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The impact of EU public organizational rules and private standards on official food controls

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1.- Official controls in the globalization era

The overwhelming technological progress of the last few decades, and the progressive globalization of markets have created significant changes in the role and function of production chains.
There has been a progressive movement from "vertical" relationships, characterized by a close connection of production and distribution to the local market dimension and by a strong role of the public control - often typified by a repressive approach - to transnational supply chains and markets. The impact of the public control on actors and operative processes in this context has had to deal with the limits of territoriality of the juridical instruments, the fragmentation of the operators and the increasing difficulty in updating the legal framework in relation to the fast-changing scientific and technological innovations.
The same model of "business operator" was radically modified and is now understood to mean a professional with a central role both from the point of view of independence in decision-making with regard to the productive process, and to ensure that legal requirements are met with respect to third parties (other business operators or consumers).
The food business operator was first asked to implement a self-control system[1], thus becoming responsible for decisions regarding food safety in the context of the business under its control; therefore to verify the application of the juridical norms and the public or private standards expected in relation to his position also with regard to other operators[2] in the chain. This has the double objective of making commercial transactions stable and transparent as well as protecting consumers.
Finally, the decreasing relevance of cultural and territorial barriers due to the increased movement of goods and consumers[3], as well as the new concerns about the lost connection between the place of production and the place of consumption, has led to new needs and new factors in the global arena, imposing new and different standards which require control: the respect of ethical, environmental and social principles.
In such a cosmopolitan panorama from both the human and productive point of view, the official control had to be largely redrawn, integrating elements which were traditionally part of the so-called "positive legislation" with new private models, more easily adapted to the global dimension of commercial trade.
Such evolution is still on the way, and questions connected to this process - as, for example, "Who guarantees what?" and on the basis of which rules[4] - are still relevant.

(1) The self-control approach is well known in food law in order to ensure the hygiene of producing chains (see Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs, now Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. However it is the basis of many instruments the recent evolution of European law has imposed in order to improve the compliance to the juridical rules of reference. See, for example, the discipline of the liability of legal persons for crimes committed by their employees or managers (in Italy the Decree 231/2001) and the similar rules in environmental law stated by Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law, and the Directive 2009/123/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2005/35/EC on ship-source pollution and on the introduction of penalties for infringements.
(2) See art. 17, Regulation (EC) No 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.
(3) In the context described the mass-mobility of the recent decades should not be underestimated. This has led to a movement not only of increasingly specific dietary needs, but also cultural and ethical factors that impose new ways of working that the competent authority has to take into account.
(4) See F. Albisinni, *Sicurezza e controlli. Chi garantisce cosa?*, in q. *Riv.*, www.rivistadirittoalimentare.it, n. 4-2011.

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Once again, the food sector on one hand, and the "multilevel" legal space of the European Union on the other, represent a preferential laboratory of this evolution, which concerns all the productive and legal systems, and probably are the best context for the development of original solutions, both from the legal and the economical-organizational point of view.

2.- Official controls in European Union Law - Regulations 882/04/CE - 854/04/CE and the problem of the impact of their organizational rules on national legal systems

It is a generally accepted that the EU Food Law, starting from the reform of the early 2000's, created one of the most advanced legal and structural systems with regard to food safety and official controls.
The system is based on two levels of guarantees.
The role of food business operator is central. He is required to assure first and foremost that foods or feeds satisfy the requirements of food law which are relevant to his activities and must verify that such requirements are met (see art. 17 Reg. 178/02/CE[5]).
Member States have to monitor and verify that the relevant requirements of food law are fulfilled at all stages of production, processing and distribution. For that purpose, they must maintain a system of official controls and other activities as appropriate to the circumstances, taking into account their economic and operational impact on food business activities. The two fundamental regulations on this matter (Reg. 854/04/CE and 882/04/CE[6]) are based on the identification of the competent Authorities at a national level that must satisfy a certain number of operational criteria in order to guarantee impartiality and efficiency in its own actions.
The competent Authorities for controls must, in fact, be made up of staff who do not have any conflict of interest (see art. 4 co. 2 lett. b reg. 882/04/CE), are qualified, receive appropriate training, keep up to date in their area of competence and receive regular additional training as necessary (see art. 6, reg. 882/04/CE). Furthermore, the competent authorities must ensure that they have, or have access to, an adequate laboratory capacity for testing, appropriate and properly maintained facilities and equipment, as well as the legal powers to carry out official controls and to take the measures provided for in the EU Regulations (see art. 4 co. 2, lett. b-e reg. 882/04/CE).
In order to balance the efficiency of the controls with production requirements the regulation states that the central Authority must ensure an efficient and effective coordination between all the bodies and authorities involved, especially when they operate at a local level or are private entities (see art. 4 co. 3 Reg. 882/04/CE). In this last case these structures must be accredited following a public procedure (see art. 5 Reg. 882/04/CE and 765/08/UE[7]).
The EU Regulation establishes, therefore, real and specific organizational rules, that the Member States are obliged to implement modifying its own control bodies, and, if necessary, the instruments which the national legal systems make available in order to carry out the assigned tasks.
The specific structure of this discipline poses delicate questions regarding the "justiciability" of any possible difference in the national enforcement law or the actual situations that may occur with respect to the obligations imposed by the EU legislator.
In particular, leaving aside the eventuality of an enforcement action brought by the European Commission according to art. 258 TFUE, it is first of all necessary to underline that, even though the EU discipline on official control cited is stated by a regulation, nonetheless it is aimed at the Member States

([5]) See note 2.
([6]) See Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption, and Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
([7]) See Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

and needs a national enforcement.
This can constitute an obstacle to the direct application of these rules by food business operators for defense purposes. So it is fundamental to clarify if individuals can challenge acts or sanctions adopted by public authorities not in compliance with the cited requirements or which come from procedures based on non-accredited methods.
In this respect the Court of Justice has already stated that the EU Regulation can maintain their qualification even if containing norms aimed only at the Member States[8].
The possibility of deriving direct effects in favor of individuals cannot be, however, merely deduced from the binding characteristics of the regulations in comment and their general application.
In fact it is necessary to pass through a case-by-case check in order to verify that the norm is exhaustive in nature and comprehensive[9], so that the judge can apply them without being obliged to take the place of the legislator, by making a supplementary effort which is incompatible with the principle of separation of the powers[10].
In fact, if on the one hand the nature of regulations described in art. 288 TFUE cannot in itself overcome the limits brought by the definition of those concerned, on the other hand the need of a national enforcement does not constitute an absolute restriction regarding the applicability of the juridical contents so long as they are self-executing.
In other words the necessity of guaranteeing an effective judicial protection implies the verification- in the same way as for the vertical effects of the directives- of the nature and the contents of the rules in comment, that can give rise to applicable rights only if they are sufficiently precise and without conditions[11].
The requirements in question are judged moreover by the Court of Justice with a certain flexibility where the effectiveness of the EU norm is invoked only in order to counter the application of administrative or judiciary acts in conflict[12].
Therefore in the case in point, with reference to possible violations of the norms of organization regarding the accreditation and structure of the national control Authorities[13] and also regarding the modus operandi[14] of these, it appears objectively possible to recognize the characteristics described in the jurisprudence of the Court to deduce the rights of the food business operators to invoke the contents of

([8]) In general terms, in EU Law the principle of substance over form prevails. So this kind of rules should be interpreted as directives instead of regulations. The ECJ has however stated that the juridical nature of the regulation can remain notwithstanding this kind of structure. See the Judgment of the EU Court of Justice 11 January 2001, C-403/98, *Azienda Agricola Monte Arcosu*, point 26, where the Courts states clearly that "by virtue of the very nature of regulations and of their function in the system of sources of Community law, the provisions of those regulations generally have immediate effect in the national legal systems without its being necessary for the national authorities to adopt measures of application, some of their provisions may none the less necessitate, for their implementation, the adoption of measures of application by the Member States".
([9]) See on this point U. Villani, *Istituzioni di Diritto dell'Unione europea*, IV ed., Bari, Cacucci, 2015, p. 294.
([10]) See the judgment of the ECJ 19 January 1982, case No 8/81, *Becker*, point 29, where the Court states that whilst a directive "undoubtedly confers upon the Member States implementing certain of its provisions, individuals may not for that reason be denied the right to rely on any provisions which owing to their particular subject-matter are capable of being severed from the general body of provisions and applied separately". On this point see also L. Daniele, *Diritto dell'Unione europea*, Milano, Giuffré, 2007, p. 193 with specific reference to the EU regulations similar, with regard to the contents, to directives.
([11]) See the judgment of the ECJ 26 February 1986, case No 152/84, *Marshall c. Southampton and South West Hampshire Area Health Authority.* Point 28 of the cited judgment *Azienda Agricola Monte Arcosu*, should be interpreted in the same terms. The Court, with reference to the regulations in exam, states that "In the light of the discretion enjoyed by the Member States in respect of the implementation of those provisions, it cannot be held that individuals may derive rights from those provisions in the absence of measures of application adopted by the Member States".
([12]) In these cases the control is limited to the verification that the procedures imposed by the EU norms are respected. See on this point the judgment of the Court 30 April 1996, C-194/94, *CIA Security International*, in Rep. 1995, p. 20021 with regard to a national law not notified to the European Commission. In the case in which an individual wanted, on the contrary, obtain a specific right, it is necessary to verify who are the beneficiaries of the rules, their substance and, lastly, the identity of those who are required to implement the rules. See on this point the judgment of the Court 19 November 1991, C-6/90 and C9/90, *Francovich.*
([13]) E.g. their number, the respect of the procedures of accreditation, the coordination, the requirements of staff and support structures cited etc.
([14]) E.g. the procedures for taking samples, the respect of the defensive guarantees in the context of analyses etc.

the regulations commented, even though directed only at Member States, as a suitable source to legitimize an opposition to public acts adopted against them[15].

In fact, a precise reference to operational and structural rules contained in the norms of reference, as well as the exactness in the definition of methods and criteria, creates a guarantee for the operators, which is capable of being severed from the general body of provisions and applied separately in order to request the disapplication of national norms in contrast. The frequent link to international technical standards for accrediting structures and operative methods appears in this sense fundamental, given that the integration of sources clearly defines the contents from which can be obtained the elements for the disapplication of the internal norms in contrast (substantial or sanctionary) as well as the related rights of food business operators.

Thus, the overall reconstruction of the system outlines a concentric circular structure, the heart of which is represented by the food business operator with his decisional and operational independence, and around which are positioned the controls of the public and private accredited structures. The requirements of the system are established in general terms by the European Union according to international technical principles and with respect for the fundamental rights of the parties, in particular the protection of the right of defense and consumer health, as stated by the Charter of the Fundamental Rights of the European Union and applied by the Member States.

The organizations and procedures adopted at the national level must therefore correspond to the standards created by standardization bodies (e.g. EN 45001 norms for the neutrality of control bodies, ISO norms for the analytical methods etc.) which are made de facto binding through the implicit or explicit reference[16] by the mentioned EU provisions.

In conclusion we have a complicate scenario, in which both controllers and controlled have a reciprocal influence resorting to "third party" sources created in an extraterritorial context. These rules become the guiding principles which the private and public operators have to respect and that influence their activities. As result soft law has lost its technical-scientific connotation, and has become a binding rule of law on the base of public norms that explicitly or incidentally link or imply them.

3.- Integration of voluntary standards in the EU legal system

The extensive use of sources that are "external" and "foreign" to the traditional mechanisms for the production of regulations defined by the democratic principles of control, accessibility and transparency, poses the problem of the real role of the standardization bodies and the meaning of such a large presence of soft law in the European Union legal system.

In this regard it is first and foremost necessary to underline that the term "soft law" usually describes the "international norms that are deliberately non-binding in character, but still have legal relevance located in the twilight between law and politics"[17]..

([15]) I.e. the use of these rules in order to oppose sanctions applied against them. National jurisprudence does not appear to have this orientation. See, as an example, the Italian Supreme Court, who did not consider relevant the lack of accreditation of an official laboratory in order to give a criminal sentence against a food business operator. See on this point Cass. Pen., 19.11.2014, case No. 36506/15, with regard to propolis contaminated with pesticides, in *Alimenta*, 1/2016, p. 20, with the comment of V. Pullini, as well as Cass. Pen. 46496/15, unpublished, which confirms the sentence inflicted based on analytical evidence carried out without an officially accredited analytical method.

([16]) In this context it is not possible to give and exhaustive explanation of the various mechanisms for the enforcement of soft law. It is only possible to mention the fact that the concept of "juridical effect" can cover both the mandatory effect of the norms, but also indirect legal effects, coming from the combination of these sources with the general principles of the law or judicial interpretation.

([17]) See D. Thürer, *Soft Law*, in Encyclopaedia of Public International Law, R. Bernhardt (ed.), 2002, 4th edition, p. 452. See also, inter alia on this point, A. Schäfer, *Resolving Deadlock: Why International Organisations Introduce Soft Law*, in *European Law Journal,* Vol. 12, Issue 2, pages 194–208, 2006; A. Di Robilant, *Genealogies of Soft Law, The American Journal of Comparative Law*, Vol. 54, N. 3, 2006, p. 499; G. C. Schaffer, M. Pollack, *Hard vs. Soft Law:* Alternatives, *Complements, and Antagonists*, in *International Governance*, *Minnesota Law Review*, 2010, p. 706 ss.

This category includes a jumble of different instruments, from the resolutions of international organisms to guidelines (e.g. Codex Alimentarius, WHO etc.) and technical criteria for producing methods and characteristics of goods adopted by standardization bodies.
In this context, it must be stressed that, even though these documents have not, in general, binding force, their legal effect can derive from many factors, including the indirect effects determined by the combination with the general legal principles or interpretation of the jurisprudence[18].
These sources are usually classified in public and private standards, based on the body who created them, the source from which they are regulated and the consequences that derive from their violation.
Public standards "are normally adopted by governments, based on laws and enforced by public sanction in case of non-compliance"[19].
Private standards are created by private bodies, (NGOs, standardizations bodies, Mass Market Retailers etc.) and the infringement of the relative rules implies private liability (contractual, non-contractual or a penalty established by the rule itself).
Furthermore, the classification of these sources is usually made according to their juridical nature: they can be mandatory, when they are legally binding, or "voluntary" when the respect of the standard responds to a business decision in order to reach economic, technological or production targets.
However this kind of classification seems formalistic at this point, as well as seems to be not so relevant the distinction between public and private standards, given that soft law has taken such an important role in the market to impose on operators a de facto binding effect equivalent to mandatory rules, thanks also to the mechanisms described[20].
In this evolutionary context the exponential increase of the use of soft law instruments to regulate and control markets appears strictly connected to the effects of globalization as well as the constantly growing complexity of production technology which inevitably generates the need of greater consumer certainty.
In the present scenario the consumer finds himself, more than ever before, in a position of extreme weakness, because of the increase distance between the place of purchase and the place of production of goods (factors that inevitably lead to lack of transparency and a general lack of confidence).
Furthermore it is materially impossible, for ordinary individuals, to know and understand the contents of what they buy, the characteristics of which are always more "artificial" and always less connected to everyday experience.
The progressive breakdown in the relationship of trust between producer and purchaser of goods does not only concern the safety aspect (which had certainly constituted the first ambit where the disconnection took place between the economic and social relationship described), but touches in a large measure ethical and environmental concerns such as respect of traditions and immaterial cultural heritage, the productive footprint, the use of underage labor or the lack of adequate rights and welfare levels in the manufacturing sector of the less developed areas of the World.
No wonder, then, if we have a crisis in the concept of "public certainty"[21], that refers to a territorial system of juridical rules aimed at giving intrinsic credibility to products based on an underlying control activity carried out by public bodies, as well as the growing perception of trustworthiness as a "value" that can be spendable on the market in relation to mechanisms and additional guarantees given by

([18]) See K. W. Abbott, D. Snidal, *Hard and Soft Law in International Governance*, International Organization, 54, 3, 2000, p. 421 ss. The examples in this field are too many to be exhaustively listed here. See, for example, the judgment of the ECJ 13 December 1989, C-322/88, *Grimaldi*, points 16-18, where the Court with reference to recommendations, states that "it must be stressed that the measures in question cannot therefore be regarded as having no legal effect. The National courts are bound to take recommendations into consideration in order to decide disputes submitted to them, in particular where they cast light on the interpretation of national measures adopted in order to implement them or where they are designed to supplement binding Community provisions".
([19]) See E. Cristiani, G. Strambi, *Public and private standards-official controls*, in L. Costato - F. Albisinni (eds.), *European Food Law*, CEDAM, Padova, 2012, 245-264.
([20]) In this respect see L. Senden, *Soft Law in European Community Law*, Portland, Hart Publishing, 2004, *passim*.
([21]) See F. Albisinni, cit.

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private subjects who are equipped with a high level of competence and impartiality.
In this context technical standards carry out, therefore, a triple function, halfway between public requirements and private interests:
- They guarantee the constant updating of expectations with respect to the behavior of food business operators considering the highest level of science and professional experience, overcoming possible slowness in updating norms and/or regulatory weaknesses;
- They create a general trust regarding the respect of specific levels of quality and safety in the productive process and in the finish products, increasing the trust of consumers and thereby promoting the circulation of goods;
- They consist in a global benchmark to which the organizations of producers and characteristics of goods have to conform, creating a global language on a scientific basis, in order to overcome technical barriers and create a shared responsibility with respect to the market.

Soft law, therefore, traditionally used in order to facilitate international commercial relationships and agreements between States, has in this way changed role, taking on a hybrid nature halfway between the authoritative function and an added-value service[22].

3.1. The role of soft law from "Meroni" to "James Elliott"

The described scenario poses delicate problems with regard to the role that soft law has taken on progressively in international trade both with reference to manufacturing activities and to the public bodies that control them.
The evolution of the function of soft law illustrated affects all manufacturing sectors, but is particularly evident in the food chain, where some standards relating to safety created in technical contexts have been deliberately integrated in public rules since the 90's, making them mandatory for complete segments of the production chain[23], as well as for public controls[24].
The regression of public sources in favour of private norms is probably an inevitable process, considering the acceleration in the progress and the productive delocalization: the loss of "territoriality" of the chain prevents the subjection of the different links of the chain to the same juridical systems. At the same time legal orders are impacted by the slowness of public norms in reacting adequately to scientific and technical evolution.
The creation of hybrid models of market regulation by means of "blank" reference to private sources and the setting up of specific bodies, with the power to determine de iure or de facto diligence standards, posed in many different situations, both from the judicial and regulatory point of view, the problem of the compatibility of the system with the democratic principles, in accordance with the Western constitutional traditions and articles 2 and 10 of the European Union Treaty.

([22]) See A. Moscarini, *L'accreditamento nel Regolamento CE n. 765/2008 e le "fonti" di produzione privata*, in q. *Riv.*, www.rivistadirittoalimentare.it, 1/2012.
([23]) I am referring, in particular, to the self-control case, and the HACCP method, originally adopted in the aero-spatial sector, and later incorporated in the Directive 93/43/EEC of the Council on the hygiene of foodstuffs as mandatory for all the business operators other than primary producers in order to guarantee the hygiene in the food production process. Regulation No 178/2002, concerning the general EU food law, states that the whole juridical architecture of this sector is based on "risk assessment" (see art. 6), in which scientific indicators created by independent international bodies play an important role. Furthermore, article 13 of this Regulation states that EU and Member States must contribute to the development of international technical standards and promote the coordination of work on food and feed standards undertaken by international governmental and non-governmental organizations.
([24]) See, as examples, article 11 of the Regulation of the European Parliament and the Council No 882/04/CE of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, with regard to the lack of UE official analysis methods and the need to adopt internationally recognised rules or protocols, for example those that the European Committee for standardisation (CEN). Article 12 states that "competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European Standards: (a) EN ISO/IEC 17025 on "General requirements for the competence of testing and calibration laboratories"; (b) EN 45002 on "General criteria for the assessment of testing laboratories"; (c) EN 45003 on "Calibration and testing laboratory accreditation system-General requirements for operation and recognition", taking into account criteria for different testing methods laid down in Community feed and food law".

In fact, the democratic legitimacy of soft law does not appear to be very strong, at least as regards parliamentary influence or control over its adoption[25]. But there again the scientific nature of soft law tends to exclude the control of superior authorities in the merit of the validity of the knowledge, so that it has the power to impede any discussion on the contents of "knowledge" by the civil society[26].
From this viewpoint, the European Union Law- and in particular the EU food Law- seems to have taken a hybrid approach to reconcile the constitutional difference in ends and characteristics of scientific knowledge and juridical rules.
The Lisbon Treaty has overcome the absence of explicit norms in the previous EC Treaty with reference to the possibility of conferring powers to bodies not expressly included in the EU institutional framework, by the introduction of the possibility that Union offices or agencies adopt acts that shall have general application, binding for individuals, under articles 263 par. 1 and 277 TFEU.
In this way, the EU Treaty has overcome the obstacle highlighted by the European Court of Justice in "Romano" judgement[27], where, in a social security legal case based on the power of an administrative commission instituted by a European Regulation[28], to determine an exchange rate, the Luxembourg judges established that "it follows both from article 155 of the treaty and the judicial system created by the treaty, and in particular by articles 173 and 177 there of, that a body such as the administrative commission may not be empowered by the Council to adopt acts having the force of law. Whilst a decision of the administrative commission may provide an aid to social security institutions responsible for applying community law in this field, it is not of such a nature as to require those institutions to use certain methods or adopt certain interpretations when they come to apply the community rules"[29].
On the other hand the most recent jurisprudence of the Court regarding articles 290 and 291 TFEU states that their content, as formulated by the Treaty of Lisbon, does not mean that certain delegated and executive powers may be attributed solely to the Commission. In fact, while the treaties do not contain any provision to the effect that powers may be conferred on a Union body, office or agency, a number of provisions in the FEU Treaty none the less presuppose that such a possibility exists[30].
Finally, in accordance with the process described, the Court has repeatedly confirmed the possibility to create this kind of bodies for the harmonization process aimed at the consolidation of the single market, stating the adequacy of art. 95 EC (now 114 TFEU) as a juridical basis of the founding acts.
In fact, according to the Court, "it should be observed that by the expression 'measures for the approximation' in Article 95 EC the authors of the Treaty intended to confer on the Community legislature a discretion, depending on the general context and the specific circumstances of the matter to be harmonized, as regards the harmonization technique most appropriate for achieving the desired result, in particular in fields which are characterized by complex technical features. That discretion may be used in particular to choose the most appropriate harmonization technique where the proposed approximation requires physical, chemical or biological analyses to be made and scientific developments in the field concerned to be taken into account"[31].
The EU Legislator, in the framework of its discretion in the adoption of measures for approximation of national laws affecting the single market, can dele-

([25]) See L. Senden, *cit*.
([26]) See M. Tallacchini, *Sicurezze e responsabilità in tempi di crisi*, in q. *Riv*., www.rivistadirittoalimentare.it, n. 1/2012.
([27]) See the ECJ Judgment 14 May 1981, C-98/80, *Giuseppe Romano v. Institut National D'Assurance Maladie-Invalidité*.
([28]) This was the Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community (see, in particular, points 80 and 81 of the judgement).
([29]) See point 20 of the judgment.
([30]) See, on this point, the ECJ Judgment 22 January 2014, C-270/12, *United Kingdom of Great Britain and Northern Ireland v European Parliament and Council of the European Union*, points 79-81.
([31]) See the ECJ Judgment 6 January 2005, C-66/04, *United Kingdom of Great Britain and Northern Ireland v European Parliament and Council of the European Union* with regard to the choice of legal basis of EFSA assessment of Smoke flavourings. The Court expressed the same position in Judgment 2 May 2006, C-217/04, *United Kingdom of Great Britain and Northern Ireland v European Parliament and*

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gate powers to a specific body or agency "in particular where the measures to be adopted are dependent on specific professional and technical expertise and the ability of such a body to respond swiftly and appropriately"[32].

Moreover, the accountability and the democratic control of these bodies is nowadays explicitly guaranteed by many norms of the Treaty on the Functioning of the European Union which extend the judicial control on the acts of these bodies (see art. 263 TFEU), assure the possibility to bring an action for their failure to act (see art. 265 TFEU) and the indirect judicial control through the mechanism of the preliminary ruling (see art. 267 TFEU) or invoke before the Court of Justice of the European Union the inapplicability of their acts (see art. 277 TFEU).

So, as far as the 'agencification' process in the European Union is concerned, as significantly intensified since the new millennium[33], we can reasonably assume that the Treaties present discipline can guarantee the balance between functional advantages and the risk of self-referencing of those bodies and their possible conditioning by third parties.

The situation appears more complex when the standards incorporated directly or indirectly in public norms are adopted by private bodies.

Even in this case, however, the EU Law has many criteria in order to assure the constitutional principles referred to previously, and to protect individual rights.

First of all, since 1958 the EU Court of Justice in "Meroni"[34] allowed private bodies to take part in the decisional process under the condition that this subdelegation mechanism does not imply the circumvention of the conferral principle, with a violation of the limits imposed by the Treaty.

Furthermore, the Court stated the impossibility to attribute to external private bodies discretional powers which cannot be subjected to a legal control, considering that "to delegate a discretionary power, by entrusting it to bodies other than those which the Treaty has established to effect and supervise the exercise of such power each within the limits of its own authority, would render" a fundamental guarantee, granted by the Treaty in particular to the undertakings and associations of undertakings to which it applies, ineffective[35].

The concerns expressed by the Court still appear to be pertinent, as shown by the opinion of Advocate general Jääskinen in the "Short selling" case[36], where it is affirmed that "Meroni remains relevant in that (i) powers cannot be delegated to an agency that are different from the implementing powers the EU legislature has conferred on the delegating authority, be it the Commission or the Council, and (ii) the powers delegated must be sufficiently well defined so as to preclude arbitrary exercise of power. In other words, the delegating act must supply sufficiently clear criteria so that the implementing power is amenable to judicial review. The delegating authority 'must take an express decision

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Council of the European Union, point 43, with regard to the role of the European Network and Information Security Agency, and 22 January 2014, C-270/12, *United Kingdom of Great Britain and Northern Ireland v European Parliament and Council of the European Union*, point 102, with regard to powers of intervention conferred on the European Securities and Markets Authority in exceptional circumstances.

([32]) See point 105 of the ESFMA Judgment.

([33])The topic is well known and it is not possible to make here a precise picture of the juridical implications of this mechanism. For a wider analysis see E. Chiti, *Le agenzie europee: unità e decentramento nelle amministrazioni comunitarie*, CEDAM, Padova, 2002; S. Griller, A. Orator, *Everything under control? The "way forward" for European agencies in the footsteps of the Meroni doctrine,* in *European Law Review* 35 (2010), pp. 3 ss; M. Chamon, *EU Agencies between Meroni and Romano or the Devil and the Deep Blue Sea, in Common Market Law Review*, 2011, pp. 1055 ss., H. Hofmann, A. Morini, *The Pluralisation of EU Executive-Constitutional Aspects of Agencification*, in *European Law Review*, 2012, pp. 419 ss.; C. Tovo, *Le agenzie decentrate dell'Unione europea*, Editoriale Scientifica, Napoli, 2016. See also the Communication from the Commission to the European Parliament and the Council *'European Agencies – the Way Forward*' COM(2008) 135 final, online.

([34]) See the judgment of 13 June 1958, case No 9/56, *Meroni & Co., Industrie Metallurgiche SpA v High Authority of the European Coal and Steel Community*, in *ECR* 1957-1958 p. 133

([35]) See Meroni judgment, p. 152.

([36]) See the opinion of Advocate general Jääskinen, delivered on 12 September 2013, C-270/12, *United Kingdom of Great Britain and Northern Ireland v. European Parliament and Council of the European Union*, point 88.

transferring them and the delegation can relate only to clearly defined executive powers'".
So, the highlighted aspects can find an answer in at least two different juridical steps, which can potentially resolve conflicts between the need for a "technical governance" of the market and the concerns linked to public control.
First of all in many judgements the Court has stated that private sources, even if they are not produced by Institutions, bodies, offices or agencies of the European Union, are by their nature measures implementing or applying an act of EU law. Therefore they are subject to the jurisdiction of the Court[37], considering the very objective of Article 267 TFEU, which is to ensure the uniform application, throughout the European Union, of all provisions forming part of the European Union legal system and to ensure that the interpretation thereof does not vary according to the interpretation accorded to them by the various Member States.
The same function of the standardization bodies, on the other hand, must be in accordance with the norms on the free circulation of goods, as affirmed in many different judgements by the Court, analysing the obstacles deriving from the compliance requirements determined by national legislations and controlled by these bodies[38].
This seems evident considering the inclusion of technical rules, compulsory de iure or de facto, in the case of marketing, among the rules that have to be notified to the EU Commission under the "warning directive"[39].
To this we need to add the mechanism of the so called "accreditation" of standardization bodies, established by Regulation 765/2008/EC[40], on the basis of which each Member State appoints a single national accreditation body who has the power to evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity[41].
In fact, in the context described, Regulation 765/08/EU constitutes a fundamental link, by imposing that all the values and the knowledge must be accredited according to methods not only attributable to the validity of science, but also based on the more traditional canons of transparency and public responsibility.

4.- Conclusions

The above considerations allow us to make some evaluations on the present normative and organizational model chosen by the European Union to govern the food market, which is very dynamic and competitive.
It has been previously observed that the globalization and production delocalization have created a transnational space for the movement of goods, that is not totally subject to "territorial" law and to the EU model of economic development, due to the increase of relationship dynamics, technological innovation and scientific progress.
Within this framework the "crisis" of juridical certainty is accompanied by a growing concern of consumers, squeezed between an exponential increase in product availability, a torrent of information about their characteristics and the need for the offi-

(37) See, on this point, the ECJ judgements 20 September 1990, Service, C-192/89, point 10; 21 January 1993, *Deutsche Shell*, C-188/91, point 17; 27 October 2016, *James Elliott Construction LTD c. Irish Asphalt LDT*, C-613/14, point 34.
(38) I am referring, in particular, to the ECJ judgment 12 July 2012, C-171/11, *Fra.bo SpA v Deutsche Vereinigung des Gas- und Wasserfaches eV (DVGW)*, where the Court stated that "Article 28 EC must be interpreted as meaning that it applies to standardisation and certification activities of a private-law body, where the national legislation considers the products certified by that body to be compliant with national law and that has the effect of restricting the marketing of products which are not certified by that body".
(39) See the Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations, refused in the Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, repealed by Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.
(40) See Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.
(41) See art. 4 par. 1 and art. 5 par. 1, 3.

cial control to take responsibility in order to remedy the cognitive asymmetry typical of the modern commercial relationship.
At the same time the necessity to maintain a high level of economic efficiency and sufficient competition with respect to the global market leads to a progressive openness towards innovation and economies of scale through the transnational structuring of the production chain.
In this context the European Union seems to have found a balance answer with respect to the conflicting interests previously outlined.
The definition of official controls with mandatory organizational rules, which lay the foundation for the activity based on the competence of operators and the efficiency of the respective bodies, avoids the diseconomies that come from improper "downward" competition between different legal systems.
Food business operators can, in this way, count on uniform rules which are applicable to all the Member States, in order to get greater coherence in the activities of public control, as well as a better protection of their fundamental rights both in the economic sphere and with regard to defensive guarantees.
The link to private standards created at an international level allows the integration of public norms with the most recent scientific knowledge, in the context of a mechanism for updating the entire system (composed of controllers and controlled operators) to the highest safety and efficiency levels.
The delegation of powers to private standardization bodies, on the other hand, cannot undermine the system of constitutional guarantees based on the democratic principle, given that "private knowledge" will be in any case subjected both to institutional and jurisdictional control, by means of the sophisticated mechanism of accreditation and the inclusion of private sources linked by public norms in the ambit of EU Law subjected to the EU Court of Justice competence.
This kind of system, which is able to keep together all the different needs described, promotes, furthermore, an increase in the added value of the goods, because it is able to give back security to the end consumer both in terms of the efficiency of controls and the reliability of products.
In order to effectively complete this juridical evolution there has to be an internal judicial transition.
In fact, it appears essential that national Courts understand the role of mechanisms such as accreditation of the control bodies and methods used, as well as the specific function of private standards included in public norms, avoiding decisions that do not take into account their content or their significance.
From this point of view it appears fundamental that national judges take a more open and courageous approach in the dialogue with the Court of Justice, in particular by means of a wider recourse to the preliminary ruling mechanism regulated by art. 267 TFEU, in order to ascertain, case by case, the meaning, impact and validity of public norms and private standards applicable to the specific case.

ABSTRACT

The EU multilevel protection system of the food market is based on three different elements relevant both for private and business operators: the direct effect of organizational norms imposed on the Member States by the recent EU food safety legislation; the role of public control and the integration of private standards in the government structure of a globalized market.
This article aims to focus on the problems arising from the integration of the EU and national legal systems about food safety, as well as to interpret the role of private standards, accreditation and public control in the new scenario, characterized by an increasing complexity brought on by the globalization of commerce and the integration of many different legal orders and sources of obligations.
The result is a juridical analysis on who controls what and on the basis of which power/rules, taking into account the increasing role of self-regulation in food production and distribution.