CHAPTER II

THE PATH TO THE EUROPEAN AND GLOBAL FOOD LAW SYSTEM

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SUMMARY: 1. The origins: common market and health protection in the first steps of approximation. – 2. The '70s: partial approximation and CAP measures. – 3. The '80s: judicial interventionism. – 4. The '90s: internal market. – 5. Multiple goals of European food legislation. – 6. Food safety crises and the new disciplinary framework. – 7. The new century: Regulation No 178/2002 and the systemic dimension. – 8. A polycentric regulatory system: Globalisation and new sources in the EU Law Making Process.

1. The origins: common market and health protection in the first steps of approximation

The European Economic Community, already in the first years of its existence, still in its original structure of only six Member States (the founders: Belgium, Germany, France, Italy, Luxembourg, Netherlands) (1), showed a significant awareness of the need to promote the introduction of common rules on foodstuffs, conscious of the quantitative and qualitative relevance of food trade within the market at that time named "*common*" (2).

But the evolutionary process toward the establishment of an unitary common framework of food law in all its aspects, related to production, trade, marketing, health and safety, was much slower and tortuous, than could be anticipated in the '60s.

(1) See EEC Treaty 1957, establishing the European Economic Community.
(2) Art. 3 TEEC 1957.

It is possible to outline some temporal partitions, which (with all the arbitrariness and tentativeness of any partition) characterize this process, in significant correspondence with institutional developments, both in the internal European dimension, and in the international dimension of the growing globalisation, together with the challenges of technological and market innovations.

Already in the '60s, only few years after the entry in force of the Rome Treaty, the European Council intervened on food matters, adopting Directive 62/2645/EEC of 1962 ([3]), to regulate colouring matters authorised for use in foodstuffs intended for human consumption.

This Directive was adopted on the basis of Article 100 TEEC ([4]), and therefore on the legal basis of the competence awarded to the Council, "acting unanimously on a proposal from the Commission [to] issue directives for the approximation of such provisions laid down by law, regulation or administrative action in Member States as directly affect the establishment or functioning of the common market".

"*Establishment or functioning of the common market*" were the key words to justify this early EEC legislative initiative, intended to approximate national food laws (i.e., in fact, to unify and render uniform – Costato 2007a), as expressly pointed out:

"Whereas differences between national rules concerning these colouring matters hinder *the free movement of foodstuffs* and may create conditions of unfair competition, thereby directly affecting *the establishment or functioning of the common market*" ([5]).

But the Directive, even before mentioning "*free movement*" and "*common market*" in Recital 2, in Recital 1 opens the text with the basic consideration that "all rules relating to colouring matters which may be used in foodstuffs intended for human consumption *must give priority to the protection of public health*" ([6]).

"*Protection of the consumer against falsification*", together with the "*needs of economy*" are expressly mentioned in the first Recital of the

([3]) Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorised for use in foodstuffs intended for human consumption (62/2645/EEC).

([4]) Later Art. 94 TEC, and now Art. 115 TFEU.

([5]) Recital 2 of Dir. 62/2645; italics added.

([6]) Recital 1 of Dir. 62/2645; italics added.

Directive, as reasons that "must also be taken into consideration". But the declared *priority* awarded to the *protection of public health* in regulating foodstuffs intended for human consumption, in comparison to any other reason or interest considered in this act, appears even more meaningful, when one considers that such decisive attention toward public health values is present in an act adopted on the legal basis of a provision of the EEC Treaty (Article 100), which made exclusive reference to the common market as the founding value of the Community policy thereby considered.

One year later, on the same legal basis of Article 100 TEEC, Directive 64/54/EEC (7) introduced provisions for the approximation of national legislation on preservatives used in foodstuffs intended for human consumption, with the even clearer specification that the value of "*health protection*" is so prominent, that even "*economic and technological needs*" can be taken in consideration only "*so far as health protection allows*":

"Whereas all laws relating to the preservatives which may be used in foodstuffs intended for human consumption must give priority to the protection of public health, but the protection of the consumer against falsification, and, *so far as health protection allows*, economic and technological needs must also be taken into consideration;" (8).

Health protection is therefore identified – even at language level – as such a prominent value, that it cannot even be weighted in comparison with other interests already mentioned in the Treaty, but must in any case prevail, due to the highest value attributed to human beings.

In other words, no balance of interests or cost-benefit analysis is envisaged in the Directive of 1964; instead an express hierarchy of values and interests is established, and health protection is situated at the top.

From these first steps, European legislation on food revealed its pluralistic nature, given its multiple objectives, and at the same time affirmed a founding rule of action, which, in a Community at that time still named *Economic Community*, privileged health protection on any protected interest, including economic interests.

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(7) Council Directive 64/54/EEC of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption.

(8) Recital 1 of Dir. 64/54/EEC; italics added.

Common market, competition, free movement of foodstuffs assume, in these early rule making acts of the EEC on themes of food law, the nature of *passepartout* tools, capable of later introducing onto the playing field of European legislation issues – like public health and consumer protection – that the writers and signers of the 1957 Rome Treaty were not able to deal with expressly (or not aware of dealing with), and that will acquire a formal legitimacy only some decades later with the Single European Act of 1986, as is also the case for environment and workers' protection ([9]).

Public goods and values not expressly mentioned in the original text of the EEC Treaty, found a way into provisions intended to approximate food legislation ([10]), due to the sensitive nature of its object (Gadbin 1996) ([11]) and to the peculiar reactivity to technological innovations largely present in food production, trade and marketing, in some way anticipating themes and issues on *food safety*, which only much later will become familiar to the political and social debate.

It must be said that the expression *food safety* (i.e.: hygienic safety of food destined to human consumption) at that time was not in use in the regulatory language of the EEC, and the expression *food security* (i.e.: security to have a sufficient quantity of food apt to human consumption) ([12]) was not commonly used either.

But the substance of *food security* ([13]) was mentioned among the express objectives of the Common Agriculture Policy (CAP), which

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([9]) See, among the new provisions introduced in the TEEC by the Single European Act, Art. 118a on health and safety of workers, Art. 130r on environment, and – with reference to the institutional framework – Art. 100a(3), which established, with reference to the new legislative competences assigned to the Council in co-operation with the EP, on proposal from the Commission: "The Commission, in its proposals envisaged in paragraph 1 concerning *health*, safety, environmental protection and *consumer protection*, *will take as a base a high level of protection*"; see also Art. 3 TCE as amended by Art. G(3) TEU 1992, where letter (o) includes, among the activities pursued by EC "a contribution to the attainment of *a high level of health protection*" (italics added).

([10]) See Chapter I.

([11]) See Chapter I.

([12]) See Chapter I.

([13]) The World Food Summit of 1996 accepted that *food security* exists "when all the people at all time have access to sufficient, safe, nutritious food to maintain a healthy and active life".

included those "*to assure the availability of supplies*" and "*to ensure that supplies reach consumers at reasonable prices*" ([14]).

Food safety, on the contrary, was not mentioned directly or indirectly in the original text of the EEC Treaty, and also the *health protection* issues made their formal appearance in European treaties only in 1986, with the Single European Act – as already mentioned.

For years, the absence of a specific legal basis relegated the early examples of EEC regulatory attention to the themes of *food safety*, to a condition of isolated testimony, not evolving into a unified systemic framework.

Moreover, the procedure envisaged by Article 100 TEEC to harmonize national rules, with the necessity to obtain the unanimity of the Council (and therefore of all MS), made it really difficult in the first decades of the EEC to go much further in the process of approximation of national rules on food products (Capelli 2010a), due to the strong differences among cultures and traditions.

Taking into account these procedural (and political) difficulties, and driven by the need to build a uniform regulatory framework for financial measures in favour of agricultural producers, basic regulatory issues regarding food products have rather been tackled within the Common Agricultural Policy, extended to cover not only primary production, but even subsequent phases.

Acts adopted with recourse to the special procedure provided for CAP measures ([15]), which required only majority consent of MS, and not unanimity as required by Article 100, did not only invest issues involving the primary activity, providing financial support to farmers mainly through price support, operating as "*incentive law*" (in accordance to their declared nature of policy tools), but intervened directly to regulate characteristics of food production and food products, along the entire agro-food chain, evidencing their coexistent nature of "*regulatory law*" (Jannarelli 2006; Id. 2007).

In coherence with the integrated approach adopted by Articles 38-47 TEEC and the multiple objectives assigned ([16]), CAP in many ways characterised itself as a complex agro-food policy, more than a mere agricultural policy, dealing also with phases subsequent to the primary activity ([17]),

([14]) Art. 39(1)(d) TEEC in its original text (now Art. 39 TFEU).
([15]) Art. 43 TEEC.
([16]) See now Artt. 38-44 TFEU.
([17]) See Chapter X.

including transformation, distribution, trade and marketing, in a framework which was very different from many national legal systems (e.g. Italy, where the area of agricultural law was traditionally limited to the primary activity *per se*, enclosed within the borders of the farm) (Jannarelli 2001).

It is sufficient here to mention Regulation No 136/66 ([18]) on oils and fats, adopted on the basis of Articles 42-43 TEEC, which in 1966 adopted common customs tariffs, established a system of compensatory amounts, import export licences, market target prices, intervention prices and threshold prices (with complex administrative procedure and bodies to apply the intervention rules), but at the same time introduced uniform definitions, including those of virgin olive oil, refined olive oil, pure olive oil ([19]), directly investing aspect which in national legislations were traditionally considered part of food law.

With an analogue approach, Regulation No 804/68 ([20]) on milk and milk products, also adopted on the basis of Articles 42-43 TEEC, in 1968 regulated the target price for milk and the intervention price for butter and cheese (with specific intervention prices for Grana Padano and Parmigiano Reggiano) ([21]), adopted common customs tariffs, import export licences, export refunds (even in this case with complex administrative procedure and bodies to apply the intervention rules), but at the same time introduced uniform quality standards applicable to "Community-produced butter" definitions, establishing that only butter which reaches such quality standards may be imported into the EEC territory ([22]).

2. The '70s: partial approximation and CAP measures

The '70s, with the enlargement of EEC to nine members, consequently including the United Kingdom, Ireland and Denmark, countries with

([18]) Regulation No 136/66/EEC of the Council of 22 September 1966 on the establishment of a common organisation of the market in oils and fats.

([19]) Annex to Reg. No 136/66/EEC. See Chapter XXIX.

([20]) Regulation (EEC) No 804/68 of the Council of 27 June 1968 on the common organisation of the market in milk and milk products.

([21]) Art. 5(1) Reg. No 804/68.

([22]) Art. 16(1) Reg. No 804/68.

significantly different food traditions from countries like France and Italy, made the need to proceed to an approximation of rules even more pressing.

Notwithstanding the Council Resolution of 28 May 1969 ([23]) aimed to eliminate technical obstacles to the exchange of foodstuffs, and the more general Directive 50/70/EEC of the Commission on the abolition of measures which have an effect equivalent to quantitative restrictions on imports ([24]), the approximation of technical rules regarding food products remained an unfinished process for a long time ([25]).

Significant the case of chocolate. A Council Directive of 1973 ([26]), adopted on the legal basis of Article 100 TEEC, and therefore by unanimous consent of all MS, admitted that, due to the great differences among national legislations and traditions, at that time it was not possible to harmonize completely all the provisions relating to these products and lay down common definitions and composition rules, and therefore expressly postponed effective harmonization to a later date ([27]); later date which arrived only three decades later, with a Directive of 2000 ([28]) (MacMaoláin 2007; Capelli 2011a).

Other attempts to harmonize rules on the characteristics of food products remained totally unaccomplished, and in some cases were not able to give rise to directives, even if only partial as the above mentioned Directive on chocolate; e.g., a proposal of the European Commission for the adoption of a Directive on "pasta", proposing to generalize the Italian recipe, was not accepted by the Council (Capelli 2010b).

As a consequence of the impasse in the harmonisation process, the recourse to CAP measures under Article 43 TEEC, already used in the '60s to regulate the characteristics of food products (as in the aforementioned cases of oils and fats with Regulation No 136/66, and of butter with

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([23]) Council Resolution of 28 May 1969 drawing up a programme for the elimination of technical barriers to trade in foodstuffs which result from disparities between the provisions laid down by Law, Regulation or Administrative Action in Member States.

([24]) Commission Directive 70/50/EEC of 22 December 1969.

([25]) See Chapter I.

([26]) Council Directive 73/241/EEC of 24 July 1973 on the approximation of the laws of the Member States relating to cocoa and chocolate products intended for human consumption.

([27]) Recital 5, 7, 8, of Dir. 73/241/EEC.

([28]) Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption.

Regulation No 804/68), became the *de facto* standard legislative tool utilized during the '70s and large part of the '80s, to adopt rules in areas of food law.

Many provisions adopted within the CAP dealt with the Common Organisation of agricultural Markets (CMO) ([29]). Those acts, adopted by the European Council exercising the powers and competences assigned by Article 43 TCEE and under the procedure thereby established, were intended to guarantee citizens the *availability of supplies* (i.e.: *food security*), farmers *increased incomes* and a *fair standard of living*, and consumers *reasonable prices*, in accordance with the objectives of CAP established by Article 39 TCEE ([30]).

As in the '60s ([31]), those acts, together with economic content, fixing prices and establishing financial aid to farmers, frequently went on regulating food products, within the framework of a regulated market, in some cases with reference to food products situated well beyond the category of "products of first-stage processing directly related to these products" mentioned in Art. 38 TEEC ([32]).

In this context, the expansive capacity of CAP regulation is confimed by the circumstance that most of the Directives expressly aimed to pursue harmonisation in the field of foodstuff and of feeding-stuff have been approved on the double legal basis of Articles 43 and 100 TEEC, considered jointly.

In other words, during the '70s and in subsequent years, CAP measures operated to promote an approximation (at least partial) that the provisions of the Treaty expressly dedicated to harmonisation were not able to assure, and Article 43 played a decisive role into the rule-making process of food law discipline, offering a sort of founding pillar.

This regulatory process led to the adoption both of vertical rules (harmonisation measures for single food chains and products), and of horizontal rules (regarding the generality or at least large aggregates of products).

([29]) Art. 40 TEEC in its original text. See Chapter XVIII.

([30]) Reaffirmed unchanged in Article 39 TFUE, as introduced by the Lisbon Treaty, in force starting from 1 December 2009.

([31]) See above para 1.

([32]) See Chapter X.

In the first group, the list includes some Directives approved in the '70s, on the approximation of laws regarding single food products: e.g. honey ([33]), fruit juices ([34]), preserved milk for human consumption ([35]), fruit jams, jellies and marmalades and chestnut purée ([36]), all adopted on the double legal basis of Article 43 and 100 TEEC considered jointly.

In the second group, the list includes some Directives, also adopted on the double legal basis of Article 43 and 100 TEEC considered jointly, regarding decisive issues of *food safety* and *health protection* (which nowadays are regulated by the "*Hygiene package*" ([37]), as a relevant part of the present food law system), among which:

– two Directives of 1970, one on the methods of sampling and analysis for the official control of feeding-stuffs ([38]), and the other on additives in feeding-stuffs ([39]), and

– two Directives of 1976, one relating to the fixing of the maximum level of erucic acid in oils and fats intended for human consumption ([40]), and the other relating to the fixing of maximum level for pesticide residues in and on fruit and vegetables ([41]).

In all those cases, measures adopted within the PAC significantly intervened in the food market, introducing some basic elements of a food law discipline rooted in agricultural law; circumstance which largely explains the growing interest of agricultural law scholars in themes of food law (Costato 2003a).

Only a few acts, nearing the end of the '70s, were approved on the basis of Article 100 alone, *per se*, among which:

– a Directive of 1976, on materials and articles intended to come in contact with foodstuffs ([42]), and not on food products as such;

([33]) Council Directive 74/409/EEC of 22 July 1974.
([34]) Council Directive 75/726/EEC of 17 November 1975.
([35]) Council Directive 76/118/EEC of 18 December 1975
([36]) Council Directive 79/693/EEC of 24 July 1979.
([37]) See Chapter XIV.
([38]) Council Directive 70/373/EEC of 20 July 1970.
([39]) Council Directive 70/524/EEC of 23 November 1970.
([40]) Council Directive 76/621/EEC of 20 July 1976.
([41]) Council Directive 76/895/EEC of 23 November 1976.
([42]) Council Directive 76/893/EEC of 23 November 1976.

– a Directive of 1977 ([43]), on coffee extracts and chicory extracts, which adopted the same approach as the Directive of 1973 on cocoa and chocolate ([44]), expressly admitting that "it is not possible in this Directive to harmonize all those provisions applying to food-stuffs which may impede trade in coffee extracts and chicory extracts" ([45]), leaving to national provisions a large possibility to maintain derogations to the harmonized provisions, with reference both to the characteristics of the products, and to names and labels, confirming a situation of substantial stall, with a partial and unfinished harmonisation.

The important Directive on labelling, presentation and advertising ([46]) must be added to this short list. This Directive, adopted at the end of the '70s on the basis of Article 100 TEEC, introduced horizontal rules applicable to the generality of foodstuffs to be delivered to the ultimate consumer. As in the first Directives of the '60s, "*Free circulation*" of foodstuffs and "*smooth functioning of the common market*" ([47]), are the key words to justify the adoption of "*Community rules of a general nature applicable horizontally to all foodstuffs put on the market*" ([48]). Also the "*need to inform and protect the consumer*" ([49]) is indicated among the reasons of the new uniform discipline. But the "*health protection*" evoked in the Directives of the '60s ([50]) is not mentioned.

With this Directive, the process of harmonisation goes a step further in the area of market communication, but does not enter into the merits of production processes, and does not deal with the sensitive issue of the "*names*" of the foodstuffs, accepting a persistent non-harmonization. Except in the few cases of previous harmonisation ([51]), the Directive

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([43]) Council Directive 77/436/EEC of 27 June 1977.

([44]) See above.

([45]) Recital 4 Dir. 77/436.

([46]) Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer. See Chapter XIX.

([47]) Recitals 1, 2 of Dir. 79/112/EEC.

([48]) Recital 3 of Dir. 79/112/EEC.

([49]) Recital 6 of Dir. 79/112/EEC.

([50]) See para 2, above.

([51]) See above.

largely left untouched the different existing rules (legal or customary) applied in any single sale market, stating: "The name under which a foodstuff is sold shall be the name laid down by whatever laws, regulations or administrative provisions apply to the foodstuff in question or, in the absence of any such name, the name customary in the Member State where the product is sold to the ultimate consumer" ([52]).

Only in the following decade, will the central issue of the names used to designate products be dealt with, but through judicial interventionism rather than through regulatory measures.

3. The '80s: judicial interventionism

Even in the '80s, provisions regarding food law were introduced within the CAP measures on the Common Organisation of agricultural Markets (CMO) ([53]).

But the material shift toward a EFL system, with common shared principles ([54]), characterised by a plurality of values, interests and objectives, and by a complex multi-level rule-making system, took place on new original bases, in strict relation with the critical issues (both of food safety, and of economic development and competition) raised by the removal of national borders and customs and by the process toward a unified European domestic dimension.

During the '80s, the accession to the EEC of three Mediterranean countries, Greece, Spain and Portugal, all with relevant and specific agro-food productions, deeply rooted in their respective traditions and a significant part of their economic systems, gave rise to an enrichment of diversities. As a result, the need to remove national obstacles to free trade of foodstuff became more urgent, requiring innovative legal tools.

The new pillars of *legal innovation* (Albisinni 2009a), which contributed to the building of the EFL system, may be identified in:

– the construction and consolidation of the judicial doctrine of "*mutual recognition*" through the creative work of the Court of Justice;

([52]) Art. 5(1) Dir. 79/112/EEC – original text.

([53]) See Chapter XVIII.

([54]) See Chapter I.

– the construction of the internal market, through the engagement of the European Institutions after the approval of the Single European Act in 1986 and of the Maastricht Treaty in 1992.

The doctrine of "*mutual recognition*" is the decisive contribution of the Court of Justice, in answer to the substantial stalemate position in the regulatory strategy intended to assure free circulation of goods in the European Community.

The judicial unification of the European market moved from a broad interpretation of the prohibition of "*measures having an equivalente effect*" to quantitative restrictions on imports and exports, established by Articles 31 and 34 TEEC.

The case which opened the way was a well known decision of 1974, the *Dassonville* case, which – with reference to a Belgian law which required importers of Scotch whisky the possession of a certificate of origin from the British custom authorities even in the case of Scotch whisky already in free circulation in France – declared that: "*The requirement of a member state of a certificate of authenticity which is less easily obtainable by importers of an authentic product which has been put into free circulation in a regular manner in another Member State than by importers of the same product coming directly from the country of origin constitutes a measure having an effect equivalent to a quantitative restriction as prohibited by the Treaty.*" ([55]).

Starting from the rationale of this case and confirming the broad interpretation of Articles 31 and 34 TEEC, in 1979 the leading case *Cassis de Dijon* ([56]) introduced the principle of "*mutual recognition*", adopting the "*equivalence*" principle as the basis to unify the internal market while respecting diversities (Torchia 2006).

It was disputed whether it was possible to authorize the import and sale in Germany of a French liqueur, the *Cassis de Dijon*, with an alcoholic grade (between 15° and 20°) inferior to the minimum (25°) required by German law to authorize the sale of fruit liqueurs.

With an historical decision, the Court of Justice affirmed that any product, admitted for sale in any MS, may be sold freely in any other MS on a basis of "*mutual recognition*" under Article 30 TEEC, because any

([55]) ECJ, 11 July 1974, Case 8/74, *Dassonville*.

([56]) ECJ, 20 February 1979, Case 120/78, *Rewe Zentral*. See Chapter I.

limitation to import and sale would be "*a measure having an effect equivalent to a quantitative restriction*", save for prohibitions and restrictions justified on grounds of public morality, public policy or public security, protection of health and life of humans, animals or plants, protection of national treasures of artistic, historic or archaeological value, or protection of industrial or commercial property, as per Article 36 TEEC.

The principle of *mutual recognition* effectively opened national markets, obtaining through *equivalence* the result that previously could not be obtained through *legislative harmonization*.

During the '80s, *mutual recognition*, initially applied to objective characteristics of food products, was progressively extended to the use of *names*. The Court of Justice reached the conclusion that a food product, sold in one MS with a certain name, must be admitted for sale with the same name in any other MS, even when it does not have the characteristics and qualities required by the national law of the MS where it is imported, save the introduction of supplementary indications and information on the label.

The principle was largely applied by a series of subsequent judgements, which clarified, e.g., that a product made in the UK and named "*pasta*" in the country of origin must be admitted for sale with the same name also in Italy, even if prepared with a flour not obtained from durum wheat, contrary to a long lasting Italian legislation admitting only durum wheat flour to produce "*pasta*" in conformity to the traditional method of obtaining this typical Italian product ([57]); and that a beverage, made in France and named "*bier*" according to French law, may be sold with the same name in Germany, even when obtained with methods and materials different from those strictly prescribed by a long lasting German legislation ([58]).

In other words, the mutual recognition principle, affirmed by the Court of justice with reference to the recipes of food products, during the '80s was rapidly extended to cover issues related to language and communication.

The case of vinegar is exemplary, due to the plurality of judicial and regulatory interventions, which saw the Court of Justice assume a central role of final rule-maker.

([57]) ECJ, 14 July 1988, Case 90/86, *Zoni*.

([58]) ECJ, 12 March 1987, Case 178/84, *Commission of the European Communities v Federal Republic of Germany*.

In the short term of five years, the Court of Justice pronounced three decisions regarding Italian legislation on vinegar.

In 1980 ([59]), deciding on the case of two shopkeepers of Bozen, who were selling a German vinegar obtained from apples and not wine and therefore were subject to a criminal trial for violation of an old Italian law prohibiting the sale of any vinegar not obtained from wine ([60]), the Court of Justice confirmed the criterion of *mutual recognition* adopted in the *Dassonville* case and declared that the Italian rule was invalid being a violation of Article 30 TEEC.

The Court recognised that food production rules adopted in one MS are applicable in any other MS, with no need of any "recognition" procedure to allow the free trade in all MS of all the foodstuffs produced according to the rules of any State, even if different from the rules of the State where the foodstuff is imported and sold.

The first judgement decided only on issues related to the rules of production, without investing the different issue of the communication rules.

Ascertained the legitimacy, on the basis of the EEC Treaty, of the trade of foodstuffs very different from those traditionally admitted in the National internal markets, the competition among food producers and traders (and among National and European rule-makers) moved towards the use of language in market communication.

One year after, with a judgement of 1981 ([61]), the Court, deciding on an application from the Commission of the European Communities, confirmed the principle on the free trade of vinegar even if not obtained from wine, and went on to deal with the issue regarding names of products, concluding that Italy, reserving the name "*vinegar*" only to products obtained through the acetic fermentation of wine, violated Article 30 TEEC.

The Italian Parliament tried to bypass the ruling of the Court of Justice, separating rules on production from rules on language

([59]) ECJ, 26 June 1980, Case 788/79, *Gilli*.

([60]) Art. 51 D.Pres. 12 February 1965, No 51, as amended by Art. 20 of Law 9 October 1970, No 739.

([61]) ECJ, 9 December 1981, Case 193/80, *Commission v. Italian Republic*.

communication, and with a Law of 1982 ([62]) allowed the free import and trade of vinegars obtained from raw materials different from wine, but reserved the specific name "*aceto*" (i.e. vinegar) only to those products obtained from wine, assigning the generic name "*agro*" (i.e. sour) to the products obtained from different raw materials. The European Commission asked the Court of Justice to declare the new Italian law illicit, and the Court, with a decision of 1985 ([63]), declared that Italy, by adopting the mentioned Law of 1982, was not complying with the judgement of 1981, and therefore was violating Article 171 TEEC.

At the end of this judicial and legislative conflict, today any product obtained through acetic fermentation of any sort of fruit, and not only of wine, may be imported and sold in Italy with the name of "*aceto*" (vinegar).

4. The '90s: internal market

The second pillar of the EFL system emerged in the '90s, within the construction process of the internal market, started with the Single European Act of 1986, consolidated with the Maastricht Treaty of 1992, and solicited by the enlargement of the EU to new MS ([64]) and by the need to tackle the challenges of globalisation and of the new international order introduced by the Marrakech Treaty of 1994 and by the subsequent negotiations ([65]).

The regulatory scenario changed radically with the introduction in the TEEC of Article 100a ([66]), on the adoption of "the measures for the approximation of the provisions laid down by law, regulation or administrative action in member States which have as their object the establishment and functioning of the internal market" ([67]), which assigned

([62]) Law 2 August 1982, No 527.

([63]) ECJ, 15 October 1985, Case 281/83, *Commission v. Italian Republic.*

([64]) Austria, Finland and Sweden.

([65]) See Chapter VI.

([66]) Introduced by the Single European Act, and partly modified by the Maastricht Treaty.

([67]) Art. 100a as amended by the Maastricht Treaty, later Art. 95 TCE, and now Art. 114 TFUE, with a drafting partially different, which leaves the special legislative procedure and adopts the ordinary legislative procedure.

the regulatory competence to the majority of Council (together with the EP, under the cooperation procedure and later under the co-decision procedure), instead of assigning it to the unanimity as requested by the original Article 100 TEEC (later Article 94 TEC) ([68]).

The new provision permitted to extend the Community rule-making process to many sectors of food production and market, previously regulated only by national rules.

Article 100a was in fact largely used to overcome regulation differences among MS; differences which were originally much greater for food products than for other products, by reason of the strong territorial roots of food traditions as an element of identity and cultural heritage.

As to the content of the forecast new measures, Article 100a specified: "The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a *high level of protection*" ([69]). Such provision was in syntony with the rules, also introduced by the Single European Act and the Maastricht Treaty, extending the competence of the Community to the protection of public health (Article 129) ([70]), to consumer protection (Article 129a) ([71]), and to preserving, protecting and improving the quality of the environment and assuring a rational utilization of natural resources (Article 130r).

The objectives of obtaining a *high level of protection of health*, together with the establishment of the *internal market*, are largely present in food legislation in those years, adopted on the basis of Article 100a.

A relevant step in the path towards the EFL system, as a legal system common and shared among Member States, may be seen in two Council Directives of June 1989, which in an innovative and explicit way

([68]) See Chapter I.

([69]) Art. 100a(3) TEEC; italics added.

([70]) Later Art. 152 TEC, amended with specific reference to cover "measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health". See Chapter I.

([71]) Later Art. 153 TEC.

expressed a renewed interest in the theme of hygienic control of food products: Directive 89/396/CEE ([72]) and Directive 89/397/CEE ([73]).

The first Directive introduced provisions on the identification of the "*lot*" to which a foodstuff belongs ([74]), adopting a definition of "*lot*" of general application, according to which "lot means a batch of sales units a foodstuff produced, manufactured or packaged under practically the same conditions" ([75]).

The second Directive introduced general principles at European level, "for the performance of official control of foodstuffs" ([76]).

The legal basis of both Directives is Article 100a TEEC, i.e. the provision mentioned above introduced by the Single European Act of 1986, entered in force only two years before the two Directives, and aimed to favour the establishment and functioning of the internal market.

Specifically, Directive 89/396/EEC on the identification of the lots of foodstuffs, after the premise that "whereas it is necessary to adopt measures with the aim of progressively establishing the internal frontiers in which the free movement of goods, persons, services and capital is ensured; whereas trade in foodstuffs occupies a very important place in the internal market" ([77]), concluded that "indication of the lot to which a foodstuff belongs meets the need for *better information on the identity of products*; ... it is therefore a useful source of information when foodstuffs are the subject of dispute or constitute a health hazard for consumers" ([78]).

It must be underlined that Article 2(2) of Directive 89/396/EEC exempted from the application of the new rules the agricultural products which, on leaving the holding, are "sold or delivered to temporary storage, preparation or packaging stations; transported to producers' organizations; or collected for immediate integration into an operational preparation or processing system;". Such provision confirmed

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([72]) Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs.

([73]) Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs.

([74]) Art. 1(1) of Dir. 89/397.

([75]) Art. 1(2) of Dir. 89/397.

([76]) Art. 1(1) of Dir. 89/397.

([77]) Recital 1 of Dir. 89/396.

([78]) Recital 3 of Dir. 89/396; italics added.

the prevailing model which, until the mad cow crisis and the approval of Regulation No 820/1997 and then of Regulation No 178/2002, focused on food only after the primary agricultural phase, exempting this phase from rules ordinarily applied to the manufacturing and transformation phases of the food chain.

Even with this limitation, adopted for reasons largely related to political and social considerations, the rules introduced by this Directive manifested their nature as elements of a general framework legislation, aimed to offer a systemic design, within which further provisions could be progressively inserted, at National and European level.

Identification of lots is not a goal in itself, but it is a measure to reach other goals, which are in the field of trade development and free circulation of goods, and at the same time in that of protecting consumers from health hazards and allowing more efficient and direct intervention when a health hazard is identified.

A similar approach is present in Directive 89/397/EEC on the official control of foodstuffs, which starts from the consideration that "trade in foodstuffs is one of the most important aspects of the common market" ([79]), underlines that "all the Member States must endeavour to protect the health and economic interests of their citizens" and that "the protection of health must be given unconditional priority and ... therefore, official control of foodstuffs must be harmonized and made more effective" ([80]), observes that "the differences between national legislations with respect to this type of control are such as to represent barriers to the free movement of goods" ([81]), and concludes that "legislation on foodstuffs ... contains provision on health, rules on quality designed to protect consumers' economic interests as well as provisions on consumer information and fair commercial transactions; ... Whereas, first of all, the general principles governing the carrying-out of such control must be harmonized; Whereas, although it is primarily for Member States to lay down their inspection programmes, *it is necessary, with a view to the completion and operation of the internal market, to arrange also for coordinated programmes at Community level*;" ([82]).

([79]) Recital 1 of Dir. 89/397.
([80]) Recital 1 of Dir. 89/397.
([81]) Recital 2 of Dir. 89/397.
([82]) Recital 16 of Dir. 89/397; italics added.

The objectives pursued are more complex than those traditionally assigned to national rules on foodstuff, and cover broader regulation areas than those typical of long lasting national criminal legislations on the composition and the objective hygienic quality of foodstuff.

In this new European legislation, alongside the typical issues of hygienic rules, emerge the economic interests of consumers, and even other consumer interests, without immediate direct economic relevance, but which rather refer to collective demands of preventive protection, such as the right to fair and complete information and fairness in commercial transactions.

A further decisive step in the construction of the EFL system was marked in 1993 by Directive 93/43/EEC on the hygiene of foodstuff ([83]).

Also this Directive indicated Article 100a TCEE as its legal basis and, only a few months after the entry into force of the Maastricht Treaty (1 January 1993), adopted an integrated approach, assuming that "Whereas the free movement of foodstuffs is an essential pre-condition for the completion of the internal market; whereas this principle implies *confidence* in the standard of safety of foodstuff for human consumption in free circulation, and in particular their standard of hygiene, *throughout all stages* of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer" ([84]); "Whereas the *protection of human health* is of paramount concern" ([85]); "Whereas, however, *a food business operator is responsible* for the hygiene conditions in his food business" ([86]); "Whereas food business operators must ensure that only foodstuffs not harmful to health are placed on the market and appropriate powers should be granted to the competent authorities to protect public health; whereas, however, the legitimate rights of food businesses should be guaranteed" ([87]).

Obtaining *confidence* in the standards of safety of foodstuff, guaranteeing the respect of standards *throughout all stages* of the food chain, counting on the *self responsibility of food business operators*, are the key words in this Directive, which introduced the HACCP method in the

([83]) Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs.
([84]) Recital 1 of Dir. 93/43; italics added.
([85]) Recital 2 of Dir. 93/43; italics added.
([86]) Recital 9 of Dir. 93/43; italics added.
([87]) Recital 12 of Dir. 93/43.

legal armoury of rules on production and trade of foodstuff, borrowing this method from the space industry (Costato 2007a), and bringing relevant innovations to the regulatory framework.

The Directive adopted a unitary category of "*food business*" covering all stages after primary production and including "*any undertaking, whether for profit or not and whether public or private, carrying out any or all of the following*: preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling or offering for sale or supply of foodstuffs" ([88]).

The agricultural phase of food production remained exempted from the application of the new rules and responsibilities, but all other stages along the food chain were submitted to a unitary regime.

All food business operators are called to "identify any step in their activities which is critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed on the basis of the ... principles, used to develop the system of HACCP (Hazard analysis and critical control points)" ([89]).

The adoption of systems of hazard analysis and management based on the control of critical points, with a particular emphasis on *self control* and *self responsibility* of food operators, introduced dynamic models of organisation and of protection, more flexible than the traditional national food safety systems, which (e.g. in the Italian legal system) ([90]) largely resolved themselves only in general and non flexible static provisions on equipment and premises, and in *ex post* checks on products.

Favouring the development and adoption of good hygiene practices, at European and national level ([91]), made it possible to maintain diversity among food products and production methods, privileging self responsibility of the operators, hinging on shared behaviour and culture on health protection as intrinsic elements of conscious food production, and not limiting rules to external order.

With this innovation, food operators are called to play a proactive role in the pursuit of food safety, requiring them to invest in education,

([88]) Art. 2 Dir. 93/43; italics added.
([89]) Art. 3(1) Dir. 93/43.
([90]) See Italian Law No 283 of 30 April 1962.
([91]) Art. 5 Dir. 43/93.

administration and management (with possible consequent difficulties for small traditional producers, not accustomed to and not prepared for such organisation), but at the same time behaviour and production methods acquire much greater relevance than is usual in national provisions.

The rules establishing "*what to do*" and fixing "*product characteristics and qualities*" are integrated, with Directive 43/93, by rules on "*how to do*".

The result – only apparently paradoxical – is that the Directive of 1993, aimed at the completion of the internal market, adopted a model of harmonization, based on *self-responsibility*, which has given single food operators ample opportunities of differentiation and variety, as long as the criteria and goals of HACCP are accomplished.

The flexible approach of Directive 43/93 is shared by other Community acts of the same years, such as Directive 92/46 of 1992 on milk products ([92]). This Directive, while adopting common health rules for the production and placing on the market of raw milk, heat-treated milk and milk based products, acknowledged expressly that "it seems necessary to exclude from the scope of this Directive certain products sold directly by the producer to the consumer;" ([93]), and admitted that "low-capacity establishments should be approved by means of simplified structure and infrastructure criteria, while complying with the rules of hygiene laid down in this Directive;" ([94]). On this basis the Directive established that "For the manufacture of cheese with a period of ageing or ripening of at least 60 days Member States may grant individual or general derogations" ([95]), "Member States may, in so far as certain requirements of this Directive are likely to affect the manufacture of milk-based products with traditional characteristics, be authorized to grant individual or general derogations" ([96]), and that "Member States may, when granting approval, grant derogations from the provisions ..., to establishments manufacturing milk-based products whose production is limited." ([97]).

([92]) Council Directive 92/46/EEC of 16 June 1992.
([93]) Recital 6.
([94]) Recital 11.
([95]) Art.8(1).
([96]) Art. 8(2).
([97]) Art. 11(1).

With those provisions, the Directive on the safety of milk products established general lines finalized to the harmonisation of applicable rules among MS, but at the same time allowed different regimes, on the basis of elements such as traditional methods of production, ageing or ripening, limited production, direct sales within limited areas.

In other words, the Directives approved in the late '80s and the early '90s on the basis of Article 100a, after the Single Act and the Maastricht Treaty, moved toward the construction of some systemic elements, mainly to favour harmonization, but not neglecting diversities and peculiarities. The rules and procedures thereby introduced were not limited to specific products, and tendentially included the entire food chain and "*any undertaking, whether for profit or not and whether public or private*" ([98]), taking into account peculiarities and responsibilities of all the phases of food production, after the primary production, aiming to integrate Community provisions and national rules.

Even the persistent exclusion of the primary phase of production from the application of the new rules, and the exclusion of farmers from the definition of "*food business*" (exclusion which will be removed only with Regulation No 178/2002) ([99]) could not be interpreted as a rejection of the emerging systemic design.

Indeed, the moment of separation of fruits (harvesting, slaughtering or milking) ([100]) marks the moment when the foodstuff enters the food chain, and from this moment all food business actors are (under the above mentioned legislation) considered in a unified way, throughout all phases.

It is therefore possible to see the emerging tendency toward the construction of a European Food Law system, which in a short time span started to be provided with rules of general application, together with provisions of specific interest.

5. Multiple goals of European food legislation

The characteristic element of European food legislation during the first half of the '90s was that of pursuing multiple goals.

([98]) Art. 2 Dir. 93/43; italics added.

([99]) See Chapter VIII.

([100]) Art. 2 Dir. 93/43.

Together with the mentioned objectives prompting the completion of the internal market through "*confidence* in the standard of safety of foodstuff" ([101]) and "*protection of human health*" ([102]), other interests and values emerged as worthy of legislative attention, above all issues of food quality and diversity.

The judicial doctrine of "*mutual recognition*" opened the borders to the free circulation of foodstuffs, but led to the risk of a "*banalisation*" of traditional recipes of food, neglecting territorial and cultural roots (Germanò 2007).

In answer to those concerns, Regulations No 2081/92 on PDOs and PGIs ([103]) and No 2082/92 on AS ([104]), adopted on the basis of Article 43 TEEC, and therefore as part of the CAP, introduced a new unified regulatory frame, applicable to a large area of quality productions, including not only agricultural products defined as such by Annex II TEEC, but also other agricultural products and – significantly – foodstuffs not included in the list of Annex II and mentioned in further lists expressly introduced by the new Regulations ([105]).

The interest in a pluralistic dimension of the food discipline found explicit expression in those acts, which expressed the European attention to peculiar qualities (and to cultural and territorial roots) of foodstuffs, recognizing the peculiarities of productions and products ([106]) and the related need of diversified disciplines, referred both to products and production methods and to labelling and market communication ([107]).

In the same perspective, Regulation No 2092/91 on organic production of agricultural products ([108]), also adopted in the early '90s

([101]) Recital 1 of Dir. 93/43; italics added.

([102]) Recital 2 of Dir. 93/43; italics added.

([103]) Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs.

([104]) Council Regulation (EEC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs.

([105]) Art. 1 Reg. No 2081/92, and Art. 1 Reg. No 2082/92.

([106]) Recital 3 Reg. No 2081/92.

([107]) See Chapter XXIII.

([108]) Council Regulation (EEC) No 2092/91 of 23 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs. See Chapter XXIV.

on the basis of Article 43 TEEC as part of the CAP, considered both the primary phase of production and the following phases of processing, preserving and packaging, and introduced provisions which regulated the production method and the inspection system, together with labelling and marketing, adopting a unitary regulatory approach, applicable to the entire food chain.

The complex pluralistic food law system, emerging (albeit with contradictions and conflicts – Albisinni 2009) within the process of harmonization of rules and implementation of the internal market, found significant new expression in the Court of Justice doctrines.

A judgement of 1992 ([109]) decided on the legitimacy of a Convention stipulated between the French Republic and the Spanish State on 27 June 1973 (before the entrance of Spain in the EEC) on the protection of designations of origin, indications of provenance and names of certain products. This Convention provided that the names "*Turrón de Alicante*" and "*Turrón de Jijona*" were, in the territory of the French Republic, reserved exclusively to Spanish products or goods.

A French Court, asked by Spanish producers to prohibit French producers the use of those names for similar products, asked the Court of Justice whether "Articles 30 and 34 of the EEC Treaty [were] to be interpreted as prohibiting the measures for the protection of designations or indications of origin or provenance laid down in the Franco-Spanish Convention of 27 June 1973, in particular the designations or indications 'Alicante' or 'Jijona' for 'Tourons'" ([110]).

During the discussion of the case the Commission concluded that the requested application of the special protection afforded by the 1973 Convention was contrary to Articles 30 and 34 TEEC, as it was not demonstrated that the product under examination "possesses qualities and characteristics which are due to its geographical place of origin and are such as to give it its individual character." ([111]).

The Court of Justice rejected the position of the Commission, considering that:

([109]) ECJ, 10 November 1992, Case C-3/91, *Exportur SA v LOR SA and Confiserie du Tech SA*.

([110]) ECJ, Case C-3/91, point 6.

([111]) ECJ, Case C-3/91, point 27.

"28 The Commission' s position, which is in line with that of LOR and Confiserie du Tech, cannot be accepted. *It would have the effect of depriving of all protection geographical names used for products which cannot be shown to derive a particular flavour from the land and which have not been produced in accordance with quality requirements and manufacturing standards laid down by an act of public authority, such names being commonly known as indications of provenance. Such names may nevertheless enjoy a high reputation amongst consumers and constitute for producers established in the places to which they refer an essential means of attracting custom.* They are therefore entitled to protection." ([112]), and decided that: "Articles 30 and 36 of the Treaty do not preclude the application of rules laid down by a bilateral convention between Member States on the protection of indications of provenance and designations of origin, such as the Franco-Spanish Convention of 27 June 1973, provided that the protected names have not, either at the time of the entry into force of that Convention or subsequently, become generic in the country of origin" ([113]).

As a result, expressions like "*reputation amongst consumers*" and "*quality requirements*", emerged as relevant regulatory criteria in a complex EFL framework which, in the first half of the '90s, was gaining a multiplicity of goals, interests and values, through the cooperative and competitive intervention of legislative and judicial rule-makers.

6. Food safety crises and the new disciplinary framework

The reference frame was dramatically modified in the late '90s, due to some serious food safety crises, which gained large eco amongst the general public: from BSE (bovine spongiform encephalopathy) to dioxin.

As a result, general confidence and trust in the effectiveness of existing rules on food safety was largely undermined, the market in beef and beef products was heavily destabilized, and the European legislator was pressed to find rapid answers, within an approach which, by its nature and its object, required an overall systemic design.

([112]) ECJ, Case C-3/91, point 28; italics added.
([113]) ECJ, Case C-3/91.

The regulatory solutions adopted were situated at different levels and operated through different tools.

On a technical level, some specific hygienic measures were introduced, e.g. the prohibition to use meals of animal origin to feed bovine animals, and to trade and use some parts of bovine animals, and the duty to slaughter the entire cattle in case of suspected BSE.

But the most original answer was introduced on the administrative level by Regulation No 820/97 ([114]), with the adoption of a new legal tool, until then unknown to the legal jargon (except limited cases in finance and public procurement law) and common only in scientific language: *traceability*.

Traceability may not be defined as a hygienic measure as such. It refers to a series of provisions including identification, controls, and documentation, which focuses on self-responsibility asking food business operators to adopt a proactive participative role in food law (as happened with Directive 93/43/CEE and the HACCP method), and introduces basic elements to favour the dialogue between controllers and producers.

The entire path of beef products is documented, using specific tools, such as the "*animal passports*" which each bovine animal should receive a few days after its birth ([115]).

And the new Regulation for the first time fully involved the primary production in the responsibilities for food safety of beef products, strongly innovating the disciplinary framework of the food chain.

With these legal innovations the Community legal system reacted in an original way to the challenges posed by technical innovations in the bovine food sector. According to prevailing scientific opinions, the BSE epidemic was originated and spread by the use of meals of animal origin to feed bovine animals, and therefore it was an unforeseen negative consequence of technical innovation.

In other words, with the Regulation of 1997, EFL reacted to risks caused by technical innovations, not limiting its intervention to the

([114]) Council Regulation (EC) No 820/97 of 21 April 1997 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products.

([115]) Art. 6 Reg. No 820/97.

consolidated area of hygienic rules, but moving toward the adoption of provisions strongly innovative in their legal design.

On this occasion, hygienic provisions were also adopted, but they were deemed insufficient as such, and were accompanied by a renewed model of regulation, based on original forms of control and responsibility.

The measures adopted include two groups of provisions:

– those introducing a system for the identification and registration of bovine animals, including eartags to identify animals individually with unique identification codes, computerized databases, animal passports, individual registers kept on each holding ([116]), compulsory labelling of any beef product put on sale including a reference number or reference code ensuring the link between, on the one hand, "the identification of the carcase, quarter or pieces of meat" and, on the other hand, the individual animal ([117]); i.e. ensuring *traceability*;

– those introducing compulsory *labelling from large areas*, establishing that the label on any individual piece or pieces of meat or on their packaging material should include indications of: "– Member State, third country or holding of birth; – Member States, third countries or holdings where all or any part of fattening took place, with partial fattening having to be specified; – Member State, third country or slaughterhouse where slaughter took place;" ([118]).

Together with the content, the interest of the new regulation lies in the legal basis adopted by the Council, Article 43 TEC alone and therefore CAP, without mentioning Article 100a, largely used in early '90s to promote harmonization (i.e.: unification) of food safety legislation ([119]).

The Commission of the European Communities brought an action under Article 173 TEC against Regulation No 820/97, contesting not the content of the Regulation, but the legal basis adopted, assuming that it should be approved on the basis of Article 100a (and therefore with the co-decision of the European Parliament), and not on the basis of Article 43 (which left the adoption to the majority of the Council). The European Parliament supported the action of the Commission.

([116]) Art. 6 Reg. No 820/97.

([117]) Arts 14 and 16 Reg. No 820/97.

([118]) Art. 16 Reg. No 820/97.

([119]) See *supra* para 4.

The Court of Justice dismissed the application, with a decision of 4 April 2000 ([120]), with this exemplary motivation:

"...Article 43 of the Treaty is the appropriate legal basis for any legislation concerning the production and marketing of agricultural products listed in Annex II to the Treaty which contributes to the attainment of one or more of the objectives of the common agricultural policy set out in Article 39 of the Treaty. ... Moreover, the protection of health contributes to the attainment of the objectives of the common agricultural policy which are laid down in Article 39(1) of the Treaty, particularly where agricultural production is directly dependent on demand amongst consumers who are increasingly concerned to protect their health. ... The contested regulation thus concerns the production and marketing of agricultural products listed in Annex II to the Treaty. ... As regards the aim of the contested regulation, it must be observed that, according to the first recital, it is intended to re-establish stability in the beef and beef products market, destabilised by the BSE crisis, by improving the transparency of the conditions for the production and marketing of the products concerned, particularly as regards traceability. ... *It must therefore be held that, in regulating the conditions for the production and marketing of beef and beef products with a view to improving the transparency of those conditions, the contested regulation is essentially intended to attain the objectives of Article 39 of the Treaty, in particular the stabilisation of the market.* ... It was, therefore, rightly adopted on the basis of Article 43 of the Treaty." ([121]).

The Court therefore recognised to Regulation No 820/97, more than to any other previous regulatory act, the nature of exemplary act, looking to food legislation within a systemic framework, unifying in a plurifunctional discipline market transparency, competition issues, health protection goals, getting over the borders among different law fields, and joining in a unified shared legal ambit the consumers and all actors of the food chain, including those operating in the primary phase.

The judicial decision was published on 4 April 2000. The date is relevant, because it was only a few months prior to the new Regulation

([120]) ECJ, 4 April 2000, Case C-269/97, *Commission of the European Communities v Council of the European Union*.

([121]) ECJ, Case C-269/97, points 47, 52, 53, 59, 60; italics added.

No 1760/2000 on beef meat of July 2000 ([122]), which repealed Regulation No 820/97 and adopted as its legal basis not only Article 37 TEC ([123]), but also Article 152 TEC, according to which "A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.", therefore following the co-decision procedure of Article 251 TEC, healing the political breach between Parliament, Commission and Council.

At the time of the decision, the conflict between European institutions was in the process of being settled, and the issue no longer concerned competences and regulatory powers, but the consolidating systemic dimension of EFL, in a fruitful dialogue between judicial and legislative European rule-makers.

In this sense, the double legal basis adopted in the new Regulation (re-echoing, in a more complex and updated perspective, the trasversal objects and goals of '70s Directives) ([124]) expressed a largely shared acceptance of such systemic dimension.

7. The new century: Regulation No 178/2002 and the systemic dimension

The decisive and declared step toward the achievement of the systemic dimension, at the end of the XX century and in the first years of the new century, is marked by the White Paper of 2000 of the European Commission on Food Safety ([125]), which planned as many as 84 different administrative and regulatory actions and measures, intended to design an overall framework.

The characteristic element of the entire proposal was the integrated food chain approach, with the inclusion of the agricultural phase of

([122]) Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97.

([123]) Ex Art. 43 TEEC.

([124]) See *supra* para. 2.

([125]) Commission of the European Communities, White Paper on Food Safety, Brussels 12 January 2000, COM (1999) 719 final.

production into a general project of food safety, intending to cover "all aspects of food products from '*farm to table*'", as indicated by the Commission with an expression which soon will become famous.

The expression well illustrates the global perspective of food safety, spreading responsibility over all the actors of the food chain, including farmers until then only partially and exceptionally subject to general rules, save the anticipatory case of Regulation No 820/97 on bovine animals.

The architrave of the systemic plan was rapidly implemented with the approval of Regulation No 178/2002 ([126]), whose Chapter II, named "General Food Law", makes specific reference to the "principles laid down in Articles 5 to 10 ... [to] form a *general framework of a horizontal nature*" ([127]).

The preamble of the Regulation indicates as legal bases, in one single context, Articles 37 (CAP), 95 (Approximation of national provisions), 133 (Common commercial policy), 152(4)(b) (Health protection), thereby evidencing – even at formal level – the multiplicity of objects, values, interests and goals affected by food law legislation ([128]).

In other words, the multiplicity of legal bases corresponds to the plurality of trasversal obiects and goals, dealing with multiple areas and needs, and to the innovative character of Regulation No 178/2002, adopting new or newly designed legal models and tools. Traditional borders between production and communication rules are weakened, and the prevalent regulatory criteria is that of *responsibilities*, both public and private, with a functional design of governance ([129]).

Undertakings and business operators are called to operate within an integrated framework of regulatory competences, with innovative rules, on organisation, relation, and liability, which operate together with the traditional rules on production and products (Albisinni 2009a), and which expresse the *proactive innovative* approach of the European legislator.

As well observed by an authoritative scholar, Regulation No 178/2002 operates on different levels: "that of *law sources*, ... [where it] introduces

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([126]) 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.

([127]) Art. 4(2) Reg. No 178/2002. See Chapter I.

([128]) See *supra* para 2 on the Directives of the '70s and para 6 on Reg. No 1760/2000.

([129]) See Art. 17, entitled "*Responsibilities*" of Reg. No 178/2002.

general principles ... establishes rules directly applicable, which do not need national execution measures; ... that of the *institutional design* to be adopted by any Member State; ... that of *cooperation* to provide among national organizations and Community organisation" (Cassese 2002).

This Regulation, in particular, expressly declares its systemic nature of act which "lays down the *general principles* governing food and feed in general, and food and feed safety in particular, at *Community and national level*" ([130]), providing principles of general interpretation ([131]), operating as general uniform criteria applicable both to new rules and to the existing ones, at Community and national level, in the perspective of unified regulation.

The "assurance of a high level of protection of human health and consumers' interest in relation to food" is confirmed as the first goal of the EFL, but "the diversity in the supply of food including traditional products" and "the effective functioning of the internal market" are also taken into account ([132]), confirming the plurifunctional approach adopted.

The Regulation establishes the European Food Safety Authority ([133]), and lays down a series of institutional provisions, competences and procedures (it is sufficient here to mention Chapter IV of the Regulation on Rapid Alert System, Crisis Management and Emergencies) ([134]).

Among the many relevant principles, definitions ([135]), and rules directly applicable (IDAIC 2003) ([136]), it is significant to mention the general definition of "*food business*" extended to include "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;" ([137]), covering all stages of the food chain, including the primary stage, as proposed in the Commission White Paper of 2000.

([130]) Art. 1(2) Reg. No 178/2002; italics added.
([131]) See Chapter I.
([132]) Art. 1(1) Reg. No 178/2002.
([133]) See Chapter IX.
([134]) See Chapter XV.
([135]) See Chapter VIII.
([136]) See Chapters I, VIII, IX, XII, XIII, XIV.
([137]) Art. 3(1) No 2; italics added.

The definition makes express reference to *any of the activities* performed in any phase of the food chain, and therefore refers to a model of *phase business*, a business which receives qualification and regime not by reason of performing a comprehensive and homogeneous set of activities, but simply as a consequence of performing a single activity, even non homogenous to the others of the phase, but in any case potentially relevant.

Reference to a *phase business* is not unknown to other legal experiences. In Italy it is sufficient to mention the new definition of agricultural business, as introduced in 2001 ([138]). The category is usually linked to those of chain and net, assigning legal relevance to models until recently considered only by economic analyses.

The result is the emersion of a *food business*, which implies legal regimes, administrative models, rules of organisation and of activity, passing through the traditional distinctions.

In other words, the object of regulation (*food*) and the goal of regulation (*health safety*) induced the European legislator of Regulation No 178/2002 to take note that in this sector a point regulation, referring to single split categories of subjects, could not be effective, and that it is necessary to adopt comprehensive rules, which qualify the actors not by reason of abstract categories, but simply by reason of their participation (whatever it is) in any production, processing or distribution activity.

Private food business actors receive rules, but at the same time they operate as rule-makers, on the basis of self regulation and self responsibility, in a dialogue with public actors, which takes food safety as basic criterion of the legal statute of competition in the food market.

8. A polycentric regulatory system: Globalisation and new sources in the EU Law Making Process

In the first decade of XXI century, and in subsequent years, after Regulation No 178/2002, a large number of regulations and directives have been introduced, building a detailed integrated framework,

([138]) Legislative Decree No 228 of 18 May 2001, modifying Art. 2135 of the Italian Civil Code.

including the "Hygiene Package" ([139]), the "Quality Package" ([140]), the new regulation on the provision of food information to consumers ([141]), the introduction of an uniform accreditation system ([142]), the Single CMO ([143]), and many other horizontal and vertical food rules, introduced or amended during these years ([144]).

The inter-reaction among national administrations and European institutions, first of all EFSA, built up experiences and procedures, within a polycentric regulatory system.

But EFL, in the sense of an institutional set of regulatory acts and of judicial and administrative decisions adopted by the Council, the Commission, the European Parliament, and the Court of Justice, is itself increasingly taking on an *ultranational dimension*, in the two aspects of being influenced (and in some cases directed or even shaped) by external sources and, on the other hand, of acting as source of rules applied well beyond the borders of European Union.

If European rules on quality wines that derive from certain specific regions must conform to the indications of the World Trade Organisation ([145]), European Union, for its part, projects its rules beyond its own borders, with technical rules and health and hygiene requirements. Accordingly, anyone who wishes to export to Europe must conform to the prescribed European technical rules and health and hygiene requirements, thereby putting into effect the model of law that becomes "*another country's national law*" (Galgano 2005).

([139]) See Chapter XIV.

([140]) See Chapter XXIII.

([141]) See Chapter XIX.

([142]) See Chapters XVI and XVII.

([143]) See Chapter XVIII.

([144]) See *infra* in this volume.

([145]) See, e.g., Commission Regulation (EC) No 316/2004 of 20 February 2004, amending Regulation (EC) No 753/2002, laying down certain rules for applying Council Regulation (EC) No 1493/1999 as regards the description, designation, presentation and protection of certain wine sector products, which has been adopted taking into account some claims entered by third parties after the notification of Regulation No 753/2002 to the World Trade Organisation – as expressly stated in whereas (2) and (3) of the Regulation No 316/2004. With reference to subsequent legislation, on the authorisation criteria of oenological practices, see Art. 120*f* of Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation). See Chapter XXVIII.

One may also cite the example – in reference to a specific class of products – of the extension of the rules on PDO and PGI products beyond the boundaries of Europe. Regulation No 692/2003 ([146]), modifying the rules originally introduced in 1992 on PDO and PGI products ([147]), provided for a specific operative procedure for the registration, and consequent safeguarding, as PDO or PGI, of agricultural or food products from third countries, external to the Community. This possibility had been already admitted by Regulation No 2081/92, but at that stage it was no more than the statement of a principle, not accompanied by operative rules, as shown by the circumstance that at the time this opportunity was not used by any third Country. In contrast, Regulation No 692/2003 introduced a specific procedure, identified the legitimated subjects, and set the rules for conflict resolution if the need were to arise ([148]).

It must be noted, nevertheless, that, even after the amendments introduced by Regulation No 692/2003, EC legislation admitted the registration of "agricultural product or foodstuff from a third country" only on the basis of a reciprocity rule, "provided that ... the third country concerned is prepared to provide protection equivalent to that available in the Community to corresponding agricultural products for foodstuffs coming from the Community" ([149]).

Therefore, even after 2003, the reciprocity clause made in fact very difficult to obtain the registration of products from a third country.

In 2005 the reciprocity clause was deemed by the WTO Panel to be unlawful, in a statement issued on the controversy between the USA and the EU on geographical indications ([150]).

([146]) Council Regulation (EC) No 692/2003 of 8 April 2003 amending Regulation (EEC) No 2081/92 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs.

([147]) Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs.

([148]) See Articles 12a, 12b, 12c, 12d, added to Regulation No 2081/92 by Regulation No 692/2003.

([149]) Art. 12(1) of Reg. No 2081/92.

([150]) WTO Panel Report, *United States* v. *European Communities*, 15 March 2005, DS174.

After a short laps of time, Regulation No 510/2006 on PDO and PGI products ([151]) which repealed Regulation No 2081/92, confirmed the possibility to assign this protection to products obtained outside of the Community, and moreover, excluded the reciprocity clause.

After the adoption of Regulation No 510/2006, many geographical designations of products obtained in non EU countries (from Columbia coffee, to tea from certain regions of India, to numerous Chinese products) have obtained effective legal protection within the European Union. ([152])

On the other hand, it must be noted that the innovative European model of PDO and PGI has been voluntarly adopted, during those years, by many third countries and introduced within national legal systems (Şule Songül - Selin Cila 2014).

In short, in this area of food law, European Union is acting as a subject laying down original rules, but providing safeguards as well, even for products obtained beyond its own borders; therefore promoting a model which by itself has transnational elements. Similar measures have been introduced in non EU countries not only through partnership agreements and Association Accords, but also through the adoption of internal rules, which are projected into an external dimension, assuring protection for third country products within the European Union, and for EU products in third countries. Even in absence of a reciprocity clause, institutions springing from within the European market acquire an ultranational dimension and convey their own original model of protection to other legal systems (Albisinni 2004b).

([151]) Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs; recently repealed by Regulation No 1551/2012, which is currently in force and which confirmed the rules of 2006 on the free registration as PDO or PGI of products of third countries.

([152]) Café de Columbia (PGI) entered in the Register of PDO and PGI by Commission Regulation (EC) No 1050/2007 of 12 September 2007. Since then many Chinese products designations have been filed in the Register of PDO and PGI: Jinxiang Da Suan PGI (garlic); Guanxi Mi You PDO (kind of fruits); Lixian Ma Shan Yao PGI (tuber called igname); Longjing cha PDO (thé); Shaanxi ping guo PDO (apple); Longkou Fen Si PGI (vermicelli); Zhenjiang Xiang Cu PGI (vinegar); Yancheng Long Xia PGI (shrimp); Pinggu Da Tao PDO (peach); Dongshan Bai Lu Sun PGI (fruit). The updated list of designations, applied, published, and registered, is published at http://ec.europa.eu/agriculture/quality/door/list.html?locale=en.

Clearly, it hardly needs to be emphasised that *globalisation* is bringing about radical change in the traditional *law-making process*, since "the announced change cannot fail to imply a reconsideration of the method applied in drawing up our rules, on the sources of such rules", on the "relation between *production* and *food*, or rather, between *agricultural product* and *foodstuff*", and this must be considered within the broader context of the interplay between *globalisation* of the rules and *territoriality* as an intrinsic element characterising the "agricultural part" as compared to the "industrial part" of the agri-foodstuff system (Jannarelli 2001).

In this sense *globalisation* appears to be a relevant engine of legal innovation in the EFLS, linked to "the proliferation, as a functional response to the changing needs of the world community, of global regulatory systems by sector" (Chiti-Mattarella 2011).

Such conclusion is especially true in this area of law, where many engines are simultaneously operating, not only by reason of relevant international treaties, recently negotiated ([153]), or under negotiation ([154]), but also (and above all) by reason of a progressive opening of the EFLS, which is increasingly accepting recommendations of international organisations and institutions ([155]), such as the Codex Alimentarius Commission, UNECE, OIV, as sources of *soft law* and in some cases of something near to *hard law* (Albisinni 2010b), as confirmed by recent regulatory experiences.

It may be here mentioned, to give some relevant examples moving in this direction:

([153]) See the EU-Vietnam Free Trade Agreement Treaty, whose text was finally agreed in December 2015, and which is expected to be ratified by both parties and to enter in force in early 2018. See http://trade.ec.europa.eu/doclib/docs/2016/june/tradoc_154622.pdf.

([154]) See TTPI – Transatlantic Trade and Investment Partnership, under negotiation between EU and USA – for a report updated at July 2016 see http://trade.ec.europa.eu/doclib/docs/2016/august/tradoc_154837.pdf; and CETA – Comprehensive Economic and Trade Agreement between Canada, of the one part, and the European Union and its Member States, of the other part – for a report updated at July 2016 see http://ec.europa.eu/trade/policy/countries-and-regions/countries/canada/.

([155]) See Chapter VI.

– Article 2.(3) of Regulation No 178/2002, on definition of "*food*", while for medical products, cosmetics, tobacco and tobacco products, makes reference to EEC directives to establish the difference with food products, for "*narcotic or psychotropic substances*" makes reference to two United Nations conventions ([156]), ruling that «"Food" shall not include: ... g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971». European Union is not a part of those conventions, but as an effect of Regulation No 178/2002 those international sources became immediately operating within the EFLS.

– The Single CMO Regulation of 2007 ([157]) confirming a guideline introduced by Regulation (EC) No 1182/2007 ([158]), established that marketing standards to be adopted by the EU Commission should be drafted "*taking into account, in particular ... as regards the fruit and vegetables and the processed fruit and vegetables sectors, the Standard recommendations adopted by the UN-Economic Commission for Europe (UN/ECE)*" ([159]). UN/ECE was created in 1947 as one of the five regional commissions of the United Nations, to promote; it includes 56 member States in Europe, North America and Asia ([160]). By its nature, UN/ECE tends to operate in favour of uniformity and standardisation, so that "*taking into account*" UN/ECE recommendations could imply to introduce within EU law making process an external source operating along lines and priorities, which may be quite different from those traditionally considered by the representative EU institutions.

([156]) The United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971.

([157]) Reg. No 1234/2007, later repealed by Reg. No 1308/2013, presently in force. See Chapter XVIII.

([158]) Council Regulation (EC) No 1182/2007 of 26 September 2007 laying down specific rules as regards the fruit and vegetable sector, which extended to processed fruit and vegetables a rule previously introduced by Reg. No 2200/96 only for fresh fruit and vegetables.

([159]) Art. 113(2)a(v) of Reg. No 1234/2007, as modified by Reg. No 361/2008 of 14 April 2008; see now Art. 75.5.e) of Reg. No 1308/2013, making reference to "the standard reccomendation adopted by international bodies".

([160]) See www.unece.org.

– With specific reference to the wine sector, both the Single CMO of 2007 ([161]) and the present Single CMO of 2013 ([162]), expressly underline that "*When authorising oenological practices in accordance with the procedure referred to in Article 195(4), the Commission shall: (a) base itself on the oenological practices recommended and published by the International Organisation of Vine and Wine (OIV)*", ([163]) referring to OIV recommended practices also to establish methods of analysis for oenological products ([164]), and to establish rules to accept oenological practice of imported products ([165]). Even in this case, recommendations of an international voluntary organisation, adopted without any clear disclosure of interests involved, may operate directly within the EU law making process.

– Finally, the Commission Regulation No 606/2009 on oenological practices ([166]) presently in force, laying down detailed rules, expressly assigns direct application within EU legal system to the oenological practice approved by OIV with reference to the purity and identification specification of substances used in oenological practices ([167]) (Albisinni 2015).

It appears therefore possible to assume that, through mechanisms of direct or indirect referral, within sensitive areas of EFL, *soft law* originating within institutions of *globalisation* is progressively influencing EU law acquiring in some cases the proper nature of *hard law*.

([161]) Reg. No 1234/2007.

([162]) Reg. No 1308/2013. See Chapter XXVIII.

([163]) Art. 120*f* of Reg. No 1234/2007; see also, with similar wording, Art. 80(3)a of Reg. No 1308/2013. See Chapter XXVIII.

([164]) Art. 120*g* of Reg. No 1234/2007; see also, with similar wording, Art. 80 of Reg. No 1308/2013.

([165]) Art. 158*a* of Reg. No 1234/2007; see also, with similar wording, Art. 90(2) of Reg. No 1308/2013.

([166]) Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions.

([167]) Art. 9 of Commission Regulation EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions, presently in force and frequently amended (last amendment introduce by Commission delegated Regulation (EU) No 2016/765 of 11 March 2016.

A respected scholar of comparative law, coming from studies in a civil law country, and then teaching in a common law country, wrote "*On Uses and Misuses of Comparative Law*" (Kahn-Freund 1974), warning against the dangers of what he qualified as "*legal transplants*" (on this expression see also Watson 1974).

To-day, we must recognize that we are facing a tendency to communication of legal models in European Food Law, which expresses a growing tendency to share models and answers on the basis of shared experiences, in the two aspects of including external sources within the internal legal system and, on the other hand, of acting as source (or at least as model qualified and complied with) of rules that have effect beyond European Union.

Not by chance in the first years of this century, three great legal systems, UE, USA and China, moving from experiences and previous regulations quite diferent among them, adopted relevant legislative reforms in this area of law, introducing substantive and institutional rules, which on many relevant issues share common innovative approaches: from the introduction of the HACCP method, to risk analysis and self-respondibility of food producres, to the unitary consideration of all the phases of the agri-food chain ([168]).

Globalisation of food trade s increasingly linked to sharing legal models in the global arena, and in this perspective comparative law appears to be a precious tool to better know, implement and in same cases reform domestic or regional law (Gorla 1955).

It seems reasonable to imagine that in the next few years we will see further relevant innovations, both institutional and on the substance of regulation, and to conclude that EFLS, with its multiplicity of legal bases, of goals, of legal tools, pays the price of giving systemic order to a sector full of intertwining tensions, but at the same time expresses a sort of *open* laboratory, a peculiar way of European rule-making, moving toward a complex polycentric governance of interests and activities, where International, Global, European, and National levels intersect, and where private and public responsibilities are brought to unity through vertical and horizontal cooperation and subsidiarity.

([168]) See Chapters III and IV.