Università
Ca'Foscari
Venezia

Master's Degree

in Management

Final Thesis

The Universalisation of Food Law in Operator Responsibilities and Innovation

Towards the Protection of the Food Producer and Consumer

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Matricolation number
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Academic Year
2019 / 2020

SUMMARY

CHAPTER 1. THE FUNDAMENTAL PRINCIPLES OF FOOD LAW AND THE NEED FOR HARMONIZATION

1.1 The spread, necessity and universalisation of Food Law

The exponential enlargement of markets, the progressive spreading of food mass consumption and a more and more standardized worldwide production[1] are just three of the many reasons why the nowadays world, especially the one side represented by food, is crossed by many fears: if on the one end sharing values, cultures and habits can enlarge each own human luggage, on the other side it certainly thrills to be exposed to such different customs regarding the most ancient and universal of the humankind routine practices: eating. Globalization has led and still keeps leading the way in a world where food produced in a backwoods town could be eaten by people living hundreds of thousands kilometers away, having a complete different bundle of rules, even concerning food, the once-upon-a time field considered to be the most private one in human life.

It goes without saying that precisely for the above mentioned reason, eating has become one of the most discussed subjects in public protection and standard setting, symbolizing a crucial theme in the debate concerning International, Community and National trade.

Even though many different thoughts have been expressed on this topic, there is one line of reasoning that is common among all those opinions, which is represented by the need of sharing a clear, ordered and universal set of rules disciplining the whole food system, with the aim of safeguarding each Nation's food producers and consumers: in such a way each Country could both benefit from it in competitiveness, simplification and innovation and, at the same time, protect the supranational right to health, better expressed by the Universal Declaration of Human Rights in its Article 25.

Food Law presents itself as «*a complex set of legal rules of National, European and International origins with the aim of protecting the food consumer. Protection is generally expressed by banning the circulation of food whose vices are directly harmful for everybody, even though consumed in small amounts ».* [2] It involves the production, trading and consumption phases of products intended for human nutrition, including rules

[1] ADORNATO F., *Agricoltura e alimentazione,* Rivista di diritto alimentare, A.I.D.A., 2007, p. 6, http://www.rivistadirittoalimentare.it/rivista/2007-01/2007-01.pdf

[2] COSTATO L., *I principi del diritto alimentare,* Studium iuris, 2003, p. 1051

regarding the production and consumption of feed aimed at animals, being themselves in turn food or producing it for the human being, on the basis of the strict connection existing between animal feeding and derived foodstuff for man nutrition.[3]

In such a challenging context the agricultural sector, interpreted as the primary sector producing commodities, loses its primacy both on economic and importance terms in favour of the entire food system, becoming just a component of a multi-units train, in which the upstream and downstream wagons of the supply chain must be properly linked in order to make the production process properly function. [4]

As a consequence of this integration and of the centrality of the food business, the filter existing between the commercial enterprise and the agricultural one gets tighter and tighter (especially in Italy), sharing rules with an old time heterogeneous sectors, which are now tied on the basis of directly or indirectly affecting food and feed safety.

This implies that the strict requirements set up by Food Law, by asking to adhere to them, are practically hindering the management of more and more agri-food businesses, especially the small and medium ones, which in the worst case scenario (but unluckily not the less frequent one) have no choice but to disappear from the market.

It is no doubt that those standards are implemented to protect the food consumer at best, but these dynamics are at risk of being separated from those of the real socio-economic agri-food system: the unifying dimension of the regulatory system is likely to lose one of the main traits of competitiveness, which is represented by the diversity of process and products. This aspect, especially in this particular sector, finds its best implementation along the agricultural and farming product-foodstuff supply chain and cannot simply be traced back to the final element. As a matter of fact, consumer protection is also granted by a sustainable agricultural development, able since the beginning of the flow of preventively affecting food healthiness through an environmentally friendly development, also granted by farming and breeding.

Given the complex settings of Food Law, as just mentioned few lines above, which is composed by lots of National, Community and International laws, it is fundamental to underline since the very beginning of this dissertation, the one aspect clearly shared among these regulations: the movement of goods among markets must be privileged, opposing whatever obstruction to it aimed at prioritizing nationalism by means of a

[3] COSTATO L., *I principi fondanti il diritto alimentare,* Rivista di diritto alimentare, A.I.D.A., 2007, p. 2, http://www.rivistadirittoalimentare.it/rivista/2007-01/2007-01.pdf

[4] ADORNATO F., *Agricoltura e alimentazione,* cit., p. 6

protectionist use of health regulations, if scientific data do not prove that International Standards are not enough for the Country asking for safer ones. This kind of measure is usually formally justified by Nations with the need of higher protection towards food consumers, while often in reality it hides the economic interests of the State causing the resistance, so the proof given by scientific evidences is fundamental in understanding what truly the State taken into consideration is asking for and which necessities it shows to have, marking the final decision.

The emergence of Global interests not only tends to prevail over National Food Law, but also on Community one: there is a strong growing trend for the commercial matters of food sector to be legislated by WTO at the expenses of single States or even the European Commission.

This shift of legislative power entails that products health issues are becoming more and more of a universal kind, concerning food movement across the globe as a whole, and so requiring sanitary standards asked at worldwide level, which rely also on soft law rules given by single States or the European Community itself.

Furthermore, recently, another trend of economic bilateral agreements has scored the shot against the "old" multilateral ones, having as frontrunner Trump's Presidency focused on aggressive policies of import duties and quota limitations thereof.[5]

It clearly appears how fragile results the equilibrium in such a conflict, where health safety protection, trade interests and free movements of goods must get on well and balance themselves out, without ending only towards one direction that would entail tremendous consequences for all the entities involved.

It still holds that the fundamental basic principle remains the safeguarding of the consumer and his own health, but for sure they are constrained, both on National, Community and International basis, by some essential elements given by the functioning of the modern world, which is inseparable from the logic of the market.

1.2 Food Law at European level

Since its origins, dated back in 1958, the European Economic Community made of agriculture one of its main priorities: the efforts were focused on achieving self sufficiency and sustaining rural areas and their inhabitants, and right after, the food

[5] JANNARELLI A., *Il mercato agro-alimentare europeo,* Diritto agroalimentare, 2020, p. 314

sector started to become regulated by its own rules.[6] At the beginning, the one in charge of regulating this field was the agricultural directorate general (DG), while immediately afterwards this position was occupied by the directorate generals of industry, enterprises and internal market, symbolizing both economically and symbolically which were the new priorities of the new born Community. From then till the spreading of the "mad cow disease" (technically Bovine Spongiform Encephalopathy, BSE) in the 1980s and 1990s, the focus of Food Law was towards the creation of an internal market aimed at the regulation of food circulation.

Among the four freedoms at the basis of the EEC (free movement of labor, of services, of capital and of goods), the one mattering the most for the growth of Food Law is without any doubt the free movement of good one, which founds its explication on Article 28 (once 30) of the Treaty Establishing the European Community, by prohibiting quantitative restrictions on imports and all measures having equivalent effect on trade, with the exception of the protection of health and life of humans, animals or plants (Art. 30 Treaty Establishing the European Community).

Getting back to the internal market creation, this stage can be divided into two smaller subparts: the first entails achieving harmonization by means of vertical directives, while in the second it was seek through horizontal ones.[7]

As concerns the first one, National Standards were widely used in establishing the quality and identity of food products, so directives containing recipes, compositional or technical standards of certain food products were issued, but not without difficulties. First of all, by then, legislation needed the unanimity of the Council, but was the Council itself in providing each Member State with the possibility of opposing new pieces of legislation with veto rights. Secondly, the quantity and diversity of food products across European Nations is simply too much to face and rearrange in compositional terms, so the Community settled for specifying only a few food items, such as sugar, fruit juices, milk, honey, coffee, eggs, fish, natural mineral water, spreadable fats, jams, jellies, marmalade, chestnut puree, chocolate, minced meat. Those elements constitute the fundamental basis upon which the rules on compositional standards in the European Union are built, to such an extent that they are being constantly updated or replaced whenever required, but no new product is added to the list.

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[6] VAN DER MEULEN B. M. J., *Development of Food Legislation Around the World,* Ensuring Global Food Safety: Exploring Global Harmonization, Academic Press, 2010, p. 43

[7] VAN DER MEULEN B. M. J., *Development of Food Legislation Around the World,* cit., p. 44 - 47

A few years later, the fear scattered by the health scandals, especially the one brought by the BSE, unveiled many black spots in European Food Law, making it obvious to everyone that it needed a clearer, safer and more stringent regulation to be legislated by. It was in such a context that in January 2000 the EC proclaimed the "White Paper on Food Safety": its view concerning the future of European Food Law, in which the fundamental shifting in focus from market to health finally happened.
The most emblematic heir of this new vision is certainly constituted by "Regulation 178/2002 of the European Parliament and of the Council", which represents the foundation stone on which modern-day European food law is still laid upon, up to the point to which the Regulation itself is often referred to as "General Food Law".

1.2.1 The Cassis de Dijon Principle (Principle of Mutual Recognition) and the Rule of Reason

Concerning the universality of food laws and the free movement of goods, the Cassis de Dijon principle has been largely adopted at European level,[8] marking a fundamental step in the achievement of Regulation 178/2002.
This Sentence's name is derived from a particular legal case concerning the French Cassis of Dijon liqueur, imported by Rewe, a German chain of supermarkets, to Germany. Immediately, German authorities opposed the importation of the above mentioned beverage, following German National Law, which considered the minimum alcohol requirement of fruit liqueurs to be equal to 25%, while, after analyzing the French one taken under examination, it was only 20%.
Even though it was clear that this was a restriction on trade since the beginning, German authorities kept on following their opinion basing it on the risks born by German people: first of all beverages with a lower alcohol percentage could induce to drink more, and secondly, but not less important, consumer could have felt betrayed by National law, believing in a certain alcohol degree and then turning out to be not true. Furthermore, German jurisdiction sustained that given the higher the alcohol percentage the higher the taxation to pay according to German National Law, the market would have faced an unfair competition: lower alcohol content beverages coming from external Countries

[8] COURT OF JUSTICE, *Judgment of 20.02.1979 (Case 120/78),* Luxemburg, 1979, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:61978CJ0120&from=IT

would have been favoured in terms of taxes and so could have been sold at a lower price, increasing their competitive advantage at the expenses of the National ones. [9]

Although these specifications were not included by the already known exceptions on free trade covered by the EC Treaty, the Court of Justice agreed that these concerns should have been taken into consideration, given the significance and urgency of the parties, interests and health issues involved.

This exception is better known as the "Rule of Reason" and it is recalled each time a contract, combination or conspiracy restricts trade in an unreasonably manner with respect to a well defined agreement. The process in settling for a final decision starts with the Court analyzing the products and markets taken into consideration, market power of the parties involved and last but not least the anticompetitive effects deriving from the non-conforming maneuver. In the end, the floor is given to the counterparties, which are in charge of explaining the justification standing behind their positions, being it both it in favour or not in favour of consumers' interests.[10]

At the end of the examination concerning the above discussed case, the Court decided that public health was not involved because firstly, there was lots of availability in the German market of liqueurs with an alcohol degree lower than 25%, and secondly, the alcohol percentage could have been clearly displayed on the label, in order to not make the drinkers feel betrayed. The importation of the Cassis de Dijon liqueur could have finally taken place. [11]

From this Sentence onwards, the Court introduced a general rule to follow, known as the "Principle of Mutual Recognition": each time a Member State legally produces and markets a product, it cannot find selling oppositions in other Member States, basing them on the non-compliance with National Law of the importing Countries. If food products obey to the National statutory requirements of the Member State in which they are sold, they must be accepted in all other Member States as a matter of principle, with the only exceptions provided by the above mentioned Article 30 of EC Treaty or by the Rule of Reason.

This Mutual Recognition Principle highlighted two fundamental aspects to be considered within the European Common Market: from the political point of view, it symbolizes a

[9] VAN DER MEULEN B. M. J., *Development of Food Legislation Around the World,* cit., p. 45

[10] https://www.businessjustice.com/antitrust-standards-of-review-the-per-se-rule-of-reason-and-quic.html

[11] VAN DER MEULEN B. M. J., *Development of Food Legislation Around the World,* cit., p. 44 - 47

progressive abatement of protectionist barriers in favour of harmonization, while from the legal one, its consequences are comparable to the ones of an implicit mutual recognition agreement of each own Member State's rules disciplining production, commercialization and selling of food products across the European Union.
The immediate concern coming from Member States went at underlying that such a decision would have entailed ambiguous consequences regarding standards, which would have internationally become based on the lowest National ones, giving competitive advantage to those Companies based on Sates where regulations were the loosest.
It was hence clear that further harmonization was needed, especially cried out by those Member States showing a more strict regulation on food: this maneuver would have required the loosest regulations displayed by some States to rise at a common level. Hence, harmonization was no longer seen as a way to make the internal market properly function, but as the possibility of mitigating what was established up to that historical moment by single National product specific legislation. The shift towards an horizontal framework of laws would have entailed the implementation of general rules, adopted as a roadmap for a broad range of food products across the entire European Union.

1.2.2 Regulation 178/2002 and the road towards and after it

It didn't took long for the Mutual Recognition Principle to degenerate into worldwide problems: one food crisis after the other led the faith of consumers towards Food Protection to zero, if not even to a worst level. BSE, Belgian dioxin, employment of growth hormones, animal diseases and other scandals shocked the 1990s food and agricultural sectors of the European Union. Furthermore, once these news were of public domain, the EU started to ban imports coming from the indicted areas, drawing a line to the once free movement of goods (in this case food) internal market.
In the awake of these trauma some provisions were taken, such as the reinforcement (and the renaming) of the "Consumer and Health Protection Policy", the setting-up of the Scientific Steering Commission to scientifically analyze consumer health, and in 1997 the establishment of the Food and Veterinary Office (FVO), the one in charge of controlling the food sector (animal health and their welfare included) on behalf on the Commission and auditing Countries willing to export in European Union ones.[12]

[12] VAN DER MEULEN B. M. J., *Development of Food Legislation Around the World,* cit., p. 46 - 48

Later, in year 2000, the Commission published its vision concerning the possible future scenarios of European food law in the "White Paper on Food Safety": the once-upon-a-time food discipline, subordinated to the internal functioning of the market, revealed the necessity of a new way of ensuring food safety, by means of augmenting and restoring consumer protection and confidence towards it. As a matter of fact, the main point of the new Document was found in the restoration of food law, with the aim of guaranteeing consistency, comprehensiveness and updating of the subject.

Finally, two years later, "Regulation 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety", in short form "Regulation EC 178/2002" or better know in English, "General Food Law" (GFL), saw the light.

Certainly, its fundamental aspect is the approach towards food law, which it is faced in a comprehensive and systemic way, by going beyond the fragmented nature of all the previous pieces of food legislation. Furthermore, it highlights the general food sector principles and dictates transversal rules applying to all food products, no more only to the single ones.[13]

Not only it safeguards the usual health and sanitary aspects concerning the food sector by means of bans and penalties, but it also first of all addresses prevention and monitoring of foodstuffs by making use of the Precautionary Principle (Art. 7 Reg. EC n. 178/2002), recalled whenever doubts about insufficient levels of health protection exist or when not enough data are available for carrying a complete and safe analysis on the topic. In these specific cases, authorities or decision makers are authorized to take non-discriminatory, proportional and provisional actions, while waiting for more pieces of information to be collected and analyzed. [14]

Regulation 178/2002 provides with uniform rules and specific risk testing institutions all the related agro-food supply chain activities, finally making of food safety the hearth of the discipline and providing measures for the resolutions of threats coming from the outside, making use of damages restoration procedures.[15]

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[13] JANNARELLI A., *Il mercato agro-alimentare europeo,* cit., p. 316

[14] https://ec.europa.eu/food/safety/general_food_law/principles_en

[15] TUCCARI F. F., *Prolegomeni a uno studio in tema di sicurezza alimentare,* Eunomia. Rivista semestrale di storia e politiche internazionali, 2016, p. 441

The European Food Safety Authority (EFSA) entered into force as a scientific benchmark for the European Union and as a means of guaranteeing higher consumer protection levels, by offering consulting on food laws and to all the fields having a direct or indirect incidence on the safeness of food and feed. It is made up by four Institutions, which happens to be the Administrative Board, the Executive Director helped by his personnel, the Advisory Forum and the Scientific Committee. The key characteristic of the EFSA is of being independent, in order to assure the highest trust and safety for consumers. At the same time, it provides help by means of scientific consultations to other Organisms, such as Community Institutions, Member States and the Commission, for which even scientific and technical assistance is granted. The opinion of the Authority is what is considered the scientific base on which elaborating measures and adopting them in the food field at Union level.[16]

The fundamental principles around which General Food Law is built, apart from the above discussed Precautionary one, are the Risk Analysis one (composed by risk assessment, risk management and risk communication) and the Transparency one.[17]

The Risk Analysis one is carried out by the European Food Safety Authority and concerns the guideline requirements to follow in order to performing scientific and technical evaluation on food and feed themes. As just mentioned, this principle is in turn divided into risk assessment, which must be developed in an independent, objective and transparent manner; risk management, obtained through the evaluation of policy alternatives and through the actions undertaken after the previous step, aimed at alienating the risk incurred; and risk communication, which instead constitutes the iterative process of sharing information throughout the whole risk analysis phase among involved parties.

Complementarily, the Transparency Principle is the one aiming at ensuring the transparency of decision-making in food safety and the protection of consumers' interests, as well as of the ones of all the other stakes involved from time to time (such as general public, non-governmental organizations, but also professional associations and trade organizations). This safeguarding is achieved by means of public consultations

[16] CORRADI A., *Il diritto alimentare nel panorama internazionale,* Studio Cataldi: il diritto quotidiano, 2017, https://www.studiocataldi.it/articoli/24662-il-diritto-alimentare-nel-panorama-internazionale.asp

[17] EUROPEAN COMMISSION, *Food Law General Principles, https://ec.europa.eu/food/safety/general_food_law/principles_en*

and by the obligations for public authorities to alert the general public whenever human or animal health is threaten, or at least the suspect of it arises.

It this way, all the steps happening along the supply chain, from the basic agricultural production to the final food product, are ensuring disclosure and accountability of the processes and allowing the check of the security standards and quality, aimed at the tuition of food consumer.

When talking about legislation concerning food, it usually can be grouped into product, process and presentation areas, and, as a matter of fact, Regulation 178/2002 is not an exception to it.

To begin with the first one, the product category can be furtherly analyzed into three smaller subparts: compositional standards, market access requirements and restrictions. [18] Usually, the general rule is that producers have no limits in deciding the ingredients composing their products, with the exception of a needed approval for the handling of those which are not included in the list of usable ones, also known as the "positive lists". The categories for which consent is obliged are: food additives (synthetic substances which are not foodstuff on their own but are added to foods for technological reasons such as sweetening, preserving, gelling, coloring, treating flour, etc[19]), genetically modified foods (food in which the genetic material has been artificially modified to obtain a certain characteristic[20]) and novel foods (food not eaten in a significant way in Europe ahead of 15 May 1997, date in which the first Regulation on the topic became effective[21]). Once again the approval test for all these exception categories is given by the scientific risk assessment method, as holds for the limitations to the existence of contaminants (e.g. undesired substances which haven't been intentionally added to food in any of its product life cycle stages but are present, or have been in touch with it by means of the environment[22]) or organisms inside foods.

Furthermore, by following with the second thematic area, legislation on the process entails that all the stages in which the food goes through, from ingredients production to the trade of the final product, must be covered by hygiene practices, aimed at the prevention of food safety risks.

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[18] VAN DER MEULEN B. M. J., *Development of Food Legislation Around the World,* cit., p. 49

[19] https://ec.europa.eu/food/safety/food_improvement_agents/additives_en

[20] https://ec.europa.eu/food/plant/gmo_en

[21] https://ec.europa.eu/food/safety/novel_food_en

[22] https://ec.europa.eu/food/safety/chemical_safety/contaminants_en

The most emblematic measure taken at the core of European Union on food hygiene is the Hazard Analysis and Critical Control Points, better known as HACCP (later covered by Regulation 852/2004), which asks food enterprises to understand and be aware of where the hygiene problems may arise and of how to acknowledge and manage them, by also documenting the implementation of the health check processes.[23]

Going back to Regulation 178/2002, the commercialization phase is covered by traceability too in order to maintain high safety standards (Art. 18 Reg. EC n. 178/2002): food and feed business operators must be able to identifying both where they took their inputs from and where their outputs are headed, by means of implementing systems in which, if asked by competent authorities, they can make that piece of information available to them to solve the problem both at the origins and in the end of it. Nonetheless, if they are concerned about the integrity of a certain product, they are obliged to withdraw it from the market and from the final consumer (Art. 19 Reg. EC n. 178/2002).

Another significant part of General Food Law is composed by presentation legislation, the last but not least above mentioned food subject theme. It considers the pieces of information given by food business to consumers about the food that they are considering, willing to buy or already bought and they are usually conveyed by means of advertising or labelling.[24]

At that time, however, the cornerstone of the just mentioned presentation legislation was found in "Directive 2000/13 of the European Parliament and of the Council of March 2000", concerning the approximation of the laws of Member States on labeling, presentation and advertising of foodstuffs, later repealed by "Regulation 1169/2011 of October 2011 on the provision of food information to consumers". Generally, labelling must not be misleading and it must use a clearly understandable language, usually the national one, while some pieces of information are mandatory, restricted or forbidden according to the importance they embody. Regulation 1169/2011 aims at assuring an high level of consumer safeguarding on food information, also considering the different perceptions and needs presented by them, but at the same time making sure that the

[23] https://www.euro.who.int/en/health-topics/disease-prevention/food-safety/areas-of-work/building-national-capacity-in-food-safety/hazard-analysis-and-critical-control-point

[24] VAN DER MEULEN B. M. J., *Development of Food Legislation Around the World,* cit., p. 50

European market properly works with flexibility.[25] Certainly, the main innovation introduced by this Regulation was that the final frame of information required on a food product label is composed not only by the General Labelling (such as name of the food, list of ingredients and quantity, date of minimum durability/use by date, country of origin, etc) as instead provided by Directive 2000/13, but also by the Nutrition Labelling (energy value, amounts of fat, saturates, carbohydrate, sugars, protein and salt), adding in this way value to the until then hidden compositional side of human diet.

Furthermore, another fundamental theme covered by Regulation 1169/2011, such as the implementation of controls concerning food information provided to consumers, has in turn been upgraded by "Regulation 2017/625 of the European Parliament and the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products". [26] This update provided that each Member State should appoint competent authorities for all the legislation covered areas, but must choose only one among them in charge of being responsible for the entire field, with the scope of running a coordinated communication with the other Member States' authorities and with the Commission itself. Furthermore, Member States should assure at the same time that competent authorities act on behalf of public interest and that support quality and coherence of official controls. In order to sustain such a tough challenge, competent authorities must be sufficiently financed and equipped, and, most importantly, they must prove to be unbiased and professional, by making use of a comprehensive control system in which they are integrated with resources, structures, dispositions and appropriate procedures. If proved deformity arises during controls, competent authorities should settle them by means of rules concerning appropriate sanctions, in such a way that they are at least equal to the economic gain obtained from the violation of Food Law, to make sure that penalties are effective, proportionate and deterrent to the fraudulent actions committed.

Going back to the hearth of General Food Law, Regulation 178/2002 deals with the risk factors and bans unsafe food that hence cannot be commercialized inside the market, being it injurious or unfit for human health. The dangerous element can be found in the

[25] EUROPEAN PARLIAMENT AND COUNCIL, *Policy - EU Regulation 1169/2011,* Global database on the Implementation of Nutrition Action (GINA) – World Health Organization, 2016, https://extranet.who.int/nutrition/gina/en/node/22917

[26] ARTOM A., *Il nuovo regolamento UE sui controlli ufficiali e le problematiche sanzioni,* Rivista di diritto alimentare, A.I.D.A., 2018, p. 54 - 55, http://www.rivistadirittoalimentare.it/rivista/2018-04/2018-04.pdf

biological, chemical, or physical agent carried inside the foodstuff itself, or given by the condition in which it lies, enabling to spread adverse effects to the product. In addition to this, on the one hand, a specific food can be considered unfit for human consumption when it results contaminated, rotted or decomposed, while on the other hand it is deemed as unsafe when it negatively effects consumer physical well-being or when its toxic effect is due to the swallow of many products of the same type (Art. 14 Reg. EC 178/2002). When a possible tremendous risk for health arises, the dangerous risky element must be analyzed, managed and communicated to protect both consumers in making conscious choices, and health itself. As a consequence, a continuous monitoring of alimentary risks must be carried on ongoing basis among competent authorities, scientists and politicians. Once the emergence of a food risk is evident, first of all scientists and the European Food Safety Authority must provide a meaningful evaluation, then the Commission must deal with it by exploring alternatives, and only in the end it must be conveyed. The one aspect that seems not to be enough stressed is the importance of the communication of risk happening along the entire risk analysis and management process to the real parties concerned, which happen to be the final consumers. As a consequence, the necessity of greater transparency took not so long to emerge, especially during the most important phases of the decision making process. Hence, "Regulation 2019/1381 of the European Parliament and the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain" represents the most recent updating on the theme, by modifying General Food Law especially through its new Articles 8 and 32.[27]

To begin with, Article 8a states the general principles for risk communication: first of all, risk communication should raise awareness and understanding of the topic being examined along the entire process and make sure «*consistency, transparency and clarity*» in decision making are preserved, while engaging the public in understanding them and being involved (Art. 8.a Reg. EC n. 2019/1381). In addition to this, the exchange of information must be appropriate and transparent also among feed and food businesses, the academic community and all the parties having a stake, which must all fight against the dissemination of false information. Article 8b instead follows with the importance of accuracy, appropriateness and timely information that must be exchanged at each stage

[27] GERMANO' A., *La trasparenza nella comunicazione del rischio: il Reg. 2019/1381,* Rivista di diritto alimentare, A.I.D.A., 2019, p. 102, http://www.rivistadirittoalimentare.it/rivista/2019-03/2019-03.pdf

of the risk analysis process, by following the principles of transparency, openness and responsiveness and including all the different opinions of the implicated parties (Art. 8.b Reg. EC n. 2019/1381). The general plan for risk communication, which should be adopted by the Commission and follow the objectives and principles previously discussed, is actually covered by Article 8c of the same. As a matter of fact, the Commission should update the plan according to new technical and scientific improvements, consult the Authority whenever needed and, of course, boost its communication flow both at National and European level (Art. 8.c Reg. EC n. 2019/1381). The key steps structuring the plan consist in indentifying the most important elements to consider when examining the type and level of the risk communication activities, followed by choosing the right channel by which addressing the communication itself according to the target audience. As a consequence, proper mechanisms of cooperation and coordination between risk assessors and managers, with the aim of reinforcing coherence and guaranteeing an open dialogue and involvement among all the parties involved, should take place.

On the other hand, Article 32 of the same deals with a more practical point of view, concerning the notification of studies along the process, the consulting of third parties involved and the studies confirming the rightness of the components of the risk evaluation process. As a matter of fact, the increased transparency and the improvement of the communication of the risk can be achieved also by means of the food operator engagement, with particular reference to the phase in which he is asking the permission to commercialize a product inside the market.[28] Authorization procedures are based on the fact that it is up to the person requesting or notifying the entrance of the product into the market to prove its safety and conformity with European dispositions, according to the scientific knowledge possessed. So, not only the Authorities are forced to prove the safeness of the foodstuff, but also the operator has no exception to it, strengthening in this way the validity of the product. In order to make such a check, the operator must find researches, studies, analysis supporting his thesis and, if some kind of risks could incur, he is obliged of reporting them too (Art. 32 Reg. EC n. 2019/1381). In this way along with the studies commissioned by the European Food Safety Authority on behalf of the Commission on the validation of the elements used in the risk evaluation, a lot of "private" studies enrich consumer protection, trying to reinforce the

[28] GERMANO' A., *La trasparenza nella comunicazione del rischio: il Reg. 2019/1381,* cit. p. 104

once lost faith in food law. In this context, it is up to the EFSA the role of instituting and managing the amount of information conveyed by all those studies, being them both private or commissioned ones. This key role run by the Food Safety Authority is crucial in order to increase the prestige and credibility of the results concerning the risk evaluation phase and the management one, two of the most delicate steps in food risk analysis.[29]

1.3 Food Law at International level: The WTO Agreement on Sanitary and Phytosanitary Measures and the Codex Alimentarius

Concerning the universality of Food Law, at International level the necessity of disciplining the food sector did not delay too: if at Community level Regulation 178/2002 built the basis of modern food legislation, at worldwide level was the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS in short form) to be the milestone, starting from 1995. As its name suggests, it deals with the implementation of basic food safety and animal and plant health regulations, affecting international trade (Art. 1, Agreement on the Application of Sanitary and Phytosanitary Measures). Its importance is also given by the fact that together with the General Agreement on Tariffs and Trade, it is part of the Final Act of the Uruguay Round of Multilateral Trade Negotiations, the one which established the World Trade Organization.

In order to be more accurate, the measures treated by the Agreement concern primarily the safeguarding of human and animal life from risks generated by additives, contaminants, toxins or organisms contained in the edible food, but also the securing of human existence from diseases carried by the same plants or animals. Even animal and plant life must be protected from all pests and various illnesses, including from the organisms spreading them. In the bottom line, it also covers topic concerning the prevention or limitation of damages that a Country could possibly incur by means of entrance, establishment or diffusion of pests. It is in this way showed that the Agreement deals only with themes related to the safeness of food, generally leaving apart labelling requirements, nutrition claims or quality and packaging regulations. Usually, these just mentioned issues fall under the Technical Barriers to Trade

[29] GERMANO' A., *La trasparenza nella comunicazione del rischio: il Reg. 2019/1381,* cit. p. 105

Agreement, while, on the contrary, if they prove to have a stake with food safety themes, they are covered the same by the SPS Agreement.[30]

First of all, the SPS Agreement clarifies the possibility of Countries to follow their own National standards, but on a scientific and justifiable basis, which means that no discrimination should happen where identical or similar situations exist across different Members: as a matter of fact, standards must be followed only with the aim of protecting human, animal or plant health. Countries taking part of the Agreement are still asked to adhere to international standards where they are in place, but also have the possibility of setting higher ones if the procedure aspired is proven to be scientific justified and not arbitrarily imposed.

All the measures taken are aimed at the safeness of consumers and at preventing the spreading of pests or diseases to animals and plants, independently from where the food, product, animal or plant is originated. As a consequence, it is understandable that a Country can ask for higher standards, but they must not be used in a protectionist way restricting free trade, by means of maneuvers safeguarding domestic products from economic competition deriving from the outside ones. This move is especially used in circumstances in which other States had already loosen their regulations, benefitting from the exploitation of their competitive and economic advantage deriving from the downward modification of the Sanitary and Phytosanitary national regulation.

To this extent, the SPS Agreement exposes which are the factors to be taken into consideration in the risk analysis determining the excessive standard implementation. Some of them are the available scientific evidences, the relevant processes and production methods, relevant inspections, sampling and testing methods, the presence of specific diseases or pests, particular treatments and relevant ecological and environmental conditions. Also economic factors should be taken into account in this analysis: examples can be considered the potential damages in terms of loss production or sales in cases of entrance, establishing or spreading of the illness, the cost of controlling it in the importing State and the analysis of cost-effectiveness of alternative methods to limit the problem taken into consideration (Art. 5 SPS Agreement).

Furthermore, the establishment of National sanitary and phytosanitary standards should be coherent with the International ones, following the process of harmonization

[30] WTO SECRETARIAT, *Understanding the WTO Agreement on Sanitary and Phytosanitary Measures,* 1998, https://www.wto.org/english/tratop_e/sps_e/spsund_e.htm

among Agreement Members. By the way, it is not the World Trade Organization itself who is setting standards at International level, but cutting-edge scientists and governmental experts belonging to WTO's Member Governments, apart from the joint FAO (Food and Agriculture Organization) - WHO (World Health Organization) Codex Alimentarius Commission for food safety, the OIE (Office International des Epizooties) for animal health and the FAO, based on the International Plant Protection Convention for plant health. Despite their authoritativeness, this collection of Organizations is always scrutinized and reviewed about its performance, effectiveness and efficiency.

Given the plurality of Members belonging to the Agreement, it usually happens to International standards to be actually higher than National ones (independently from the fact that the reference point is represented by a developing or an already developed Country) because differences in climate, existing pests or diseases and food conditions justify the variety of single States' laws, but not if these discrepancies restrict trade. To be more precise, the use of alternative measures, with the prerequisite of being both technically and economically efficient, is highly recommended to be implemented according to the equivalence principle dispositions, if able to obtain the same level of healthiness that would have been achieved by means of an higher standard restricting commerce. At the same time it is likewise suggested the application of equivalent measures already in place in other WTO Member Countries, implying the same level of health protection (Art. 4 SPS Agreement)

In all these different scenarios, the Sanitary and Phytosanitary Agreement deals with three types of precautions to adhere in setting International standards. The first one entails the routinely adoption of safety margins when the risk analysis is implemented, in order to guarantee the primary aim of safeguarding health. The second one instead covers the autonomy of each Member of the Agreement in setting its acceptable risk level, by taking into account National concerns on health, safeness and appropriate considerations on the theme. Last but not least, the third one gives each Country the possibility of adopting precautionary maneuvers when, according to that specific State, scientific evidences are not met in order to take a decision on the go-ahead healthiness of the product being questioned.[31]

[31] WTO SECRETARIAT, *Understanding the WTO Agreement on Sanitary and Phytosanitary Measures,*cit.

In this context, each Government is asked to inform the others about any modification on the SPS standards concerning trade, and to organize appropriate offices aimed at answering questions about the changes or concerning the already existing measures. Whenever a Member is intended to modify its scheme of Sanitary and Phytosanitary measures, both in case of adding new ones or upgrading the already existent ones, and this amendment both differs from the International provisions and undermines trade, the State must first of all notify the WTO Secretariat, which is in charge of spreading the news. If other WTO Members do not agree on that, they have the possibility to comment upon its handling. In addition to this, a special Committee inside the WTO has been appointed with the scope of favouring the exchange of information among Governments on the International SPS themes and to check the adherence to them.

It must not be forgotten that in the bottom line who benefits the most from the Agreement is the consumer, independently from his Country of origin. As a matter of fact, the Sanitary and Phytosanitary Agreement aims at guaranteeing and improving food safety by means of systematic practices making use of scientific information and data, obtained through risk analysis processes, management and implementation. In such a way, the autonomy of Sates in taking arbitrary, unnecessary and discriminatory actions is, if not erased, at least limited and reduced. Transparency of information is the key in order to make the Agreement properly function and, no less importantly, increasing the choice of food products in the market, being reassured in terms of safety and fair International competition. Not only are consumers the ones in taking advantage of it, but at the same time both exporters and importers benefit from the SPS Agreement: the first ones are lighten by the demolition of unjustified barriers with protectionist purposes and by the decline of uncertainty and impairment when facing stranger markets, while importers are granted the certainty of safeness and healthiness of the products bought, erasing the insecurity and vagueness surrounding them. Furthermore, all the interested parties have access to the knowledge to challenge measures retained not enough safe or even restricting trade in an unnecessary and wrongful way.

In addition to the just discussed Agreement on the Application of Sanitary and Phytosanitary Measures, another landmark concerning International food standards can be found in the Codex Alimentarius: a collection of standards, guidelines and codes of practices elaborated by the Codex Alimentarius Commission, which was established by

the collaboration of the FAO and the WHO in 1963. As the SPS Agreement, its aim is the one of protecting consumers' health and assuring the maintenance of fair practices in International food trade, by driving and encouraging the development and enforcement of food requirements. These goals are chased by means of standards and texts built on the basis of scientific evidences, provided by International risk assessment bodies or by specific consultations carried by the Food and Agriculture Organization and the World Health one.[32]

The Codex content is firstly used as sort of suggestion for Governments to voluntarily follow on food subjects, but at the same time it should be a grounding basis on which the same States could build their own National legislation. As a matter of fact, the Codex also deals with solutions in resolving trade controversies, given its role in removing barriers to food trade.

Openness, transparency and inclusiveness are they key words in setting, establishing and applying measures on food produced, commercialized and carried all over the world. Indeed, reassuring all the parties having a stake in the final foodstuff, whether are they consumers requiring healthiness, or importers requesting products bought to reflect their expectations, is the main road to pursue in order to make travelled food the safest and the interested parties feel safe and comfortable with it.

As in the SPS Agreement, if Members taking part of the Codex are willing to tighten their measures, a scientific reason must be provided, which should justify the excessive protection required. By the way, standards included in the Codex do not substitute or provide alternatives to National Legislation, which must be followed no matter what, but simply represent a way to harmonize food themes frameworks among Countries and simplify trade in the smoothest possible manner.

The Codex content aims at supplying solutions, suggestions and requirements for granting safety of food products in being free from infringements, but always labeled and presented in the right way. It deals with standards for all the principal foodstuff, independently from the food status of being processed, semi-processed or even raw. It only matters the final destination of the product: being addressed to the consumer.

[32] FAO/WHO, *About Codex Alimentarius,* Codex Alimentarius International Food Standards, 2020, http://www.fao.org/fao-who-codexalimentarius/about-codex/en/

For this reason, the Codex can be divided in key areas: animal feed, antimicrobial resistance, biotechnology, contaminants, nutrition and labelling, pesticides and last but not least, the recently introduced thematic page on COVID-19.

To begin with, the strict connection existing between food and animal feed is likely to increase, given the growing consumption of proteins deriving from animal products.[33] This one in turn is driving upwards the demand for livestock production, which is no longer sustainable by means of only natural components, but it is needing the industrial help to keep up with. It is in this context that not only feed plays a fundamental role in animal health, but as a consequence also in human life too, whether considering the consumer eating products deriving from the animal, or even producers or handlers taking part in the supply chain producing, working on or having some kind of relations with the foodstuff. Recent years scandals on food and feed contamination have risen the attention towards the need of guaranteeing product safety from its origins, by means of preventing and controlling the existence of possible hazards from the beginning of the food life cycle, by trying to eliminate and reduce risks of all the unwanted and undesired substances from the early stages of the production. This Codex section only deals with food safety and not with problems related to animal wellbeing, apart from the ones connected to its primary aim of guaranteeing food healthiness, highlighting the roles and responsibilities of the feed sector to working towards that direction. Whenever animal feed has an impact on food safety by means of other agents such as contaminants, pesticides, veterinary drugs, or food hygiene, the work of the Feed Committee is complemented by the ones of the other responsible elements, in order to elaborate the best fitting solution.

Antimicrobial resistance (AMR in short) is another tipping point, if considered that each year around 500.000 human being die of diseases related to antimicrobial resistance.[34] Food represents a fundamental player in the spreading of diseases, exposing human health to microorganisms such as bacteria, parasites, viruses and related hazards, but at the same time also to the AMR components, incorporated inside of the food product with the aim of killing or stopping the above mentioned diseases. It is not a surprise that the

[33] FAO/WHO, *Animal Feed,* Codex Alimentarius International Food Standards, 2020, http://www.fao.org/fao-who-codexalimentarius/thematic-areas/animal-feed/en/

[34] FAO/WHO, *Antimicrobial Resistance,* Codex Alimentarius International Food Standards, 2020, http://www.fao.org/fao-who-codexalimentarius/thematic-areas/antimicrobial-resistance/en/

use of AMR divides the world, generating lots and lots of National and International debates and finding different grounds according to different regions.

The reason for such a division is due to the fact that once a human being eats food containing antimicrobial agents, which are used with the aim of bacteria killing, there exists a possibility of catching a disease from the ingested foodstuff, if not even transferring the resistance to other microorganisms, as the ones of human pathologies.

Therefore, the need for a clearer and multi-subject answer to the AMR related clues is evident and makes itself felt more and more, especially as the consequences of their use become increasingly serious over time. In the meantime, the Codex has settled for scientific guiding the approach towards assessing and managing human health risks linked to AMR existence in food and feed, their each other transmission and only recently, given the worldwide concern, along the entire food chain.

To continue with the third Codex macro-section, biotechnology deals with the use of both traditional and innovative technologies and the relative implementation in agriculture has spread since the 1990s.[35] On the one hand, its employment allows producers to obtain specific desired features of the products, such as resistance from insects or diseases, increasing their livelihood, developing certain characteristics to make them stronger or more interesting from consumers' points of view, but, on the other hand it certainly presents some drawbacks. It must be taken into consideration that, with regard to lots of food products, the acceptable level of food risk is the one provided by the product historic conventional (e.g. non modified D.N.A.) consumption throughout the years. Therefore, in such a context, the Codex must provide guidelines to conduct processes of food risk assessment on modified food, in order to verify if any hazard, nutritional or other shortcomings are present, and, if any, elaborate strategies to solve them. The key elements in the analysis are found in the similarities or differences between the food derived from the use of biotechnological solutions and the conventional obtained one. In addition to this, the Codex also provides details about the labelling of foodstuffs produced by means of cutting-edge biotechnologies.

Contaminants, differently, are substances which have not been intentionally added to food, but have met it in along any of the food chain steps: the contact can happen during its production, packaging, transportation, storage, or even by means of environmental

[35] FAO/WHO, *Biotechnology,* Codex Alimentarius International Food Standards, 2020, http://www.fao.org/fao-who-codexalimentarius/thematic-areas/biotechnology/en/

contamination.[36] In order to guarantee the quality and safety of food, these substances must be constantly monitored and checked, and, with the aim of limiting them, the Codex establishes the maximum levels of concentration for which retaining them to be legally permitted, by considering that the zero level cannot be achieved given the natural occurrence of these substances in the environment. These levels and the relative list of contaminants are constantly updated and revised by the Codex Committee on Contaminants in Food, which in turn elaborates the priority list for the risk assessment analysis on them, carried by the Joint FAO/WHO Expert Committee on Food Additives and meeting twice a year to keep up with new discoveries, threats and updates on the theme.

All these technological improvements opened the way to a world where food is produced according to different preferences and expectations, offering the greatest possible array of options among to choose ever imagined. In this picture, consumers must be aware of what they are exactly eating and understand what stands behind the selected products, given that 3.4 million people die each year for overweight and obesity, and 793 million people suffer from chronic hunger.[37] As a consequence, food information, by means of nutrition and labelling, has gained a new importance in helping consumers taking conscious choices for their health. In order to pursue this aim, the Codex Alimentarius addresses compositional requirements for food to be retained nutritionally safe, included real packaging meaning of expressions such as "low/high fat" or "light", under the guidance of the Codex Committee on Food Labelling, which, together with Member countries, leading industry associations and consumer organizations, has the power of influencing the global food system.

At the same time, the increasing demand for food led producers no choice but to make use of pesticides to obtain both quality and quantity of their productions at the same time. However, the use of these substances exposes consumers to the threats of eating unsafe food, by means of the dangerous chemical residuals that still remain inside it, whether being it from livestock or crop origins. The Codex Alimentarius, in order to contain to the maximum possible extent the spreading of pesticides by means of ingested food, has set limits to them, to once again reassuring that the final product

[36] FAO/WHO, *Contaminants,* Codex Alimentarius International Food Standards, 2020, http://www.fao.org/fao-who-codexalimentarius/thematic-areas/contaminants/en/

[37] FAO/WHO, *Nutrition and Labelling,* Codex Alimentarius International Food Standards, 2020, http://www.fao.org/fao-who-codexalimentarius/thematic-areas/nutrition-labelling/en/

turns out to be safe to eat and not hindering trade too. As a matter of fact, the majority of Member Countries have established maximum legal limits to the allowances of pesticides residues in food, undermining trade and bearing difficulties whenever these limits differ one from the other. For this reason the Codex Committee on Pesticide Residues is the one in charge of setting those limits for specific food products or subsets of them at International level.[38] As usual, the risk assessment analysis must be carried before the limit enforcement, to guarantee that the food traded is safe. Once again, the collaboration between the FAO and the WHO turns out to be fundamental in safeguarding consumer health, by means of the Pesticide Specifications, in which standards concerning quality of pesticides and both consumer and environmental protection are established. It is also up to this union of forces to review and revise scientific data on the already approved use of pesticides.

The last theme introduced by the Codex Alimentarius is the most recent and relevant one: from its first appearance on 31 December 2019 in Wuhan, China, to its spreading and declaring of Public Health Emergency of International Concern, till its pandemic official announcement on 11 March, COVID-19 is the biggest challenge faced by the modern world nowadays.[39] One of the main discussed arguments is about the possibility for food (or food packaging) to carry SARS-Cov-2, the one bacteria causing the virus. Actually, there is no evidence of the spreading of Covid-19 through food, but it certainly cannot grown on it, given that it requires a living being to multiply. In this context, the one element playing a key role is the attention towards hygiene, which, by means of environmental and personal sanitation and adequate safe food practices, is the main precaution that can be taken in avoiding the virus and assuring the needed level of safety in food. Food supply chains all over the world have started to fear delays due to port closures, logistic setbacks and supply disturbances involving interactions among Covid-19 diseased workers, jeopardizing in this way the already unstable linkages standing behind the International trading food organizations and hence mining the access to safe and nutritious food. In this picture, the Codex Alimentarius has intervened with its Commission by means of International best practices to follow, aimed at assuring food hygiene as a whole, monitoring viruses on food, encouraging food

[38] FAO/WHO, *Pesticides,* Codex Alimentarius International Food Standards, 2020, http://www.fao.org/fao-who-codexalimentarius/thematic-areas/pesticides/en/

[39] FAO/WHO, *Covid-19,* Codex Alimentarius International Food Standards, 2020, http://www.fao.org/fao-who-codexalimentarius/thematic-areas/covid-19/en/

businesses to follow adequate guidelines based on scientific data and implementing the new improved International standards. In the bottom line all the measures taken are established with the intention of reinforcing transparency in the management of food safety, fostering the smooth flow of trade at International level and safeguarding consumers' health in such a challenging and never before experienced context.
In order to be always on point and up to date, the Codex Alimentarius Commission revises its entire content, from animal feed themes to the last discussed ones, by removing, modifying or adding standards or texts according to the available scientific knowledge. This routinary check starts in first place from the single members of the Commission, which are in charge of providing and bringing the attention to the right theme committee about any new piece of information that could be worthy of any modifications.[40]

1.4 The peculiarity of the food subject and the multilevel system

Going back to the hearth of this dissertation, it must be first of all highlighted the key difference existing between the protection of the generic stuffs consumer against the one reserved to the food one.
While for the first one the legislator is usually concerned with the aim of defending the consumer's rights from being exploited by the smartest professional counterparty, which is represented by the seller having greater competencies and knowledge in the field of the product being sold, and so deriving a greater economic power from it, with respect to the food consumer the approach is completely different. [41]
Regulation 178/2002 once again reveals the true nature of the relationship existing between the food consumer and the food (or feed) business operator, identifying the food business 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 of food»* and the food business operator as *« the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control »* (Art. 3 Reg. EC n. 178/2002).
The just mentioned definitions are worthy of a deeper reflection, especially if considered that the economic power recognized to the usual foodstuffs operator is said to be not

[40] FAO/WHO, *About Codex Alimentarius,* cit., http://www.fao.org/fao-who-codexalimentarius/about-codex/en/
[41] COSTATO L., *I principi fondanti il diritto alimentare,* Rivista di diritto alimentare, cit., p. 4

even considered for the food business one, given that profit is no longer taken into consideration. The food business operator instead must worries "only" about the safety of food: it only matters for food to be eatable without any additional threats, if not those caused by normal food intolerances or overeating. This transition highlights the deep nature of Food Law: it disciplines the production and commercialization of products which are not meant for remaining outside of the consumer organism (Art. 2 Reg. EC n. 178/2002), but are destined to become even part of it, hence giving birth to a complete different relationship of physical nature, which is not even attainable by means of medicinal products, instead interpreted as extraordinary solutions and not as everyday ones.

Furthermore, the feed inclusion in the food legislation themes is an additional confirmation of the special linkage existing between the human being and his nourishment: if feedstuffs are aimed at animals producing human food or even becoming food they are covered by the Legislation, while feed for animals not intended with those purposes is not disciplined by General Food Law, emphasizing once more the differences with respect to all the other tradable products.

This peculiarity of food, together with the unique function performed by the regulatory system in protecting consumer's health, contributes to the more and more specificity of food laws, turning them into a real stand-alone legislation with per se principles, interests and general rules, no needing other sources to be integrated with (or at least with minimal help of them).

This discipline is not only born with necessities of securing food safety, hence sanctioning non-fitting parties, but also with the aim of being connected to the market, the one element on the grounding basis of the European Union and of the WTO. The focus on trade not only is the consequence of a sort of innovation – reaction approach, which explains the introduction of new pieces of legislation according to the emerging trends, but it also depicts an innovation – action one, by means of establishing extremely innovative operational units, institutions, ways of behaving and disciplining the food sector with respect to the older single Members' ones, emphasizing once again the interdependency of the nowadays world with globalization mechanisms.[42] As a consequence, a shifting in hierarchical State coordination happens in favour of a more

[42] ALBISINNI F., *Dalla legislazione al diritto alimentare: tre casi,* Rivista di diritto alimentare, A.I.D.A., 2007, p.4, http://www.rivistadirittoalimentare.it/rivista/2007-01/2007-01.pdf

collaborative and independent one, in which public and private actors intervene at all governmental levels, overcoming the National dimension towards a more Supranational one and hence resulting in a multilevel system composed by sources of different origins. The same Regulation 178/2002 is proof of this union of forces: Community Law establishes the general guidelines to follow, then each Member State must implement the framework according to its necessities and requirements, but at the same time, both Community and National law must ensure collaboration between their organizations, favouring transparency of information and of measures and running the whole mechanism in the best possible way.

In this context, the food business is at the same time both recipient and maker of rules, by taking its responsibility and establishing its autonomy in a market competition perspective, where, along with traditional measurable product and production rules, find their spots the new running business ones, composed instead by organizational, relationship and responsibility elements. Nevertheless, the new disrupting feature regards the food/feed product: it is no longer enough for it to be safe, to be produced, transferred, preserved, distributed and commercialized in healthy places and having its production techniques carried in the proper way. Furthermore, it must have been produced in a food supply chain arranged according to specific requirements, with the contribution of some protocols and the implementation of supervisory mechanisms.

By the way, in the multilevel arrangement are not only the regulatory players at competing one with the other, but they also face business confrontations and take part in the ones happening between businesses and consumers, therefore emerging in a regulatory arena where International, Community and National Law must balance themselves out.

For this reason, a creative destruction process in legislation it is thought to be the best resolution, by means of innovatively combining the certainty and effectiveness of laws with the flexibility of implementing them according to modern modi operandi, which must be tailored on present needs.

1.5 The failed project of the Italian Food Law Code

A noteworthy mention is also reserved to the Italian scenario, where, still nowadays, an agreed solution to the incredible amounts of disordered dispositions and laws

concerning the food sector, including their simplification and delimitation around specific principles, has yet to be found.

The hearth of the Italian Food Industry is represented by Federalimentare, which is in charge of symbolizing, safeguarding and promoting the Italian Food and Beverage Industry, the one sector ranking as second in the National chart and gaining up to 145 billion Euros each year, hence representing the 8% of the Italian GDP. [43]

The Association is involved, together with the appropriate competent National Institutions, in seeking and supporting the Italian healthy and high-quality diet, by both encouraging food entrepreneurs in taking the right available opportunities and in providing consumers with the best Made in Italy array of food alternatives, keeping up with their demanding changing tastes. In addition to the just mentioned assignments, Federalimentare is engaged with cooperating in the establishment of a complete and apposite food legal framework, aiming also at safeguarding Italian food businesses with respect to the other States' ones, by leveling the playing the field and guaranteeing the same grounding conditions, especially when facing the same supporting or hindering elements in competition or regulations. [44]

Dating back to year 2007, the then-President of Federalimentare, Mr. Auricchio, highlighted during the Association assembly held for the inauguration of Cibus Roma 2007 (a fair in honor of the celebration of Made in Italy food), that in order to regain competitiveness in the worldwide food market, the Italian and Community Food Industries needed to be no longer pressed by the enormous amount of already existent constraints, especially if considered that the Italian food products were already presenting a competitive disadvantage even with respect to the little less regulated European ones. Hence, the need for further harmonization towards European food regulations took no longer to emerge, having as one of its principal aims the one of helping the food operator in orienting between National and European legislation.

Furthermore, an additional upgrade in the identification of an appointed Institution, responsible on food safety themes and empowered of taking actions on them according to the most urgent necessities, by operating in collaboration with the Italian National Institute of Health and with cutting-edge scientific and technical bodies, was soon required, proving there was no more time left to awaiting for.

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[43] http://www.federalimentare.it/new2016/ChiSiamo/CompanyProfile.asp

[44] ROSSI D., *L'industria alimentare e le riforme mancate,* Rivista di diritto alimentare, A.I.D.A., 2007, p.30, http://www.rivistadirittoalimentare.it/rivista/2007-01/2007-01.pdf

The then-Minister of Health, Ms. Livia Turco, took up the request and assured that an appropriate Food Code, as Law 229/2003 provided, would have soon been released and that an Institution inside the National Institute of Health, named "Scientific Committee on Food Safety" would have been established in collaboration with the European correspondent body.[45] The just-mentioned law gave the Government as deadline 9 September 2007 (the initial one was one year before, but it was postponed) for the implementation of a complete rearrangement on food sector provisions according to the following clear and specific guidelines.

The first and probably most important one concerned the harmonization of the production and the commercialization phases of the food supply chain towards the one provided by European Food Law, specifically drawing the attention towards the free movement of goods aiming at ensuring fair food businesses competition.

Then, as usual, the themes about the safeguarding of health and relative consumer tuition achieved by means of quality products, and the ones regarding environmental, animal and plant protection were not left aside, given their role in building the heart of food legislation, almost independently from its places of origins.

The third one was about the updating of food laws according to the food sector evolution, by abrogating or modifying all the dispositions no longer in force as a consequence of their status of being outdated, obsolete or even overtaken by technological innovation, but by always taking into account the right of consumers to be informed about those changes.

Furthermore, as previously anticipated, the sanctioning of non-conforming operators had to be uniformly legislated, as the ways in which they should be controlled and supervised, apart from specific products requiring extraordinary rules to be guided by.

In addition to this, the simplification of existing procedures was one of the main cornerstones around which focusing the innovative food legal framework too, by erasing all those practices bearing additional non-obliged burdens against foodstuffs produced by Italian enterprises with respect to the other European Member States counterparties.

Last but not least, laws concerning production and commercialization of food products had to be separated ones from the others, by taking into account all the technicalities of

[45] ARTOM A., *Il codice alimentare come disciplina organica,* Rivista di diritto alimentare, A.I.D.A., 2007, p.17, http://www.rivistadirittoalimentare.it/rivista/2007-01/2007-01.pdf

those subjects and the specific products' ones, and hence establishing appropriate measures in analyzing them.

This framework of guidelines was studied in 2003 by an independent Scientific Committee composed by Professors Costato, Borghi and Artom and by Lawyer Iorio, and it ended its analysis in 2005, then collaborating with the then-Ministry of Industry (now Ministry of Economic Development) with the aim of providing a complete snapshot of the Italian Food Law Code by means of a comprehensive sector approach.

The final Code project resulted in both vertical and horizontal dispositions on food products, whose grounding basis truly implemented, according to which disciplining the Italian food sector, were found to be firstly the harmonization towards European food laws, especially to the one provided by Regulation 178/2002, and secondly the simplification of existing procedures, by erasing all those not obliged drawbacks born only by the Italian food sector with respect to the other corresponding Member States' ones.

The Italian Code of Food Law was supposed to be composed by five sections: the first one was about the general principles building the cornerstones of the food discipline; the second and third sections were respectively about laws concerning the production and commercialization of food products, treated separately as Law 229/2003 explicitly ordered; the fourth one was about inspections and sanctions, included both the penal and administrative ones; while the last one dealt with the final dispositions, by listing all the repeals and abrogating all the laws in turn introducing, modifying or erasing repealed provisions.

One of the first steps in achieving the realization of the Code project was taken by means of the alignment of words belonging to the two different languages, seeking a common vocabulary on the basis of the definitions provided by Regulation 178/2002, and hence expressions such as "food", "foodstuff", "food product" and relative synonyms and Italian counterparties found their identification in the above discussed Article 2 under the term "food", being them one and the same. [46]

Lots of difficulties were found in the application of the above mentioned guidelines, especially concerning the sanctions theme, in which there was almost no correspondence between the European and Italian laws on the violation of Community

[46] BORGHI P., *Il progetto di codice di diritto alimentare,* Rivista di diritto alimentare, A.I.D.A., 2007, p.20, http://www.rivistadirittoalimentare.it/rivista/2007-01/2007-01.pdf

rules, while National ones had instead to be implemented when European directives were the ones to be violated. Administrative and legislative simplifications encountered obstacles as well: the first one tried to introduce a sort of self certification on the compliance of places and businesses instead of the more time consuming and complicated sanitary authorization when opening a new food business (with the exception of some particular cases, such as food for specific diets, babies or frozen one), as provided by the options given by the European Community, but, in the end, this maneuver ended up to preserving the status quo, as the then-Ministry of Industry settled for a universal solution regarding all food businesses, independently from their food destination. The administrative simplification tried also to give a regulatory rank to order all the dispositions, and, in order to simplifying to the maximum possible extent the Code structure and make it understandable, accessible and easily implementable, the Code project was divided into two sections: the first one regarding the whole general Food Law discipline, and the second one about all the detailed technicalities applying to it. This split was aimed at granting flexibility and almost real time updating, but turned out to be not enough efficient to be approved by the single Italian Regions, which instead had to follow the Italian Constitution first of all.

Unfortunately, on 9 September 2007 the legislative delegation concerning the rearrangement of Italian food laws expired. Government inertia was the main reason why the Italian Food Law Code didn't see the light, bearing consequences for all the involved parties: Italian food consumers could have been safeguarded as European ones are, Public Administration could have more easily carried its inspection duties and Italian food businesses could have been as competitive as their European counterparties.[47] Ultimately, the delegated legislator settled for a sort of open referral to the Community food regulations instead of harmonizing with them and granting consumers rights on health tuition, quality and safety food requirements and, last but not least, information and fair advertising.

Considering the nowadays Italian position inside the European Union food market it is even more clear the necessity of being guided by a clear, ordered and well structured food law code, capable of granting on the one hand quality and healthiness, and on the

[47] ARTOM A., *Il codice alimentare non è stato adottato,* Rivista di diritto alimentare, A.I.D.A., 2007, p.50, http://www.rivistadirittoalimentare.it/rivista/2007-02/2007-02.pdf

other business efficiency and speed according to ever changing environments and technologies.

Concrete needs such as interdependencies among Member Countries, internal European market, high food standards, health protection and whole food sector efficiency need the political attention to be drawn again towards such themes, with the hope of achieving more tangible results.

On the one side food business operators need sources fragmentation to be solved, since inconsistency and instability cannot foster their activities, even more if regulated by excessive and not properly working mechanisms, which are in turn not permitting the calculation of the possible risks incurred in violating them. On the other side, food consumers are asking the Legislator both of making them disposing of adequate pieces of information, clear enough to take conscious choices for their nourishment, and of establishing a legal framework in which the non-complying food operators are forced of being accountable for their wrongful actions, both on healthy and informative issues.[48] More generally, both parties are asking for a greater certainty provided by food legislation, a sort of guiding light in responsibly helping them at taking their actions, being consistent with itself along the various dispositions and not revealing to be confusing or misleading, as still nowadays it presents itself.

[48] GERMANO' A., *Le sfide del diritto alimentare,* Rivista di diritto alimentare, A.I.D.A., 2007, p.23, http://www.rivistadirittoalimentare.it/rivista/2007-01/2007-01.pdf

CHAPTER 2. AGRI-FOOD SUPPLY CHAIN CENTRALITY: THE ROLE OF THE OPERATORS AND THE WEAKENESS OF THE PRODUCER ONES

2.1 The shifting of focus towards the entire agri- food supply chain dimension

The discipline regulating the commercialization of food products, deriving from both the National and the International agri-food sectors, has been lately the focus of an increasing backfire: not only are regulators dealing with its formulation and interpreters with its understanding, but also society has found its stake in it. As a matter of fact, the increasing innovation process undergoing this subject and, most of all, the awareness of this trend, are spreading the interest for the food law theme, which has recently crossed its old boundaries, once considered to be strictly defined and related only to the expert class. At the heart of this "new" group of interest, along with the obvious concerned final consumers, food producers and relative businesses are leading the way, focusing on the elements building their everyday practical management and working routines and impacting the course of their lives. Indeed, the adequate regulation faced by the involved parties is difficultly to be found inside specific codes provisions, given that more and more often the appropriate solution is not yet provided by them or finds itself to be no longer applicable on the reason of its outdatingness.

In this scenario the research for the best fitting solution is giving the way to the so called "law in action", where multiple sources, both of internal and external sector origins, interact and construct the road to follow. This aspect is worth of a particular mention, especially if considered the increasing number of agri-food supply chain members taking part to the final food product with respect to a few decades ago and hence requiring to be properly regulated, both from the food safety and commercial perspectives. Therefore, National, European or International food laws haven't substituted one for the other, but, in order to perform effectively, they must collectively intertwine with reality and actual real world stakeholders' challenges. As a consequence, traditional trade contracts are inappropriate too in this picture, being unable to explain the complex food sector relationships and requiring to be revised both on the individual and collective business perspectives and to be integrated by new sources, which happen to be of both of public and private nature.[49]

[49] ALBISINNI F., *Mercati agroalimentari e disciplina di filiera,* Rivista di diritto alimentare, A.I.D.A., 2014, p.5, http://www.rivistadirittoalimentare.it/rivista/2014-01/2014-01.pdf

The discipline fitting this new food settings highlights the common agrarian origin shared between the "agricultural" and the "food" sectors as a demonstration of the new real subject of nowadays world: the entire agri-food supply chain. In this perspective it is clear the shifting of the focus from just the final food product considered by itself towards the entire flow of processes giving birth to it. On top of that, the key role played by the globalised market and, most of all, the importance of the first fundamental phases of production carried by food producers must be deeply analyzed and understood, in order to properly discipline and valuing them.

It must be also said that in European food law the attention towards the entire set of food supply chain steps has been clearly and explicitly recognized only at the end of last century, in the light of the health issues caused by BSE scandals, which highlighted the need of tracking back foodstuffs paths in order to provide food hygiene and safety. Nevertheless, some prior episodes belonging to the pure agricultural production can date back the European emergence of this new supply chain perspective, which since the 1960s was aware of the consequences deriving from the choices taken in the primary phase and spreading towards the market and consumption ones.

As a confirmation of this emphasis being at the heart of food European legislation, the latest reformulation of the Common Agricultural Policy (CAP) operated at the end of 2013 and extended with few amends till the end of 2022 (due to European Parliament and Council delays complication on specific subjects), is again focused on the market and its composing parties: not only by means of the Single CMO Regulation, which has obviously its center in it, but also through the Direct Payment Regulation and the Rural Development one, which even if undergoing some modifications are still reserved to the entire agri-food supply chain.

The meaning of this new supply perspective developed by agrarian economists can be found in the synthesis expressed by the collection of businesses operating in the agri-food sector and collaborating in giving birth to the final foodstuff with respect to the more individualistic previous approach: each firm must be analyzed and interpreted not as a single subject, but as a unit taking part of a complex system in which sharing relationships is the key to properly function. In such a way, each firm finds itself in being both provider and user of goods and services, hence impacting the proper and overall dimensions in a relational approach where agriculture, industry and distribution reflect the interconnections happening among them. The single unit autonomy is left behind for

a joint analysis of the multiple components collectively operating and giving birth to the complex agri-food system: a unique context where its discipline, starting from the final food product and going backwards until its farmers, unifies the agricultural and food sectors up to the point of even questioning the real boundaries between this two once standalone worlds.

2.2 Agri-food supply chain operators responsibilities: how to behave in the European Union

Regulation 178/2002 strongly contributed in the formalization of the unifying concept of agri-food supply chain, always with the aim of providing a final safe food product in the market. In order to accomplish this goal, the control of the activities performed along the supply chain and disciplined by the Regulation had to be increased, and hence, each food business had to have clear requirements and responsibilities to be guided by.

Agri-food supply chain responsibilities can be examined under a double perspective: the first one entails the vertical relationships established between the single food enterprise and the National public bodies in charge of granting food safety, while the second concerns the horizontal relationships happening among all the supply chain activities.[50]

In order to begin with, a supply chain deconstruction must be applied to deeply understand the role assigned to the single food businesses, which must ensure food safety in each single step of their performance; only later the single units can be regrouped again towards a more comprehensive vision guided by the traceability theme. As a matter of fact, the European Commission made of "From farm to fork" one of its main slogans, at highlighting the attention reserved to each single phase of food production. Hence, each firm in this view keeps its autonomy at individual level, but at the same time is part of the continuity given by the comprehensive food production system in which it is integrated.

Even though the eatable food is the subject of the already discussed Regulation 178/2002, the food discipline is the one in charge of regulating the activities performed by the chain of enterprises involved. This goal is achieved by means of obligations settled on right production procedures, verified not only by means of the resulting peculiarities or composing requisites checks on the final food product, but also by

[50] CANFORA I., *Sicurezza alimentare e nuovi assetti delle responsabilità di filiera,* Rivista di diritto alimentare, A.I.D.A., 2009, p. 14, http://www.rivistadirittoalimentare.it/rivista/2009-04/2009-04.pdf

establishing right behavior ways of producing and processing, in such a way that food safety is granted along the entire flow in which the foodstuff is going through. In this manner each single firm is subject to specific duties, entrusted to it by Article 18 and the followings of General European Food Law in the fields of traceability, specific food and feed business operators responsibilities and liabilities.

To begin with the first, traceability of both food and feed and of any other substance aimed at human consumption must be implemented since the beginning of the journey, and hence it must cover all the production, processing and distribution phases. Furthermore, at the same time, the food or feed firms operators involved in the process must be able to identify both the sources from which they have been furnished and to which they have supplied the food or substance under consideration. In order to accomplish this goal, those operators must dispose of adequate settings, procedures or systems to let this pieces of data being available to the competent authorities upon check requests. In addition to this, food and feed commercialized in the European market must respond to specific requirements on labelling or displaying identifying elements in order to make the traceability system working smoothly (Art. 18 Reg. EC n. 178/2002).

The responsibilities in chief on food and feed business operators instead are quite similar the ones to the others, especially if considered that they are both established at granting the superior aim of food safety. Those figures, if they have reasons to assume that a particular food (Art. 19 Reg. EC n. 178/2002) or feed (Art. 20 Reg. EC n. 178/2002), according to the field of interest, which has been going through any of the importation, production, processing, manufacturing or distribution stages inside their firm, does not respect food safety standards, they must immediately remove it from the market if they are still in a position to reach it and, of course, inform competent authorities of the damaged product. In the hypothesis of a foodstuff which has already reached the consumers, food or feed business operators must let them know about the reasons why the product should be removed from the market, and if necessary, they must enact procedures to recall it if other additional measures cannot ensure the desired level of health safeguarding. With particular respect to feed business firms, if their products result to be not enough safe, or the entire batch does not reflect the desired safety conditions and if competent authorities do not provide other satisfying measures, the involved goods must be destroyed. Furthermore, concerning health

injurious products, operators must also inform competent authorities of the actions taken at containing the risk incurred by the consumer and, most of all, they must not hinder any entity in cooperating with the appropriate bodies to erasing or at least diminishing the hazard caused by the damaged foodstuff or feed.

In this way, the framework of requirements strengthens the vertical relationships taking place between the agri-food businesses and the public authorities with the aim of reaching a comprehensive food supply chain safety, independently from the diversity of the food firms involved. Indeed, among the questioned agri-food businesses, also the agricultural ones find their place according to Article 3 of EC Regulation n. 178/2002: it clarifies that under the food business category can be found any undertaking related to the production, processing and distribution phases of the food element, even though usually extreme specificity is reserved to the agricultural firms under the National or Communitarian arrangements.

A slightly different position is instead covered by the importing food businesses, which often deal with both European and extra European imported products. As a matter of fact, their struggle consists in the assessment of food safety achieved by means of European food requirements concerning European foodstuffs, while by means of equivalent European measures for products not coming from Member States. Nevertheless, the general rule remains the one of granting the safety conditions requested by the Community in order to put those foods in the market, so, if the examined products are the ones coming from an extra European Country they must necessarily respect European food law provisions or at least reflects them by means of equivalent measures, which must have been mandatorily recognized by the Community as valid. This holds if specific agreements between the exporting State and the European Union aren't in place, otherwise the rules to follow are the ones provided in them, if specified (Art. 11 Reg. EC n. 178/2002).

The same applies to European exporting food or feed businesses, which must always respect the Community food requirements, if not otherwise provided by the extra Member importing Country. As a matter of fact, those National competent authorities must always approve the exportation or re-exportation procedure, basing their decision on informed judgments and motivations (Art. 12 Reg. EC n. 178/2002).

Nevertheless, the same Community and its Member States must cooperate in the evolution of International standards on both food, feed, sanitary and phytosanitary

themes and encourage, where necessary, the establishment of agreements recognizing equivalent European safety measures. Furthermore, most of all, they must not hinder the deal achieving by means of inappropriate restrictions (Art. 13 Reg. EC n. 178/2002).
The just discussed framework of provisions aims at enhancing the duties carried by the single food or feed firms, by increasing their sense of responsibilities in the activities performed, and at strengthening their relationships with competent National authorities. The latter, however, remain in charge of granting food safety by means of controls on individual business compliance to those requirements and spreading information about possible food risks incurred and relative remedies.
To continue with the second mentioned perspective, that is to say the one regarding the horizontal relationships taking place among the single food and feed firms composing the entire supply chain, traceability is again the key in providing a new kind of interpretation on the theme. As a matter of fact, being the involved businesses subjected to strict and specific requirements concerning also the transparency of the origins and the destinations of their products, consequences on the safety of the entire food or feed journey are brought too. In this way, the single inputs coming from the activities performed at the beginning of the supply chain must already respond to food law specifications imposed to them by the Community, being in turn a guarantee for the firm which is acquiring those products. The supply contract, which is the one in charge of linking the agreements established by those production steps and assuring that the negotiated elements are safe according to food law, operates by means of the producers identification and, where possible, by the implementation of controls on the sold items, the ones that will be in turn part of next phase of the supply chain activity performed by the buyer. [51]
In addition to the traceability peculiarity, other features are added to the supply contract to counterbalance the power disparity born by the weakest counterparties, which are not disposing of enough information on the safety of the food product bought or are simply occupying an inferior bargaining power position along the food supply chain. The most emblematic example on the subject can be considered the agricultural businesses, which since the dawn of time have always been "mistreated" by their most powerful sisters: the agro-industrial and agri-food enterprises; from here rose their necessity of finding better management tools in the regulation of the supply chain relations.

[51] CANFORA I., *Sicurezza alimentare e nuovi assetti delle responsabilità di filiera,* cit., p. 16

Particularly significant can hence be considered the exception reserved only to the primary food production by "Regulation 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs", which exempts it from being covered by the HACCP system, scoring a great difference with respect to all the other supply chain related activities. As the content of its Article 5 (paragraph 3) states, all the food business operators must adhere to the above mentioned procedure, which is covering all the stages of production, transformation or distribution after the primary production and thereof have already taken place. Hence, the possibility of adhering or not to the HACCP system is left to the agricultural businesses, with the aim of helping them at balancing their weakest position also due to the different bearing of costs, and considering that those primary ingredients must still be later verified on safety terms along with the following phases of production. Therefore, a recognition of the different power positions occupied by the various kind of businesses along the food supply chain has been put into place, but a drawback on the exemption still exists: the choice of adhering to the HACCP system is upon willingness for the primary production, but the one of making use of components proved to respond to accurate food safety requirements for all the subsequent phases carried by other food and feed businesses is not. Hence, the need for agricultural firms of guaranteeing the safeness of the food products, also by means of the HACCP system, is still in place. The only difference with respect to the "regular" HACCP system is that is up to the various National bodies to elaborate specific agricultural rules on the one HACCP fitting primary production specificities according to the Countries under examination, instead of setting them free from the obligation of adhering to it.[52]

Last but not least, always at the heart of this second perspective on the horizontal food supply chain relationships, a more practical instrument has been lately implemented more and more often with the aim of self-protecting the food and feed businesses: the private certification. As a matter of fact, this feature adds value to the supply contract by integrating regular requirements with the additional ones provided by the specific certification, which is instead granted by a third party body. The positive aspects highlighted up to now, aimed at adding superior validation to the intrinsic product characteristics and acting as a safety guarantee for both selling and acquiring firms, on the other hand, ceil also some drawbacks. Those can be identified especially on the extra

[52] CANFORA I., *Sicurezza alimentare e nuovi assetti delle responsabilità di filiera,* cit., p. 16 - 19

costs incurred by the firm implementing the private certification and on the possible lack of transparency thereof.[53] Hence, those mechanisms need to be properly taken care of and regulated, especially the ones entitled to discipline the agricultural quality of food. It's no longer enough to only admit and understand the extreme difficulties challenging the agricultural businesses, but it's time to help those primary firms in gaining the attention, power and protection they have always asked for.

2.3 The common journey of the European food and agri-food laws: consequences for the sector operators

It is not a secret that in the last sixty years the two main fields disciplining food safety, which is to say the food and agri-food law disciplines, have more or less followed the same path. As a matter of fact, the two subjects' origins at European level can be traced back to the year 1962, the one in which the first significant practical measures on the themes were firstly adopted by the European Community, even though some sporadic events, such as the 1957 Treaty of Rome dealing with the CAP institution, happened also before. The concerned 1962 actions, in fact, were dealing with both the agri-food and the food laws on the basis of their interrelated deep linkage, despite the fact that there was not yet recognized their guiding aims of food safety and consumer protection first. [54]

It hence has to be said that the regulations under examination, such as the ones on the very first CMOs on cereals, meat, eggs, fruit and vegetables and wines, laid down the fundamental basis for the competences, procedures, ways of management and functionally disciplining the food and agri-food sectors that would eventually become the European grounds, especially the ones dealing with practices setting requisites on food products. Worthy of a particular mention in this scenario is Regulation 23/1962, the one that worked for the establishment of a common market for fruit and vegetable products and for the abolishment of the equivalent measures restricting trade. The Regulation operated by means of common standards on quality, associated to specific product features such as dimensions and the like. Furthermore, in order for those foods to respect the requirements and hence being commercialized inside the European market, the need for enacting controlling mechanisms and related products information emerged at the same time. Hence, the 1960s saw the beginning of the modern European

[53] CANFORA I., *Sicurezza alimentare e nuovi assetti delle responsabilità di filiera,* cit., p. 17

[54] ALBISINNI F., *La nuova OCM ed i contratti agroalimentari,* Rivista di diritto alimentare, A.I.D.A., 2013, p.5, http://www.rivistadirittoalimentare.it/rivista/2013-01/2013-01.pdf

supply contracts features for food themes, where the food and agri-food sectors shared almost the same regulations, sometimes impacting only the one, sometimes instead only the other, but increasingly often dealing with both of them.

Three decades later two Council directives, named "89/397/EEC" on foodstuffs official controls and "89/396/EEC" on the lot identification of the food product, scored a fundamental goal on the theme. As a matter of fact, they highlighted that the concerned aims can be found in the health protection and food quality and composition in order to safeguarding both the economic and sanitary consumer profiles (Directive n. 89/397/EEC), and, at the same time, if aiming at the development of International trade and relative fair transactions, the specifications on the food lot had to be clearly stated (Directive n. 89/396/EEC). In this way, together with the traditional topics linked to the hygiene and food safety problems and the consumer interests ones, the market perspective clearly saw the light, unifying the food and agri-food sectors once and for all by means of an entire supply chain regulation, starting with production requirements and ending with the commercialization ones.[55]

The most significant updates were brought by the CAP reforms on the decoupling of the financial aids with respect to the production and the establishment of the Single CMO, introduced respectively by Regulation 1782/2003 and by Regulation 1234/2007 at the beginning of the new Century. To begin with the first, its innovative capacity was due to the overall multiannual budget planning, which was no longer concerning only a specific CMO, but all the different types of food sector ones (maintaining the exclusion of the processing industry from the class, as provided by 26th Whereas Reg. EC n. 1782/2003), which had never before been organized by means of a single financial aid scheme with the aim of administrative simplification. Furthermore, the European agricultural legislation, which up to then had always operated by means of specific management and assistance contents but always leaving to each Member State the choice of which definition to choose for itself, as consequences of the decoupling procedure and of the market-centered perspective, it understood the importance of being the one in charge of dictating the clues. It took no longer also for recognizing the need of taking part in the establishment of market agricultural prices, given the great uncertainty and volatility characterizing the relative field. [56]

[55] ALBISINNI F., *La nuova OCM ed i contratti agroalimentari,* cit., p. 7
[56] ALBISINNI F., *La nuova OCM ed i contratti agroalimentari,* cit., p. 9

The new structure brought about by Regulation 1782/2003 was significant also under the overall formal perspective: all the different food sectors covered by the unique supporting scheme were grouped by a single Regulation, no more by means of different ones according to the specific food product sets, giving birth to a single systematic body of universal European provisions on both crop and animal productions. This union of previous singular CMOs impacted also the meaning of the discipline, which finally linked the entire agri-food sector, as a proof of the interrelated mechanisms taking place among the various food and feed products that difficultly concern only one specific sector and leave the others aside. As for the sake of update, Regulation 1782/2003 was repealed by Regulation 73/2009, in turn substituted by Regulation 1307/2013 on direct payments to farmers.

To continue with the second above mentioned significant CAP reform, concerning the establishment of the Single CMO, the protagonist is now Regulation 1234/2007, which contributed in reshaping the old food law landscape. As a matter of fact, it did not only formally reorganize the set-up of the different scattered single CMOs provisions and regulations (Art. 201 Reg. EC n. 1234/2007), but most of all provided in the process of giving a new arrangement to the overall European agri-food law organization by granting the superior jurisdiction over the subject to the European Commission. Regulation 1234/2007, together with the other less significant regulations, it went at modifying the institutional framework upon which the oldest CAP has been built across the ages and hence it resulted in a multilevel intersection of both National and Community legislation, both equally needed but also necessiting to be properly regulated. With the years passing by, the powers recognized to the European Commission were amplified, ranging from dictating specific product features, relative dimensions and origins to commercial names, labelling and denominations.

At the same time, an increasing opening towards the internationalization of processes took place as well, paving the way for the implementation of unconventional regulating sources, both of private and of International origins.

Regulation 261/2012 amended the 1234/2007 one on the contractual relations in the milk and milk product sector theme. Again, some adjustments were made in the producer organizations, contractual negotiations and relationships, not leaving aside the supply regulation of PDO and PGI cheese and some formalities in the stipulations of milk sector contracts. Among the modifications implemented, two were the greatest novelties

that led to the overturning of two ancient taboos: the bans on preventive producers agreements, the first aimed at disciplining the supply and the second at fixing prices. [57] Even though the first one was already granted only to the producers organizations aiming at fitting market needs and increasing product quality, it has always been simply intended as a general rule, always bearing in mind that whatever producers agreement born with the intention of controlling and fixing production remains illegal. Opening the way towards PDO and PGI cheese producers deeply symbolized a change of pace, pulling the trigger on a bottom-up approach able to substitute the institutionalized and centralized planning and put instead at its heart the interested producers, which really happen to know the strengths and weaknesses involving their sectors. This change of course was hence hoped to be extended to all the qualitative food products, independently from the sector of belonging, included the ones coming from the wine one. The other significant measure dealt instead with the written agreements on the milk delivery, which from that moment on could included the price to pay for the business acquiring it, according to specific intrinsic and objective features previously identified. As already discussed above, those producers organizations were already dealing with those possibilities (such as the one of including already fixed prices in the contracts being analyzed now), but the turning point was now represented by the fact that was no longer needed a placing on the market phase to exist in order to let the milk producers collectively agreeing on the price of the concerned products. Hence, those figures of the producers organizations became finally protagonists in a network of relations, together with the individual producers taking part of them and with the Member States, all involved in the disciplining of the food regulatory arena.

At the end of 2013, Regulation 1234/2007 (and hence its amendments, such as Regulation 261/2012) was in turn repealed by a piece of legislation that was destined at becoming one of the European cornerstones of food law: Regulation 1308/3013. Its aim was clear since the beginning: establishing a common organization for the agricultural products markets, providing them with a safety network of market supporting tools, specific sectors aids and exceptional measures (Art. 1 Reg. EU n. 1308/2013). Cooperation between producers organizations and the ones in charge of representing production, commercialization and transformation of food products, which is to say the inter-branch ones, was stressed, hence not leaving aside the minimum food quality

[57] ALBISINNI F., *La nuova OCM ed i contratti agroalimentari,* cit., p. 12

requirements to respect in the supply chain transactions and the right competition disciplining it.

The key features of the common organization of the market can be found in the market intervention by means of both public and private actors, in the emergency measures that can be taken by the European Commission and in the new ways of controlling the market supplies.[58]To begin with the first one, public intervention rules regard circumstances in which food products are bought and stored by European governments till their disposal, while private intervention ones are called when private operators are the ones in charge of storing them. Hence, both systems are being revised and renewed according to market and ages updates. Furthermore, the European Commission has increased its powers, with the possibility of intervening whenever market distortions are caused by significant price fluctuations or when extraordinary events, such as measures aimed at stopping animals diseases or increasing the once lost consumers faith and degenerating into market shocks need to be taken care of. In addition, in the remote hypothesis of great market distortions, the source from where to take additional financial aids has been identified as the reserve designed for crises. Differently, market supplies instead saw the end of milk and sugar quotas, respectively terminating in year 2015 and 2017, with the aim of letting producers finally being more competitive not only at European, but also at International level. Furthermore, it must not be forgotten that Regulation 1308/2013 has encouraged also the creation of producers organizations in order to strengthen their bargaining power along the supply chain, later complemented by the fundamental themes covered by Regulation 2017/2393.

If all these reasons gave Regulation 1308/2013 its importance, up to now it has not yet been explained the real motivation under its canonization: the need of establishing producers-processors or producers-distributors contracts in the written manner, contracts that furthermore must contain specific content requirements.[59] As a matter of fact, Article 168 of the Regulation suggests Member states to make use of this formality in covering them, with the exception of contracts concluded between cooperatives members: in this specific case, if their statues do provide similar clauses, the producer-purchaser contracts doesn't have to obligatory exist. Whereas, the items reported to be included in the regular written contract are identified as the price agreed, which should

[58] https://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:02013R1308-20190101

[59] ALESSI R., *Tecniche di regolazione del mercato agro-industriale e diritto comune,* Rivista di diritto alimentare, A.I.D.A., 2018, p.114, http://www.rivistadirittoalimentare.it/rivista/2018-03/2018-03.pdf

be fixed and obtained on the basis of the interested components (such as market indicators mirroring the market state-of-the-art), the quantity and quality of the food products being sold, the time in which the delivery will be carried, how long does the contract last (definite or indefinite duration), ways in which the payments will be executed and when, manners in which the foodstuffs will be picked or supplied and last but not least, eventual dispositions on force majeure accidents (Art. 168 Reg. EU n. 1308/2013). Nevertheless it must be also said that the provisions required by the just mentioned article are considered to be optional to the single Member States to adhere: as a matter of fact, on the sake of the harmonization procedure, the choice of adopting or not the legal framework under examination has been left to them; the latter can hence implement it or not according to their National legislative policy. This act of freedom on not opting for a unifying measure on selling contracts has hence led to a greater universal inefficiency of the corrective power system, resulting in scattered results on the tuition of the weak figure of the agricultural producers and their bargaining power along the agri-food supply chain.[60]

As a result, different forms of instruments have been used in balancing out the obvious disparity of powers, with the aim of rightly and weightily spreading the value created along the entire journey the food element is going through. Examples of solutions can be found in the collective contractual negotiations carried by the organization of producers with the aim of setting the selling price of their output, in order for it to be fairly representing the efforts they made in producing it and not bending towards the most powerful large supermarket chains now-a-days, or towards the transformation industry in the past. On this reason, a potential resolution can be considered the definition of objective criteria in setting those prices, starting from the legislative intervention, the agreements obtained among the involved agri-food supply chain actors or even by means of a collaboration of the two.[61] Concerning the European Union, the pilot run has been brought by France, in which the National legislator has understood the importance and necessity of setting the agri-food prices in a clear and unambiguous manner, by making use of explicit benchmarks upon which to adjust them. The main novelty introduced by the French experience was the stakeholders participation to the price

[60] CANFORA I., *Raggiungere un equilibrio nella filiera agroalimentare. Strumenti di governo del mercato e regole contrattuali,* Roma TrE- Press, 2020, p. 237-244, http://romatrepress.uniroma3.it/wp-content/uploads/2020/06/11.ibri-canf.pdf

[61] ALBISINNI F., *La nuova OCM ed i contratti agroalimentari,* cit., p. 13 -14

debate, letting the agricultural entrepreneurial representation and the others of the agri-food supply chain giving voice to their necessities in granting a dignified standard of living to the agricultural population. Hence, the need of considering the production costs at the heart of the criteria to follow in setting the agri-food prices has been recognized as crucial. Nonetheless, the effectiveness of the measure has been jeopardized: the choice of which indicators to follow has been left to the involved parties and the use of a third body, in charge of clearly identifying the appropriate benchmark to adhere from time to time, is completely upon willingness, hence hypothetical. Therefore, the non-obligatory leaning on a external competent source has not scored a goal in favor of the weakest producers, given the possibility for the counterparties to choose a market-based framework of prices instead. In this way farmers are obliged to bear all the costs, resulting in a particular unprofitable solution for a sector in which prices are extremely unstable because of the different products and of the different local markets status.[62]

The contract centrality has hence being revised at European level over the past few years and it is developing itself towards new horizons. However, all these new forms share two common traits, which can be identified as the freedom of contract and the regulatory intervention.[63] The first one, as its name suggests, deals with the freedom in setting and managing contracts, with the exception of some specific bad behavior episodes which are subject to already defined sanctions and therefore must be accurately punished. The regulatory intervention instead can be faced under two perspectives: on the one hand the one carried by the public authorities, while in the other hand the one executed by the private actors. According to the specific theme being involved, the one kind of operators or the other is being chosen, reserving particular attention to the topics being dealt by the public authorities on the reason of their extreme relevance. Nevertheless, making use of the private legitimized authorities, independently from their being categorized in an individual or collective manner, brings the same validity to the object analyzed. These days, more and more often the measures taken both by the National and Community legislators found themselves to be part of the second perspective, which achieves the regulation and management of the food businesses and their relationships by means of a new approach. This innovative way is based upon a methodic way of behaving and weighing alternatives, which seriously

[62] CANFORA I., *Raggiungere un equilibrio nella filiera agroalimentare. Strumenti di governo del mercato e regole contrattuali,* cit., p. 246-249

[63] ALBISINNI F., *La nuova OCM ed i contratti agroalimentari,* cit., p. 14

takes into account the fundamental cornerstones upon which the modern market properly works. It has to be also said that it is nowadays clear that the market cannot self-regulate itself, given that the need for those external measures, independently from being started by public authorities or private ones, still arises. As a matter of fact, outstanding asymmetries on economic, productive, financial and informative themes still threaten the smooth functioning of the internal and external trade. Consequently, new forms of autonomy, especially the collective ones, are leading the way in the attempt of rebalancing the different powers displayed along the supply chain and making sure that the access to the food market results to be fair to all the different parties involved.

2.4 Producer Organizations and Inter-branch ones: how to counteract the individual producer weakness along the agri-food supply chain

As of the end of 2019, the Agriculture and Rural Development Department of the European Union recognized 11 million farmers within its territory[64], almost all running their small family businesses independently the ones from the others. Different positions are instead occupied by both the other agri-food supply players, which are highly concentrated with respect to their weaker counterparties: few processors represent 90% of the turnover, while some other distributors rule the entire market.[65] On the reason of such a great imbalance, where often specialized farmers produce outputs already conforming to the needs of their counterparties, it results unavoidable for producers to associate with the aim of strengthening their negotiating authority and giving voice to their rights. [66]

In order to counterbalance these disparities of bargaining power, the European Union has started to see farmers in a different light, supporting the ones of them who desire to cooperate and collaborate in the ways of running their businesses, hence giving rise to the so called "producer organizations". Not only is the implementation of the just

[64] AGRICULTURE AND RURAL DEVELOPMENT DEPARTMENT, *Producer and interbranch organizations*, 2019, https://ec.europa.eu/info/food-farming-fisheries/key-policies/common-agricultural-policy/market-measures/agri-food-supply-chain/producer-and-interbranch-organisations_en

[65] DG AGRI, *Producer Organisations – Key Facts and Findings,* 2019, https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/key_policies/presentations/producer-organisations-key-facts-and-finfings_en.pptx

[66] JANNARELLI A., *I contratti dall'impresa agricola all'industria di trasformazione. Problemi e prospettive dell'esperienza italiana,* Rivista di Diritto Alimentare, A.I.D.A, 2008, p.5, http://www.rivistadirittoalimentare.it/rivista/2008-02/2008-02.pdf

mentioned tools encouraged by the Community Law, but also the one collectively involving the different productive sectors of the agri-food supply chain, taking the name of inter-branch organizations, is boosted too.[67]Different roles hence assume the organizations of producers with respect to the inter-branch ones: as a matter of fact, the first ones can be considered horizontal tools aimed at establishing an economic cooperation among agricultural producers in order to cope with the other participants to the agri-food supply chain in a collective and unified way, always giving voice to the producer economic interest and dealing with it. The second ones instead are not economic organizations at all, but can be identified with the need of economically managing the vertical cooperation established along the different members of the entire agri-food supply chain. [68] The contracts of the latter therefore share the aim of disciplining the relations and the interests of the different parties composing the agri - food flow: the cultivation and selling contract is an example of what governs the farmer and the processor linkage inside the inter-branch agreement.[69]

All those relatively new forms of contracts assume a completely different spot at the heart of European Legislation, on the reason of their extreme speciality: their origins are due to the aim of safeguarding the precarious economic equilibrium governing the agri - food sector, in order to avoid extreme market and prices imbalances both for the involved businesses and consequently for the final consumers. Hence, it is not surprising that the rules and therefore exceptions regulating the food production sector apply only to it and not to all the remaining others.

In order to properly discipline the complex network of relations building the agri-food sector, the European Legislator faced it in three steps: the first one concerning the so called "Omnibus" Regulation (Reg. EU n. 2017/2393) on recognized producer organizations, the second one on the unfair trading practices and the last one on the extension of the market transparency to the entire agri-food supply chain, no more only

[67] BORGHI P., *Lo status di produttore e di consumatore di alimenti, e i contratti del settore alimentare,* Rivista di diritto alimentare, A.I.D.A., 2008, p.3, http://www.rivistadirittoalimentare.it/rivista/2008-02/2008-02.pdf

[68] BUFFARIA B., *Efficienza economica delle filiere agro alimentari e ruolo delle Organizzazioni di Produttori,* Cooperazione e coordinamento della filiera agroalimentare: lo strumento delle organizzazioni di produttori, 2020, p. 13, https://www.reterurale.it/flex/cm/pages/ServeAttachment.php/L/IT/D/4%252F9%252F4%252FD.18ea49ad0a4675b8fd0a/P/BLOB%3AID%3D21311/E/pdf

[69] BORGHI P., *Lo status di produttore e di consumatore di alimenti, e i contratti del settore alimentare,* cit., p.3

to its agricultural component, having the latter the goal of granting an economic help aimed at boosting investments proportional to the amount of sales.[70]

To begin with, the opinion of the European Legislator on producer organizations is clearly stated in the 52th Whereas of Regulation 2017/2393, which can be considered as sort of a bench mark on the topic being dealt. The just mentioned organizations can be established with the aims of concentrating supply, upgrading the marketing, planning and adjusting the agri-food production to the relative demand. Furthermore, they can seek to optimize production costs and set the price at the production, but also aim at investing and promoting research, best practices as well as supplying their members with technical assistance and devices to manage the risk incurred and byproducts (52th Whereas Reg. EU n. 2017/2393).

All these activities are carried in order to improve the role played by the single food producers and reinforce their status and power along the entire agri-food supply chain, in accordance with both the CAP aims and with Article 39 of the TFEU. As a matter of fact, the just mentioned Article identifies as CAP fundamental objectives the increasing of agricultural productivity and the assurance for the agricultural communities of an adequate standard of living, especially by means of the income enhancement of the people involved with these activities. At the same time though, other sort of contradictory goals must be granted, such as the market stabilization and the making sure that enough offer is granted in the market at a reasonable price, which must be accessible for the interested consumers. The European Legislator is hence in charge of finding sort of a trade-off among all the conflicting objectives.

All the above unfolded activities granted to the organizations of producers by derogation from Article 101 TFEU (on the ban on competition distortion and agreement on prices and market partitioning) and 102 TFEU (on the ban of the abuse of dominant economic position), which both strictly prohibit all the practices affecting trade in an unfair manner on the reason of the internal market incompatibility, are allowed only to the recognized producer organizations for which Regulation 1308/2013 has provided a common market organization. Furthermore, those rights should be granted only to the producer organizations effectively operating with the aim of economic integration and concentrating their members' supply and placing it on the market. The same

[70] BUFFARIA B., *Efficienza economica delle filiere agro alimentari e ruolo delle Organizzazioni di Produttori,* cit., p.12

derogations hold for associations of producer organizations. Nonetheless, adequate measures shall be implemented in order to make sure that competition remains in place, and hence, whenever competent authorities doubt on the implementation of the concerned activities, they can intervene and bend them according to their superior will (52th Whereas Reg. EU n. 2017/2393).

The just explained 52th Whereas can be considered so fundamental in the establishment of producer organizations on the reason why for the first time it is clearly stated by the European Legislator that, if the questioned organizations follow the imposed limits, regulations and conditions, they can be not covered by competition rules. Furthermore, this approach can be horizontally extended to all the agri-food productive sectors.

The fundamental criteria for the producer organizations to benefit from the exceptions are hence firstly to be recognized as a producer organizations and secondly to effectively run economic activities, which is to say that they must concentrate members' supply and put it on the market, independently from the fact of transferring its ownership or not. Once these requirements are respected, the organizations of producers can divert from competition rules established by Articles 101 and 102 of the Treaty on the Function of the European Union, as also provided by Article 152 and 209 of EU Regulation n. 1308/2013.[71] As a matter of fact, producer organizations which carry at least one of these activities, such as joint processing, distribution, packaging, labelling or promotion, quality control, equipment or storage facilities use, waste management, inputs provision or any other activity related to the already discussed producer organizations' funding aims, can deviate from Article 101 TFEU. Hence, those entities are allowed to planning production, optimizing production costs, collectively putting the involved products in the market and bargaining contracts for the supply of them, both on behalf of the entire organization or simply for just a part of it (Art. 152 Reg. EU n. 1308/2013). Furthermore, as sort of additional confirmation made available by the same 1308/2013 Regulation, Article 209 for producer organizations and Article 210 for inter-branch ones make clear that as long as those organizations are recognized according to above explained Article 152 (for producer) and 156 (for inter-branch), the prior derogations from Article 101 TFEU still hold, provided that the previous discussed Article 39 of the same Treaty does not risk to be threatened. On top of that, an additional "special" exemption for producer

[71] BUFFARIA B., *Efficienza economica delle filiere agro alimentari e ruolo delle Organizzazioni di Produttori,* cit., p. 13

organizations, associations of them and inter-branch organizations in case of severe marker imbalance periods is granted, always holding that the implementation of the following activities must not undermine the internal market functioning and aims instead at further stabilizing it (Art. 222 Reg. EU n. 1308/2013). Examples of the subsets under which those activities fall under can be considered products withdrawals from the market or free distribution of them, their storage, transformation or processing and joint promotion but also cartels on quality requirements and on joint purchasing of inputs to fight pests or diseases and last but not least, the most important aspect concerning the temporary planning of production studied on the peculiarities of the concerned products and relative production cycles are included as well. Nonetheless, it must be clear that those exceptions can be considered valid if their lifespan lasts at maximum six months, if not otherwise provided by the Commission itself. It must be also said that other derogations are in place, but they strictly refer to the specific sectors dealt from time to time, such as the sugar-beet one, the milk one or even the geographical indications one.

Up to now more than three thousands producer organizations have been recognized at European level, the majority of which (52%) belong to the fruit and vegetable sector, on the reason of their long time prior access to extra helping funds, while 9% is related to the milk and dairy products and 39% belong to other sectors. Among the European Countries in which the majority of producer organizations have been recognized, the top three is occupied by France, Germany and Italy, scoring respectively 724, 692 and 583 producer organizations each. It must also be noticed that as 2018, Estonia, Lithuania and Luxemburg present none of them inside their territory.[72]

2.4.1 European contractual networks at the heart of the Small Business Act and their Italian implementation in the agri-food sector

Another form of possible collaboration instrument at European level among agri-food enterprises in order to strengthen their position along the agri-food supply chain can be identified as the contractual network. As a matter of fact, contractual networks are particular forms of organizations characterized by the fact of being sort of hybrid structures placed between the market and the hierarchy ones. Actually, they differ from

[72] AGRICULTURE AND RURAL DEVELOPMENT DEPARTMENT, *Producer and interbranch organizations*, cit., https://ec.europa.eu/info/food-farming-fisheries/key-policies/common-agricultural-policy/market-measures/agri-food-supply-chain/producer-and-interbranch-organisations_en

the first ones on the reason of their being composed by specifically detected players chosen on resource complementarity basis, while the discrepancy from the second ones is found on their legally independence among composing members, while at economic level they are free to decide if relaying one on the other or not. Those forms of organizations can include both multilateral contracts established among their funding members or even networks of single bilateral contracts linked between them as well.

Four main features are at the heart of contractual networks and can be identified as interdependence among composing parties and in setting a common goal, related network relations stability, while long term duration and multiplicity of agreements, both of formal and informal nature, should be maintained likewise. At the same time, cooperation and competition do not exclude one the other: as a matter of fact, members can help ones the others on some specific matters, while competing on others. With this solution, a great overall level of flexibility is granted inside the network. [73]

This particular form of contract in the European context is inserted in the "Small Business Act", which, born in 2008, aims at boosting and sustaining the small and medium enterprises development, as well as their entrepreneurial and innovative spirit. Inside the Communication, additional possible Community and National enforcement ways are included, even though the nature of the Document is not of a binding one.

Ten principles guide the just mentioned Act and the relative implementation, in order to keep the fundamental priorities straight and clear. Those basic standards are: Think Small First, Entrepreneurship, Second Chance, Responsive Administration, State Aid and Public Procurement, Finance, Single Market, Skills and Innovation, Environment and Internationalization.[74] To begin with the first, it almost reassumes the aim of the entire European Communication: in order to be properly fitting the concerned enterprises, the interests of the small and medium businesses must be respected since the beginning of the decision making process studied by the Competent Authorities, so as to be conducted by a simplified and appropriate administrative and legislative framework of provisions. Entrepreneurship instead is more linked to the act itself of taking an opportunity, be properly guided along the journey and being satisfied by the results accomplished and by the context in which the entrepreneurs are operating, with

[73] CAFAGGI F., *Contractual Networks and the Small Business Act: towards European principles?,* European University Institute – Department of Law, 2008, p. 1-2, https://cadmus.eui.eu/bitstream/handle/1814/8771/LAW_2008_15.pdf?sequence=1&isAllowed=y

[74] COMMISSION OF THE EUROPEAN COMMUNITIES, *"Think Small First", A "Small Business Act for Europe",* 2008, p.4, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52008DC0394&from=IT

particular attention reserved to the youngest of them. The third principle, which is to say the Second Chance one, aims at rewarding the honest entrepreneurs which, even if having failed during their previous experiences with bankruptcy, deserve quickly a second opportunity for their fair behavior. Responsive Administration alternatively concerns more the side of the public administration, which must be coherent and reactive to the needs provided by the SMEs', while State Aid and Public Procurement should do the same, other than using in a more clever way the resources aimed at the deserving businesses. Similarly, the Finance one entails helping the access to funds as well as supporting the establishment of a legal and business environment in which transactions take place on time. Instead, the seventh principle, dealing with the Single Market, is about assisting small and medium enterprises at taking advantage of the opportunities provided by the European Market. Differently, the Skills and Innovation principle is aimed at boosting the learning, improvement and implementation of new skills and at valuing whichever form of innovation fostered by the concerned businesses. On the same level finds itself the Environment principle, which has the role of enabling SMEs in turning environmental challenges into opportunities. Instead, the last but not least Internationalization one deals with encouraging and supporting the one businesses desiring of taking advantage of the European chances of markets growing and spreading. It must also be said that, even though all those measure promise and sustain a particular approach reserved to the most weak supply chain components, along with all the positive achievements some failures are still present. Some of them have been identified as the administrative and legislative burdens on the shoulders of the small and medium enterprises, together with a difficult access to the needed financing and to the European market, needing superior efforts in opening the way towards the accomplishment of other related European programs.

Going more into details, in 2018 more than 25 million small and medium enterprises were counted in the European Union, 93% of which were even micro ones. [75] If instead taking a look at the results provided by the first 2019 findings on Italian businesses census, run on available 2018 data, it is impossible not to notice that on a sample of around 280,000 enterprises with at least three employees each (representative of approximately 1 million of businesses, which constitutes the 24% of all the Italian ones),

[75] EUROPEAN COMMISSION, *Executive Summary on SME Annual Report 2018-2019*, 2019, https://ec.europa.eu/docsroom/documents/38366/attachments/2/translations/en/renditions/native

79.5% of them is composed by micro businesses and the 18.2% by the small ones.[76] Furthermore, if specifically considering the overall amount of registered enterprises at the end of year 2018, on a number of 6,099,672 total businesses, 750,115 were belonging only to the agricultural sector, scoring 12.30% of them.[77] Therefore, the backbone of the Italian economy is made up almost entirely by nearly invisible economic entities from the dimensional point of view, while instead they are practically composing 2/3 of all the businesses present on the concerned Land, with the agri-food sector deserving of a particular mention.

The contractual network joined the Italian legal framework by means of Art. 3, subparagraph 4-ter of Decree - Law 10 February 2009, no. 5, turned into Law 9 April 2009, no. 33 and later modified in further occasions until the integration of the concerned contractual network for agri-food entrepreneurs with Decree - Law 18 October 2012, no. 179, later become Law 17 December 2012, no. 221. Furthermore, the European Commission specified that no State aid should be enlarged to the Italian contractual networks, which however can take advantage of a reduced taxation system on the reason of being part of the network.[78]

The just mentioned Decree – Law 10 February 2009, no. 5, introducing the contractual networks to the Italian Country, stated the topic being dealt as a contract in which «more entrepreneurs join with the aim of individually and collectively improving their innovative and competitive capacities by means of a biding collective network program» (Art. 3 subparagraph 4 – ter Decree – Law 10 February 2009, n. 5). The agreement provides that partners must collaborate ones with the others on the field of their respective business activities and hence exchange information or industrial, commercial technical or technological services among them.

Some contractual features are mandatory to be included, while others are up to the members to be selected, such as the collective family trust and the enforcement of a common body in charge of managing and executing the deal signed. On this reason three

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[76] ISTAT, *Censimento permanente delle imprese 2019: i primi risultati,* 2020, https://www.istat.it/it/files/2020/02/Report-primi-risultati-censimento-imprese.pdf

[77] INFOCAMERE, UNIONCAMERE, *Comunicato Stampa*: *Movimprese - Natalità e Mortalità delle imprese italiane registrate alle Camere di Commercio – anno 2018,* 2018, https://www.infocamere.it/documents/10193/114876492/Imprese,++32.000+nel+2018+(+0,5%25),1+su+4+nel+turismo/4f73e224-7ab4-4336-85bc-86eee3c096e2?version=1.1

[78] CAVICCHI A., COMPAGNUCCI L., SPIGARELLI F., *L'efficacia del contratto di rete nel settore agroalimentare Italiano: una rassegna normativa e della letteratura,* Economia Marche Journal of Applied Economics, 2016, p.3, https://core.ac.uk/download/pdf/145220253.pdf

different contractual network forms exist: the weak one, the strong one and the subject one. The first one entails neither the trust nor the competent body, letting its members keeping their fiscal and juridical autonomy with the aim of reaching a specific objective. This forms presents itself in opposition to the strong one, which instead by requesting both of the additional features is more appropriate whenever a more complex agenda is seek. The subject contractual network instead differs from the others on the basis of constituting a separated fiscal and juridical entity with respect to its single members.[79] In all this ways, the contractual network proves to be a flexible solution, being capable of adapting to the different entrepreneurs' needs from time to time and conjugating the best suitable resources, experiences and expertise.

A study on the performance displayed by contractual networks enterprises in 2020 conducted by InfoCamere, RetImpresa and the Management Department of Ca' Foscari University of Venice revealed that a positive correlation exists between taking part of the concerned networks and improving the individual firms profitability, in addition to representing an opportunity for the overall performance enhancement and a significant tool in facing change and innovation. But being a contractual network partner is not enough: understanding how to make use of and manage the network is the key in succeeding. On top of that, a deeper analysis on agri-food enterprises revealed that 22% of all Italian contractual networks are made by the concerned businesses, ranking first among supply chains displaying of this type of contracts. Furthermore, in this specific sector, the network helps in practically realizing the entire supply chain idea, going beyond the deep fragmentation given by the single small operators and fostering the integration of processes, assets and competences in a complementary and enhancing way, both at National and International level.[80]

Among the founding reasons for adhering to a contractual network, agri-food enterprises have chosen as the most common motivations for collaboration the suppliers and customers exchange of information, the local agricultural specialities promotion and tuition, the collaboration with research centers or universities in order

[79] CAVICCHI A., COMPAGNUCCI L., SPIGARELLI F., *L'efficacia del contratto di rete nel settore agroalimentare Italiano: una rassegna normativa e della letteratura,* cit., p.7

[80] INFOCAMERE, RETIMPRESA, UNIVERSITÀ CA' FOSCARI, *Recovery Fund: Valorizzare il contratto di rete nel piano nazionale di ripresa e resilienza,* InfoCamere, 2021, https://www.infocamere.it/documents/10193/117074590/Recovery+Fund%2C+valorizzare+il+contratto+di+rete+nel+piano+nazionale+di+ripresa+e+resilienza/9a9924d2-5bcc-6c74-0a82-c5104096f3f5?version=1.0

to carry products or processes consulting or trials, and finally, the supply purchasing and land infrastructuring expenses sharing. Less frequent causes instead have been signaled as common brand institution or import and export practices.[81] Hence, contractual networks are overall useful in efficiency, effectiveness and innovation achievement. At the same time though, new ideas, know-how and services, cost sharing and the strengthening of the relative position along the supply chain make sense only if the overall value created turns out to be superior with respect to the single realities: hence, choosing the right partners to cope with is the key to succeed.

2.5 Unfair Trading Practices along the agri-food supply chain: how to recognize them and deal with them by means of the European Directive 2019/633

In a context in which the different bargaining powers and derived positions occupied by the multiple role players along the agri-food supply chain need to be better regulated, unfair trading practices insert themselves in a preponderant way. As a matter of fact, they typically concern power imbalances carried by a stronger party to the detriment of a weaker one and can be defined as practices diverting from good commercial behavior.[82] The key aspect paving the way for their occurrence is the impossibility for the weaker counterparty of changing contractual partner or closing the bad relation with him: almost always the costs of doing so that are too high or the possibility doesn't even exist. Furthermore, the exploited contractual party often fears a retaliation carried by the strongest one or even that the agreement reached by the contractual negotiation, once the bad behavior treatment is revealed, risks to be terminated. Unfair trading practices oppose themselves to the concepts of good faith and fair dealing and can take place in any phase of the partners' contractual relationships, which is to say that they can happen while negotiating, once the contract is closed and the parties must execute it or even at the end of its implementation, by means of post contractual consequences. The European Commission clarified that as unfair trading practices taking place during contract performances, two episodes can best represent them: the first one is about following the unfair terms contained in the contract, while the second concerns more the abuse of the strongest party dominant position over the other weaker one. It must

[81] CAVICCHI A., COMPAGNUCCI L., SPIGARELLI F., *L'efficacia del contratto di rete nel settore agroalimentare Italiano: una rassegna normativa e della letteratura,* cit., p.9

[82] WIEWIOROWOWSKA – DOMAGALSKA A., *Unfair Trading Practices in the Business – to – Business Food Supply Chain,* Department of Economy and Scientific Policy, European Parliament, 2015, p.1-4, https://www.europarl.europa.eu/RegData/etudes/BRIE/2015/563430/IPOL_BRI(2015)563430_EN.pdf

be said that, even if the terms agreed in the contract seem to be reasonable, it is not granted their fair dealing. In fact, on the reason that usually contracts do not contain all the existing provisions disciplining both the possible parties behaviors, or that sometimes they are so complex that the adherent members do not fully comprehend what they clearly imply, or even that often the contractors do not dispose of the same level of information, what can be considered as fair must be clearly scrutinized, especially when the weaker party happens to be a business belonging to the small or medium size sector. Furthermore, additional examples of unfair trading practices can range from contract-related changes (when the contract is not written, incomplete or brings retroactive consequences), unfair use of information, price-related measures or additional payment requirements (from forced discounts to listing fees and contributions for having some non concerning actions performed), to purchase – related obligations, transfers of commercial risk and the above mentioned unfair termination or disruption of commercial relationships.[83]

At Community level, the first occasion in which unfair trading practices were dealt with in the agri-food field happened in 2009, when consumer prices rose against the context of agricultural price spikes; the Parliament instead strongly intervened in occasion of the evergreen farmers' revenues topic. To begin with, the Commission settled with the consideration that consumers were not provided with enough offers from the product variety and price points of view and that, at the same time, the ones figures occupying the intermediate positions of the agri-food supply chain, which is to say industrials and retailers, were leaving no sufficient margins for the "poor" producers. The Parliament instead recognized that contractual disparities and enormous bargaining power ones were taking place as well and that, on this reason, ad hoc measures should have been adopted by the Commission and the single concerned member States.

In this picture assumes significant weight the ultimate European Directive n. 2019/633 on "Unfair trading practices in business – to – business relationships in the agricultural and food supply chain", taking a cue from the one disciplining the weaker consumers' contractual relationships and leveraging also on the above discussed Regulation 1308/2013 on producers organizations and their role in bargaining power enhancement. As a matter of fact, despite the existence of these pieces of legislation, the

[83] WIEWIOROWOWSKA – DOMAGALSKA A., *Unfair Trading Practices in the Business – to – Business Food Supply Chain,* cit., p. 2 - 3

European Legislator understood the importance of furtherly formalizing some aspects of the concerned discipline in a more extensive way. The cornerstones upon which the new Directive is based range from the agricultural and food specific fields of application to the suppliers safeguarding with respect to the more powerful buyers; from the principles presumably establishing when a power disparity arises, basing their existence on the different parties turnover, to a minimum standard of harmonization to implement in each Member State and a responsible enforcement Authority in charge of it. Furthermore, a list of totally ("Black List") and of relative ("Grey List") banned practices is provided, as well is the encouragement of making use of alternative ways of controversy solving with respect to the more traditional ones.[84]

The Directive aim is stated since its beginning: the one of « *combating practices that deviate from good commercial conduct […] and that are unilaterally imposed by one trading partner on another* » (Art. 1 Directive EU n. 2019/633). In addition to this, in order to fully clarify the objects disciplined by the Directive in the agri-food field of application, a specification on theme is also provided. As a matter of fact, they are the ones listed in the TFEU's Annex I, which is to say that they go from live animals, meat, fish and dairy products, to edible vegetables, fruits, coffee, tea, cereals and sugar (full list in the Annex). On top of that, animal origins products not explicitly included in the framework but which have been obtained starting from the present ones, are still covered by the Directive (ex yoghurt, prepared foods, toppings).

The role played by the different counterparties taking part to the contract is explicated too, stating as buyer whichever natural or legal person or public authority (or group of them) who buys agri-food products, while as supplier the same person characteristics disposition, but he is instead in charge of selling the products. In order for the Directive to be applicable, at least the buyer or the seller, or both of them in the best possible option, must be located within the European territory.

The above mentioned "Black List" of prohibited practices is composed by the minimum episodes to be considered completely forbidden and hence punishable whenever a disparity of power, based on the respective turnover differences, arises. In order to sum them up, some instances are worth of mention. Payments executed after 30 days of the

[84] ARNAUDO L., *Pratiche Commerciali Sleali nella filiera alimentare: la nuova Direttiva UE 2019/633,* UNIVERSITA' LUISS GUIDO CARLI, 2019, p. 8 - 10, https://www.academia.edu/41203124/Pratiche_commerciali_sleali_nella_filiera_alimentare_la_nuova_Direttiva_UE_2019_633

date established as acceptable for perishable agri-food products or after 60 days for the more general ones should be considered prohibited, as well as episodes concerning the cancellation of perishable orders with a short time notice inferior to 30 days, giving hence the supplier no possibility of finding an alternative buyer. Unilateral changes to the contract (such as frequency, location, time, volume, quality standards, price and payment methods) brought by the buyer are not permitted the same, together with requiring extra payments not connected to the sale of the concerned goods. The transferring of costs to the supplier for no appropriate and fair reasons, such as selling losses or products deterioration or even clients complaints in which the supplier has no fault of, is included among the forbidden actions, along with commercial retaliations, diffusion and implementation of commercial secrets and the buyer refuse of agreeing on a written supply contract upon request (Art. 3 Directive EU n. 2019/633).

Furthermore, other eligible additional practices can be banned as well, but they need an express approval and a deep case analysis before entering the category. Examples of these suitable ones can be considered the restitution of unsold products to the supplier, his charging for the buyer stocking of products, for the act of making them available on the market and even for marketing, personnel and advertising expenses incurred by the buyer in dealing with the supplier's products.

The enforcement aspect of the concerned Directive left though many open questions. As a matter of fact, being a Directive requires Member States to adapt the content, implement it and enforce it according to the National necessities and legal framework, giving hence rise to big discrepancies among the individual Nations. It is not a secret that some Countries are more market oriented and hence more skeptical in the perspective of following the guidelines provided, while others are more willing of rebalancing the different bargaining powers.

Unfortunately, some frequently happening unfair trading practices have not been taken in consideration by the Directive, such as the imposition of private standards requirements, pressures on price reductions, advance payments for keep the contract in place or even the transfer of the theft risk on the seller.

As a matter of fact, a general proper definition of what should be intended as unfair trading practice is missing and making use of a list of unacceptable behaviors turns out to be reductive in fulfilling all the existing bad behaviors episodes, ending in this way for

leaving a lot of them not persecuted.[85] On top of them, sometimes basing the bargaining power discrepancies on turnover differences gives rise to unreasonable solutions.[86] Actually, the Small and Medium enterprises belong to the same category but often, in reality, happen to be completely different one from the other. Thus, in this way, they also dispose of equally different instruments in challenges and problem solving: the small producer running a family business and employing just a few people operates in a complete different environment with respect to a medium size firm, in which dozens of operators work and generate a turnover of hundreds of millions. Hence, the first one needs more appropriate tools to face the supply chain market in a safe and fair way, in order to be not afraid of running his business according the requirements provided by the Law and being able to stand up for himself and not fearing retaliations.

2.6 The difficulties brought by Covid-19 to the agri-food producers and the role played by them in granting consumers the needed supply of food products

Given the disparity of power evolving along the agri-food supply chain, the single producer is not able to display of a significant reaction to the fluctuation of market prices and consequently adjusting his production to the needs provided by the incoming demand, hence remaining in sort of a "price-taker" position. As a matter of fact, factors such as product seasonality, demand flexibility, geographical mobility, a fragmented and not well integrated productive system as well as informal and not controlled working dynamics characterize the involved agricultural environment, strongly impacting the costs incurred by producers. In this picture, a large share of the final product price is represented by the costs related to the employed personnel, but at the same time it is almost the unique cost component considered to be possibly squeezed whenever hard times hit and the bargaining and collective power displayed by both producers or even organizations of them prove to be not strong enough.

During the just experienced lockdown period, where both goods and people were confined on the reason of the spreading of the pandemic brought by Covid-19, the extreme difficulties usually stressing the agri-food sector have been brought to light to a huge amount of consumers, usually unaware of the proper dynamics ruling it and that,

[85] GRINELLI F., *La regolazione negoziale all'interno della filiera agroalimentare,* Rivista di Diritto e Giurisprudenza Agraria, Alimentare e dell'Ambiente, 2020, p. 12, https://www.rivistadga.it/la-regolazione-negoziale-allinterno-della-filiera-agroalimentare/

[86] ARNAUDO L., *Pratiche Commerciali Sleali nella filiera alimentare: la nuova Direttiva UE 2019/633,* , cit., p.7

specifically in this particular circumstance, have gotten further worst. The unsustainability lived by agri-food producers, the ones giving birth to the entire agri-food supply chain, has been hence clear and undeniable, together with the once considered to be extinct gangmaster system and illegal hiring, that turned out to be not so far away in implementation.[87] In fact, in addition to the fact of being exploited and underpaid, the just mentioned workforce often has been working in labour, health and hygiene environments not respecting the minimum standards provided by the Law. Furthermore, sometimes these workers were not even disposing of the adequate protection devices such as masks or operating in conditions of respecting social distancing.

It must also be said that, if one the one hand many episodes of the kind happened, on the other a lot of positive experiences have been taken place as well.

Actually, agri-food supply chains have been working the same during quarantine, jumping ahead in quality and economic terms in the position occupied in consumers' minds: 89.2% of Italian people sustain that after the pandemic experience, the involved agri-food sector will be the key in order to make the economy rise again on the basis of the role played during tough times, while 87.9% retain that it will be the most appropriate filed to create new jobs, in addition to the possibility of taking new entrepreneurial opportunities available also to the youngest population.[88]

The small agricultural businesses are the ones that have been more successful during the lockdown phase, because even if flattened by a non gratifying rewarding and oppressive system, they were the ones that managed to reach consumers confined in agricultural areas, producing both environmental, social and qualitative products and not needing to make use of traditional market channels. At the same time, it must also be confessed that the majority of CAP funds are and were aimed at big agri-food business, leaving the small and medium ones again at the mercy of an inappropriate system. Hence, it is not surprising the need for small producers to further compressing production costs in order not only to gain the highest possible share of profit to sustain their activities, but also to reach the majority of consumers by means of an affordable price and therefore at least remaining in the market. The effort made by businesses

[87] PAOLONI L., *La sostenibilità "etica" della filiera agroalimentare,* Rivista di Diritto Alimentare, A.I.D.A, 2020, p.7-12, http://www.rivistadirittoalimentare.it/rivista/2020-04/2020-04.pdf

[88] OSSERVATORIO DEL MONDO AGRICOLO ENPAIA-CENSIS, *Il valore dell'agricoltura per l'economia e la società italiana post Covid-19. Sintesi dei risultati,* Enpaia Censis, p.4-5, https://www.adepp.info/wp-content/uploads/2020/09/Sintesi-dei-principali-risultati_Osservatorio-Enpaia-Censis.pdf

taking part to the short form of agri-food supply chain has in this way gained greater prestige, not only from the productive, utilitarian and qualitative point of view, but also from the social one of helping the lockdown population in sustaining its daily livelihood.[89]

As a consequence, the number of consumers settling for products displaying of a clear, easy and transparent traceability and coming from a short agri-food supply chain has sharply increased, favouring the ones belonging to a certain "life" journey with respect to the others. In this light, a new trend has clearly emerged: the one of requesting agri-food businesses that prove to be sustainable from both the economic, social and environmental points of view. This framework of requirements is built upon specific needs, which correspond to the ones of conjugating product quality, dignified working relations and environment, business potential and the increasing of the population wellbeing along the entire agri- food supply chain and across different areas.

On top of that, a new type of product certification collecting all this aspects could be the solution in order to reward the "right-behavior" producers, the ones proving to run an ethical behavior in their business, in addition to implementing appropriate ways of cultivation, production amounts and effectively granting quality and specific guarantees for their employees. Sustainable agri-food products characteristics should be included as well, ranging from the environmental impact caused with the production of the goods, wasted products and wasted food obtained while bringing them to life, packaging implemented and related characteristics, to even covering the energy consumed and its quality. Furthermore, animal wellbeing maintained, improved, or worsened, pesticides employment and the status of working conditions, together with the child labor component should be counted the same. [90]

This additional product qualification, of course, will bear additional costs for the already overwhelmed agricultural entrepreneurs, but consumers aware of the complete meaning of the certification said they would be willing to pay a premium price for being granted the involved values.[91] Furthermore, if analyzing only the pure social aspect component, 74.41% of Italian people firmly stated that they are even open to pay

[89] PAOLONI L., *La sostenibilità "etica" della filiera agroalimentare,* cit., p.16

[90] BOLOGNINI S., *Il consumatore nel mercato agro-alimentare fra scelte di acquisto consapevoli e scelte di acquisto sostenibili,* Rivista di Diritto Agrario, 2019, p. 636, https://www.editorialescientifica.com/index.php?plugin=jklibs&file=SW5kaWNlJTIwUkRBJTIwNC0yMDE5JTIwJTI4MSUyOS5wZGY=njsrK&download=1

[91] PAOLONI L., *La sostenibilità "etica" della filiera agroalimentare,* cit., p.19

whatever price it takes to obtain a food product free from the above discussed dynamics, while 21.8% sustained that the price component remains the one overall mattering the most.[92]

[92] ARDU' B., *Gli italiani dicono no allo sfruttamento nei campi: 3 su 4 disposti a pagare di più per una «spesa responsabile»,* La Repubblica, 2019, https://www.repubblica.it/economia/2019/07/09/news/gli_italiani_dicono_no_allo_sfruttamento_sui_campi_3_su_4_disposti_a_pagare_di_piu_per_una_spesa_responsabile_-230768767/

CHAPTER 3. TECHNOLOGICAL INNOVATION FROM THE AGRI – FOOD OPERATOR PERSPECTIVE AND NOVEL FOOD: AN ONGOING CHALLENGE

3.1 Technological Innovation and the "new" consequences for the agri-food operator

According to a 2008 investigation carried in the agri-food field and concerning the new emerging and innovative trends born with the globalization process, the involved sector, with particular regard to the Italian one, has shifted its position from being an undiversified generator of low value added raw materials to an high value one, worldwide known for its superior quality results. On top of that, if examining the agricultural component apart from the other structural ones, it is becoming more and more evident that not only final goods are the outputs of the involved supply chain, but increasingly often they happen to be actual services. Independently from the specificity of the products obtained from the agri-food processes, being them foodstuffs or particular procedures aimed at increasing the value of specific goods or its awareness and conscious use, the food operator is completely and interdependently integrated in a complex system of relations, where they key to succeed is no more only identified with the price of the item obtained from the various activities. As a matter of fact, the producer's ability of differentiating and valuing his own goods from the competitors' ones according to the evolving market changes and consumers' preferences is the game changer breakthrough. [93]

The just mentioned two turning-point necessities find themselves as part of a more complex picture, which is the one brought to light by the European Legislator and that, in order to be properly performed, requires both of a complete reinterpretation and reorganization of the involved governance and related entities, starting it though from the bottom.

The one revolutionary and guiding light the Legislator was dealing about is the instance of innovation, which is paving the way towards a complete different way of working and carrying new opportunities as well as routine practices, but it is also changing the way in which the world around is conceived. The boost received to the implementation of new technological instruments and to innovation itself, both deployed along the agri-food

[93] ESPOSTI R., LUCATELLI S., PETA E.A., *Strategie di innovazione e trend dei consumi in Italia: il caso dell'agroalimentare,* Ministero dell' Economia e delle Finanze, 2008, p.7, https://www.mise.gov.it/images/stories/recuperi/Sviluppo_Coesione/3_.pdf

supply chain, is due to specific motivations, which have been clearly made explicit by the European Legislator in the 29th Whereas of the ultimate Regulation 2015/2283 of the European Parliament and of the Council on Novel Foods. The grounds on which they are sought can be principally identified as the environmental impact reduction due to the production of food, the improvement of food security and last but not least, the additional benefits brought to food consumers, always bearing in mind and assuring that an high level of food safety must be maintained, if not even an higher one given the relevance of the theme. At the same time tough, it necessary to clarify that the use of innovation could bring unfavorable consequences, all in turn negatively impacting the aspects it should instead improve.

In order to further analyze what technological innovation and relative use imply, a closer look to what is intended as the proper key world meaning should be firstly given.

According to the Italian Treccani Encyclopedia, as technological innovation can be intended « *the kind of activities implemented by businesses or Institutions and aimed at introducing new products or services, or even ways to produce, distribute or make use of them».* It must be also said that*, « in order for those innovations to find a profitable ground, they must first of all being accepted by who is going to deal with them, being them the consumers buying the innovative products or the ones making use of the innovative services »*.[94] By the way, innovation can display of various levels of novelty, ranging from the incremental to the radical one: while the first one concerns the improvement of an already existing product, process or service and aims at making its version better in quality or costs terms, the radical one consists of a big qualitative jump ahead from its pre-existing versions and it usually presents itself as the result of extensive and complex researches. Furthermore, with specific reference to technological innovation, it can't be simply locked up in these strict definitions related only to the scientific and technical fields of discussion, but it must also be taken into account its deep social dimension, which is characterized from being ever changing in its nature. As a consequence, innovation applied to the agri-food sector shows off particular implications concerning food products safety which must be deeply analyzed and scrutinized, in order not to hinder the fundamental cornerstone upon which the entire food legislation is based: the assurance of the highest level of protection for human health, coordinated with both a

[94] SIRILLI G., *Innovazione tecnologica,* Treccani – Enciclopedia della Scienza e della Tecnica, 2008, https://www.treccani.it/enciclopedia/innovazione-tecnologica_%28Enciclopedia-della-Scienza-e-della-Tecnica%29/

diversified products offering and internal market dynamics, as stated in the previous extensively discussed Regulation 178/2002, which must be never forgotten or left aside.
The just mentioned piece of legislation, in order to properly and efficiently discipline the entire agri-food supply chain from its beginning to end, makes use of sort of a preventive system of tuition, in which the precaution principle and the risk analysis and management ones are identified as keys. It goes without saying that the effectiveness of the complex and interrelated system is given by the duties and responsibilities adherence of all the supply chain members, ranging from the food operators to the final consumers, but not leaving the Public Authorities aside.
But sticking to the preventive system is not enough for granting the desired level of food safety. As a matter of fact, the Legislator understood the importance of providing also a compensatory system for indemnifying the food consumer which has suffered harm from the healthiness point of view. This allowance can be obtained by means of various instruments, among which the preferred one is the objective civil liability in chief on the food producer, the one in charge of responding to the non proper fulfillment of his responsibilities and hence being faulty of having them degenerated into the defective product and relative effects.[95]
By the way, in order to fully comprehend the negative twists brought by the innovation of both products and processes, it must be also highlighted the low propensity of the agri-food sector of making use of it with respect to other fields in which technological innovation and relative implementations have been used in an extensive way. As a matter of fact, when talking about the entire agri-food sector, it is never considered as belonging to the leading ones in matter of science and high use of technological expertise, and hence being one of those profitable sectors servicing the others with new and profitable high-tech discoveries, but rather it happens to occupy more of a conservative position. Actually, especially in the last few years, the consumer himself shifted his role from being merely the one to which the products or services were addressed to being an active player in the journey made by the foodstuffs, hence giving voice to the quality aspect stressed by the innovation process. In light of these considerations, the real and tangible innovation that could be implemented in the agri-food sector can be represented by the solution provided by the food operators able of

[95] GIUFFRIDA M., *Innovazione tecnologica e responsabilità dell'operatore del settore alimentare,* Rivista di Diritto Alimentare, A.I.D.A., 2018, p.6-10, http://www.rivistadirittoalimentare.it/rivista/2018-04/2018-04.pdf

conjugating in an innovative way the three already existing categories of qualitative food products, which, up to now, have always been obtained by means of traditional techniques. These particular traditional subsets according to which innovation can make the difference are: products displaying of naturalness requisites (such as PDO, PGI, typical and biological products), functional products and last but not least both time and price convenient ones.

At the same time, the increasing spreading of modular agri-food technologies is in turn disseminating the ever-growing implementation of new applicable technologies, which is to say biotechnologies, nanotechnologies and information and communications technologies, summed up in ICT.

The first of the just mentioned technologies, by obvious reasoning, seem the ones to be quite sort of a contradiction, because since their origins the qualitative element to be found in biological products is the mirroring of the consumers' desires of traditions and naturality to be found on them. Hence, the linkage with the territory or being produced without synthetic chemicals occupy a position which is quite in opposition to the ultimate instance of innovation leading nowadays world. Actually, in contrast, especially concerning the high quality and high price biological products, in order to keep an high level of organoleptic features and a strong guarantee of origin, as well as assuring the highest level of food safety possible, a lot of technological interventions must be applied on ongoing basis. Furthermore, modular technologies can be the solution in obtaining the best fitting combination of naturalness and functionality in the new generation of biotechnological agri-food products.

It is no doubt that if on the one hand technological innovations are able to respond in the desired way to food safety requirements and already known drawbacks, on the other hand they exponentially increase the emergence of new and negative implications, especially if used in a combined way. To tell the truth, if some technologies have already been tested according to their singular use and the relative effects provoked are acknowledged, it is not know what a combination of them could imply. Of course, the burden of the consequences has to be carried by a responsible figure: the food operator, the one taking the innovative choice and hence bearing also its often unknown effects. In fact, according to the European Legislator, the food operator is the one in charge of granting that all the requirements provided by the law on the theme must be respected and fulfilled within the firm he is entitled to run and control.

The concept of responsibility, however, can assume sort of a double meaning: the first one concerns more the side of the preventive consumer tuition and all the relative measures taken at avoiding possible damages in advance, while the other is more linked to the compensatory side of the "missed" full protection, and hence taking place in a subsequent phase to the consumption. The failed fulfillment of the operator duties in carrying an extensive control over the activities performed by the business and which he is in charge of granting, gives rise to the consumer's right of being compensated. Hence, according to the European Legislator, the food operator is responsible for the items produced, processed, distributed or whichever activity has his business implemented related to the product's life, even when the output is out of the immediate entrepreneur's control. In the concrete, procedures such as market withdrawal and recall work in the perspective of being implemented as results of both direct and indirect controls arrangements, basing them on the precautionary principle of General Food Law. If all these preliminary measures happen to be not executed in any of these alternatives, the agri-food operator can be blamed for the missing fulfillment of civil, administrative or in the worst case scenario, criminal liability, according to the seriousness and kind of damage caused.

A different layout has been instead arranged whenever the damage caused to the consumer by eating the food product has been provoked by the use of technological innovations. As a matter of fact, if the agri-food operator is able to prove that he has fully carried all his controlling duties, as provided by the precautionary principle, and no potential harmful effect was revealed, he could be freed from the compensation aspect. This procedure is especially useful when dealing with innovative food product, eligible as better known "novel food", independently from the fact that the innovation involves the final product or the process implemented in obtaining it.

As will be later discussed, as novel food can be intended "*any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union"* (Art. 3 Reg. EU n. 2015/2283). Furthermore, it has to be included in at least one of the subsequent innovative categories following presented, ranging from disposing of a new molecular structure, to being consisted, isolated or produced from microorganisms, fungi, algae, mineral materials, plants or their parts or animal and their parts.

The relevant consideration moved in order to reach such a conclusion on the operator alienation from the damage incurred, it is not to be based on the so called "developmental risk", which instead is founded on the state-of-the-art technological knowledge available at the moment of the initial product commercialization, but rather it is built upon the released patent, accompanying notes and evaluation carried when the product was granted the authorization to be sold, better expressed by the 30th Whereas of Regulation 2015/2283.[96]

The importance of being covered by a patent protecting the industrial property under certain specific circumstances can be explained on the justification of boosting research, development and the process of innovation in itself. In order for the latter to be successful and reach such a noble goal, the great and expensive investments made by brave entrepreneurs on exhaustive studies and researches, so that the eligible novel food can dispose of all the necessary information to be approved by the competent authorities and hence reach the market, need to be protected. These covered data and pieces of information should not be made public for a limited time amount, corresponding around to five years, unless the food operator himself is authorizing so (30th Whereas Reg. EU n. 2015/2283).

On the reason of its innovative capacity, in order for the novel food product to legally reach the European market, it must firstly be approved by the European Commission and the EFSA, being the latter in charge of carrying an extensive scientific risk analysis evaluation on the reason of food safety and health protection aims, and secondly, once the previous step has been successfully overcome, it has to enter the authorized products list (Art. 6 Reg. EU n. 2015/2283). It must though be specified that the analysis carried by the EFSA, aiming at excluding any food safety and human health related problem connected to the product being investigated, is based on scientific evidences which are available at the moment of the examination (Art. 7 Reg. EU n. 2015/2283).

It is up to the food operator asking for the permission of commercializing the new product to provide all the necessary compliance certificates and additional other information requested by the Authorities, which must be sure that according to the studies accessible at the moment of the analysis execution, the product respects all the food safety requirements.

[96] GIUFFRIDA M., *Innovazione tecnologica e responsabilità dell'operatore del settore alimentare,* cit., p. 7 - 10

Hence, if health damages happen consequently to the novel food consumption, they cannot be found on defective product reasons, since the foodstuff has been prior authorized by the Competent Authorities and it has officially and legally entered the authorized products list. Furthermore sometimes, where required, additional specifications other than the usual ones provided by Regulation 1169/2011 on additional information to consumers are added to the product label of novel foods. These data can range from their description, origins, to proper use and other essential details, all aimed at further safeguarding consumer's health.[97]

If all these just explained reasons on the one hand shall release the food operator from being accused of missing his responsibilities fulfillment and hence having it degenerated into damaged product liability, on the other hand this culpability exclusion does not authorize him in getting rid of all the other involved accountabilities.

As a matter of fact, a turn of events can happen if the damaged consumer is capable of proving that the agri-food operator, who was even with no doubt initially legally commercializing the novel food, in the meantime has been made aware of new scientific discoveries able of turning the tables on product safety. If the concerned operator did neither informed the Commission (Art. 25 Reg. EU n. 2015/2283), nor implemented any action aimed at withdrawing the product from the market, as universally provided by the general procedures established by Regulation 178/2002 (Art. 19 Reg. EC n. 178/2002), the food operator could be accused of both administrative and civil liabilities. The same holds if the Commission, according to the EFSA advice, provided for keeping subsequent monitoring duties on the product even if already placed on the market and it assigned them in chief on specific identified operators, which have screwed their obligations. More challenging, for not saying almost impossible, is instead the case of proving the missing accomplishment of duties in chief to the competent authorities, such as the to EFSA or the European Commission, which could have failed in providing the right food safety assessment at the time.[98]

By the way, in all the just mentioned cases, the consumer has the full right to be compensated for the damage suffered.

The only way for the food operator to free himself from compensating the consumer, which has reported to have experienced health consequences from the consumption of

[97] GIUFFRIDA M., *Innovazione tecnologica e responsabilità dell'operatore del settore alimentare,* cit., p.13
[98] GIUFFRIDA M., *Innovazione tecnologica e responsabilità dell'operatore del settore alimentare,* cit., p.14-15

the novel food being commercialized, remains to prove that he has followed all the responsible behavior procedures provided by the European food law on the theme, which again aims at ensuring that his conduct has been fully mirroring the entire food safety framework of requirements considered to be appropriate at protecting human health. Once all these burdens have been comprehensively and extensively acknowledged, the food operator can't be retained guilty of missing compliance to his responsibilities anymore. Hence, he is not obliged of making reparations for the damaged accused of being accountable for.

3.2 Novel Foods and their ongoing challenge: a comparison between the old Regulation and the new one

The difficult equilibrium among food safety and food security has always been an hot topic to deal with since the dawn of the European Union, which considered it as one of its main priorities since its beginning. But only recently the real ultimate protagonist of the debate has made its entrance in a preponderant way: food insecurity. With a world population estimated to be by the FAO around 9 billion people in 2050, the food requirement should increase about 70% to satisfy the future necessities if compared to the nowadays ones.[99] Meat consumption instead, if not restricted, will reach 465 million tonnes. The latter field of consumption is worth of particular mention on the reason of its already 5 times increased demand registered at the beginning of the new Century with respect to the previous fifty years one: from 45 million tonnes recorded in 1950 to 45 million ones eaten in the year 2000.[100] The trend, hence, is increasing at a rate that results impossible to keep up with traditional production techniques and methods.
Furthermore, in such a scenario, the purchasing power displayed by several worldwide communities is decreasing more and more rapidly as consequence of the particular uncertain situation currently lived by the entire world, where the resource scarcity, the pollution phenomenon, the economic and social gap as well as the last pandemic

[99] FOOD AND AGRICULTURE ORGANIZATION (FAO), *Feeding the world in 2050,* World Summit on Food Security, 2009, p.1, http://www.fao.org/tempref/docrep/fao/meeting/018/k6021e.pdf
[100] FOOD AND AGRICULTURE ORGANIZATION (FAO), *Livestock's long shadow: environmental issues and options,* FAO, 2006, p.4-5, http://www.fao.org/3/A0701E/a0701e.pdf

consequences are seriously testing the habits, certainties and stability of the entire population.[101]

The possible solutions to the just presented worldwide problems have been identified by means of three different options: maintaining the current already in place consumption and industrial system, converting the entire world population to the vegan diet or finding alternative ways for nourishing it. If the first alternative has already proved to be no longer sustainable, the second one seems almost impossible to reach on the extreme incompatibility with the actual most diffused eating habits. Hence, the only viable road to follow seems to be the third, but not without some clarifications on top.[102]

As a matter of fact, the chosen alternative is boosted by the instance of innovation, which has been recognized as the only viable means being able of granting both a real sustainable development along the agri-food production and breeding fields of application, as well as being also capable of balancing at the same time both the increasing necessity of food procurement with the opposing one of lowering the human impact on the environment, climate and overall ecosystem.[103]

Novel foods, on the basis of being novel either for the innovative methods implemented or for the Occidental cultural eating habits perspective, could hence represent the most concrete solution to the just presented problem: by means of sort of a trade-off between traditional food and innovation, they unify the already known and habitually consumed nutritional components with new and innovative techniques in obtaining them. Benefits increasing could also be addressed to the human and animal wellbeing, as well as to the environmental, climatic and entire ecosystem ones obtained by making use of novel food products instead of the traditional actual consumption patterns. Emblematic and extraordinary example of this innovative capacity brought by innovation in the agri-food sector can be identified by the sunless vertical farm: a new cultivation technique where vegetables such as leafy salad greens and the like (hence both traditional but also innovative ones) are produced in a completely controlled environment, in which the use

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[101] WORLD FOOD PROGRAMME, *Global Report on Food Crisis 2020 – Joint analysis for better decisions,* FSIN, 2020, p.4-5, https://docs.wfp.org/api/documents/WFP-0000114546/download/?_ga=2.70859929.827850093.1615325770-2056767524.1615325770

[102] FERRERO E., *Novel foods e tecnologia alimentare come strumenti di salvaguardia ambientale,* Rivista Giuridica dell'Ambiente, 2018, http://rgaonline.it/categoria1/novel-foods-e-tecnologia-alimentare-come-strumenti-di-salvaguardia-ambientale/

[103] SCAFFARDI L., *Novel Food, una sfida ancora aperta tra sicurezza alimentare, innovazione e sviluppo sostenibile,* Università degli Studi di Parma, 2020, p. 736-737, https://www.academia.edu/43459676/Novel_Food_una_sfida_ancora_aperta_tra_sicurezza_alimentare_innovazione_e_sviluppo_sostenibile

of pesticides is not conceived and both water and air are pure. The most revolutionary features of the technique have been recognized as being two: the first one entails the place in which these new products are cultivated, while the other is related to the resources consumption. To begin with the first, vertical farming takes place in vertically arranged layers, which can be identified as unutilized vertical spaces, independently from their being located in skyscrapers, containers, warehouses or even simpler houses. Furthermore, in order to reveal the second one, according to the data up to now available, such a way of cultivating has proved that water savings can reach 97% with respect to the traditional implementations modus operandi.[104]

On top of that, also different foods such as edible insects or products deriving from them, as long as synthetic meat, have entered the novel foods list, in addition to products which have not been significantly consumed by European citizens prior to 1997, but are instead part of the traditional way of eating of the extra - European ones. To make the telling point, examples of them can be considered quinoa, chia seeds and even baobab.

To begin with, the European Legislator understood the importance of balancing the opposing different forces of freedom of foodstuffs commercialization inside the Community market, also derived from the scientific and technological progress, with the consumer health and interests protection ones since 1997. As a matter of fact, prior to that date, different National dispositions on the theme gave origins to confusion and unfair competition on the reason that were the Member States themselves in settling for the authorized commercialization of new products in the European market and that no specific risk assessment evaluation was to be carried prior to their market placing at excluding all possible health related damages. These motivations were considered to be so relevant that the European Legislator included them on the grounds for which a specific regulation on the theme was required. Hence, he explicitly addressed them on the 1st and 2nd Whereas of Regulation 258/97 of 27 January 1997, the first one introduced at European level in order to properly regulate the innovative sector of Novel Foods and Novel Food Ingredients.

The first significant novelty brought by the involved Regulation was the provision of a general European definition for Novel Foods, for which were intended all those agri-food products not consumed by human people to a significant degree inside the

[104] PRAKASH A., PULIDINDI K., *Vertical Market Trends – Growth Potential 2019 – 2026,* Global Market Insights, 2019, https://www.gminsights.com/industry-analysis/vertical-farming-market

European territory. Article 1 then followed with all the different categories of food products entering the "Novel Food or Ingredient" definition. It is not a case that the first of these categories happened to be the one with food and food ingredients containing or consisting of genetically modified organisms, better known as GMO. This inclusion was due to very practical reasons: the common need shared with the Regulation main topic, which is to say Novel Foods, of being evaluated before being commercialized on the market for human consumption. As a matter of fact, the necessity for GM organisms and products obtained from them of being regulated by a tailor-made framework was already clear at that time, but in the meantime a legislative hole could no longer be accepted. After all, both Novel Foods and GM ones represented causes of possible health and environmental damages and hence, they both needed to be ascertained first. For the sake of update, GMO are now covered by Regulation 1829/2003, the one legal framework that has been introduced in 2003 specifically addressed to them.

Going back to the general Novel Food definition, the following categories explicitly stated to be included in the first 1997 piece of Regulation, apart from the GM one, were food or food ingredients with a new or intentionally modified primary molecular structure, the ones consisting of or being isolated from microorganisms, fungi, algae, or plants and the ones isolated from animals. By contrast, with particular reference to the last mentioned animal group, a specification was made: all the food products that could be included in the category but have been obtained by means of traditional practices and were also disposing of a past food safe consumption were not covered by the Novel Food legislation. Furthermore, as conclusion, were instead included all those food or food ingredients obtained by means of processes not usually used at that time, that however could be able of change in a significant way the compositional structure of the involved products and consequently impacting their nutritional value, metabolism or the presence of undesired substances within them (Art. 1 Reg. EC n. 258/97).

On top of that, it was also provided that it wasn't enough for the Novel Food to satisfy the food safety requisite, but it also had to not make the consumer confused or sort of cheated in substituting the old usual ingredients to which he was accustomed with the new and disadvantage ones from the nutritional point of view (Art. 3 Reg. EC n. 258/97).

In order for the eligible products the be placed in the European market the steps to be followed were the followings: first the operator asking for its commercialization had to commission a complex and extensive preliminary risk analysis and presenting it to the

National Authorities. Then, the just mentioned Bodies were in charge of implementing another control mechanism on the product examined and, when produced, the notification had to be extended to all the other European Member States and the Commission itself. Once all these steps were successfully carried and no other extra pieces of information were required, a decision on the product examined had to be taken, independently from its being approved or rejected. If instead at Community level additional and integrative studies were requested on the topic being dealt, it was up to the Member State in which the application was submitted to provide them. Then again, the final decision had to be taken collectively at European level. Specifically, it was the Standing Committee on Foodstuffs, later substituted by the current EFSA, at examining the additional material. Differently, if the food or ingredient requiring to be authorized was found to be equivalent to another one already being sold in the European market, a simpler procedure could be implemented. As a matter of fact, in the last mentioned hypothesis, even though it was still up to the operator ascertaining the equivalence of the Novel Food, once this procedure was completed, the foodstuff could enter the European market. Without the necessity of adding the formal and always necessary risk analysis first for those products, a simpler notification was considered to be enough.[105]

Concerning the overall category of Novel Food, it must be said that if the authorization was allowed, the foodstuff could be commercialized inside the entire European territory, hence across all Member States. However, it was that specific product only that was granted the permission, not other similar ones. Meaning that if other comparable products were desired to be sold as well, the procedure had to be started again from the beginning. The only way for making it easier it was by making use of the simplified notification for similar foodstuffs, but again the similarity had to be proven first.

Among the many drawbacks detected in the discussed Regulation 258/97, the huge and extremely high amount of costs borne by the food operators in providing the adequate scientific studies, as well as the almost infinite timing taken at obtaining the final permission due to the missing expiring of a specific deadline (35 months on average), combined also with the unsure ending procedure results, worked all in the perspective of making the Regulation not so successful in its implementation. Furthermore, by means of the Rapid Alert System for Food and Feed a lot of unauthorized novel foods

[105] SCAFFARDI L., *Novel Food, una sfida ancora aperta tra sicurezza alimentare, innovazione e sviluppo sostenibile,* cit., p. 743-752

were found to be illegally commercialized and this number was increasing faster and faster. On top of that, there was still a regulative hole for those products considered novel for the European Union, but traditional for extra-European Countries, which were obliged to follow the entire application procedure even though they could claim a long time safe use in the native land.

All these negative backlashes reflected themselves also on the kind of economic operators being able to fully follow and adhere to the entire legislative procedure. As a matter of fact, given the great economic burden to bear completely on their shoulders, only the wealthier entrepreneurs were attempting at chasing the explained confused and unclear framework of provisions. Moreover the absence of both an harmonized and centralized procedure, as well as of a universal scientific evaluation, resulted in a scattered approval rate throughout the Community territory. Actually, it was ranging from the highest ones in the North of Europe and the UK to the lowest ones in its South, hence resulting in sort of what can be considered a commercial barrier (almost protectionist one) hindering not only the European Countries, but also the extra European ones. Furthermore, in the light of the persisting of these problems accumulation, many third developing Countries highlighted the unfavorable and enduring situation to the WTO, in particular to the SPS Committee.

As a matter of fact, according to these States, the drawbacks brought by the then Novel Food Regulation openly contrasted with the SPS Agreement, whose only limitation should still be based on food safety matters. Actually, those concerns must be scientifically examined and the relative commercialization limited only if resulting in impacting human health in a negatively way. It was hence clear that Regulation 258/97 wasn't on the same page with the prior, and most of all superior, SPS Agreement.

On top of that, it became also evident that the legislative framework contained in the Regulation was hindering any attempt of innovation in the agri-food sector. Not only the entrepreneurs could not make use of the most advanced techniques in producing, but also the consumers couldn't dispose of an adequate product variety to choose among. The European market itself instead in being so conservative in its structure wasn't anymore considered attractive for the other Countries appetites too.

The necessity of substituting the Regulation with a more transparent and efficient one has been clear since 2002, when the Commission, after having consulted all Member States, settled for a public consultation on the theme, which ended in 2008 with an

amending proposal. However, because of the Parliament opposition to the hot theme of foodstuffs deriving from cloned animals, it has to be waited until 2015 for the new Novel Food regulation to be approved. [106]

First of all, the new Regulation aim was clear since the beginning: *« ensuring the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests »* (Art. 1 Reg. EU n. 2015/2283), contrary to what happened in the previous one. Furthermore, the definition of Novel Food has been refined, by taking into consideration all those scientific and technological implications that happened from the 1997 till nowadays. Hence, with sort of a continuity link with Regulation 258/97, but at the same working also in opposition to it, at establishing what can be considered as Novel Food is now a temporal criterion. As a matter of fact, as Novel food now can be intended whichever food not significantly consumed prior to 15 May 1997 inside the European territory, independently from the date in which the different States joined the Union (Art. 3 Reg. EU n. 2015/2283). The meaning of the date can have sort of a drawback, revealed with the years passing by. When the legislation was firstly adopted, it seemed useful in establishing the deadline on the date in which the previous Regulation entered into force, because it was considered to be easier in identifying some Member States' foodstuffs already commercialized in the market and hence not requiring to be furtherly regulated, if their placing on the market date was available. With the time going on, it turned out it was not so easy neither ascertain their market entrance date, nor finding a list in which the already marketed product prior to 15 May 1997 were present. [107]

With regard instead to the classifications considered eligible as Novel Foods, many of them have been added, pursued by the necessity of updating the new piece of legislation with the ones of the nowadays world, where technology has made great jump ahead and hence also the products obtained by making use of it. As a consequence, the categories counted in the new and elaborated list are now ten, but at the same time they also keep sort of a halo in order to be flexible and adaptable to the ever-changing needs. By the way some of them are still a bit confusing, on the reason that the continuous discoveries brought by science keep incessantly to open up the possibilities of new ways of

[106] FERRERO E., *Novel foods e tecnologia alimentare come strumenti di salvaguardia ambientale,* cit., http://rgaonline.it/categoria1/novel-foods-e-tecnologia-alimentare-come-strumenti-di-salvaguardia-ambientale/

[107] SCAFFARDI L., *Novel Food, una sfida ancora aperta tra sicurezza alimentare, innovazione e sviluppo sostenibile,* cit., p. 754

obtaining foodstuffs or even new kind of food products directly. In this way some possibilities never before thought can enter already existing category and disposing of the belonging requisite to enter the authorization procedure, even though ethically they can break the public opinion into opposing perspectives.

However, the borders in which enclosing the Novel Food definition weren't the only modification brought to the previous Legislation. As previously discussed, the authorization procedure needed as well of being revised on the reason of its extreme complexity, high financial outlay requested and different scattered positions occupied by Member States dealing with its interpretation.

First of all, the involved procedure has changed entirely by means of Regulation 2015/2283, shifting from being merely decentralized to sort of a complete centralization of both processes and decisions. Actually, all the application requests, independently from which Member State the operator asking for a new product commercialization is from, are now submitted to a specific Commission website and then examined at European level, before being addressed to the EFSA's scientific evaluation. Once the latter has given its favorable opinion, it's again up to the Commission of providing an executive act in which the eligible Novel Food has reach the authorization, or contrarily denial, to legally reach the European market. However, before the last mentioned piece of legislation reaches the official publication, it has to be scrutinized again by the Standing Committee on Animals, Plants and Feed, which, after having granted its positive verdict, gives the ultimate go-ahead to the almost official Novel Food. On top of that, the most significant modifications brought to the authorization procedure, apart from being centralized and no longer doubled in steps, are firstly the introduction of specific and detailed deadlines to be mandatory respected for each contributor taking part to the evaluation procedure, and secondly the permanent involvement of the European Food Safety Authority in granting that what should be primarily ensured is the superior food safety aim.

Other relevant improvements have been made and the most significant of them will now follow.

To begin with, once a food product has been authorized to be commercialized in the European market, that permission can be considered valid not only for that specific foodstuff, but represents sort of a generic concession for also all the so called similar and equivalent products, hence not even requiring of the simplified procedure dealt above.

Once the authorization has been granted to the first food operator, all the comparable products are by office approved. By the way, for well deserved and verified competition reasons, an entrepreneur can ask for the individual license to be allowed to his product only and not be used for other competitors' advantages. In this hypothesis, however, the maximum concession of time for covering the first applicant is five years only from the moment in which the novel food has been authorized. When the time span has expired, it can be no longer renewed.[108]

Nevertheless, if sticking to the normal procedure, once a food product has been granted the permission of entering the market, it enters also the European Authorized Novel Food List, where, apart from its specific name, it appears also how to use it in the most appropriate way, how to label it and when and how frequently, if needed, to check upon its safety requirements. This list is continuously updated by the Commission and happens to be very useful whenever an agri-food operator desires of reaching the European market: for the principle of transparency he can hence openly consult it in the possibility of finding already authorized products comparable to his own one (Art. 1 Commission Implementing Reg. EU n. 2017/2470).

Another key topic has been brought to light on the reason of the treatment reserved to the extra European traditional food products, which have been faced differently in the innovative Regulation 2015/2283 with respect to the previous one. As a matter of fact, among the categories considered as appropriate to be disciplined by the concerned Legislation, finally food products already disposing of a history of safe use in a third Country appear. As specified, as safe use past must be intended a food product which has already been in place in a third Country by at least 25 years and has been eaten by a significant part of that population, hence not presenting health related risks (Art. 3 Reg. EU n. 2015/2283). All these features bring positive consequences also on the ways in which these applications should be submitted. As a matter of fact, it is no longer needed for them to follow the entire procedure, but those operators should only send a notification to the Commission, which, after having heard from the EFSA and all the Member States and having received the green light by all of them, authorizes the commercialization of the involved product. Only in the hypothesis of not finding

[108] FERRERO E., *Novel foods e tecnologia alimentare come strumenti di salvaguardia ambientale,* cit., http://rgaonline.it/categoria1/novel-foods-e-tecnologia-alimentare-come-strumenti-di-salvaguardia-ambientale/

favorable grounds from the just mentioned Bodies, the authorization procedure has to be started from the beginning, as holds for all the other Novel Food products.
Of course, the fact of belonging to the field of traditional food products, even though coming from extra European Countries, has a completely different impact on consumers' perceptions with respect to the proper Novel Food ones. As a matter of fact, belonging to a Nation safe consumption patterns sorts of reassures even the most skeptical consumers, which instead happen to be quite worried about the innovative implementations of the new production techniques or even scared by the kind of new marketed products, hence obstructing them. It is in this picture that the additional pieces information displayed on their label play a completely different game.[109]

3.2.1 Two much debated Novel Food cases: edible insects and food derived from cloned animals

It is no doubt that among all the hot topics brought by Regulation 2015/2283, edible insects and products derived from cloned animals have proved to be the most discussed, hence generating opposing positions on the themes.
To begin with the first, in the light of the disproportionate increasing of the population with respect to the availability of resources, edible insects have been identified as a viable solution. As a matter of fact, they can represent another potential source of edible proteins such as the ones provided by meat from animals like poultry, sheep, beef and swine and other fundamental dietary components, in addition to contributing in solving problems such as the just mentioned one of the increasing food requirement or the one of reducing the environmental impact caused by traditional breeding methods. Once again though, the need of innovation needs to be balanced with the food safety and consumers protection priorities.
Going back to the previous Novel Food regulation, edible insects have always been represented as an unsolved mystery: if on the one hand there was no doubt in considering them as new food products, on the other there wasn't an appropriate category matching with them. As a matter of fact, the only field that could be more or less linked to them was the one dealing with *« food or food ingredients consisting of or isolated from plants and food ingredients isolated from animals »* (Art. 3 Reg. EC n.

[109] CANFORA I., *Alimenti, nuovi alimenti e alimenti tradizionali nel mercato dell'Unione europea dopo il regolamento 2015/2283,* Diritto Agroalimentare, 2016, p.43, https://www.osservatorioagromafie.it/wp-content/uploads/sites/40/2020/09/Fascicolo-1-2016-1.pdf?waf=1

258/97). Actually, if there were no doubts on the Novel Food inclusion of ingredients isolated from insects, being them exactly corresponding to the just mentioned part of the definition, differently, whole edible insects, parts of them or even ingredients obtained or derived from them found not so stable grounds.

As a consequence, this uncertainty strongly impacted the European market for the involved products, whose producers could not compete on a par with other extra European Countries ones. If also adding the enormous money amounts required for legally undertaking the Novel Food authorization procedure, the almost infinite time taken for having a final answer, combined with the uncertainty of its results, it is not surprising that European agri-food operators tried in every possible way to break free from the inclusion of edible insects, parts of them or ingredients obtained by them in the complex 258/97 Regulation. Furthermore, if also considering that a centralized procedure was missing, completely different positions were taken by the various Member States' Authorities, the ones in charging of implementing the safety assessment after sufficient studies were provided by the applicant food operator. As previously discussed, once this step was carried, the report on the product safety was made available to the Commission and to other Member States, which, if contrary to its market commercialization on the basis of scientific evidences hindering food safety, could oppose the new foodstuff to enter the European market. In the last mentioned hypothesis, it was up to the EFSA to intervene with the final decision. Hence, it follows that, if the at the beginning of the needed authorization the concerned Member State settled with retaining that the questioned foodstuff was not to be considered as belonging to the Novel Food categories or requisites, it consequently didn't have to be later scrutinized by the EFSA. All to say that in the latter hypothesis the food products were hence not risking of not being granted the commercialization permission for being sold in the European market.

In the light of all these considerations, different approaches were therefore adopted by the European Union Members with specific reference to the whole edible insects (and parts of them), all because with respect to the same subparagraph plant category, on the animal one was missing the "constituted of" terminology.

Some Member States, such as Austria, Denmark, Finland and United Kingdom opted for a literal interpretation of the Regulation, according to which the entire insects were not included, while instead ingredients derived from them were covered, independently

from which production method was made use of. Hence, in this perspective, edible insects and their parts were treated with tolerance by these Countries, on the reason of their exclusion from Regulation 258/97.[110]

Holland, for instance, instead occupied an even more stringent interpretation of the above piece of legislation, which, if sticking to the exact same words reported, excluded also all those insects derived ingredients that were not even obtained by means of specific advanced technological extracting procedures. In this light, all those food products put together by means of traditional techniques, even concerning the edible insects field, such as insect meals, were not considered as Novel Foods on the reason of being derived from and not "isolated" from.

In opposition to all the just exposed points of view, Italy and Portugal, moved also by their more traditional and conservative cultures, interpreted the missing inclusion of the debated word as a Legislator's oversight. As a matter of fact, according to these Countries, if in the same category the plant component was disposing of both the "*consisting of or isolated from*" terms, there was no reason for which edible insects had to be excluded from the Regulation, especially if considered that both plants and animals new foods were deserving of primary food safety assessments no matter what.

Last but not least, Belgium, differently, implemented sort of a balanced solution: its Authorities recognized the uncertainty of the legislative statement and hence settled with granting allowance to insect foodstuffs, but not without imposing a lot of restriction on the ones ending to be authorized, which, however, had to be bred in the same involved Country.

It is hence clear that the different interpretations provided by the Member States reflect not only the economic side of the problem and the missing centralization one, but also, most of all the cultural discrepancies among them. As a matter of fact, it is not a coincidence that Nations such as Italy and Portugal, occupying sort of a southernmost position inside the European Union, settled for a more restrictive position on the opening of the market towards the Novel Food products. Actually, in such States habits and culture are strictly connected to culinary tradition, which is believed to be threatened and contaminated by all those foods not disposing of a safe past and not belonging to the tradition of the concerned Lands.

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[110] FORMICI G., *Novel Food e insetti per il consumo umano tra interventi legislativi e Corte di giustizia: alla ricerca di un difficile equilibrio,* Rivista di Diritto Alimentare, A.I.D.A, 2020, p.51-58, http://www.rivistadirittoalimentare.it/rivista/2020-04/2020-04.pdf

When in 2016 a French firm saw the market withdrawal of all its insect food related products at the hands of the Paris Prefect of Police, up to the moment in which the involved edible insects would have obtained the authorization of being commercialized, the situation saw a change of pace. The affected firm, on the basis of retaining that its products were removed as a consequence of the wrongful interpretation of Regulation 258/97 carried by the State's Authorities, brought the case to the French Council of State, which in turn addressed it to the European Court of Justice, on the reason of the needed superior interpretation of the Regulation.

To begin with, according to the Advocate General Bobek, which recently released his opinion 9th July 2020, the Legislator first of all was not mistaken by not including entire insects (or their parts) in the Regulation, as instead sustained by the Italian and Portugal Authorities perspective. In fact, if taking a deeper analysis at the exact terms that have been used in the usual language, by ingredient it must be intended the single component of a wider product, and hence, insects in their entirety cannot be considered as ingredients. Furthermore, by analyzing also the real meaning of the expression "isolated from animals", by isolation it must be intended the process by which an ingredient is extracted from an animal or its parts, or even by means of a mechanical extraction. On top of that, if taking a look also at the historical context in which the Legislator provided that framework, at European level that kind of food wasn't already existing, hence it wasn't it his mind. After all, the innovative Regulation on Novel Foods was aimed at bridging the gap between the "old" world and the new one, where innovation, its technological implementations and consequently population's eating habits have made infinite jumps ahead.

All these reasoning made the Advocate General clearly settling for the non inclusion of edible insects and relative parts in Regulation 258/97. He also added that, if any Member State instead had proved reasons to be worried for health protection, it should have instead complied with Article 12 of the questioned EC Regulation n. 258/97. Actually, the involved Article stated that if after the market entrance of a food product new information was revealed changing the status of involved foodstuff, that specific Nation could have limited or stopped or the product commercialization inside its territory, in addition to the possibility of making use of the already provided by General Food Law framework of solutions on the theme.

To the same conclusion, even if in a more synthetic way, has reached the European Court of Justice by means of its judges, which, once again confirmed the fundamental role of the States in supplying adequate measures at avoiding food risks, if not otherwise provided at a centralized level. The Regulation hence did not miss in fully covering a topic, it instead had to be clearly interpreted as that entire edible insects and their parts were not dealt by it. Nonetheless, if retained that specific products commercialization was bearing health consequences for the consumers, it was up to the single State to intervene.

Contrary to what has been said up to now, the new Regulation 2015/2283 on Novel Foods has instead clearly faced the involved theme, settling once and for all the topic being discussed. As stated by its 8th Whereas, this piece of legislation was brought to light because of the necessity of updating the Novel Foods categories to the scientific and technological developments happened from 1997 on. Immediately after, few words later, the need of covering also whole insects and their parts has finally appeared. As a consequence, the new Article 3 definitely solved all the previous scattered doubts: as Novel Foods can be considered all those foods «*consisting of, isolated from or produced from animals or their parts*». Hence no doubts on their inclusion should still remain. However, not all the dilemmas concerning whole insects and their parts treated in the new Regulation have been solved.

As a matter of fact, Article 35 of the same Regulation 2015/2283 has also provided sort of a transitory disposition: all those food products once non entering the Novel Food field of application, but now included by the new Regulation, could dispose of sort of a grace period until the Commission's green light to be legally commercialized in the European market has been granted (or rejected) to them. The needed requirements to make use of this allowance period happened to be three: the first fundamental one entailed the not already belonging to the previous 258/97 fields of application; the second one instead dealt with the prerequisite of being already legally sold in the market prior to the date in which the new 2015/2283 Regulation was entering into force, which is to say 1st January 2018; while the third one addressed the application procedure. The latter in fact had to be presented, either by means of the usual complete request or through simplified notification in the case of extra European traditional products, no later than 2nd January 2020.

This transitional phase statement, however, has brought consequences on its interpretation. According to a more stringent perspective, since in order for the transition to be applicable the new Novel Food product required to be already legally commercialized in its Country, the allowance could be only implemented by those Member States reading Regulation 258/97 in the more rigorous narration, hence excluding whole insects from being covered by it. Consequently, those other European Nations that instead saw the old Regulation in the light of the Legislator's oversight, found their insects related businesses in a competitive disadvantage position with respect to the others, according to this standpoint of the new article 35 of the Regulation. If truth be told, as a result, those firms, on the reason of the 258/97 Regulation interpretation carried by their Member State, could not legally sell their products under the previous Regulation and therefore could not still sell them by taking advantage of the grace period. On this ground, unreasonable disparities have arisen according to the Nation in which the operator was located. Relating to this, IPIFF, which is to say the International Platform of Insects for Food and Feed, has strongly encouraged another possible and more inclusive interpretation of Article 35 of Regulation 2015/2283: all those operators that were already working in the market under the previous Regulation and have been hindered from commercializing their food products because of the wrongful interpretation provided by the State, which is to say the one including insects in this specific case, should be counted as well.[111] Hence, even though they could not legally sell their foodstuffs in the past on the reason of being scrutinized by the EFSA, or even they tried to sell them without permission but have been sanctioned later, they should not be discriminatorily penalized for mistakes made by their State. It is though still unknown what the results of this alternative interpretation provided by IPIFF are: actually, no sufficient data are available on the possibility of adhering to the transitional discipline for those businesses located in the more inclusive perspective Member States.

If comparing the number of applications for whole insects, parts of them or derived food products accomplished under the previous Regulation with respect to the actual one, a significant change of pace has been made. As a matter of fact, prior to the implementation of 2015/2283 Novel Food Regulation, none of the applications

[111] FORMICI G., *Novel Food e insetti per il consumo umano tra interventi legislativi e Corte di giustizia: alla ricerca di un difficile equilibrio,* cit., p. 62-63

submitted on the discussed theme has reached the authorization phase, while lately, on the contrary, several of them are being scrutinized. At the moment though (up to the results of December 2020), among the 20 requests that have been sent, only 3 of them managed to reach the EFSA analysis phase. But it must also be said that even though the deadlines have been expired for all of them, no answer has still been provided by the Authorities. It can hence be understood that even though the field of implementation has been clarified, the same cannot be said on the needed operator documentation or the efficiency of the deadlines provided on grating the safety of the novel food product.

It is up to these days the ultimate notification published by the EFSA on the proved safety of one of the eligible, and hence now effective, insects as Novel Food from Regulation 2015/2283. Going in more details, the one edible insect discussed is the dried yellow mealworm, thermally dried as a whole or becoming powder, in order to be used as a whole in snacks or as ingredient in other specified products. After having analyzed that its main components happened to be proteins, fat and chitin and having conducted appropriate risk analysis procedures, no safety concerns have been revealed under the proposed implementations and with the presented quantities.[112] Hence, the dried yellow mealworm can almost officially enter the European market and the Novel Food approved list.

Now, a slight change of scenario has to be firstly made in order to keep covering the second title presented topic in dissertation, which is to say food derived from cloned animals.

It is not a secret that the involved theme has faced enormous ethical issues, which, by not having reached the point by the time in which the new Novel Food Regulation was entering the European Union, a compromised and temporal solution has been found: including the food derived from cloned animals in Regulation 2015/2283, on the reason of the implementation of untraditional breeding practices, better expressed by its 14th Whereas. Hence, until further notice of a specific regulation on the subject, as what happened to GMO, in order to not commercialize food that can potentially damage health, the involved category needs an authorization procedure as well.[113]

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[112] EFSA, *Safety of the dried yellow mealworm (Tenebrio Monitor Larva) as a Novel Food pursuant to Regulation (EU) 2015/2283,* ej - Efsa Journal, 2021, p. 18, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6343

[113] CANFORA I., *Alimenti, nuovi alimenti e alimenti tradizionali nel mercato dell'Unione europea dopo il regolamento 2015/2283,* cit., p.38

Up to now, two regulating proposal have been advanced by European Authorities, and both of them have not being successful in finding favorable grounds.[114]

The first one has been released as Parliament Directive Proposal, better known as COM(2013)892, aiming at banning the cloning of animals of the bovine, porcine, ovine, caprine and equine species for food and breed purposes, while the second one is a Council Directive Proposal COM(2013)893 dealing with prohibiting the placing on the market of those food products obtained from cloned animals.

By the way, up to now, the ban on the market commercialization of food derived from cloned animals has not yet been implemented and, according to the state of the art dispositions, the Regulation to follow is still the 2015/2283 on Novel Foods one. Hence, also food derived from cloned animals needs to dispose of the authorization to be sold and to follow the appropriate labelling requirements provided by it. Actually, the label under consideration must specify that the food on which it is affixed has been obtained from cloned animals, risking hence of not being so appreciated by European consumers.

All these worries have been scattered not only by food safety reasons, but most of all for the ill health that cloned animals have presented along their lives. To tell the truth, EFSA, when asked to state its position on the topic, said that the hesitations on the involved products authorization are due to the limited number of data available, which often revealed that the wellbeing and healthiness of the concerned animals happened to be compromised. Actually, if sticking only to the food safety concern, both meat and milk produced by cloned animals show no evidences of being worst than the ones obtained from traditional breeding methods, though both having been examined on animals corresponding to high-standards requisites of healthiness, frequency of food safety controls and ways of growing them.

The most debated and challenging aspect has with no doubt been identified as the suffering cloned animals are exposed to. As a matter of fact, the European Food Safety Authority especially recognized health related problems linked to the surrogacy and clones themselves, whose embryos, if considering the low effectiveness of the technique, need to be implanted in more than one surrogate in order to obtain a successful result. Furthermore, clones anomalies and relative enormous dimensions have been ascertained as the causes of extreme severe births and newborns deaths.

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[114] SCAFFARDI L., *Novel Food, una sfida ancora aperta tra sicurezza alimentare, innovazione e sviluppo sostenibile,* cit., p. 765-769

Nevertheless, some extra European Countries such as Australia, Canada, Brazil, Argentina and United States have adopted a more favorable opinion on the theme, accepting the implementation of cloning procedure, sometimes not even requiring an authorization prior to the products market commercialization. With particular regard to the United States instead, the Food and Drug Administration, which is the one entity corresponding to the European EFSA in the USA, authorized food products obtained from cloned animals offspring of being commercialized and eaten, even without having on the label the reference to their indirect cloned origins, given that they have been bread by traditional techniques methods. As a matter of fact, while a list of cloned animals exists, the same cannot be said for their offspring.

On the same level, even if with regard to completely different parameters, finds itself the challenge of obtaining meat, milk and eggs by means of laboratory techniques not implying the use of living animals as has always been intended. These procedure though, even if brought to the public attention in 2013 with the "strange" hamburger obtained from meat grown in vitro cooking demonstration, is just at the beginning. Actually, the involved piece of meat cost about 250,000 $ to be properly produced at the time and it is believed to be starting commercialized in the market by Memphis Meats, an American start-up by year 2022,[115] in a cheaper way than what was initially thought by the firm. This "meet in vitro" food product is obtained by means of a particular procedure, by which some stem cells are removed from the animal's muscle and then inserted in apposite plates, which being immersed in a serum substance boost their reproduction through electro stimulation. Later, fibers are frozen and assembled up to the desired food product necessities. On top of that, this particular and innovative process can be extended to other types of meat, such as the ones of chicken or ducks, or even to other kinds of animal cloned derived foodstuff such as the cow's milk, which instead is obtained by synthesizing the sought-after sugars, proteins, fat and water together.

A few considerations on the disserted theme are now necessary.

With no doubts all these innovations brought and still are bringing infinite advantages to the nowadays world, which thanks to these ingenious scientific discoveries can make immeasurable jumps ahead from the way it functioned and was conceived up to a few years ago. These innovations though, in order to perform in the most effective and

[115] FERRERO E., *Novel foods e tecnologia alimentare come strumenti di salvaguardia ambientale,* cit., http://rgaonline.it/categoria1/novel-foods-e-tecnologia-alimentare-come-strumenti-di-salvaguardia-ambientale/

efficient way and at the same time safeguarding consumers' health and wellbeing, as well as the involved animal ones, need to be regulated by an appropriate and specific framework of provision. The latter, even if few steps forwards have been made, up to now is still missing. Moreover, both food, culture and eating habits have still to find an equilibrium with the aim of being sustainable not only from the economic or environmental points of view, but, most of all, from the social one, which, after the globalization of the market has still yet to find a stable ground, bringing drawbacks also to the concerned agri-food legislative side of the coin.

3.3 4.0 Technological innovation implementation on the agri-food sector: Internet of Things and smart labels (RFID), cloud computing, single unit batch and Distributed Ledger Technologies (block-chain)

If so far it has been analyzed the use of innovation as means of obtaining Novel Food products, now it's time to see how the new technological tools can be implemented in the agri-food sector and which consequences can derive from.

Four have been identified as the main practices in which the 4.0 technological revolution can bring innovative opportunities and challenges for the involved operators: food traceability, recall and reciprocal exchange of information by means of smart labels and IoT, cloud computing for optimizing management and logistic decisions and, last but not least, the so called "single unit batch" to satisfy the new personalization trend pursued by consumers.[116]

To begin with the first topic, food recall consists in the procedure by which whenever food doesn't respect the appropriate safety requirements, it must be immediately withdrawn from the market.

The reasons according to which the food product must be cleared from the commercialization can be many, ranging from consumers complaints to the presence of damages in the product, which can plausibly have happened along the supply chain or that can even been detected after the implementation of specific controls or audit checks. Furthermore, labelling mistakes can happen as well, consequently having the label imprinted data differing from the real ones, either in ingredients contained or in the effective expiry date terms. On top of that, products can suffer damages not only by

[116] ROESEL L., *Industria alimentare 4.0, campi di applicazione e vantaggi,* Industry 4 Business, 2020, https://www.industry4business.it/industria-4-0/industria-alimentare-4-0-campi-di-applicazione-e-vantaggi/

going through the agri-food supply chain flow, but defects can also be caused by the operators' firms themselves while carrying out the needed tasks. In point of fact, foreign matter such as steel, plastic, glass or even oil related to the machine producing the foodstuff can happen to be involuntarily included in the final product, as well as can occur for pesticides, natural inappropriate substances, fungi, or unsafe additives levels. Over and above, another possible cause of detriment can also be considered the unsuitable wrapping of the concerned foodstuff.

By the way, in all the just mentioned cases, the food operator needs to recall the damaged product or batch as fast as possible.

In order for this emergency procedure to be efficient, the supply chain knots must be linked in the most transparent and reactive way, hence being able to grant the fundamental principle of food and feed products traceability.

Internet of Things (IoT in short form) describes the automatic networking between objects, without necessitating the human aid in between. Those objects, by having computing devices within, are allowed to connect one with the other. Among the instruments making use of the concerned technology, smart labels have made a huge step forward with respect to the usually commercialized ones. As a matter of fact, they are not only able to identifying and tracing back the exact specific product, but also an entire batch of them. Furthermore, apart from the localization function, they can play also the one of detecting foodstuffs modifications or food safety concerns related to them, permitting the food operators to intervene in the exact needed moment. This innovation has brought consequence also to the way the European Union safeguards food safety: actually, if by means of smart labels food harms can be immediately detected and spotted, the Precautionary Principle is no longer needed to be applied as sort of preventive measure. Each label, by being attached to every food product, could change the entire way food law operates on the theme: each step can hence be traced back and the relative food operator intervened can clearly appear and be responsible for his contribution. However, the utility given by smart labels is not only applicable to the just mentioned fields of traceability and recall: as a matter of fact, they can also be a precious insight to consumer choices, giving rise to a reciprocal exchange of information. With reference to this specific need, RFID labels are leading the way. The latter etiquettes are able to perform by taking advantage of Radio Frequency Identification, a specific technology implementation making use of the unique automatic recognition of

either products, objects, people or even animals, which, by means of electromagnetic waves spreading in the air, can spot the concerned items, also from a significant distance.[117] Actually, it is no longer a secret that consumers claim both food safety and truthfulness of information conveyed to them by means of product labels when settling for a precise foodstuff. By means of the involved smart labels, not only the producer can trace back all the relevant product information and the activities carried by all the engaged operators with the aim of keeping the desired food safety levels high, but also the consumer can access all these data, check personally their veracity and deep his knowledge on the product, either while taking a purchase decision or even when the product has been already bought. It is exactly in this precise moment that the reciprocal exchange of information happens: once the consumer enters in touch with the concerned labels, the operator can acquire his choices, GPS location, personal data and eventual other information conveyed on the reason of the RFID tags association with them. As a consequence, the agri- food producer, distributor or whoever in connection with the labels, can use them as precious insights at increasing his competitive advantage over his competitors ones.

By the way, the utility provided by the involved RFID labels doesn't stop here.

The intelligent sensor technology upon which they are based can be very useful in providing improvements to both consumers' health and most appropriate techniques by which conserving products (for example by measuring the environmental temperature to which they are exposed to), in addition to the possibility of avoiding food wasting and identifying the absence of food risks in already expired, even if only formally, products.[118]

It goes without saying that, data management and cloud computing, which represent the third jump ahead in the implementation of digital technological innovation in the concerned agri-food activities, are the key turning to make agri-food business working in a smoother, faster, more efficient and effective way. As a matter of fact, the improvement of data management and storage, both within the single firm and along the entire supply chain, can also be advantageous whenever concerned operators need to take challenging decisions according to the available data, or when past actions have to

[117] SOFTWORK, *Tecnologia RFID: concetti base,* RFID Global Value Chain, 2020, https://www.rfidglobal.it/tecnologia-rfid/

[118] SPOTO G., *Gli utilizzi della Blockchain e dell'Internet of Things nel settore degli alimenti,* Rivista di Diritto Alimentare, A.I.D.A., 2019, p.34, http://www.rivistadirittoalimentare.it/rivista/2019-01/2019-01.pdf

be revised or even shared with other supply chain players. To go in further details, cloud computing finds itself as being particularly useful in firms dealing with of perishable goods, whose storage must be accurately managed. Indeed, stock forecasts, obtained by means of all the products data such as life cycle, seasonality, value and weight losses, in addition to the other information provided by costs incurred in carrying the product related activities such as trucks' capacities, transportation and storage costs and the like, are aimed at optimally running the warehouse. Not only in-house inventory is the one being addressed, but it also involves food products to be removed because of logistic necessities or because have been spoiled or rotten. However, the primary aim of data handling has been identified, in addition to the one of reducing the number of errors made while managing the firm, most of all in minimizing the economic cost of making errors. Actually, cloud computing gives the possibility of finding among the various possible future scenarios the one most profitable to choose and deal with, ranking therefore the alternatives according to clear and specified criteria upon which basing the future of the firm.[119]

The last but not least field of 4.0 innovation application is with no doubt the ultimate frontier of technological improvement in the agri-food sector: the so called "single unit batch". It must be said that, among the trends consumers are settling for, the tendency of choosing local, regional or at most National food products, joined with the one of eating food containing low levels of alcohol or calories, and with the one of preferring personalized foodstuffs are leading the way. However, mixing together these three necessities is not so easy for businesses producing sort of standardized products in great quantities. Nevertheless, by means of both intelligent sensor technology combined with automation systems, some firms are trying to challenge their limits. Up to now, the far most objective to be realized consists in producing unique breakfast cereals to be personalized according to each customer need by following the requested submitted recipe and labelling the final foodstuff package according to it. Then, once the product has been completed, it can be directly sent to the customer's home address. However, so far, the only multinational company that has managed in creating something far approaching this challenge was Coca Cola, which, by asking the consumer to add 8 more

[119] ROESEL L., *Industria alimentare 4.0, campi di applicazione e vantaggi,* cit., https://www.industry4business.it/industria-4-0/industria-alimentare-4-0-campi-di-applicazione-e-vantaggi/

Dollars for each bottle, could personalize the package by writing on top of it the buyer's name instead of the brand logo.

If, up to now, the main agri-food applications of technological innovation have been explained, the fundamental building block almost connecting all the different procedure has not yet been mentioned: Distributed Ledger Technology (DLT), better known as block-chain.

When Bitcoins creators developed the so called transaction method, its aims was to be originally found in giving birth to a transaction system based on trust and certainty of the results among the involved operators, without having the Bank to intervene. With the years passing by, additional goals have been added to the first one, such as the fundamental one of creating sort of an unchangeable transaction register to which the additional players, represented by the different network knots, could access and navigate in finding each authorized movement within the involved system.

Each time a transaction is approved, it enters the accessible list and can be seen by all the network participants, as well as each time a new member enters the "club", a copy of the entire transaction list is automatically available to him.

Different types of block chain networks exist, ranging from the permissionless ones, which is to say the ones in which all members can authorize transactions, to the permissioned one, in which contrarily to the previous one, only few members can ascertain the deals and, at the same time, the structure of the net must be one of a closed type. In between them another possible option is present, the so called "hybrid" structure. In the latter, some members dispose of a more powerful position with respect to the others and, according to the specific case being dealt, the network arrangement can be either closed or opened to the public.

Summing up, the block- chain mechanisms is based upon the fact that all the agreement members dispose of a copy of the transaction list, which cannot be erased or modified according to their interests. Actually, in order for a modification to be effectively applied, it has to be executed by half plus one members composing the entire web chain.

On the reason of its extreme transparency, recording memory and non-modifiability, the block-chain has been thought as perfect at fitting the required traceability of foodstuffs along the agri-food supply chain.[120]

[120] SPOTO G., *Gli utilizzi della Blockchain e dell'Internet of Things nel settore degli alimenti,* cit., p. 25-26

As a matter of fact, supply and production processes management, as well as food safety and quality controls, but also logistics, waste and returns handling could be better implemented by means of the involved technology. If truth be told, block-chain technology can lower transaction costs since intermediaries figures are removed and, at the same time, it can most of all enhance transaction transparency and relative checking. It is hence not surprising that it is also known as way of "industrializing" the cost of trust,[121] whose weight is about 35% of the total production value amount in a not technological innovated firm. Consequently, the single firm, as well as the entire supply chain in which it is involved, can overall benefit from its implementation.

Indeed, prior to the accomplishment of the involved technology, it didn't exist the chance of granting the overall fairness and coordination of the single supply chain activities without having an appropriate entity or institution ensuring that none of the members had illegally modified data according to his necessities. In order for the block – chain mechanism to be more enforceable, rules are no more written in a piece of paper, but are translated into codes and beforehand established, hence not letting anyone freely interpreting or contesting them.

If, up to now, a few of the many positive aspects and opportunities brought by its implementations have been revealed, some drawbacks still exist.[122]

First of all, the involved network is not yet so diffused among agri-food firms, hence a long burn-in has still to be awaited and implemented. Another obstacle, even though one of more of a technical nature, has to be considered as well: the length of the supply chain knots. As a matter of fact, the more are the single firms taking part to the supply chain, the more are the information to be registered. However, the storage of too many transactions could weigh too much on the smooth functioning of the technological system, with the risk of slowing it down. On top of that, the bigger and more open the network structure, the greater the difficulties in granting the helpful role of the overall monitoring mechanism, especially if firms find themselves in different Nations, where agri-food regulations differ the ones from the others. Furthermore, it must not also be left aside that digitalizing all the transactions means not disposing of human beings able to intervene whenever unforeseen event happen, or even when human judgment, based on the required discretion and flexibility of the different circumstances, is needed.

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[121] AMMANATI L., *Information in agri-food market: the role of digital technologies,* Rivista di Diritto Alimentare. A.I.D.A, 2020, p. 54, http://www.rivistadirittoalimentare.it/rivista/2020-01/2020-01.pdf

[122] SPOTO G., *Gli utilizzi della Blockchain e dell'Internet of Things nel settore degli alimenti,* cit., p. 29-33

However, if block – chain allows to double check the different steps a food product is going through by means of both temporal and non - modifiable data, the main drawback is with no doubt presented by the uncertainty and dubious truthfulness of the information provided by the different involved knots. As a consequence, nowadays it still cannot be used as sort of alternative means in granting product specific certifications, where quality must be undeniable and the different relative sources from which the data are originated must be trustworthy and verified.

Nevertheless, until recently, the role now run by the involved system has instead almost always been carried by public authorities or by the ones entrusted by the latter in doing so rather than by private entities, of course both not by making use of this innovative tool. In the future, however, a mixture of both regulating forces, if properly applied to the block – chain network, is believed to be more effective in granting the smooth functioning of the entire system. In particular, if dealing with the tasks division, on the one hand private entities should better fit with competition and economic functioning management themes, always respecting the contracts the supply chain members have already adhered to, while on the other hand, public authorities should be more concerned with the accreditation procedures, the registration and identification to the appropriate bodies in charge and certifications related topics.

However, the best combination of both private and public sources of regulation at disciplining block – chain activities has hence yet to be found.

Notwithstanding, the turning key of the involved system has been identified in grating the concerned freedom at initially setting the desired requirements arrangement upon which later basing the entire arrangement on, and hence, consequently, both internal firm activities and external supply chain ones implementations.

Of course, the next enormous challenge to be overcome is the one governments and regulators are sort of obliged to deal with: the one of finding an appropriate framework of provisions able to discipline such an innovative technology. In order for this future regulation to be effective, the Authorities in charge of establishing it must firstly remember the peculiarities of the agri-food sector as well as the market and consumers ones. However, at the same time, they must also consider that an excessively heavy regulatory scheme could only make things worse, hence hindering the already difficult transition of the agri-food sector towards processes streamlining and innovation in itself.

CHAPTER 4. CONSUMER PROTECTION AND DIFFERENT LABELLING SYSTEMS: THE ROLE OF THE LABEL AND THE EFFECTIVENESS OF THE DIFFERENT SYSTEMS

4.1 The contractual role of the label in the producer – consumer interaction

If taking a look at human daily routines, lots of contracts are established unknowingly on ongoing basis: from the moment in which the food product (since it's the specific theme being analyzed, but the same reasoning could be extended to whatever marketed good with no exceptions) is selected in a shop, validated by the cashier and paid by the consumer sealing the deal, to the one in which instead foodstuffs are acquired by means of computerized procedures, such as by online ordering them after having scrutinized the few available information on the website or even by purchasing them through social media advertisements, contractual agreements are established, each of them implying later its relative execution.

The different deals are based on specific parties obligations presented to the final consumers by means of the label information, which hence plays the instrumental role towards the contract formalization. It is in this picture that, with specific regard to the now most diffused prepacked goods, the label substitutes the once active exchange of information between the producer and the consumer. The informative transaction was aimed at directly examining and valuing the interested goods and receiving a fair feedback on them, basing later the purchasing decision on the reciprocal trust trade-off.[123]

The label hence now acts as sort of gap filler on the asymmetry of information displayed by the consumer party, which, by not disposing of all the adequate and full detailed products characteristics, must based his decision on his knowledge and upon what's provided by the concerned tool.

Actually, the involved label plays three roles all in one: the individualizing, the protective and the informative ones.

As a matter of fact, if it wasn't for the information provided by it, it wouldn't be so easy differentiating and distinguishing one food product from the others, especially if concerning the same food category, as can for example happen for different kinds of bottled oils, butters or even milks. As a consequence, apart from the other most complex

[123] ALBISINNI F., *Etichettatura dei prodotti alimentari*, Diritto alimentare. Mercato e sicurezza, 2011, p.4

dynamics ruled by the etiquette, it first of all stands for the simplest identification of the single product in itself among all the other commercialized ones in the same shop.

The protectionist side of the label can be instead better expressed by the need of mirroring the consumer particular exigencies, ranging from respecting their intolerances to specific product requirements such "free from", "light" or with low salt levels, in the meticulously sought product: in this perspective, the label provisions reflect the exact content of the foodstuff, whose consumer can preserve himself only by accurately standing to what is explicitly and entirely conveyed by means of the label, with no possibility of modifying or objecting it. Actually, the only alternative is the one of directly settling for a similar product instead commercialized by a competitor. [124]

Complementarily, the informative role played by the label can be better expressed by means of two aspects: the one related to the market and the one connected to the contract itself. The first one concerns the ex ante phase to the purchase process, which is to say the one shared by all the common consumers and that aims at safeguarding them as a whole, in order to lift them up from the position they usually occupy and granting a fair, transparent, smooth and competitive market functioning.

Given that nowadays the dialogue between the involved parties has been substituted by the consumer mental elaboration of the information received by the label, the communicative side of the latter has assumed a significant task in revealing what buying a specific product really implies, hence helping the consumers at taking conscious choices. As a matter of fact, the etiquette guides the customers in being fully aware of the product characteristics, both strengths and drawbacks, since they wouldn't otherwise dispose of the adequate means and time at running the necessary food quality and veracity checks of information.

In this context must be interpreted Article 3 of European Regulation 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, which clarifies that the Regulation's aim has to be found in the highest level of protection of consumers' both health and interests. The latter in turn must be at least achieved by means of a basic minimum standard upon which they can take conscious choices and make the best and most adequate use of food products, especially when concerning fields such as healthiness, social, economic and environmental concerns, as

[124] TAMPONI M., *La tutela del consumatore di alimenti nel momento contrattuale: valore delle indicazioni obbligatorie e volontarie nella formazione del contratto,* Trattato di Diritto Agrario, 2011, p. 598

well as ethical issues (Art. 3 Reg. EU n. 1169/2011). Hence, the addressee of the Regulation can be considered both the single consumer and the community of food operators as a whole, ranging from the producers to the transformers and the distributors, up to covering the entire agri-food supply chain in its entirety, with the aim of safeguarding apart from food safety, also market dynamics and competitiveness.[125]

It is in this picture that the consumer can be defined not only by means of his necessity of safeguarding himself, but he is hence depicted as the representative agent of the entirety of consumers, which should be coherent and foreseeable in his choices.[126] As a consequence, it is clear that the main aim of the Regulation is consumers empowerment, achieved by means of the most appropriate tools in making them active and smart players. In order to reach such a goal though, consumers must as a prerequisite master some key and primary skills, such as the ones of recognizing the meaning of specific symbols, being able to compute simple calculations or the ability to perform comparisons among different options where information is provided by the label.

It goes without saying that, given that the label is the main protagonist of the involved framework of provisions, it must be clear, understandable and readable, in order to enable the maximum level of adherence for all the stakeholders involved, not only the consumer ones.

For the label to be effective three assumptions must be considered and strongly respected: don't drown consumers with too much information, otherwise they would end up by not understanding which are the fundamental one; the label must be as clear and short as possible, because of consumers' needs of optimizing their time and lack of field-specific skills when choosing among different products; and last but not least, cultural diversities, as well as the most technical linguist ones, can hinder the assimilation of the label information into consumers' thoughts and consequently impact purchase decisions. By following these reminders, the Regulation understood the importance of adopting different additional specific forms at conveying information, which must be appropriate for each Country and consumer characteristics involved,

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[125] FRANCO R., *L'etichettatura dei prodotti alimentari: il "luogo di provenienza", il "paese d'origine", la "sede dello stabilimento di produzione", la "sede dello stabilimento". L'anagramma di un problema senza fine?,* Rivista di Diritto Alimentare, A.I.D.A., 2019, p. 27-33, http://www.rivistadirittoalimentare.it/rivista/2019-04/2019-04.pdf

[126] MASINI S., *Sulle fonti dell'obbligo di informazione degli alimenti: etichettatura, comunicazione e responsabilità,* Rivista di Diritto alimentare, A.I.D.A., 2019, p. 55, http://www.rivistadirittoalimentare.it/rivista/2019-03/2019-03.pdf

proving that sort of an homologation of standards can't be effective in reaching the desired goal, which in opposition to the past beliefs, must be balanced with the cognitive biases and real distorting mechanisms that operate in the daily consumer routine.[127]

4.2 Regulation 1169/2011 and the right provision of information to food consumers

As just explained, one of the main aims of the agri-food Law has to be found in providing consumers with the right pieces of information at taking conscious choices about the marketed products that especially deal with the health side of consumer interests. As a consequence, the framework of provision addressing this tuition must as a principle hinder whatever fraudulent and misleading practices carried at the detriment of the agri-food consumer, as well as prevent any situation of food adulteration from being present in the market, together with combating any misleading action that can misguide the consumer in his choices, independently from them in being accidental or deliberate in their nature.[128] The aspects hence covered by the Legislation concerns both food safety and its qualitative and compositional aspects to be considered as a whole, together with not undermining the fundamental principles of market competition and pursuing European rules for the smooth functioning of the internal market.

In order to fully cover the theme of adequate information to consumer, Regulation 178/2002 again has anticipated the most appropriate way to follow: if the intention is the one of preventing unsafe food to be commercialized in the market, all the available pieces of information must be considered, included the ones addressed to the final consumers by means of the foodstuff's label, where specifications on the themes such as the right use of the product or how to avoid health problems must be provided as well, if harmful effects can be caused by the food consumption (Art. 14 Reg. EC n. 178/2002).

The main framework of provisions dealing with the subject now being discussed at European level has instead been identified by the above mentioned EU Regulation n. 1169/2011, which specifically concerns the provision of food information to consumers. It started to be implemented by December 2014, apart from the distinctive topic of the

[127] AMMANATI L., *Information in agri-food market: the role of digital technologies,* Rivista di Diritto Alimentare, A.I.D.A, 2020, p. 51, http://www.rivistadirittoalimentare.it/rivista/2020-01/2020-01.pdf

[128] AVERSANO F., *La corretta informazione del consumatore: il Reg. UE n. 1169/11,* Il mio cibo, Fondazione Osservatorio sulla Criminalità nell'Agricoltura e sul Sistema Agroalimentare, 2017, https://www.ilmiocibo.it/media/approfondimenti/la-corretta-informazione-del-consumatore-il-reg-ue-1169-11/

nutrition declaration, which instead had to be followed from December 2016, leaving two more years to the involved operators to arrange all the requirements needed by the disposition. The Regulation, in addition to the general way of furnishing the adequate information to the customers, addresses also the safety side of the label and, in this picture, it also provides additional insights to Regulation 1924/2006 on nutrition and health claims made on foods.

By the way, Regulation 1169/2011 addresses all the agri-food supply chain operators and all the food products aimed at human consumption, independently from their being eaten by the single consumer or by many of them, like it happens in restaurants, schools or even canteens, all grouped the by mass caterers category (Art. 1 Reg. EU n. 1169/2011). As a consequence, dispositions must be clear, easy and readable, given the many recipients of the Regulation, all of them rightly requiring the transparency of product strengths and drawbacks to be respected (Art. 7 Reg. EU n. 1169/2011).

In order to make the point, the two main purposes of the framework happens hence to be the highest level of consumers' health protection, along with them being granted the right to be adequately informed about what they're buying and introducing in their organism. As has been clearly understood, the main protagonist of Regulation 1169/2011 is the food label at European level, but additional forms of information provided by the different Member States can also be added, if aimed at public health and consumers protection, fraud prevention, tuition of industrial property rights or the repression of unfair competition. Registered designations of origin and provenance indications can be integrated too by National dispositions. If retained instead necessary, each single Country can also provide additional information on the country of origin or place of provenance of a product, whenever not specifying them could mislead consumers (Art. 26 Reg. EU n. 1169/2011). With reference to this particular aspect, it will be later discussed in the concerned dissertation.

Furthermore, Member States can differently liberally legislate in the field of not prepacked foodstuffs, the ones sold without being wrapped or being wrapped at the purchase moment upon consumers' requests.

First of all, going back to the Regulation, all the ways in which information is provided must dispose of the good readability property, in order for the addressee to be coherent and convinced of their choices. This specific feature appears by means of the way in which information is visually furnished and it can be best expressed by the font

dimension, its spacing, thickness, color, as well as by the kind of surface upon which the data are presented and the relative contrast with the written information.[129] As will in a few lines discussed, the most relevant details on the product must be clearly visible on the principal field of vision, the one most likely to be seen at first glance whenever a consumer approaches a specific foodstuff.

To begin with the first key aspect of Regulation 1169/2011, which is to say mandatory food information, a list of different requisites is provided at classifying or not a specific piece of information into the compulsory ones to be supplied by the food operator to the consumer. As a matter of fact, in order to take part to the involved list, the piece of data must be either referring to the product identity, composition and relative features; aiming at the protection of consumers' health or explicating the most appropriate food use; or even being connected to the nutritional specificities of the foodstuff, with the aim of enabling the consumer at taking conscious choice, especially if particular dietary schemes are involved (Art. 4 Reg. EU n. 1169/2011).

By taking a deeper look at the second listed case, a specification has been made. Actually, in order to be categorized under the health protection class, the pieces of information must be referring to the compositional side of the foodstuff, which, in opposition to the first mentioned food identity field, can be linked to potential health damages if consumed by specific consumers subsets. Instead, it goes without saying that under the most appropriate product use are grouped info related to foodstuff's durability, preservation manners and how to make use of it in the right way. Furthermore, facts on the health impact generated by the food ingestion and the risks incurred by the wrong food eating are included as well.

On top of that, when analyzing the pieces of information to be retained as mandatory for a food product, a wise examination has to be taken at understanding which are the fundamental evidences consumers make use of when settling for a food product in an informed and conscious manner, which insights are considered by them as most significant or, generally speaking, which details are believed to be more useful to them (Art. 4 Reg. EU n. 1169/2011).

To make the point, mandatory food information must be generally clearly visible and easy accessible. When dealing with prepacked foodstuffs instead it must directly appear

[129] AVERSANO F., *La corretta informazione del consumatore: il Reg. UE n. 1169/11,* cit., https://www.ilmiocibo.it/media/approfondimenti/la-corretta-informazione-del-consumatore-il-reg-ue-1169-11/

on its package or attached label, to assure the immediate information storage and elaboration in consumers' minds, as well as product consciousness (Art. 12 Reg. EU n. 1169/2011). Furthermore, apart from the good readability quality above explained, whenever required, the mandatory pieces of information must be also indelible and always not obstructed by other intervening written, pictorial matter or other kind of materials (Art. 13 Reg. EU n. 1169/2011).

Article 9 of the Regulation can be instead considered sort of a guiding light for the topic being dealt: it clarifies once and for all the mandatory information to be included on prepacked foodstuffs no matter what. To start with, food name, ingredients in descending order of weight (included the processed ones that could cause allergies or intolerances and are still present in the final product, better specified in Regulation's Annex II), quantities of some of them and net quantity of the concerned product, as well as the date of minimum durability (or use by date when goods are highly perishable) and the appropriate preservation techniques must be clearly specified. Moreover, the name and address of the food operator, together with the country of origin or place of provenance, whenever according to Article 26 the requirements are sufficiently met; the most appropriate product uses must be revealed too. Along with the just listed pieces of information, but linked more to the health side of the label, the alcoholic content must be disclosed for beverages containing more than 1,2% by volume of alcohol, while the nutrition declaration can be left off for them; only lately food operators have been encouraged by the Regulation in revealing their energy value. Apart from the just mentioned exceptions, the nutrition declaration must be present no matter what for all the other prepacked food products commercialized (Art. 9 Reg. EU n. 1169/2011).

All these disposition hold for prepacked foodstuffs that are directly sold or given to the consumer in mass caterers, such as the ones mentioned above.

If instead the purchase and hence commercialization of them happens through distant communication, which is to say by means of the so called "distance selling" practice, all the just presented mandatory facts must be available in advance by means of the material ancillary to the purchase or accessible through other means (Art. 14 Reg. EU n. 1169/2011). The only obvious missing fact is the one concerning the date of minimum durability or expiry one, that must be instead added when the order is being process according to the specific product features or examining the available ones to be shipped.

By the way, all the mandatory facts, included the previous exempted ones, must be available when the product is being delivered.[130]

If mandatory food information has been dealt up to now, voluntary one can be added to the foodstuffs too, but some conditions have to be respected first: they must not be misleading or ambiguous up to the point of confusing the food consumer. Furthermore, where appropriate, they also have to be based upon scientific evidences (Art. 36 Reg. EU n. 1169/2011).

As a matter of fact, in order to respect the first two prerequisites, the information must be inspired to fair practices, which means that they must not insinuate false properties to the product or that special characteristics are unique for that foodstuff only, when instead all the similar products share the same peculiarity, as sometimes happens with goods claiming the presence or absence of debated ingredients such as sugar, palm oil, gluten or lactose. Moreover, the fair standards of information adherence include not cheating consumers by means of images, descriptions or appearances that elude them in believing that a specific component or ingredient is part of the foodstuff, when it actually isn't or has been substituted by another one (Art. 7 Reg. EU n. 1169/2011).

Among the above listed mandatory food information, from 2016 on the nutrition declaration is faced as well. It must first of all contain the energy value and then the quantities of fat, saturates, carbohydrates, sugars, proteins and salt. Moreover, where considered necessary, the specification that no additional salt has been added but only the one already present in the nature of the food product ingredients is included, can be added near to the nutritional declaration. On top of that, the food operator in charge of labelling the foodstuff can freely add the amounts of mono-unsaturates, polyunsaturates, polyols, starch, fibre and any of the vitamins or minerals listed in the relative part of Annex III and that are present in significant quantities (Art. 30 Reg. EU n. 1169/2011). All these nutritional data should be clearly presented together in the same field of vision and if the available space permits, the preferred solution is to expose the data in a table chart with numbers aligned, otherwise they can be also displayed linearly (Art. 34 Reg. EU n. 1169/2011). Where the nutritional declaration is mandatory, the main insights, which is to say the energy value only or together with the amounts of fat,

[130] AVERSANO F., *La corretta informazione del consumatore: il Reg. UE n. 1169/11,* cit., https://www.ilmiocibo.it/media/approfondimenti/la-corretta-informazione-del-consumatore-il-reg-ue-1169-11/

saturates, sugars, and salt can be repeated on the principal field of vision, again with a font size equal or greater than 1,2 millimeters.

If up to know has been said that Regulation 1169/2011 covers all the information for prepacked food products to be revealed to consumers, a clarification has to be made. It is no doubts that the framework of provision deals with prepacked foodstuffs, but not all of them must adhere to the entire mandatory dispositions. The one compulsory evidence that can be avoided for certain products is the nutritional declaration. As a matter of fact, Annex V of the Regulation lists all of the exonerated ones by means of 19 categories. In detail, they can range from unprocessed products composed by a single ingredient (or category of them) or processed ones that however present the same unique feature, but have been going through processes like the maturing one; to waters drinkable by humans (even the ones containing CO2 or flavorings) and aromatic herbs, spices, or both of them blended together in once. Salt and its substitutes, edible sweeteners, as well as both coffee and chicory extracts, along with whole or milled, decaffeinated or not coffee beans can be excluded too from the application of the concerned mandatory piece of information. Herbal and fruit infusions, tea and its extracts (independently from the type), however all with the prerequisite of being "pure" in their nature, meaning that no other ingredient other than flavourings have been added to them, can be left off too. Fermented vinegars and their substitutes, flavourings, food additives, processing aids and food enzymes, together with jelly and relative jam thickening components, yeast and chewing - gums take part to the list of exclusions likewise. Last but not least, two other fundamental categories are mentioned. The first deals with food that should contain all the mandatory information, included the nutritional declaration, but on the reason of its small package dimensions presents the largest surface area of less than 25 cm^2. The last one instead follows the line given by the entire Regulation: food that is provided in small quantities from the manufacturer directly to the consumer or to local shops, in turn selling it to the consumer, can do without the nutritional declaration.

If looking at the overall picture of exclusions from the mandatory food information set, foodstuffs that are not prepacked can be exempted from it too, apart from the only details that must nonetheless be specified even when selling them: all the ingredients listed by Annex II (or derived from the nominated ones) that are still present in

whatever form in the final food product and that can cause allergies and intolerances for the final consumers (Art. 44 Reg. EU n. 1169/2011).

As briefly mentioned on the top of the topic being discussed, Regulation 1169/2011 does not only address the theme of food information to be made available to consumers, but it also integrates the sanitary aspects treated by European Regulation 1924/2006, which instead treats nutrition and health claims made on food. As a matter of fact, the latter was introduced at European level because of the necessity of hindering misleading nutritional and health claims on commercial communications, labels included, to influence consumer in an unfair manner (Art. 1 Reg. EC n. 1924/2006).

The conditions for those commercial communications to be legally presented in the European food market products are for their nutrition and health claims to firmly respects some mandatory golden rules.

First of all they must not be false, misleading in their nature or questioning the safety side of other similar products. Furthermore they must be balanced in their claim, by not suggesting or demonizing foodstuffs consumption, as well as by not standing against a variegate nutrition scheme to be followed in daily consumers meals. Last but not least, they must not be referring to possible changes in bodily functions and exploit the effects caused to consumers' emotions at their will, independently from the way in which the evocations are expressed (Art. 3 Reg. EC n. 1924/2006). For the sake of clarity, by nutritional claim it must be intended any non mandatory message or whatever form of representation that suggests particular food beneficial characteristics on the reason of its bringing (either to normal, increased or reduced levels) or not bringing energy by means of its consumption, or because of the presence (again normal, reduced or increased) as well as absence of specific nutrients inside the foodstuff. Specularly, by health claim must be instead intended any assertion that some kind of relationships is established between the food consumption and health related functions, independently from their being improved or worsened in status (Art. 2 Reg. EC n. 1924/2006). By the way, both nutritional and health claims must be based upon scientific evidences and justified by the operator making use of them. As a consequence, the appropriate Authorities can ask the food operators, or who is in charge of commercializing the products, to find all the corroborating evidences proving that all the requirements provided by the framework of provisions have been respected. Anyway, the Regulation provides also for specific claims details to be authorized by the combined efforts of the

European Commission with the EFSA, together aiming at providing the appropriate technical guidance and instruments to help food operators in furnishing them the adequate information and assessing health claims applications (Art. 15 – 17 Reg. EC n. 1924/2006).

4.2.1 The theme of responsibility

In one of its Whereas, precisely the 21st, Regulation 1169/2011 opened by clarifying that in order to settle once and for all the fragmentation of responsibilities in charge to the agri-food operators on the theme of the provision of appropriate food information, it was necessary to face the debate with no possibility of additional postponements. Furthermore, it was also specified that this clarification should have been coherent with the disposition already provided by Regulation 178/2002 on the fields of operator duties towards the final consumer.

As a matter of fact, prior to the entry into force of Regulation EU n. 1169/2011, Regulation EC n. 178/2002 was the only one dealing with the agri - food supply chain operator responsibilities. In particular, its Article 17 highlighted the importance for the operators' controlled businesses of adhering to all the adequate food safety requirements along the entire supply chain, hence covering all of them and checking their full conformity compliance. However, this consideration holds for the one aspects more related to the food safety side, while the ones concerning more food commercialization, labelling and advertisement sides, which is to say all those not strictly and directly belonging to the primary health protection, can be better regulated by more specific dispositions on the relative themes.

By the way, the fundamental feature to be again respected according to the Regulation is the one of not misleading consumers (Art. 16 Reg. EC 178/2002).

It must likewise be considered that the right provisions to be applied were not so clear, especially when dealing with the specific responsibilities division in charge to the different food operators and upon whom they had to be in charge. The most peculiar example can be considered the difficult partitioning of responsibilities between who was in charge for the product labelling and who for its labelling infringement, especially when the latter did not touch sanitary aspects but rather was dealing more with commercial ones. On these reasons the European Legislator understood the necessity of shedding more light on the concerned topic.

It is hence not a case that Regulation 1169/2011 has faced the debated hot topic by asserting that the one food operator in charge for the rightness of the information provided on the label is the one whose name or business name is used for the product commercialization. A specification has also been made: if the concerned food operator is not located within the European territory, the torch has to be passed to the one that instead has imported that specific good inside the Union (Art. 8 Reg. EU n. 1169/2011).
It is hence up to the supply chain operators themselves of setting under which name (or commercial one) the foodstuffs has to be sold. According to the choice of the parties, the one operator the ends up to put his name on the foodstuffs consequently becomes responsible for its labelling. However, the greatest novelty on the theme has been brought by the introduction of another role in the theme of food responsibilities: the one food operator which is in turn responsible for the compliance violation.[131]
As a matter of fact, the same Article 8 of the 1169/2011 Regulation has followed with the duties of the other supply chain operators, especially the ones not directly taking part to the labelling system. Even though they are excluded from the obligation regarding the adequacy of the information supplied, these last operators must respect a mandatory provision: not selling all those foodstuffs which either they know to be or believe to be not adequately fulfilling the frameworks of European rules on the theme. Of course, all the assessments are made upon their knowledge and expertise as professionals of the sector. The just mentioned disposition must be read together with the one presented few lines later by the same Article, confirming once again the role of each food operator in making his controlled business adhering to the provisions settled by the law, hence controlling and verifying their compliance.
By the way it must also be said that the verification controls must be executed limitedly to the fields of their respected run activities, which is to say that, for example, in the case of the distributor mansions there are the ones of checking the ingredients presence on the label, together with verifying the expiry date or minimum durability one. On the contrary, the one regarding instead the veracity of the information provided on the label can't be executed by the concerned supply chain member, on the reason of not disposing of the adequate tools.[132]

[131] CAPPELLI C., *Il Regolamento (UE) n. 1169/2011 e le sue guide spirituali,* Rivista di Diritto Alimentare, A.I.D.A., 2014, p. 13 - 18, http://www.rivistadirittoalimentare.it/rivista/2014-02/2014-02.pdf
[132] CAPPELLI C., *Il Regolamento (UE) n. 1169/2011 e le sue guide spirituali,* cit., p.19-21

Some doubts could instead arise whenever it is not the producer to appear on the label of the commercialized product, but rather the distributor or retailer, which gets his products done and sell them under his name by means of the so called “private labels”. By the way, if both parties agree on the theme, once again the one that happens to be responsible for the label is the one whose names and address are reported on the product being commercialized. A good solution could be represented by displaying both names and addresses on the label, specifying who is the producer and who the distributor, hence splitting the responsibilities according to the different roles performed. The most risky aspect is the one of misleading both the consumers and the Authorities by making use of this expression, therefore the appropriate measures should be taken at granting the highest transparency and clarity. However, in case of infringements, it is up to the Authorities to verify who has committed mistakes and hence has to be identified as responsible for the violation of the provisions, bearing also the relative consequences.

A slight different scenario presents itself when the producer of the private label is instead established in a Third Country. A double perspective opens the ways towards two different solutions according to the specific case being dealt. In the first hypothesis the distributor plays both the roles of the importer and of course the one of the distributor, while in the second it plays only the latter.

To begin with, if both roles are carried by the distributor and hence he is the one figure directly importing the foodstuffs into the European Union, he automatically becomes the responsible of both the labelling and the one of its infringement, if any violation happens to be ascertained by the Authorities. If instead the distributor buys the product from another supply chain operator, which is importing the product from the Third Country to the European Union, he is excluded from the labelling obligation. As a matter of fact, the latter it is up to the food product importer, while any eventual later violation, if it exists, it is instead up to the distributor.

The scattered confusion on the theme has been originated by the wrong general conviction that food operators had to be all responsible for all the aspects covered by the food consumption towards the consumers eating the foodstuff no matter what.

To tell the truth, the legislative frameworks already in place were already grating the maximum protection to the consumers, independently from the one subject dealing with the labelling requirements. As a matter of fact, if consumers buy products not mirroring

the ones characteristics written on the label, they can ask the retailer or distributor to substitute that product with another "right" one, while, if the labelling error instead has brought also some kind of damages to the concerned consumers they can even ask to be reimbursed for what suffered. If again, contrarily to what has been described up to know, the kind of injuries made are of physical nature, consumers can deliberately act against the producer of the foodstuff. As can hence appear, whenever consumers suffer damages, independently from who caused them, he can find the adequate protection in the already provided Directive 85/374/EEC on the liability for defective products at European level. Different instead is the case in which the consumer doesn't suffer harm from the consumption of the food product, hence he doesn't necessitate of being safeguarded from it. It is in this picture that competent Authorities intervene.

For example, in all the just mentioned cases, apart from the possible solutions listed on the reason of the tacit contractual agreement infringements, consumers can likewise stand up for themselves and denounce the violations at the supervisory Authority. The latter, after having appropriately examined the situation, can settle for who is really the responsible of the violation and to whom the penalty has to be addressed, according to the criteria above listed.

To make the point, after the entrance into force of Regulation 1169/2011 a clear framework of provisions has been identified on the labelling responsibilities: the one operator responsible for the label as individuated by the European Legislator, the one for its infringement as instead indicated by the Supervisory Authority and hence the sanction addressee as depicted by the Judicial Authority, at clarifying who really has to bear the burden of the actions committed.

4.2.2 Some debated cases emerged with the practical application of the Regulation: gluten free expressions, cross contamination, suitability for vegans or vegetarians and the mandatory indication of Country of Origin or Place of Provenance

Even though more than 6 years have passed since the entrance into force of the concerned Regulation, some doubts have been raised only when facing its practical application in daily life.

To tell the truth, the Regulation has been interpreted as sort of an incomplete one on two groundings. The first one entails the not fully covering of food labelling aspects,

given that some food products, such as the not prepacked ones or the ones not addressed to the final consumers, are not treated by Regulation 1169/2011 and hence leave the floor to a not harmonized framework of provision at European level. The second one instead has to be found within the Regulation itself. As a matter of fact, the latter has granted the European Commission the possibility of sort of filling the gaps left by means of supplementing and integrating acts. By the way, some of them are still waiting to be approved, while others, even if having received the green light and hence having being approved, still present some doubts on the theme.[133]

To begin with, the provision of voluntary information to consumers is one of them. As a matter of fact, food operators can settle for supplying further information on a specific product in order to make the consumer more conscious of his choices, together with his basic interest of boosting the product purchase.

On the same level of mandatory pieces of information, voluntary ones must adhere to the fundamental requirements provided by the 1169/2011 Regulation, which is to say they must not be misleading in their formulation and whenever necessary be based on scientific data, as stated by its Article 36. At the same time tough, the latter, few lines later, grants the possibility for the Commission to intervene by means of integrating acts on four specific groups of additional voluntary information: the possible presence of unintentional substances causing allergies or intolerances; the adequacy of the food product to the vegan or vegetarian diets; specific reference intakes for some categories or population groups; and last but not least the reduced presence or even absence of gluten in the foodstuff. With reference to these, only the one linked to the gluten topic has been implemented, namely as Commission Implementing Regulation EU n. 828/2014 and addressing the requirements to be respected by food operators when dealing with providing consumers with the pieces of information on the absence or reduced quantitative of gluten in food products.

In its Annex, the concerned Implementing Regulation has allowed the use of the term "gluten free" only when the food product being commercialized contains less than 20 mg/kg of gluten, while instead the statement "very low gluten" can be only used when the initial product has been processed with the aim of reducing the gluten presence, hence resulting in a quantitative no greater than 100 mg/kg.

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[133] PAGANIZZA V., *An European overview on Regulation (EU) No. 1169/2011 after the entry into force,* Rivista di Diritto Alimentare, A.I.D.A., 2020, p.11, http://www.rivistadirittoalimentare.it/rivista/2020-01/2020-01.pdf

A doubt automatically emerges when dealing with food products containing no more than 20 mg/kg of gluten naturally, such as maize, rice and the like. If these foodstuffs shall be categorized, they would be of course covered by the "gluten free" expression, but, with reference to the latter an infringement of the labelling Regulation 1169/2011 would be caused: it is not possible to suggest that a specific product presents a peculiarity when instead all the similar products share the same feature, on the reason of misleading consumers. The final answer has been provided by the 10th Whereas of the same Implementing Regulation 828/2014. As a matter of fact, it grants the possibility for naturally gluten free products to likewise exploit the expression, but always remembering the arrangements provided both by the concerned Implementing and Labelling Regulations.

If taking a deeper look at the recital, three scenarios can be depicted in cases of products composed by naturally gluten free ingredients.[134]

The first entails a food product composed by more ingredients that are naturally gluten free, but, at the same time on the market similar products that instead contain gluten are also commercialized: in this hypothesis the "gluten free" declaration, without further specifications to be clarified, can be adopted. The second and third readings present sort of a more complex solution. As a matter of fact, the second scenario can be unveiled as one in which the involved foodstuff is again composed by many ingredients that are naturally gluten free, but, by contrast, at the same in the market no other similar products exist which contains the debated characteristics. It is hence impossible to purchase same category foodstuffs including gluten at their inside. The third picture instead deals with products that, in oppositions to the prior examples, are composed by a unique ingredient, such as rice, which is universally by definition devoid of gluten.

According to the more suitable interpretation of the two last mentioned scenarios, the "gluten free" declaration can be used for products which are naturally gluten free in their essence, but additional insights should likewise be provided in making sure that consumers understand the common characteristic to the entire category of food products of which the examined one is part of. Examples of these adequate specifications concerning rice as a gluten free product can be considered sentences such as "all rice is gluten free" or " « specific brand name» rice is gluten free as any other

[134] PAGANIZZA V., *An European overview on Regulation (EU) No. 1169/2011 after the entry into force,* cit., p.12

rice".[135] Hence, following this explanation, Implementing Regulation 828/2014 totally fits with the 1169/2011 one on the provision of food information to consumers, contributing in this way to the superior aim of supplying not misleading insights and helping in such a manner the consumer at taking conscious choices. By the way, the specific term "naturally" in gluten free slogans seems not to be hindered in its utilization, as long as it does not cheat food customers.

To continue with the second mentioned theme on which the Commission is authorized by Article 36 of Regulation 1169/2011 to intervene, which is to say the provision of information on the unintentional presence of allergens or substances causing intolerances in the food products, better known as cross contamination, a little confusion has been generated as well.

As a matter of fact, Article 9 of the same 1169/2011 Regulation, dealing with mandatory insights, treated only those food ingredients or substances causing allergies or intolerances which have been voluntary added to the product, hence having consciously been provided by food operators. As a consequence, the field of mandatory information does not cover the necessity of pointing out the presence of unintentional ones, but on the reason that a specific Regulation on the theme still doesn't exist, those pieces of information can be added only on voluntary basis. Therefore, some food operators have settled for making use of the "may contain" formula in order to prevent consumers suffering from specific allergies and intolerances to consuming foodstuffs that could include the allergen, or better saying, foodstuffs in which the allergen cannot be completely excluded from having encountered the food product in any of the production processes. However, this modus operandi has lighted an intense discussion on its legitimacy. If additional pieces of information supplied to consumers must always not be misleading or confusing in their nature, as can be easily understood, this is not the case. As a matter of fact, what should be helpful for consumers is instead in this way sort of confounding them. To tell the truth, the concerned "may contain" expression has furthermore been used in the majority of the nowadays marketed products, brining sort of a useless help to the concerned consumers, which are forced to choose among foodstuffs almost all presenting the same indication. At the same time though, it must also be highlighted that the debated expression can't be used by the food operator as

[135] PAGANIZZA V., *An European overview on Regulation (EU) No. 1169/2011 after the entry into force,* cit., p.13

sort of responsibilities discharges towards the fundamental requirements provided by the law and towards the consumers themselves, whose health protection and adequate information on food product characteristics must be preserved no matter what.[136]

Given that an appropriate implementing regulation on cross contamination has not yet been adopted by the Commission, the latter has clarified that in its absence it's up to the food operators themselves to take the necessary precautions on the labelling theme and that, most of all, the latter must not turn out to be misleading. However, in an answer lately provided by the Commission to the European Parliament, the former has highlighted the fundamental role of food insights to consumers as one of the cornerstones of the European "From Farm To Fork " strategy, leaving the floor for the implementation of the voluntary information on the unintentional presence of substances causing allergies or intolerances open.[137]

Food products adequate to vegan or vegetarians diets are included in the possible implementing acts of Art. 36 Regulation EU n. 1169/2011 too.

However, in order for them to be successful, a definition of what should be intended as vegan and what as vegetarian must be provided first. As a matter of fact, an uncertainty halo surrounds the two fields, which up to now have always been based upon different interpretations or ways of thinking generally displayed by people, but not on specific guides officially impacting food products and thereof. In practical terms, many doubts arise when dealing with routine practices, such as how to treat food obtained by means of animals aids, that however are not present in the final foodstuff, or how should be considered jams, drinks and the like obtained by means of industrial processes in which, for example, insects could have been unintentionally incorporated.[138]

Up to now, until further indications will be released, the concerned food operators have been labelling foodstuffs displaying these peculiarities by means of private standards, each of which following its own disciplinary. Nevertheless, with regard to the possibility of making use of the vegan or vegetarian expressions for products naturally presenting these characteristics, a specification has to be made. If a food operator can assure that by making use of appropriate technologies no other extra contaminants are part to the final

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[136] PAGANIZZA V., *An European overview on Regulation (EU) No. 1169/2011 after the entry into force,* cit., p.13

[137] EUROPEAN COMMISSION, *Parliamentary Questions*, European Parliament Official Website, 2020, https://www.europarl.europa.eu/doceo/document/E-9-2020-001276-ASW_EN.html

[138] PAGANIZZA V., *An European overview on Regulation (EU) No. 1169/2011 after the entry into force,* cit., p.14 - 16

product, he can lawfully exploit the vegan or vegetarian labelling, while, if instead the usual and universal diffused practice can always obtain foodstuffs without having any other undesired substance intervening, the indications can't be used. However, it must be also signaled that the studies and practices executed by the working group on the vegan and vegetarian theme, as provided by Article 36 of Regulation 1169/2011, have already begun, starting from the utmost definition of the two specific categories of dietary schemes.

Last but not least, not covered by the discussed Article 36 of the labelling Regulation but constituting a controversial subject likewise, is the provision of the mandatory indication of origin or place of provenance of the primary food ingredient. As a matter of fact, these data are necessary only when indicated by Article 26 of the same, which is to say whenever not revealing them could mislead the consumer on the true provenance of the food product or when the foodstuffs involved is swine, sheep, goat or poultry meat.

If the requirements are met and the indication of the origin of the food is revealed, but this happens to be different from the ones of its primary ingredients, many clarifications have to be made.

First of all, this specific theme is treated by Commission Implementing Regulation EU n. 2018/775, which instead has become in force since April 2020: its practical enforcement is kind of new. However, the concerned Regulation provides that the indication of the different origin of the primary ingredient must be disclosed either by means of reference to the geographic location or by a clear statement specifying that. The geographic areas of both the origins can be expressed by means of the following terms: "EU", "non – EU" or "EU and non – EU", as well as by Member States, Third Countries, Regions or by geographical areas (both between States or within them) names recognized by average consumers. The geographical deepness must be the same for the insights on the product origin and the one of its primary ingredient, with the possibility of adding more detailed data as voluntary information for one of both of them: example can be considered "EU and non – EU", but also "EU (Germany) and non – EU (Switzerland), as well as "EU and non – EU (Switerland)". FAO fishing places or seas can be included too in the geographic areas category, always bearing in mind the relevance in consumers' mind; precise additional locations on the reason of specific Union dispositions can be used too. If instead the statement is not making use of geographical areas, the sentence has to be expressed as follows: *« (primary ingredient name) do/does not originate from (the*

country of origin or the place of provenance of the food) » or by means of any other similar paraphrases (Art. 2 Commission Implementing Reg. EU n. 2018/775).
Given the relevance of both the pieces of information, they must both be provided on the same field of vision (Art. 3 Commission Implementing Reg. EU n. 2018/775).
In order for the concerned Regulation to be effectively applied, the Commission at the beginning of 2020 made a clarification on the theme and presented a Notice on it. Among the topic treated, there was also the one instead dealing with those foodstuffs not covered by the Implementing Regulation. As a matter of fact, it must not be applied to geographical indications already treated by other European dispositions or by International agreements, organic products and registered trademarks. Furthermore, excluded from the Implementing Regulation are also situations in which geographical insights are not related to the food origin but rather to the name and address of the food operators, which instead can be grouped under the mandatory pieces of information.[139]
In opposition to what immediately stated, the Notice likewise explains that every sentence hypothetically referring to the origins of the foodstuff (examples can be considered statements like "made/produced/ manufactured in") together with flags or maps, can be treated by Regulation 2018/775 too. Different is the case of expressions such "as packed by" which instead difficulty mislead consumers, on the idea that the concerned specific production phase is not linked to the territory in which the product saw its origins. However, given that the perception depends on the context, a case by case analysis should be better fitting. The same holds for products whose labels display picture or symbols like monuments, evocations or other famous and recognizable visuals that stand for specific geographic areas.
If up to know the attention has been drawn on the different origins of the final food product from its primary ingredient, it has not yet been unveiled what must be intended as the latter. According to Article 2 of Regulation EU n. 1169/2011, a primary ingredient is *«an ingredient (or ingredients) that represents more than 50% of the food product it composes or which is usually associated with its name by the consumer and for which in most cases a quantitative indication is required »*. If taking a deeper look at what has just been stated, a double interpretation of primary ingredient is hence presented, being either a quantitative or a qualitative one: the former with reference to the quantity that

[139] PAGANIZZA V., *An European overview on Regulation (EU) No. 1169/2011 after the entry into force,* cit., p.16 - 17

has to be greater than 50%, while the latter connected with the name of the food. By the way, a food product can also be composed by more than a single primary ingredient (as in the case of having both qualitative and quantitative one), but can likewise happen to be formed by any, which is instead the situation of many ingredients neither reaching at least the 50% quantity nor making the consumer settling for that specific product, as can occur with vegetable soups.

By the way, a food product can also be formed by a unique primary ingredient, which has undergone different production processes in order to obtain the final food product as it is commercialized in the market. The original product, which is to say its raw material, happens to be different from the final obtained one on the reason of its substantial transformation. Actually, as processing can be intended any action that substantially changes the status of the initial foodstuff or even the union of more of them. As a consequence, for example heating, drying, extracting are considered as eligible, while dividing, cutting, freezing, cleaning or milling are not.[140]

With reference to the origins of the primary ingredient undergoing substantial processes, another issue has been brought to light. As a matter of fact, according to the Union Customs Code, a guideline has been offered in identifying the origin or place of provenance of a food product whose stages of production have been carried in more than one State. Generally speaking, as origin of food products must be intended the place in which they « *underwent their last, substantial, economically-justified processing or working, in an undertaking equipped for that purpose, resulting in the manufacture of a new product or representing an important stage of manufacture »* (Art. 60 Reg. EU n. 952/2013). In order to classifying a process a substantial, it must have led to a different name in the Combined Nomenclature or it must have given rise to a new different food product, whose composition and properties are dissimilar to the ones presented before the transformation.[141]

If sticking to the theory everything seems to be clear, but when it comes to the practice some enigmas are unveiled, especially with regard to some debated products. Among them, products composed by flour, such as pasta or baked products find their place. As a matter of fact, the hot topic concerns the origin of flour, since it should not be classified

[140] PAGANIZZA V., *An European overview on Regulation (EU) No. 1169/2011 after the entry into force,* cit., p.18

[141] PAGANIZZA V., *An European overview on Regulation (EU) No. 1169/2011 after the entry into force,* cit., p.19

as a processed ingredient on the reason of being simply milled from cereals, which is one of the non processing activities. Since the primary ingredient of these products is non processed flour, the debate hence is if pasta or similar products' origins are to be found on flour and consequently in its milling place, or if instead they must be searched on cereals and consequently in their place of harvesting. However, since pasta or baked products origin should be found in the place in which the last substantial and economically justified operation has been carried, even if not belonging to the processing ones, the milling location has been identified as the right one. Furthermore, as an additional confirmation, new foodstuffs with different properties and compositional aspects are obtained by the concerned working activity with respect to the initial cereals, displaying also of a different classification in the Combined Nomenclature. [142]

If this has been proved to be the best fitting solution, Italy and its Italian Competition Authority don't believe the same. According to their opinion, the primary ingredient of the debated products has to be found in the hard wheat, on the reason that consumers are interested in the place in which it has grown and not where it has been milled, because it is the former at making the difference when talking about product quality and relative properties. However, the answer they received on the doubts raised dealt with the fact that the primary ingredient of pasta or baked products is flour and not cereals on the reason that when producing pasta the physical ingredient to be used is the former and that the Regulation must be applied to it and not to additional obligations that would only go beyond and confuse its requirements.

If tying up loose ends, the Commission Notice didn't help food operators in determining the primary qualitative ingredient by means of a clear framework of provisions, but it only suggested that they should base their origin indication disclosure decisions upon the consideration of how it affects consumers' mind, in the hypothesis of being provided or not. A pragmatic consideration has hence unluckily to be made: even though in few cases consumers' reactions are easily foreseeable, in the majority of them it is very difficult, if not even sometimes impossible, for food operators and the Authorities themselves to understand in advance when the information provided can be considered as misleading for their customers. Food operators hence can only rely on insights

[142] PAGANIZZA V., *An European overview on Regulation (EU) No. 1169/2011 after the entry into force,* cit., p.18 - 20

provided by their previous surveys on the theme, aimed at knowing better their consumers.

4.3 Main Front – of – package food labels at European level: which are, how they work and how consumers react to them

If truth be told, consumers settle for a specific food product rather than for another according to many reasons, ranging from the more ethical, environmental and psychological ones to the more practical ones, such as those involving economic and health related sides. The choice is made on the basis of which of them mostly satisfy their desires and expectations.

It is in this picture that front – of – pack food labels insert themselves, assuming the fundamental role of helping consumers in evaluating alternatives in order to choose the best fitting one and being conscious of the decision taken.

Paragraph 5 of Article 35 of the discussed 1169/2011 EU Regulation assigned the Commission the task of providing a report on the use of additional forms of expression and presentation currently in use by Member States and their impact on the internal market functioning, in light of a possible harmonization of forms at European level. The dissertation had to be submitted by December 2017 to both the European Parliament and Council, but on the reason of the extreme theme novelty and limited experience displayed by the single implementing Member States, it was postponed. Finally, in May 2020 the report saw the light, not without bearing also some inconclusive observations too.

First of all, the theme on which the report was supposed to be carried has to be unveiled: a nutritional declaration on the majority of prepacked food products was already provided by food operators, often on the back of foodstuffs. However, in order to be more effective in the aim pursued, the information could (and still can) be improved by means of a voluntary repetition of the main product nutritional insight (energy only or energy with fat, saturates, sugars and salt indications) in the principal field of vision of the package, better known as front – of – pack. These insights can be displayed by means of different forms of expression, that are going beyond numbers and letters as used for the usual nutritional declaration on the back of the package and hence, given the absence of a European standard, each Member Sate has adopted the best fitting solution according to its necessities.

In addition to the task requested, the Commission has amplified its dissertation, including also the impact of the concerned schemes on consumers and the relative effectiveness.

To begin with, the main aims of the front - of - package labelling happens to be two: the first one is in line with the provision of information to consumers in order to settle for healthier food products, while the second is direct towards food operators, which are encouraged to revise their products with the intention of obtaining better versions of them, healthier for consumers' wellbeing.

If considering the bigger and bigger role played by obesity and overweight, as well as by dietary related diseases in consumers' life, it is not surprising the increasing interest that Public Authorities have started to presenting on the theme, which is even destined to grow more and more. Furthermore, once the most appropriate front – of – package solution is determined at European level, it will be used also for the possible prevention of the mentioned diseases on all food products labels.

With reference to the voluntary information provided, a framework of requirements has to be met, all having as reference the average consumer. Additional insights must always not be misleading towards the consumer, be based on scientific evidences of his understanding and make it easier for him to comprehend the role played by food in the daily diet. They must be objective and non discriminatory in their nature and have to be obtained by means of a consultation of different stakeholders on the theme. Last but not least, given their European relevance, they must not hinder the free movement of good within the internal market (Art. 35 Reg. EU n. 1169/2011).

In order to provide such a report, Member States and food business operators helped the Commission in understanding the different schemes functioning and effectiveness, by notifying it the relevant information on them.

It must also be said that some forms of front – of – package labels are not covered by Article 35 of Regulation 1169/2011, on the reason that they don't replicate the main back package nutritional data, but they instead provide sort of a qualitative judgment on the food product components by means of symbols or letters. The latter schemes are hence disciplined by Article 36 of the same labelling Regulation, being the one in charge of guiding voluntary information provisions. Nonetheless, the discussed specifications must not mislead consumers and be based on scientific evidences likewise, especially when conveying an overall positive message linking the consumption of the food with

the beneficial effects deriving thereof, representing in this way a full – fledged nutritional claim.

According to the Commission report, the concerned front – of – package schemes in use by Member States can be first of all divided into nutrient specific and summary indicator ones: the former supply detailed insights on the singular composing nutrients, while the latter are sort of a synthesis of the whole nutritional healthiness or quality brought by the food consumption. Again, the nutrient specific can be in turn categorized under numerical or color coded subsets; the summary ones instead into positive indicators or graded ones. The positive ones are applied only when food reflects some specific positive requirements, while the graded ones can be applied to all the products and aim at furnishing grades to the quality of the concerned foodstuffs.

The level of directiveness, which is to say the strength or direct manner in which the evaluation on the product is provided, can change as well.

The last categorization concerns the level of interpretation provided to the consumers: reductive against evaluative ones. The former repeats the information displayed on the back of the package in a reduced version, leaving the consumer to draw the conclusions; the latter instead already assesses and interprets the quality of the product for the consumer, which hence finds an already provided answer on its nutritional aspects. Independently from the kind of evaluative schemes, being they nutrient specific or summary ones, they are all based on the so called "nutrient profiling". This expression can be considered as the classification of the examined foodstuff according to some preset standards: either by nutrient thresholds, as can happen when attributing a color to the food quality, or by more complex algorithms giving rise to an overall summary score. By the way, this practice can be applied to all food products indistinctively, or can even be category specific or group specific according to the different schemes chosen.[143]

The main front – of – pack (FOP) labels implemented, or being scrutinized with that aim, at European level happen to be the followings: the Keyhole, the Healthy Choice, the NutriScore, the (Multiple) Traffic Light and the last added NutrInform Battery.

To begin with, the Keyhole has been identified as the oldest of all the concerned scheme. It was initially introduced in Sweden in 1989 by a national retailer and was later

[143] EUROPEAN COMMISSION, *Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration,* European Commission Official Website, 2020, p. 4-5, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0207&from=it

adopted by the Swedish National Food Agency. From that moment on, it became the Nordic symbol for healthier food, on the reason that was also selected by other Nordic Countries such as Denmark, Norway and Iceland as main FOP symbol. Countries such as Lithuania and Macedonia followed as well. The Keyhole is depicted by a green symbol, which stands at identifying the healthier products among each food category by means of specific criteria for each group. The subsets being individualized are 33 and range from bread to cheese and even ready meals; instead it does not apply to hedonic products such as salted snacks, sweets or soft drinks. It is based on the evaluation of nutritional aspects such as the levels of fat, sugars, salt, wholegrain and fibre and, on this reason, it is also aimed at bettering the healthiness of already existing foodstuffs by means of their reformulation. The Keyhole can be considered both a summary, positive and directed label, which covers both qualifying and disqualifying elements in its evaluation.[144]

To continue with the next FOP scheme, which is to say the Healthy Choice, it is the only one among the main analyzed to be subject to a membership fee. As a matter of fact, it is property of the Choices International Foundation and in order to make use of the tick symbol food operators must pay for it. The logo again identifies the healthier options among food categories, each of which making use of specific standards. The nutritional aspects being analyzed for each group are the levels of saturated and trans fatty acids, added sugars, salt, dietary fibre, while the energy value can be included or not. Similarly to the Keyhole, it is a summary, positive and directive logo, serving both the aims of healthier food choice individuation and product reformulation. On the contrary, scoring a difference with the latter, the Healthy Choice covers all food categories, hedonic products included. Actually, the European Member States making use of the logo are Czech Republic and Poland. The Netherlands initially introduced its establishment but later in 2017 settled for its removal.[145]

The third and most diffused front – of – package label is instead the NutriScore one, leading nowadays the way in European Countries. To begin with, its origin is quite recent, since it was firstly adopted by France in 2017 on the basis of extensive studies on the theme. As the previous discussed ones, it aims both at identifying the healthier

[144] LISSNER L., VAN DER BEND D.L.M., *Differences and Similarities between Front – of – Pack Nutrition Labels in Europe: A Comparison of Functional and Visual Aspects*, MDPI, 2019, p. 4-5, https://www.mdpi.com/2072-6643/11/3/626/pdf

[145] EUROPEAN COMMISSION, *Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration,* cit., p. 9

choices and at conversing food operators towards healthier food to be produced and commercialized. The application of the NutriScore scheme to a food product identifies and assesses the quality of its nutritional components as a whole by means of both a scale of 5 colors and of a grading system of 5 letters together. The scheme ranges from dark green to dark orange, being the dark green the color associated to the healthiest nutritional components and corresponding to the A letter, while the dark orange to the lower quality ones, hence instead represented by the E letter. Both qualifying elements (such as protein, fibre, fruits, vegetables, legumes) and disqualifying ones (sugars, saturated fats, salt, calories) are taken into account by the algorithm establishing the right color and letter to be associated to the concerned product. Differently from the previous discussed labels, the NutriScore one is based on a unique framework of criteria, not differentiated for each specific food category. However, some modifications have been introduced on cheeses, fats and non – alcoholic drinks on the reason of their score not fitting dietary suggestions. On the reason of being a summary indicator conveying a mixed message by means of both grades and colors, but no providing additional information on the specific product components to be freely analyzed by the consumer, it can be classified as a directive label. Apart from the France as a pioneer, other European Member States following its line and hence adhering to the NutriScore scheme as the preferred FOP one are Belgium, Germany, Netherlands and Luxemburg. A controversial position is instead occupied by Spain, whose Government is splitting into two, even if has already approved the concerned label: the Minister of Agriculture, especially on the reason that Spain is the world's leading producer of extra – virgin olive oil, firmly opposes to a scheme hindering National interests and rather supports the one chosen by Italy, more similar on the reason of the shared Mediterranean diet.[146]

The (Multiple) Traffic Light is the voluntary scheme adopted by the United Kingdom in 2013 on initiative of its Department of Health and took several years of studies and many stakeholders meetings to reach a conclusion. Differently from the other discussed FOP scheme, the Traffic Light one identifies as its primary aim the one of helping consumers in settling for healthier products, while the one of product reformulation is left quite behind. The peculiarity of the concerned scheme is the one of providing sort of a semi – directive information, on the reason that it unifies color coding with percentage

[146] EUROPEAN FOOD AGENCY, *Nutri – Score: the Spain Government splits up*, EFA NEWS, 2021, https://www.efanews.eu/item/17737-nutri-score-the-spanish-government-splits-up.html

reference intakes, which is to say the maximum suggested daily amount assumptions of energy and nutrients. In order for the labelling scheme to be better understood and hence more often implemented by food operators, UK Authorities have provided a guide in how to create it for products aimed at retail outlets. The label gives details on the amounts of fat, saturated fat, sugars and salt contained in the serving or food portion, as well as on the energy that the food consumption brings to the consumer. The use of colors is functional to the meaning that is desired to be expressed: red means that that nutrient is present in huge amounts within the product, hence consumers should not eat other foodstuffs containing the same nutrient within the same day, or at least they should reduce its quantities or the occasions in which it is consumed; amber instead signifies that no specific precautions have to be taken with regard to that nutrient consumption throughout the day, hence if the majority of the colors presented are amber, consumers are not limited in its assumption; the green color instead signals low amounts of the belonging food component within the food product. The more the green colors presented on the label, the healthier the overall foodstuff consumption.[147] The colors are assigned according to upper and lower thresholds based on 100 g/ml for food/drinks, given that they dispose of the same generic criteria and are not differentiated according to category specific products. If the portion or service size is greater than the one on which the colors are based, the thresholds of the red colors should be considered as the reference ones.[148]

Last but not least, the NutrInform Battery is a nutrient specific label, as the Traffic Light FOP just discussed. With respect to the latter though, Italy has strongly criticized its formulation, on the reason of being considered too much simplistic and not being able of properly evaluating products belonging to balanced diets, such as the Mediterranean one. As a consequence, the concerned Member State settled for another front – of – package labelling option, which was only lately introduced in the Italian food law framework. As a matter of fact, the NutrInform label scheme has been formalized by means of the publication of the 19 November Decree 2020 on the Italian Official Journal on 7th December 2020. It is the result of the consultation of agri – food supply chain operators with the National Institution of Health nutritionists and the Council for

[147] FOOD STANDARDS AGENCY, *Check the Label*, UK Food Standards Agency Official Website, 2020, https://www.food.gov.uk/print/pdf/node/3581

[148] EUROPEAN COMMISSION, *Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration,* cit., p. 8 - 9

Agricultural Research and Agrarian Economy Analysis, together with Ministry of Economic Development represented by Patuanelli, Ministry of Health represented by Speranza and Ministry of Agricultural, Food and Forestry Policies by Bellanova instead. All three Ministers have subscribed its implementation, which started on the day after its publication on the Official Journal.[149] Its peculiarity is the one of being a scheme based on the real portion of the food and not on the standard one of 100 grams or milliliters, hence it is up to the food operator the quantitative choice of the food portion. The label allows to graphically represent the energy and each main nutrient components' (fats, trans fat, sugars and salt) percentages obtained by the consumption of the concerned food portion with respect to the percentages of the single nutrients daily assumptions in a balanced diet, which is to say by referencing to the daily suggested intakes for an average adult consumer. Furthermore, apart from the single nutrients percentages, the quantities of the components within the single portion are also expressed by its quantitative grams indication, apart from the calories brought by its entire consumption. By the way, the amount of calories for 100 grams of products is reported on the bottom as well. The charged part of each battery stands for the percentage of the single nutrient brought to the daily recommended reference intake of the same. For the sake of clarity, they should not exceed the total amount of 2000 Kilocalories and, in further details, they should not be more than 70 g of fats, 20 g of saturated fats, 90 g of sugars and 6 g of salt per day. Always bearing in mind that the reference consumer is the average adult, he must pay attention to not overcome each nutrient daily "full" battery, by following a balanced and varied dietary scheme and by taking into account also all the other foodstuffs eaten during the day. The use of the label is upon willingness for the food operators and they do not have to pay fees to the label owner, which is identified as the Ministry of Economic Development.[150] However, some foodstuffs cannot make use of the concerned label, on the reason of being too big for packages whose greatest surface is less than 25 cm^2 or for those PDO, PGI or TSG food products that could confuse consumers by making use of the discussed label in addition to the requiring ones needed to individualize and differentiate the specific food quality

[149] MINISTERO DELLO SVILUPPO ECONOMICO, *In Gazzetta il decreto sul NutrInform Battery,* Governo Italiano Ministero dello Sviluppo Economico, 2020, https://www.mise.gov.it/index.php/it/198-notizie-stampa/2041788-in-gazzetta-il-decreto-sul-nutrinform-battery

[150] MINISTERO DELLO SVILUPPO ECONOMICO, *Manuale d'uso del marchio nutrizionale "NutrInform Battery",* Governo Italiano Ministero dello Sviluppo Economico, 2021, p .1, https://www.mise.gov.it/images/stories/documenti/Manuale_uso_NutrInform_Battery.pdf

from the other ones. The main reason according to which the Italian Government has settled for the NutrInform label rather than for the most diffused NutriScore one at European level has to be found in the necessity of helping consumers making better food choices, by informing them of the foodstuffs characteristics and hence by empowering them, not by choosing for them instead what's right or wrong. Consumers must adopt a varied, balanced and healthy dietary scheme, based on all the necessary food products consumed in the right amounts and not on the demonization of many of them, such almost all the ones belonging to the Mediterranean diet like cheese, ham and olive oil. As a matter of fact, by means of the concerned labels consumers should be able to sharp their critical abilities of evaluating and hence settling for an overall healthy nutritional scheme, in which a multidisciplinary approach must be granted for its smooth functioning. Always according to the Italian perspective, it should not be an algorithm at deciding what's best for each consumer, being the nutritional wellbeing the result of the consumption of many different products presenting in turn many different compositional attributes, all of which required for different functions. It is not necessary to undeservedly penalize by stating as "good or bad" food products which instead should be consumed as well, especially those being the fundamental layers upon which the entire Italian food system is based upon and having also been scientifically proved to bring benefits to consumers' health.[151]

If up to now all the strengths of the Italian FOP labelling system have been presented, some criticisms brought by the other Member States have emerged as well, especially from the ones instead settling for the NutriScore scheme. First of all the main drawback is the one of not being an immediate system to understand at a glance, on the reason of not making use of neither the color nor the grading system, in addition to containing lots of information to be understood, elaborated and interpreted by the average consumer. Furthermore, the logo dimensions and hence its single box components happen to be quite small to look at once applied to the food package. On top of that, the theme of the free establishments of food portions according to the food operators necessities is an hot topic as well. As a matter of fact, on the reason of the non universalized existence of a standard food quantity portion, food operators can choose the one fitting the most the

[151] MINISTERO DELLE POLITICHE AGRICOLE, ALIMENTARI E FORESTALI, *Comunicati Stampa: NutrInform Battery: Firmato il decreto che introduce il logo del modello di etichettatura volontaria italiana. Bellanova: "Poniamo al centro il consumatore e i principi della dieta Mediterranea",* Governo Italiano Ministero delle Politiche Agricole, Alimentari e Forestali, 2020, https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/16147

need of making the food product presenting the lowest possible nutrients amounts, sometimes presenting portions which happen to be unattainable in real life and hence difficultly comparable with other similar products. On top of that, it has also been signaled that the maximum reference intakes for an average adult are not mirroring the ones presented by the World Health Organization or even by the Italian ones, on the reason of being too generous with respect to the ones that should be respected instead, especially when dealing with sugars and salt.[152]

As a consequence, in order to understand which FOP labelling scheme fits the most consumers' needs some considerations have to be made first.

If stating to the same consumers declarations on the theme, the majority of them have reported to find the use of the concerned tool very useful, especially on the reason that they fill the existing informational gap between food operators and consumers, with particular reference to the latter when presenting obesity or overweight diseases or when elderly people are the involved ones. However, in order to understand if the implementation of the FOP schemes happens to be really game changer, other elements must be considered as well: first of all, they need to attract consumers attention, be accepted by them and thirdly be understood by the same. Once this stages have been met, then an analysis of consumer food choices and consequences on their dietary schemes can be finally carried.[153]

To begin with the first mentioned element, it has been strongly proved that labels displayed on the front – of – package rather than on its back receive stronger consideration, drawing the attention of consumers on the food item in a stronger manner. By the way, additional components must be considered as well in order for the FOP to be successful in attention seeking: large label dimensions, not many other pieces of information, bright colours and contrast with the background on which it is applied. Nevertheless, consumers features such as age, education level and healthiness seeking should be counted as well.

Secondly, consumer acceptance is essential too, on the reason that even if labels are able to catch the attention but they are not embraced by who is supposed to make use of

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[152] CECCARINI I., *Nutriscore vs NutrInfrom Battery, più chiarezza in etichetta,* Rinnovabili.it – Il quotidiano sulla sostenibilità ambientale, 2020, https://www.rinnovabili.it/agrifood/nutriscore-vs-nutrinform-battery-piu-chiarezza-in-etichetta/

[153] EUROPEAN COMMISSION, *Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration,* cit., p. 12 - 19

them, they will be likewise ignored. Attractiveness and liking have been depicted as fundamental goals to pursue when searching for consumers approval. When coming to their tastes, the use of minimal numerical content with the amplification of graphics and symbols is preferred, along with the careful color decision to be coupled with. The directiveness level instead has found to be dividing public opinion: on the one hand, it is no doubt that it enables faster choices to be taken, but on the other hand some consumers do not like being told what to do, with no additional insights provided at supporting the supposed healthiness of the product making use of the label. As a consequence, researchers suggest that the best general fitting solution would probably be composed of both directive and non – directive elements, in order for food consumers to have their necessities satisfied.

Consumer understanding instead is the key to succeed. If taking a look at consumers choices, the FOP schemes have been evaluated as helpful tools in making them settle for healthier products, with respect to circumstances in which foodstuffs do not make use of FOP labelling schemes. On top of that, the best FOP solution has been identified in the majority of cases by schemes making use of evaluative criteria as well as of color coding mechanisms, together with the graded element: in other words, by the NutriScore label. Furthermore, another observation on the color aspect has been drawn: consumers are more focused on avoiding the so called "red" labels, than on searching for only the "green" ones when it comes to the healthfulness mindset.

If finally analyzing the impact of the FOP labelling schemes on the consumer purchasing behavior, the state of the art studies strongly crashes with the dissertation evolvement: scientific analysis on their real and actual impact are extremely rare up to now. As a matter of fact, the majority of the available material regards the intention of consumers rather than their real behavior when dealing with purchasing decisions based on FOP labels. The first preliminary results from a study taken at International level and dealing with the best FOP schemes at improving consumers choices towards healthier options found the Nutriscore and the Traffic Light ones as having emerged as the preferred ones. On top of that, if the concerned labelling schemes are combined with campaigns aiming at raising awareness together with the ones mirroring at communication goals, the result has proven to be even more significant. However, the food category under consideration has also to be taken into account: actually, consumers tend to not look at FOP labelling schemes when dealing with food products that are already known for not

belonging to the healthy side of the nutrition patterns, especially when the so called "comfort food" is the one to be involved.

In order to understand if FOP schemes really impact also consumers' health and diet, a daily look at what they eat in each meal should be taken in a long run perspective, which so far is still missing. As a consequence, up to now only potential effects can be interpreted and postulated. Among the latter, the possibility for consumers to eat more than enough of food products considered as healthy has been signaled, especially if the concerned label doesn't alert on the benefits brought only by its limited consumption. Consumers confusion has been instead identified as one of the main obstacles towards the effective implementation of FOP schemes, especially when different FOP labels find themselves to coexist in the same market. As a matter of fact, by definition, voluntary labels must not obligatorily been applied to all the food products, causing in this way confusion on consumer's perception, especially when the labelled foodstuffs can be considered as healthy as the ones without the logo applied, or even less wholesome than the latter. Furthermore, consumers often have presented loss of trusts when the FOP label classifies an unhealthy product by means of schemes considering it as "relatively nutritious", as can for example happen with the Traffic Light Scheme or with the single nutrient batteries displayed by the Italian NutrInform Battery system.

However, consumers are not the only supply chain players affected by the implementation of FOP schemes, but generally speaking all food operators are bearing consequences as well, both on the side of products reformulations on the reason of obtaining more favourable results on the label (such as green logos, better grade and so on), but also on the other one dealing with the free foodstuffs movement within the internal market.

With regard to the former, one of the potential biggest risks is about the reformulation of only the ingredients taken into account by the FOP label elements, leaving aside all the other nutrient components not counted by it. As a consequence, attention should also be granted to the other constituents aimed at substituting the analyzed ones, in order for the food product to be truly brining positive effects to consumer's health. On top of that, a trade – off between reformulation and not reformulation should be at first carried, with the aim of settling for what's best not only for the consumers, but also for the food firm, which by changing products taste or other related features could bear also significant losses. The ones suffering the most from the reformulation necessities are

small and medium enterprises, often not disposing of the adequate financial or human resources to make the big step. However, at the same time, when dealing with positive well – known labelling schemes, the concerned food operators have been reporting that by making use of them, their products have gained greater quality and health awareness with respect to a previous no logo situation.

The consequences of FOP schemes on the European internal market should be counted as well. The one observation mattering the most concerns the use of different labels among Member States. As a matter of fact, when a Member State makes use of a specific labelling scheme, consumers expect all the food products commercialized in that specific State to present the concerned official labelling solution. As a result, if imported food displays instead of a different scheme or does not even have one, consumers tend to prefer the National ones making use of the suggested solution, creating in this way sort of protectionist barriers. Food operators hence experience pressure and consequently higher costs for the necessity of labelling foodstuffs according to the destination of the different European markets, scoring an additional goal towards the need for further harmonization.

When coming to Member States and their experts, the opinion on which FOP labelling scheme is best at European level is divided. It seems that the preferred solution has been identified by the NutriScore label, sustained by a coordination of already 6 main European Member States: France, Belgium, Germany, Luxemburg, Netherlands and Spain. Lately, also Switzerland joined the club, whose aim is to achieve a greater audience at Brussels. The union is based on the common objective of making the adoption of the concerned label easier, especially for small producers. The main multinational corporations have already settled for approving the concerned label, while main PDO producers strongly oppose its implementation. Among the latter, Italy and its agri – food operators are leading the way, followed by Czech Republic, Cyprus, Greece, Hungary, Latvia and Romania, all sharing the line that not only nutritional components should be looked at, but also their consumption quantities must be evaluated.[154]

The final answer though will be given only by March 2022, when the European Food Safety Authority will supply the European Commission with its scientific elaboration on the theme, in order to understand which nutritional (and non) components must be

[154] CAPPELLINI M., *In salita la battaglia dell'Italia: nasce in Europa il coordinamento pro – Nutriscore,* Il Sole 24 Ore, 2021, https://www.ilsole24ore.com/art/in-salita-battaglia-dell-italia-nasce-europa-coordinamento-pro-nutriscore-ADk2McJB

looked at when choosing for a specific food product. Once these insights are available, the Commission will hopefully settle for which is the preferred road to be followed at European level.[155]

4.4 A final consideration: the ethical food consumer and the decline of the average one

The European Legislator has suffered not only from the new and active role of both food producers and consumers, but most of all from the change of perspective carried by the latter. As a matter of fact, consumers are no more oriented towards food as a way of filling mere survival necessities, but rather as a dignified element, where also health and personal choices are involved. As a consequence, food consumers must be adequately and accurately informed of food risks, agri – food products quality, particular relations among food and health, as well as of any other aspect linked to the way of perceiving the particular linkage between food and ways of living. The role performed by the involved players has hence shifted from being just sort of a spectator to an active and critical one, where the cultural dimension strongly impacts the result. Article 3 of Regulation EU n. 1169/2011 in turn sort of confirms this perspective: both consumers health and interests must be preserved, with the aim of granting food consumers the possibility of taking informed choices, especially when dealing with health, economic, environmental, social and ethical aspects impacting their life.

The critical point is hence the following: the ethical element by definition is the one breaking public opinion into many different perspectives, which is to say that the deeper a specific topic is faced, the greater the number of different interpretations and points of view generated on the reason of divergences in education, knowledge, sensibility and cultural and eating habits. It is hence clear that the stereotype of the average consumer, upon which the entire legal framework aimed at his tuition is based, it is not so appropriate when dealing with consumers' specific necessities.[156]

It seems hence more effective to find sort of a compromise between public and private regulators: the first ones should limit themselves in providing only essential and neutral pieces of information with the aim of leaving consumers free to make their informed

[155] REDAZIONE ANSA, *Authority UE EFSA prepara parere su etichette nutrizionali*, Ansa Terra & Gusto, 2021, https://www.ansa.it/canale_terraegusto/notizie/istituzioni/2021/02/08/authority-ue-efsa-prepara-parere-su-etichette-nutrizionali_b31855f7-db69-40f2-bc65-690aff635f31.html

[156] BAIRATI L., *L'etica del consumatore nella governance globale del cibo,*Rivista di Diritto Alimentare, A.I.D.A, 2020, p. 23 – 35, http://www.rivistadirittoalimentare.it/rivista/2020-04/2020-04.pdf

choices, while the second ones, on the basis of disposing of a better knowledge of their customers, could go a little further and consequently cover more the ethical side of consumers necessities. It is not surprisingly that private initiatives have started to emerge as a way of effectively filling the gap left by the private ones when dealing with specific standards, logos, labelling certifications and the like. As a matter of fact, private regulators, among which food producers, distributors, certifiers and so on are found, do not face the same regulatory obstacles as the public ones and hence can afford to address specific consumers groups, which share the same values and beliefs.

Vegan or vegetarian logos, as well as biological certifications and sustainability themes linked ones (limited carbon emissions, no deforestation or biodiversity reduction), workers' rights, together with territoriality indications are all covered by the concerned initiatives.

If on the one side there is no doubt on the derived strict approaching and connection between consumers and producers espousing the same cause, on the other side some criticalities have emerged. Among the latter, worthy of particular mention is the evidence that sustainability certifications deal with data that are difficulty measurable and hence are aimed more at reassuring consumers about the products they're buying. The possible solution in order to grant the reliability of the certification mechanisms has been found in the Participatory Guarantee Systems, according to which all the interested stakeholders, ranging from producers to consumers, actively participate with the aim of increasing its credibility, on the basis of sharing the common products and processes quality standards and ways to check upon them.

To make the long story short, the collaboration between public and private institutions is more than required, leaving the floor to the latter even when dealing with themes that could be covered by public Authorities, such as animal wellbeing, environmental sustainability and workers' rights, but that by means of the private ones can be assessed in a more effective and specific way, on the reason of the missing necessity of taking a universal position on the themes. As a consequence, public Authorities should not be concerned with setting too much detailed rules for agri – food supply chain operators, but rather with overseeing private regulators in effectively carrying out their consumers necessities and expectations, notwithstanding that the concerned private bodies must not impact the fundamental principles upon which the entire food legal framework is based upon.

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