authority and for the final consumer.

[171] D. PISANIELLO, op. cit., p.297.

4.3.2. Ingredients and substances that cause allergies or intolerances

An allergen is as any substance capable of causing allergy, their presence on aliments together with the ingredients and substances that cause allergies or intolerances are governed by EU Regulation 1169/2011. According to the Regulation on the provision of food information to consumers, it is mandatory to indicate the presence of "any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food still present in the finished product, even if in an altered form". Detailed provisions concerning this information on pre-packaged products are contained in article 21 of the aforementioned Regulation, the article regards the labelling of certain substances or products causing allergies or intolerances and mandates that such substances shall be indicated in the list of ingredients, with a clear reference to the name of the substance or product listed in Annex II; the name of the substance in question shall be emphasized through a typeset, by means of the font or style or background color, that clearly distinguishes it from the rest of ingredients; in the absence of a list of ingredients, the indication of the particulars shall comprise the word 'contains' followed by the name of the substance or product as listed in Annex II, it shall not be required in the cases where the name of the food clearly refers to the substance or product concerned; where several ingredients or processing aids of a food originate from a single substance or product listed in Annex II, the labelling shall make it clear for each ingredient or processing aid concerned. Certain ingredients or other substances which, when used in the production of food, remain in food, may cause allergies or intolerances in certain persons or groups of persons, thereby constituting a danger to wellbeing with respect to which that high level of protection of health, provided for in European legislation, compels to act. One of the stated objectives pursued by the European legislator when drawing up EU Regulation 1169/2011 was to strengthen transparency, and therefore, safety in food consumption of people with food allergies or intolerances[172]. The importance of protecting the health of every living being combined with the increase in scientific knowledge, and economic interests related to the food allergens, has led to a significant evolution of

[172]D. PISANIELLO, op. cit., p.320.

European legal discipline and not only. The starting point of the EU Regulation 1169/2011 has been the finding, previously mentioned, that most of the problems arising from food allergies originate in non-prepacked foods and that, therefore, information on potential allergens should always be provided to the consumer. The EU Regulation 1169/2011 clearly states that the main objective of legal provision on allergenic ingredients is to provide information on the presence of food additives, processing aids and other substances or products with a scientifically proven allergenic or intolerance effect to consumers, in order to enable them, particularly those suffering from a food allergy or intolerance, to make informed choices which are safe for them. In this regard, the aforementioned Regulation establishes that information on potential allergens is also mandatory for foods offered for sale to the final consumer or to mass caterers without prepackaging, or where foods are packed on the sales premises at the consumer's request or prepacked for direct sale. For the purposes of law enforcement laid down in Community legislation, it is not necessary for the Member States to lay down detailed provisions, as national intervention on this point is optional. Having made this introduction to the rationale of EU Regulation 1169/2011, it is necessary to premise that for the purposes of the obligation to inform, descending from rules of Articles 21 and 44, 'allergen' means any of the substances listed in Annex II of the Regulation, list that is systematically analyzed and, if necessary, updated taking into account scientific progress and the latest technical knowledge by the Commission. The clarification now provided on the notion of allergen should help to correctly understand the use of indications on the label such as "may contain traces of" or "product made in a production line that also handles" or similar, widely used on food products in the world: these are voluntary indications intended to limit exposure to liability risk of damage from defective product[173].

4.3.3. Information requirements for mass caterers

A further innovation introduced by the EU Regulation 1169/2011 was the clear introduction of the food sale/supply phase by mass caterer industry in the scope of its application. It is worth a mention that the Directive in force before the aforementioned, namely the Directive 2000/13/CE, applied to "pre-packed foodstuff to be delivered to the final consumer or to

[173]D. PISANIELLO, op. cit., p.321.

restaurants, hospitals, canteens and other similar mass caterers", thus making mass caterers equal to the figure of the final consumer and, in practice, avoiding a series of information obligations of this operators towards the consumer. It is important to mention that EU Regulation 1169/2011 provides for the definition of mass caterers, it states as such:" means any establishment, including a vehicle or a fixed mobile stall, such as restaurants, canteens, schools, hospitals and catering enterprises in which, in the course of a business, food is prepared to be ready for consumption by the final consumer". According to EU Regulation 1169/2011, the opposite principle is stated, namely that products supplied by mass caterers are subject to the regulation of the supply of food information to consumers, as far as applicable.

4.4. Relationship between intolerant persona and the right to health

The fourth chapter of this dissertation shed a light on the regulatory framework, adopted at European level, in regards of the definition and protection of vulnerable personas as well as on the evolution of the tutelage thereof. The interest is now to treat the relationship between the intolerant persona and the right to health, preceded by a mention to the general notion of consumer "vulnerability". The concept of vulnerability is impossible to define through preset and unquestionable parameters involving a multiplicity of factors, which already considered individually can affect the life and choices of each individual, moreover these elements, interacting with each other, create a range of vulnerability situations with peculiar characteristics not attributable to the singleness[174]. Vulnerability, in this sense, is in a "fluid state" since it is difficult to frame in a single and preset scheme, consumerist discipline has flattened the notion of weak consumer into impersonal subjective characteristics that usually are not capable to reflect the problems of the individual. Beyond the clear requirements of the legislator to issue clear and rigid definitions, the concept of weak consumer is therefore extremely mutable as it is directly dependent on a multiplicity of factors that modulate the weakness of the consumer, making him, in some cases, in major need of protection with respect to the "average consumer". In most cases, although in the form of soft law intervention, there is a widespread enhancement of certain subjective

[174] G. BERTI DE MARINIS, La tutela del cliente 'vulnerabile', in Banca, borsa, tit. cred., 2018, I, pag. 653.

factors, such as age, health, social and cultural situation, economic capacity, income, computer literacy, financial education and sudden changes in the consumers' life, leading to market awareness on particular subjective situations of discomfort that place a "weak consumer" within the subcategory of "vulnerable consumer", all of this with the main aim of increasing consumer protection[175]. The availability of products that tend to be rigidly modulated on the figure of the "perfect consumer", also called one-size-fits-all, are difficult to adapt to those most exposed to factors of vulnerability, vice versa the presence of flexible products made with a tailor fit approach would facilitate all the interested parties. The vulnerable persona if is protected by the law from a paternalistic and sciolistic perspective, receives a conceptual protection but that has no a practical, tangible and substantial advantage for the subject itself. It would be preferable to adopt a tailor fit regulatory approach, as it could lead to real benefits for consumers, peculiarly for the vulnerable category. The agri-food market, however, is characterized by critical issues that have inevitably led the European legislator to outline the vulnerable persona's protection as the protection of its own fundamental property, that is the right to health. The most important "tool" used for the protection of vulnerable consumers is the information, remembering that the information in the agri-food market cannot be separated from the label. Hence the tangible means in which legislation is embodied, and through which information is disseminated, is the label. The label is a source of information, it should not only provide basic notions but instead should offer as much detail as possible, with a dynamic method. This latest prospective would be possibly strengthened by European Member States in the near future through an increase of adoption of technologies that would conceivably permit to do so. The general problem related to information provision, and in turn to labelling, if transposed in the peculiar case of intolerant personas results, in terms of significance, even greater. The difficulty appears to be lying in the approach to the problem, if the tutelage is generic, one-size-fits-all, and the same information is provided to all the consumers in order to protect them as such, regardless of their health problems or intolerances, then the approach to the problem could be defined as exclusionary. Consumers face asymmetries of information in the act of buying foodstuff, moreover it is important to make a distinction

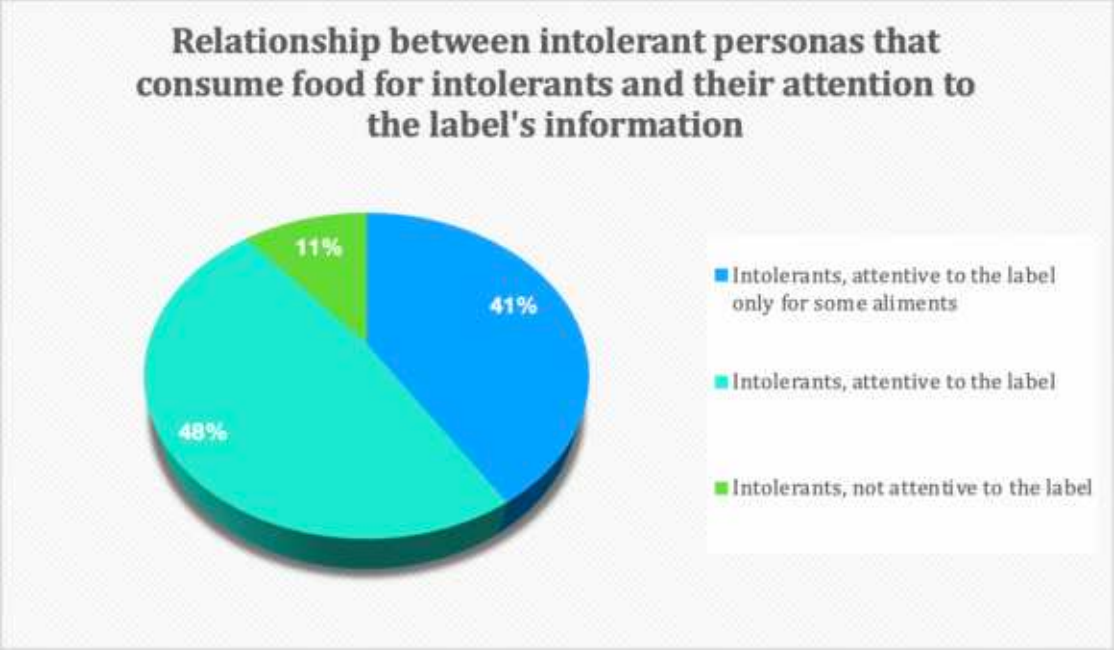
[175] G. BERTI DE MARINIS, op. cit., p.654.

between passive and active consumers. Passive consumers are usually not really concerned on the information to them provided, usually are the ones that do not have any health problem related to aliments, vice versa active consumers are proactive in their grocery shopping, often also in relation to specific needs of theirs such as intolerances. Active consumers often tend to seek for information about foodstuff not only in the label but also use tools such as queries on the internet, QR codes or toll-free numbers. Therefore, if the information does not take the connotation of one-size-fits-all but instead is shaped in a tool tailored to the consumer who is really vulnerable, because of intolerances or issues of other nature, then also the difficulty hidden in the approach to the general problem of information provision mitigates.

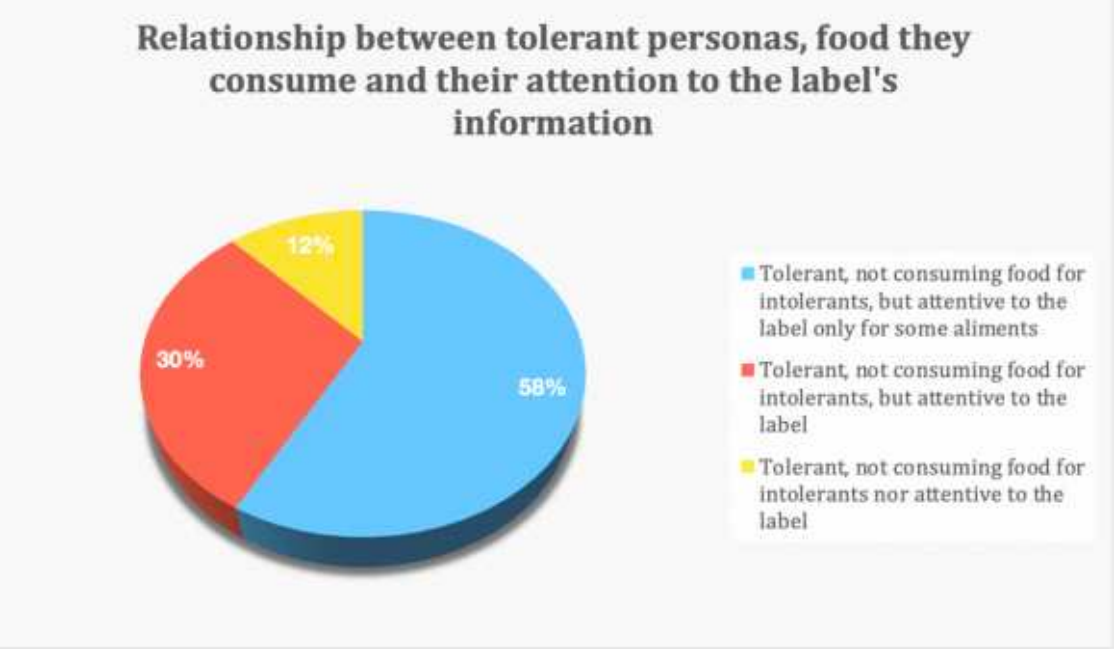
4.5. Survey

Willing to examine the practical aspects and to assess how the public takes into consideration the aforementioned topics, it will be presented survey with a sample of 285 people in the following section of the dissertation. The survey regards the labelling and its relationship with information of aliments, as well as the importance of food quality and origin, and consumers habits in grocery shopping. The survey's core research question has been the assessment of the importance of the label according to the point of view of both intolerant and not consumers. The survey's sample is composed in terms of respondents' gender by 72,2% of women and 27,8% man. In relation to the age groups, the sample has been divided in six age categories, namely: 10-25 years, 25-35 years, 35-45 years, 45-55 years, 55-65 years and over 65 years. The majority of respondents have been registered in the 10-25 years category accounting for 31,4% answers of the total, followed by 20,8% of the 45-55 age bracket. The over 65 accounted, in terms of answers, only for the 3,9%, and the remaining groups submitted 14% of answers each. The survey has mainly been conducted in Italy, the 96% of the respondents come from many different regions of Italy and the left 4% from other Nations, also outside the European Union, such as Mexico and United States. The grocery shopping habits of the sample indicate that 21,1% of consumers buy everything at the supermarket, 30,7% tries to buy as much as possible at km0, 34,6% declared to decide whether to shop at the supermarket or km0 according to the amount of time at their disposal and the remaining 13,6% of respondents have been neutral declaring

just “depend”. The aforementioned data shows that the impact of short food supply-chains is relevant in shopping habits of the sample, however the amount of time at their disposal is still an important variable that affects the capability of increasing the consumption of KM0 foodstuff. In regards of the attention of buying Italian products, 29,7% of the interviewed declared that is maximum. The sum of all the answers above the average up to the maximum level of importance account for 92,2% of the total, consequently Italian agri-food products are perceived as pretty valuable. The importance of food quality, according to the respondents, is fundamental, since 54,8% registered the highest grade of importance for it. Moreover, as regards the quality, the 97,9 % of the surveyed submitted grades above the average. The question related to whether the persona is intolerant or allergic to certain aliments showed that 188 personas, equal to 67%, of the sample are not. The intolerant or allergic are 92 and account for 33% of the total. It is now interest of the dissertation to investigate the relationship between the personas, whether they consume aliments for intolerants or not and whether they pay attention to the information in the label before buying a food. In order to do so the cross-sectional data of three different questions of the summary have been merged for each persona, the result is shown here below.



The graph presents the relationship between intolerants, their habits and whether they are attentive to the label. The intolerants that eat food specifically for them account for 63 personas, out of which 48% are attentive to the label, 11% are not attentive and the remaining 41% are attentive to the label just for some aliments. It appears that the described above segment thoughtfully read the information before buying a product and evaluate the related details. The following chart displays instead the relationship between the tolerant personas, not consuming food for intolerants, namely 160 personas, and the attention they pay in reading the label before a purchase.



Tolerant users that are not attentive to the information in the label account for 12% of the group's total, the attentive ones sum up to 30% and the ones that pay attention only for some aliments are the remaining 58%. It is clear that for this segment of the sample, not affected by health problems or intolerances, the information reported on the label is relevant only for a part of the surveyed. The empirical evidence, as far as this specimen is concerned, demonstrate that vulnerable consumers are inclined towards the research of details in the label with a proactive attitude, whereas the rest of the sample providers are mainly inattentive. The survey further investigated the attitude of consumers in the search for information in the context of the use of digital technologies. As regards the relationship

involving respondents' research of information related to the aliments with the usage of technology, the 36,3% of the sample looked for additional information on the internet or contacting toll-free numbers, while 63,8% have never done so. Among the just-mentioned 36,3% of information seekers, the 44,7% are intolerants. Another technology, used in the agri-food market, that the survey has considered has been the QR code. Precisely, the 62,9% of the sample has never scanned a label's QR code, just the 37,1% of the people surveyed did it, therefore, for what it can be deduced from this result, there is a wide margin of improvement in the adoption of technologies to expand the information provision in the label dynamically.

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