

Approfondimenti

Eu Food Law Regulation: which opportunities for Italy?

edited by

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Summary

MIRIAM ALLENA, LETTERIO DONATO and MICHELE TRIMARCHI	
I. Preface	5
FRANCESCO FOLLIERI	
II. Risk Management Standards in EU Food Law: Risks of Risk Decisions	9
SCILLA VERNILE	
III. Food Safety between European and National Authorities.....	33
LETTERIO DONATO	
IV. Brief Considerations on the Regulation of Food Labelling	47
LORENZO CUOCOLO and FRANCESCO GALLARATI	
V. Responsibility and Penalties under Regulation 1169/2011 on Food Information ...	55
ANDREA GUERRINI	
VI. Foodstuffs Traceability and Fraud	65
PASQUALE PANTALONE	
VII. The Authorisation Procedure of Health Claims Made on Foods under EC Regulation no. 1924/2006	77
BERNARD O'CONNOR and MIRIAM HAMDAN	
VIII. Geographical Indications as Public (and Private?) Rights.....	91
ALICE VILLARI	
IX. The European System of Protection of the Qualified Geographical Indications	99
MIRIAM ALLENA	
X. Private and Public Organizations in the Protection of Typical Foodstuffs.....	111
ROCCO STEFFENONI	
XI. EU Regulation on Food Waste: A New Challenge?	127
MATTEO FINCO	
XII. Safety, Risk, Opportunity. A Sociological Framework from the Point of View of Social System Theory.....	141
ARISTIDE POLICE	
XIII. Conclusions.....	153

I. Preface

MIRIAM ALLENA, LETTERIO DONATO and MICHELE TRIMARCHI

Public regulation of the food sector within EU is a relatively new phenomenon interconnecting a few extra juridical profiles.

First, the regulation on food may be viewed as a remedy against the s.c. market failures: in terms of reducing asymmetric information between producers and consumers (as it happens, for instance, in relation to the rules on labelling and information that have to be mandatorily given to consumers); in terms of management of food waste and food donations (in view of rebalancing the unfair distribution of food opportunities); or in terms of protecting small and high quality producers through a system of geographical indications that will enable consumers to make more informed choices.

At the same time, a hystorical development is at stake: the relative abundance of foodstuffs in Western Countries which have overcome the hunger problem triggers higher level of attention not only on the safety of food, but also on its quality and on its nutritional aspects. As a matter of fact, the public opinion is increasingly aware of the circumstance that a healthy diet is an essential feature of a healthy and long lasting life. Furthermore, different aspects, such as the ethical ones, may nowadays play a role in dietary decisions of people: as a consequence, regulators are required to face new tasks in order to protect correct information to consumers and to empower them in their food choices.

In particular, in pursuing these objectives, public intervention has assumed three main regulatory approaches: permit powers, *ex post* controls (for instance, on labelling or on the informations to consumers) and a number of initiatives to promote good practices among consumers and producers, often inspired by the s.c. “behavioral economics”.

In other words, even in this field public law as shown (and it continues to show) its peculiar ability to address and regulate new phenomena through the application of traditional principles as well as the creation of new approaches and norms.

This volume presents the results of a *symposium* held at Bocconi University in October 2015, on the occasion of the Universal Exposition of Milan “*Feeding the Planet, Energy for Life*”, and it brings together the inter-disciplinary viewpoints of different academics and practitioners that in their day to day work are in many ways exposed to this emerging area of study and practice.

In particular, the broader purpose of said *symposium* was to critically reflect on the current state of the food legislation in Europe with the aim of encouraging further debate in a country, like Italy, in which for historical and cultural reasons food has always played a very special and prominent role. Furthermore, in a time when the European project is facing one of the deepest crisis of its history (with the dramatical result of Brexit and anti-european parties challenging the EU's very existence all over the continent) the European regulatory framework is also increasingly perceived as a constraint which stifles creativity and reduces opportunities for small and medium-sized enterprises (which make-up the bulk of Italy's industrial fabric): thus, it seems the right time has come to investigate whether the model of food regulation implemented so far is still effective or needs to be revisited, as many claim, in light of more flexibility.

The volume begins with a contribution of Francesco Follieri on the classical theme of precaution and risk management in the food law sector: the way precautionary principle is understood undubitably underpins the whole food regulation and thus constitutes a good starting point in the light of which all the other contributions are layed out.

A few contributions focus on organizational profiles: in particular, Scilla Vernile's paper addresses the topic of public authorities in charge of implementing and applying the rules on food safety at European and National level, while Miriam Allena's paper considers the traditional models of cooperation between public and private subjects drawing on the Italian scholarship on 'private bodies exercising functions of a public nature'.

A number of contributions address the complex and wide set of regulations on labelling and health claims: from an overview of the main objectives and purposes of labelling legislation (Letterio Donato), to a deeper analysis of the EU Regulation No. 1169/2011 and its still incomplete implementation in Italy (Lorenzo Cuocolo e Francesco Gallarati), to the authorisation procedure of health claims made on food products under EC Regulation no. 1924/2006 (Pasquale Pantalone). Furthermore, the topic of consumers' information is addressed by Andrea Guerrini in relation to its pathological side, i.e. the remedies against food frauds.

Two papers address the topic of geographical indications: in particular, Alice Villari's paper on qualified geographical indications in Europe underlines the double purpose of said indications of (again) protecting consumers and ensuring competition between producers, while Bernard O'Connor and Miriam Hamdan's paper focuses more broadly on the public/private nature of geographical indication as a whole.

The end of life of food, when it comes to waste, has also been analysed: in particular, Rocco Steffenoni's paper reviews the institutional debate around

the need for a common and comprehensive European framework on food waste ranging from the early '90s to the recent Circular Economy Package in 2015 and draws attention on donation of food which plays a crucial role in preventing food waste and combining it with ethical concerns.

Finally, a broader sociological analysis of the topic of the volume is provided by Matteo Finco in order to develop a fuller understanding of how the food sector works in practice and how the resulting norms interact with and impact on society.

According to the tradition of the series of volumes "*Approfondimenti on line*" of the '*Il diritto dell'economia*' Journal, while the contributions are mainly authored by young researchers, the conclusions are assigned to an Italian senior academic, Prof. Aristide Police.

II. Risk Management Standards in EU Food Law: Risks of Risk Decisions

Francesco Follieri

Contents: 1. Precaution and Precautionary Measures in EU Food Law. – 2. Precautionary Strategy Analysis. – 3. Risk Management Analysis. – 4. Risk Management Standards. – 4.1. Two Concepts of Precaution. – 4.2. ‘Acceptable Risk’ and Common Sense. – 4.3. ‘Acceptable Risk’, Costs-benefits Analysis, Reasonableness and Proportionality. The Role of Precaution. – 5. Risks of Risk Decisions.

1. *Precaution and Precautionary Measures in EU Food Law.*

In EU Law, precaution is a criterion of action and/or decision to face uncertain future harm [ZEI, 2008, 671; GILIBERTI, 2013a, 2 f.; *Communication from the Commission on the Precautionary Principle*, COM/2000/0001, § 1] to the high level of protection ensured to health and environment by articles 168, 169 and 191 TFEU. The harm which precaution faces is uncertain because of the lack of scientific knowledge (*Nicht-Wissen*) [DI FABIO, 1994, 30]. Prevention, instead, is a criterion of action and/or decision to face future harmful events to health and environment, which are predictable with reasonable certainty. The harm which prevention face is less uncertain, but it is however uncertain: you cannot forecast a future event with complete certainty [CALLIESS, 2001, 155; HUBER, p. 4; BVerwGE, 45, 51]. It is the German distinction between *Risikovorsorge* and *Gefahrenabwehr* [PRITTWITZ, 1988, 49 ff.; DI FABIO, 1994, 30 ff.; MURSWIEK, 1994, 803 ff.; CALLIESS, 2001, 169; GRAGNANI, 2003, 16; BRENNER - NEHRIG, 2003, 1025 ff.; SCHMIDT ASSMANN, 2006, 161; HUBER, 3; SAVONA, 2013, 29 ff.]. Art. 191 TFEU makes the same distinction: it refers to «precautionary principle» and to the principle «that preventive action should be taken» (§ 2) as different “principles” of EU environmental policy which shall aim to protect human health too (§1) [JORDAN, 2001, 143 ff.; F. DE LEONARDIS, 2005, 66 ff.].

Precaution for health and environment rules the definition and the implementation of all EU’s policies and actions, even if they don’t concern directly environment or health (arg. ex articles 9 and 168 TFEU for health and 11 TFEU for environment) [KRÄMER, 2002, 90; CAVALLARO, 2007, 467; FRACCHIA,

2015, 88]. In other terms, a precautionary approach is a way to protect environment and health, which EU shall take care of in every decision. So a precautionary measure is not a policy or an action not provided by Treaties or by EU Law. A precautionary measure is one of the policies or actions provided by EU Law that aim to protect health or environment against a possible future harm which you do not have enough scientific information about: precaution is a criterion of action and/or decision not a criterion of conferring competences [CORSO G., 2008, 169].

Art. 7, § 1, regulation (EC) no 178/2002 of the European Parliament and of the Council of 28th January 2002 (laying down the general principles and requirements of food law) about ‘precautionary principle’ states when and to what extent you can adopt precautionary measures in food safety Law (that stands for ‘food Law’) [COSTATO, 2003, 1051; COSTATO, 2007, 1; PERFETTI, 2014, 6 f.]. Precautionary measures can be adopted «in specific circumstances where [...] the possibility of harmful effects on health is identified but scientific uncertainty persists» (art. 7, §1), in order «to achieve the high level of health protection chosen by Community» (art. 7, §2). This provision matches with the former general sketch of precaution measures in EU Law, with the exception of the aim. But one can easily argue that art. 11 TFEU applies to precautionary measures too: public authority must take care of environment even in precautionary measures whose aim is human health.

All precautionary measures are market regulations: they restrict trades and economic freedoms. Usually, market regulation is divided into economic regulation and social regulation. The former mainly aims to avoid market failures. The latter aims to avoid, reduce or eliminate externalities to values that even an efficient market cannot ensure. Precautionary measures are social regulations: They protect health and environment against possible and uncertain harms by economic activities and so they restrict trades and economic freedoms. So every (social) regulation of food market can be a precautionary measure too: Labeling, authorization to place food stuff on the market, banning a production system under public control, quality certification, production standards under private control (like HACCP) e so on. According to art. 7, §2, reg. 2002/178, indeed, precautionary measures are restrictions of trades.

Since precautionary measures are public regulations, they shall be proportionate [ECJ, 16.7.2009, C- 165/08 ‘Commission v. Poland’; ECJ, 8.7.2010, C- 343/09 ‘Afton Chemical’; TAR Napoli, sez. V, 2.11.2009 n. 6758; DI FABIO, 1994, 574; BRENNER- NEHRIG, 2003, 1027]. Since precautionary measures are grounded on uncertain scientific knowledge they shall be provisional and be reviewed within a reasonable period of time, depending on the development

of scientific knowledge [EC], 12.7.2005, C-154/04 and C-155/04, ‘*Alliance for Natural Health and others*’, §68; EC], 12.1.2006, C- 504/04, ‘*Agraarproduktion Staebelow*’, §40]. Art. 7, §2, repeats these norms for precautionary measures in food Law: Precautionary measures «shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen by Community» and «reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty» (art. 7, §2).

2. Precautionary Strategy Analysis.

Precautionary measures as just described are not that interesting for a law scholar: they are provisional social regulations. A deeper analysis instead points out some problematic issues.

“Precautionary strategy” is usually divided into risk assessment, risk communication and risk management [*Communication from the Commission on the Precautionary Principle*, COM/2000/0001, § 5; DE LEONARDIS, 2005, 130 ff.; A. BARONE, 2006, 80 ff.; SAVONA, 2013, 80 ff.]. This distinction plays a role in conferring competences to European Food Safety Agency (EFSA) and other European institutions. In EU “risk law”, risk assessment and risk communication are conferred to an Agency (or an Authority) [KREHER - MARTINES, 1996, 97 ff.; ARENA, 1998; MAJONE, 2002, 171 ff.; CASINI, 2003, 392; CRAIG, 2006, 143 ff.; M.P. CHITI, 2007, 442 ff.; ID., 2011, 311 ff.; E. CHITI, 2010, 57 ff.; ID., 2014], risk management instead to the “political” institution (Commission, Parliament or Council). It is an implementation of the ‘Meroni doctrine’ [EC], ‘*Meroni v. Alta autorità*’, C-9/56 e C-10/56; MAJONE, 2002, 174 f.; E. CHITI, 2010, 57 ff.; SAVONA, 2013, 223]. According to this doctrine, discretionary powers or decisions ought to be conferred to Institutions provided by Treaties [But see EC], 22.1.2014, C-270/12, §53]. Risk management is a discretionary decision, so it has to be taken by Institutions provided by Treaties [VIOLINI, 1984, 21 ff.; SAVONA, 2013, 223]. In food law, risk assessment is conferred to European Food Safety Agency (EFSA), while precautionary measures ex art. 7 reg. no. 2002/178 are conferred to European Commission, and in other cases (every decision involving a possible future harm to health and environment) to the European Institution in charge of that.

More in detail, risk assessment is a scientifically based process of collecting information about the harm you fear (framing) to forecast whether, when, where, how and why the harm will happen (forecasting) [BOUNDS, 2010, 19; WIENER,

2010, 141]. Because precautionary measures are adopted in a situation of scientific uncertainty, framing is incomplete or barely stable and forecasting is not enough reliable [*Communication from the Commission on the Precautionary Principle*, COM/2000/0001, § 5.1.3]: because of the lack scientific knowledge (*Nicht-Wissen*) you cannot evaluate the probability of the harmful event (uncertainty in wide sense), you cannot evaluate the probability of its effects (uncertainty in strict sense) [SCHMIDT ASSMANN, 2006, 161; see also DI FABIO, *Risikoentscheidungen*, 1994, 105 ff.; SCHERZBERG, 2004, 220 ff.].

Risk communication is a commitment for the Authority which the risk assessment is conferred to. This commitment does not concern the risk measure: every assessed risk ought to be communicated to people. However this commitment knows few exceptions in sector regulation¹.

Risk management asks for a choice whether or not to act and in case which measure to be adopted against a risk (possible but uncertain future harm), based on the results of risk assessment. So risk management consists of two decisions: whether or not to act and how to act. The contrast ‘risk assessment and communication vs. risk management’ reflects a real sequence of phases in decision-making (conferred to two different institutions). The contrast ‘decision whether or not to act vs. decision how to act’ instead is just an *a posteriori* distinction, not reflecting a real sequence in risk management – as well as in every discretionary decision [L. BENVENUTI, 2002, 100; LEVI, 1967, 217; PASTORI, 1987, 3168; POLICE, 1997, 90 ff.]: in specific circumstances decision whether to act depends also on which kind of measure you can adopt. Nevertheless this distinction is useful to identify risk management standards.

3. Risk Management Analysis.

As seen above, food risk management leads (or not) to social regulation of food market. So food risk management is the choice whether or not to regulate and in case how to regulate (directly or indirectly) food stuff.

To decide how to act implies a choice of the measure to be adopted. It is a discretionary decision concerning the way you pursue health or environment protection in case of uncertain risk. It is a *Rechtsfolgeseite* [COGNETTI, 1993, 69 ff.; DE PRETIS, 1995, pp. 14 ff.; GALLIGAN, 1986, 13 ff.]. This kind of deci-

¹ E.g., in food safety regulation (EC reg. no. 2002/178), articles 39 and 52 rule exceptions to the commitment to communicate risk in cases in which there is information required to be confidential by who gave it to the EFSA (art. 39) and covered by professional secrecy (art. 52). Nevertheless in both cases, «information which must be made public if circumstances so require, in order to protect public health» (art. 39, §1 and art. 52, §1) cannot be covered by any confidentiality.

sion is a political decision or “pure discretionary” decision [GIANNINI, 1939, 49 ff.; PIRAS, 1964, 82; CAPACCIOLI, 1983, 284; G. BARONE, 1989, 3 f.; CAVALLO, 1983, 28 ff.; CERULLI IRELLI, 2008, 268 ff.; VILLATA-RAMAJOLI, 2006, 87 ff.].

Decision whether to act instead concerns the condition of precautionary measures. *Prima facie*, this decision is taken because the situation to face is qualified as a ‘risk’. Authority decides whether the situation (as emerging from risk assessment) matches with the definition of ‘risk’ [SAVONA, 2013, 246]: it answers the question ‘the situation to face is a possible, but uncertain future harm?’. ‘Risk’ is a vague term [about vagueness – PEIRCE, 1902, 748; LUZZATI, 1990, 3; DICIOTTI, 1999, 360 ff.], an indeterminate concept (*unbestimmt Rechtsbegriff*) [JELLINEK, 1913; CAMMEO, 1902, 277; PRESUTTI, 1910, 12 ff.; GIANNINI, 1939, 157 ff.; ROMANO TASSONE, 1987, 303 ff.; COGNETTI, 1993, 69 ff.; DE PRETIS, 1995, 11 ff.; LAZZARA, 1996, 306 ff.; MARTINI, 1997, 11 f.; GALETTA, 1998, 37 ff.; GILIBERTI, 2013b, 103 ff.]: ‘risky’ turns into ‘dangerous’ or ‘innocuous’ without ‘either-or’ distinction – it is a matter of degree [MAJONE, 2006, 15 ff.]. Within this framework, authority has epistemic discretion on the condition of precautionary measures [ALEXY, 1994, 617 ff.], but this discretion is strictly bound by risk assessment results.

This hypothesis does not consider that no human activity is risk-free (or however risk-free activities are very rare) [G. CORSO, 2008, 165; BARTOLOMMEI, 2001, 326]. So this *wertfrei* [But see MARZUOLI, 1985, 211 ff.] hypothesis about decision whether to act entails to renounce to development and to a very significant part of nowadays wealth [SUNSTEIN, 2010, 42 ff.]. This consequence is unacceptable, as everyone can argue [BverfGE, 49, 89 – ‘*Kalkar I*’; GC, 21 November 2003, T- 392/02 ‘*Solvay*’, §129; GC, 11 July 2007, T-229/04 ‘*Sweden v/ Commission*’, §170; ECJ, 9 September 2003, C-236/01 ‘*Monsanto Agricoltura Italia and others*’, §106; DI FABIO, 1994, 69 ff.; CALLIESS, 2001, 162; DE LEONARDIS, 2005, 107 ff.; SAVONA, 2013, 33]. For this reason, we have to rephrase our hypothesis.

The existence of a risk is practically unavoidable: the question is whether a risk is acceptable (*Restrisiko*) or not. Condition of precautionary measures is the ‘unacceptable risk’, not “simple” risk. A risk is unacceptable depending on how much you are willing to gamble the values which precaution protects (health and environment) in order to realize other values (economic development, competition, economic freedoms). It is an evaluation [DI FABIO, 1994, 111 f.] which balances health and environment on one side, and economic values on the other side. Balance (or evaluation) is a preference [ALEXY, 1994, 109 ff.; VON WRIGHT, 2000, 348 ff.; ID., 1963; ID., 1972, 68 ff.]: who decides whether or not a risk is acceptable prefers a value to another, health or environment to economic values

or *vice versa* in the concrete circumstances [ECJ, 23 September 2003, C-192/01 ‘*Commission v/ Denmark*’].

So judgment about the condition of a precautionary measure merges with judgment about the concrete aim of the measure [GIANNINI, 1939, 79; LEVI, 1967, 303 ff.; CANNADA BARTOLI, 1972, 6; SORACE, 1988, 745 ff.; VIPIANA, 1990, 37 f.; A. PUBUSA, 1994, 402; BOMBARDELLI, 1996, 258 ff.; F.G. SCOCA, 2000, 1070, note; MANGANARO, 2000, 112 ff.; VILLATA-RAMAJOLI, 2006, 96 ff.; A. ROMEO, 2008, 136 ff.]: e.g., if you consider an unacceptable risk using a new food preservative whose effects against human health are still unknown, you have to adopt a measure suitable for protecting health from that preservative, to the detriment of economic values which using that preservative could favour.

Balances are normative discretionary decisions [R. ALEXI, 1994, 617 ff.], that is “pure” or political discretionary decisions as seen above. So decision whether or not to act (that is whether or not a risk is acceptable) is normative discretionary or «eminently political» [*Communication from the Commission on the Precautionary Principle*, COM/2000/0001, §5.2.1; see also DI FABIO, 1994, 214; SAVONA, 2013, 214].

4. Risk Management Standards.

We usually say that risk management decisions shall respect precaution and proportionality [*Communication from the Commission on the Precautionary Principle*, COM/2000/0001, 2000, §5; DE LEONARDIS, 2005, 22 ff.; S. PUDDU, 2015, §1]. Judges and scholars think that decision how to act shall be adequate to achieve health or environment protection and necessary (among equally adequate measures authority must choose the less restrictive one for trade and economic values and freedoms) [e.g.: *Communication from the Commission on the Precautionary Principle*, COM/2000/0001, §6.3.1; ECJ, 16.7.2009, C- 165/08 ‘*Commission v. Poland*’; DI FABIO, 1994, 574; BRENNER - NEHRIG, 2003, 1027; I.M. MARINO, 2001, 3]. In other words, this decision ought to be proportionate (at least for what is relevant among proportionality standards for decision how to act) [GALETTA, 2012, 400 ff.]. Art. 7, §2, reg. 2002/178/CE also repeats this rule, as seen above (§1). But how do you decide whether a risk is (un)acceptable? This question is the most important: decision whether to act is the core of risk management [SAVONA, 2013, 61]. But this question is also the most difficult to answer.

4.1. Two Concepts of Precaution.

First of all, the answer depends on the concept of precaution you embrace. There are (at least) two concepts of precaution [SUNSTEIN, 2005, 31].

i) Precaution is a *procedural* standard [EWALD, 2001, 359]. It imposes to decide without certainty and truth of fact premises, that is without the usually acceptable degree of knowledge: the lack of knowledge and the unreliability of forecasting is not a valid reason not to decide [Rio Declaration, principle n. 15; art. 5.7 SPS Agreement; HOFFMANN RIEM, 2005, 147]. Nevertheless decision has to be taken on the ground of the best available scientific knowledge and after having heard every interested person in an open procedure. Because of the lack of (sufficient) scientific knowledge, scientific research shall be continued after decision and decision (even not to act) shall be reviewed within a reasonable period of time or however in case of a development of knowledge [art. 5.7 SPS Agreement, *Communication from the Commission on the Precautionary Principle*, COM/2000/0001, §6.3.5] – as already seen above. It is the «weak» concept of precaution [SUNSTEIN, 2005, 31; CGARS, 3 September 2015 n. 581 §29].

ii) Precaution is a *substantial* standard [EWALD, 2001, 361]. It imposes to avoid a possible harm to health or environment (that is to values protected by precaution) [BARTOLOMMEI, 2001, 322; EWALD, 2001, 361; SUNSTEIN, 2005, 33] in addition to procedural standards seen above. It is the «strong» concept of precaution [SUNSTEIN, 2005, 33]. Depending on what you consider a ‘possible harm’, precaution obliges to forbid something when you can reasonably forecast that it will be harming health or environment («moderate» version [Conseil d’État, *Rapport public* 2005, 278]) or to forbid everything until it has been proven that it is not harmful to health or environment («radical» version [Conseil d’État, *Rapport public* 2005, 278]).

In this conception, precaution is a standard to decide whether or not a risk is acceptable: values protected by precaution must be preferred to other colliding values. In the “moderate” version, this rule of preference shall be implemented when the harm to health or environment is certain enough: it concerns danger (*Gefahr*), it merges with prevention [Conseil d’État, *Rapport public* 2005, 278]. So this version is not useful to identify a standard for decisions in case of uncertainty: uncertainty excludes reliable forecasting. In the “radical” version, this rule of preference shall be implemented in case of unavoidable scientific uncertainty: *in dubio pro natura* [DE SADELEER, 2002, 203; CROSETTI, 2008, 45] *ac salute*. More in detail, it obliges to forecast the worst case scenario (catastrophism), to avoid all risks to health and environment (zero risk) and to burden who will act to

prove that the activity is harmless (reversing the burden of proof) [SAVONA, 2013, 296 ff.; JONAS, 1979, 38 ff.].

The lack of a “constitutional” definition of precaution implies that public authority (first of all the legislator) is free in implementing precaution: sometimes precautionary law seems to be grounded on the procedural concept of precaution, sometimes it seems to be grounded on the substantial concept of precaution².

Food law gives examples of the implementation of both concepts of precaution. For GMO and food additives, European law maker chose a prior approval system with the reversion of the burden of proof: you can authorize to grow and place on the market a GM vegetable only if the farmer or the trader proves that it is innocuous to health and environment (that is, only if it is for sure innocuous even in the worst case scenario); you can authorize to place a food stuff containing additives (vitamins, colorants etc.) on the market only if the producer or the trader proves that it is innocuous to health and environment. It is a clear implementation of the substantial concept of precaution. Commission instead, facing a food risk, can adopt «provisional risk management measures [...], pending further scientific information for a more comprehensive risk assessment» (art. 7, §1, reg. no. 2002/178/EC) and these measures «shall be reviewed within a reasonable period of time» (art. 7, §2, reg. no. 2002/178/EC). It is a clear implementation of the procedural concept of precaution.

The substantial concept of precaution sets a hierarchy of values: health and environment are higher ranked than all the others, especially economic ones [GC, T-158/03, 28 June 2005 ‘Industrias Químicas del Vallés v/ Commission’; TAR Trento, sez. I, 8 July 2010 n. 171; TAR Lombardia, Brescia, sez. I, 9 October 2009 n. 1738]. This hierarchy puts in doubt the fundamentals of pluralism³. It is not a standard to decide whether or not a risk is acceptable: this rule of preference states that every risk to health and environment is unacceptable (zero risk criterion) [BARTOLOMMEI, 2001, 329 f.]. As seen above, there is no risk-free human activity. Even precautionary action implies a risk: the risk to ground on premises which will be discovered wrong (so called second level risk – risk of risk

² In USA and EU there has been a “inverse” trend. From a chronological point of view, USA have gone from the older principally substantial concept of precaution to a principally procedural one; rather EU has gone from a principally procedural concept of precaution to a principally substantial one. See SAVONA, 2013, 274 ff., also for others quotes. From a subject point of view, EU chooses the substantial concept of precaution most of all in food law, USA instead choose that notion most of all to face terrorism, alcohol abuse and secondhand smoke [POLLAK - SHAFFER, 2009, 23 ff.].

³ Particularly, values hierarchy and burden of proof reversion contrast to case balance and equilibrate discussion to solve conflicts among values/principles/fundamental rights. Values hierarchy ranks once for all values: you shall not balance again values. Burden of proof reversion alters one of the fundamental conditions of the discourse (theory): you cannot be loaded with the burden to refute unwarranted or still unwarranted objections – [ALEXY, 1978, 155 ff.; forward §4.3].

decisions) [HOFFMANN RIEM, 2005, 147]. So, we repeat, who tries to avoid every risk condemns himself to paralysis and to renounce to development: you cannot implement precaution in this sense to every fear. For this reason, substantial concept of precaution lends itself to be implemented in a discriminatory way: why are risks by GM food faced with “strong” precautionary approach (worst case scenario, zero risk, reversing the burden of proof), but risks by not GM food are not faced by this “guillotine” [BARTOLOMMEI, 2001, 331]? In the very end, substantial concept of precaution, even if it matches to everyday meaning of ‘precaution’ [SALVIA, 2002, 615], hides the real reasons why you consider a risk unacceptable. Therefore, only procedural concept of precaution can be embraced.

Nevertheless, procedural concept of precaution is not a standard to decide (and to judge decision) whether or not a risk is acceptable [BARTOLOMMEI, 2001, 322]. It requires a wider participation of citizens in decision making process, increases transparency guarantees (by ensuring them the full knowledge or risk – the commitment to communicate risk) and forbid irreversible measures, because precautionary decision has a much larger margin of error (the already quoted second level risk). But it does not suggest how to balance values to decide whether or not a risk is acceptable.

4.2. ‘Acceptable Risk’ and Common Sense.

According to the European Commission in the Communication about «precautionary principle», decision whether or not to act is «a function of the risk level that is “acceptable” to the society on which the risk is imposed» [*Communication from the Commission on the Precautionary Principle*, COM/2000/0001, §5.2.1]. For this reason, you can argue that the decision whether a risk is acceptable depends on ‘common sense’, on what society considers an acceptable risk. Thus the participation of citizens in decision-making aims to keep in contact authority and society so that the former knows what the latter considers an (un) acceptable risk. According to this hypothesis, ‘acceptable risk’ is a “*Generalklausell clausola generale*” (more or less a “legal standard”) like ‘public morality’: authority shall identify which risk is acceptable according to the society and use this standard to decide whether or not to act. In this way, decision whether to act is a sort of poll: an acceptable risk is the risk which the majority of people will run⁴.

⁴ Nevertheless in a *Rechtsstaat* ruled by popular sovereignty, a decision grounded only on the subject who adopt it (that is legitimated only by the fact of being taken by the people) shall be unanimous. In the *Rechtsstaat* indeed decisions are from the people’s will, with the equality of everybody who is part in it. Decisions can harm someone (majority who harm the minority). So deciding implies injustice. Nevertheless, who decides for himself does not commit injustice (*volenti non fit iniuria*). So if everybody agrees, that is if everybody decide for

Let us avoid theoretical issues which “*Generalklauseln/ clause generali*” imply [About these issues see, e.g., ENGISCH, 1970, 170 ff.; FALZEA, 1987, 1 ff.; TARUFFO, 1989, 312 ff.; LUZZATI, 1990, 302 ff.; VELLUZZI, 2010; PERFETTI, 2012, 1213 ff.; SALA, 2012, 1191 ff.]. Let us admit that this inquiry is empirical and is not an evaluation itself. Let us admit also that you can poll in an enough accurate and representative way a people (even a varied one, like European people) to find out what it considers to be an acceptable risk. Let us even admit that this (populist [L. CORSO, 2014, 67 ff.]) way to decide whether or not a risk is acceptable does not imply that public decision maker abdicate from his institutional responsibility.

In a perfect society, that is a biases-free society (or nevertheless a society ready to discuss its biases), this solution could be optimal. But this situation is utopian, especially when people has to face risk. Risk perception is indeed distorted.

First of all, five “individual” factors distort risk perception [SUNSTEIN, 2005, 54 ff.]:

i) availability heuristic [SUNSTEIN, 2005, 54; KAHNEMAN - SLOVIC - TVERSKY, 1982] – “proximity” (that is a higher level of emotive availability) of a possible harmful event makes it appear riskier than an equally possible but “far” harmful event. Proximity may concern time, space or social relationships: the more recent, closer or more “familiar” an event is, the more it fears [SUNSTEIN, 2005, 54 ff.]. In other words, the more vivid is the emotion excited by a harmful event, the more unacceptable you consider the risk of its occurrence – instead of considering the risk on the ground of the best available scientific knowledge;

ii) probability neglect – emotions excited by some kind of harmful events induce to neglect probability of occurrence in considering whether the risk is acceptable. In the very end, because you neglect probability of its occurrence, you consider more serious than it really is an event which you are sensitive to [SUNSTEIN, 2005, 58 ff.]. It is an effect of availability heuristic but it boosts the distortion of risk perception;

iii) loss aversion – people evaluate goods they already have more than goods they can get by a risky action or decision [SUNSTEIN, 2005, 61; THALER, 1991, 137 ff.]. For this reason, people are more sensitive to the possibility of losses than to the possibility of benefits which they give up because of precautionary measure [SUNSTEIN, 2005, 62]: it is the motto ‘better safe than sorry’ which resumes the status quo bias [SUNSTEIN, 2005, 64];

himself what is deliberated, injustice is impossible. For this reason, against who dissent «la maggioranza [non può] vantare una forma di legittimazione esclusivamente soggettiva», majority cannot «pretendere obbedienza per il solo fatto di essere maggioranza» [CORSO, 2014, 477, who grounds this conclusion on Kant’s thinking, which in his turn is grounded on Rousseau’s thinking].

iv) benevolent nature bias – people are inclined to consider more beneficial natural state-of-things than human action on nature: nature cannot be harmful. For this reason people under-estimate natural risks (e.g., the famine caused by a parasite) and over-estimate risks of human action (e.g., the uncertain effects on human health of the pesticide against that parasite) [SUNSTEIN, 2005, 64 ff.];

v) system neglect – people do not (or cannot) get large scale and side effects of an action (or inaction), including those ones of a precautionary action. People neglect this kind of effects because these effects are far (in time and space) [SUNSTEIN, 2005, 67 ff.].

Risk perception is strongly influenced also by group dynamics: availability cascades and group polarization.

Availability cascades substitute a scientific proof with a very emotionally impressive anecdote, so the availability of an harmful event is increased. These accounts create unwarranted fears: one person's warning transfers to other people without scientific reasons or scientific uncertainty neither [SUNSTEIN, 2005, 131 ff.]. For instance, everybody remembers the anecdote of the "whitening" effect of Coke on a cent: tale strikes by evoking that the soft drink may have analogue effects on our stomach, but it is scientifically proven that our gastric juice is much more corrosive than a Coke. But, as someone said, 'in order to create a false conviction you need a second and an idiot, but you need years and dozens of experts to demolish them'.

People with this kind of beliefs are inclined to talk mostly with people with same beliefs. In this way people strengthen and emphasize their beliefs: consent grounds the idea that a thesis is correct. So they create closed groups, which firmly resist to discuss the beginning thesis: People in these groups point at people with arguments against group mainframe as heretic. This phenomenon is group polarization [SUNSTEIN, 2005, 137 ff.]. You can identify group polarization, for instance, in the recent campaign against palm oil.

Internet boosts these dynamics. Internet indeed makes communication much easier and faster. So availability cascades form very quickly and in huge scale and group polarization is accelerated [SUNSTEIN, 2005, 131 ff. and 137 ff.].

All these factors also depend on culture [SAVONA, 2013, 18 ff.]. For this reason, functional illiteracy, which includes the lack of any critical ability (*scilicet* being unable to distinguish a "howler" from a reliable information), helps availability cascades to form and increases propensity to take part in a polarized group.

All the factors above make unwarranted fears run high, even against scientific evidence. And these fears can be ridden or set up by lobbies, politicians and medias to "egoistic" extent [SUNSTEIN, 2005, 142 ff.]. For these reasons this approach to decision whether or not to act cannot be shared.

4.3. 'Acceptable Risk', Costs-benefits Analysis, Reasonableness and Proportionality. The Role of Precaution.

Who points out the factors which distort social risk perception suggests to solve by cost-benefits analysis the clash of values to decide whether to act [SUNSTEIN, 2005]: those distortions are arguments to prefer costs-benefits analysis in deciding whether to protect health or environment against possible but uncertain future harms caused by activities which produce benefits for economic values [CECCHETTI, 2006, 104]. Other authors who accept the procedural concept of precaution, as who writes does, suggest to decide whether or not to act (and to judge that decision) by reasonableness [among the others: TONOLETTI, 2001, 144; DE LEONARDIS, 2005, 128; COMPORTI, 2005, 226; DELL'ANNO, 2004, 94] or proportionality [e.g. SAVONA, 2013, 292; PUDDU, 2015, 12 f.].

At least to our extent, in English speaking legal dogmatics costs-benefits analysis corresponds with what Italian, French and German legal dogmatics call reasonableness or proportionality (according to the legal tradition they refer to). Reasonableness and proportionality combine indeed criteria of pure reason (*reine Vernunft*) or rationality (empiric truth, logic and aim/instrument or strategic rationality⁵) [WEBER, 1922, I, §2; HABERMAS, 1981; LUTHER, 1997, 343; ALEXU, 2002, 153] with criteria of practical reason (*praktische Vernunft*) [SPADARO, 2002, 327; ABBAGNANO, 2013, 897; DEWEY, 1938, 19 ff.; LEDDA, 1987, 274 AND 276; LUTHER, 1997, 343], play the same role in public decision-making (and in judicial review on those decisions) and mirror economic costs-benefits analysis [GC, T-13/99, 11 September 2002 '*Pfizer Animal Health*'; TAR Puglia, Lecce, sez. I, 11 June 2007 n. 2248; TAR Friuli Venezia Giulia, 28 January 2008 n. 90; TAR Lazio, Roma, sez. II bis, 16 May 2011 n. 4214; TAR Sardegna, sez. II, 8 October 2007 n. 1809; TAR Toscana, sez. II, 4 February 2011 n. 225] – but they balance values not only by their economic measure [MERUSI, 2011, 20]. Proportionality and reasonableness can be distinguished because proportionality is more analytic than reasonableness and reasonableness instead (or at least the Italian version of reasonableness) includes commitment to consistency and non-discrimination too [SCACCIA, 2000, 27 ff.; D'ANDREA, 2005, 25 ff.]. After all a balance, that is a discretionary decision, is reasonable/proportionate whether: it is grounded on true fact premises (truth), it follows from those premises without logical or argumentative fallacies (logic), it considers all the values concerned by decision without extremism (pluralism) [ZAGREBELSKY, 1992, 203 ff.; ALEXU, 1994, 156 f.;

⁵ For instance, strategic rationality includes economic theories of decision and game theory [about the small role of game theory in administrative decision: CLARICH, 2001, 284 ff.; MERUSI, 2007, 427 ff.; Id., 2011, 17 ff.

LUTHER, 1997, 343 and 347; D'ANDREA, 2005, 425 ff.] , it admits all arguments for every solution and evaluates them with equilibrium in an adequate discursive context (discourse) [ALEXY, 2002, 153; LOMBARDO, 1997, 942; SPADARO, 2002, 339; CHIARLONI, 2012, 7 f.; PATTI, 2012, 11] , it is in keeping with the standard 'the higher the harm to a value is, the higher the benefit to the opponent value shall be' [ALEXY, 1994, 143] (proportionality in strict sense)⁶, it solves in the same way all the enough analogue clashes of values (non-discrimination), it does not change solution without reason and it is compatible with other related balances (consistency) [*Communication from the Commission on the Precautionary Principle*, COM/2000/0001, § 6.3.2 and 6.3.3]. If a decision is in keeping with these standards, there will not be only one valid decision, but you will be sure that it is one of the reasonable or proportionate decisions.

In other words, according to this thesis, in order to decide whether or not a risk is acceptable you shall use the same standard which you use to decide in any other situation. So there is no place for precaution: proportionality rules the decision how to act, proportionality/reasonableness/costs-benefits analysis rules the decision whether or not to act.

But risk decisions are not usual decisions. So, at least decisions whether a risk is acceptable cannot fulfill reasonableness, proportionality or costs-benefits analysis.

First of all, decision whether a risk is acceptable *never* respects 'truth-standard' and 'logic-standard'. In risk decisions fact premises are never (enough or reasonably) warranted or complete: they are uncertain. So you cannot say whether or not they are true: you still do not know (lack of knowledge- *Nicht Wissen*). Because of uncertain premises, the justification of risk decisions is not rigorous: from incomplete or unwarranted premises only a dubitative reasoning can follow [SAVONA, 2013, 214].

Precaution remedies to the lack of truth and logic. It substitutes commitment to truth and logic in risk decisions. In risk management, decision whether to act grounds on inevitable uncertainty, rather than truth: an uncertainty which cannot be eliminated by the best scientific studies ('the best available scientific knowledge' standard). Decision whether to act grounds on the proof that the uncertainty was inevitable and authority could not delay decision until science got an enough complete knowledge ('uncertainty shall not be a reason to not act').

Furthermore, you cannot implement proportionality in the strict sense to the decision whether a risk is acceptable as you can to "normal" decisions. Proportionality in the strict sense presupposes that the prognosis about benefits and

⁶ Other criteria, which are related to aim/instrument rationality, concern how to choose the measure, not whether or not to act.

harms (or costs) to values, which are concerned by decision, is certain enough. If there is no sufficient certainty or reliability in forecasting, you cannot implement proportionality in the strict sense: You cannot say whether the harm to trade (that is economic development, competition and economic freedoms) is proportionate to the benefit to health and environment if you do not know with sufficient reliability which these harms and benefits are, where they will be, whom they are imposed to and so on [DI FABIO, 1994, 453]. And risk decisions are risk decisions because they are adopted in a situation of scientific uncertainty: decision whether or not a risk is acceptable cannot be taken or judged by proportionality in the strict sense.

Sociologists and economists indeed remark that ‘risk’ is not a ‘cost’: while ‘cost’ is a pretty sure negative effect of an action, ‘risk’ is a negative effect of an action which you are not sure it is going to occur [KNIGHT, 1921; SOFSKY, 2005, 17]. But they state also that risk can be evaluated: you can say how probable a risk is [KNIGHT, 1921; SOFSKY, 2005, 16 f.]. For these reason some Authors [e.g., SAVONA, 2013, 292 f.] propose to implement “inverse proportionality” to decision whether or not to act. This standard was formulated by German dogmatics for preventive action (*Gefahrenabwehr*). It states that the heavier the harm is, the lower the probability of its occurrence shall be to act [DI FABIO, 1994, 103 ff.; BRENNER - NEHRIG, 2003, 1025; SCHERZBERG, 2004, 220 ff.; HUBER, 3; SAVONA, 2013, 29 f.]. But when a risk is uncertain, you cannot evaluate its probability or the probability of its effects (as seen above): forecasting is unreliable, because of the lack of knowledge (*Nicht-Wissen*). And without probability evaluation you cannot implement inverse proportionality.

According to another thesis, you can implement proportionality and inverse proportionality by embracing a subjective conception of probability [MAJONE, 2003, 6]. According to this conception of probability, you can give a quantitative measure to possible but uncertain future harms to health and environment. So you can use these weights in costs-benefits analysis or reasonable/proportionate balance to decide whether a risk is acceptable. Nevertheless, this conception of probability hides whim under a curtain of numbers or other kind of measures: the standard of this system of measure is just what decision-maker will or guess. Embracing subjective conception of probability in order to implement these standards means sweeping problems under the carpet.

While the procedural concept of precaution (the only you can embrace) substitutes truth and logic standards, it cannot substitute the proportionality in strict sense or inverse proportionality⁷. Procedural precaution answers to this

⁷ A substantial concept of precaution *prima facie* can. Nevertheless, it does not concern decision whether a risk is acceptable, but compels to act against every risk – as seen above.

problem by strengthening participation and transparency, that is the instruments to a stronger enforcement of other criteria or reasonableness/proportionality (discourse and pluralism).

All that does not mean that you have to abandon costs-benefits analysis or reasonableness or proportionality (even inverse proportionality) as standards to decide whether or not a risk is acceptable. These standards still design the best decision making process we have, also for risk decisions. It means instead that those standards cannot assure that risk decision is reasonable. For this reason, precautionary measure shall be provisional and reviewed within a reasonable period. If precautionary decisions by reasonableness assured their reasonableness as other decisions by reasonableness do, precautionary decisions would be stable until new decisions, as “normal” decisions are: no more cares would be needed.

5. Risks of Risk Decisions.

As seen above, every action and every decision implies a risk: at least the risk to be “wrong”, that is the risk to harm a value or a right or an interest without pursuing the aim. If the decision-maker could have a complete knowledge of the problem and an absolutely reliable forecasting about the effects of his action and inaction, a decision by reasonableness/ proportionality/ costs-benefits analysis would ensure to adopt a reasonable measure. That is an ideal and impossible state-of-the-world. Humans have to decide without perfect knowledge and infallible prognosis. But deciding by reasonableness criteria can avoid most of the error. In other words, in “normal” decisions we content ourselves with a sufficient degree of truth and certainty and so with a sufficient degree of reasonableness. But a margin of error and risk always remains.

In other word, it is a matter of degree. The lower the degree of truth and certainty is, the lower the degree of guaranteed reasonableness is, the higher the risk of decision is. But there is no decision which is totally certain, reasonable and risk-free. Some decisions are grounded on more certain premises, so they guarantee a higher degree of reasonableness and imply a lower degree of risk; other decision are grounded on less certain premises, so they guarantee a lower degree of reasonableness and imply a higher degree of risk.

As also seen above, risk decisions are adopted without the usual degree of certainty and without the guarantee of reasonableness. Decisions against risk are the most risky decision we take – the second level risk. The risk to unwarrantedly restrict freedoms is very high. Notice that precautionary measures restrict not only economic freedoms, but also non-economic freedoms like, in food risk decisions, freedom to choose the food you prefer.

Second-level risk is related to another risk of risk decisions.

Legitimacy of public authority can be subjective or objective [ROMANO TASSONE, 2013, 567]. Legitimacy is subjective if the mandatory respect to public decisions is grounded on the qualification of the decision-maker. The qualification of the decision-maker may be nature, birth, divine choice and so on [ROMANO TASSONE, 2013, 567; ID., 2007, 259]. This kind of legitimacy does not concern the content of decisions and the decision-making process: whatever the statement is, whatever its reasons are, whatever procedure has been followed or not, people shall obey that decision [ROMANO TASSONE, 2013, 567 f.; ID., 2007, 259 f.]. Which effects the validity of the decision: if it is taken by the qualified subject (body or person), it is valid [ROMANO TASSONE, 2007, 260] – or, if you like, you can discuss the validity of the decision only by discussing (the validity of) the qualification [ROMANO TASSONE, 2013, 568]. Legitimacy is objective, instead, if the respect to public decisions is grounded on the features of the decision: form, procedure, content [ROMANO TASSONE, 2013, 567]. In this framework a public decision is valid if it meets formal, procedural and content standards provided by legal system [ROMANO TASSONE, 2013, 568].

In the contemporary *Rechtsstaat*, every public decision has subjective and objective legitimacy [ROMANO TASSONE, 2013, 567]: subjective legitimacy is people's election, objective legitimacy is form, procedure and reasonableness. Subjective and objective legitimacy are in an inverse ratio: the higher the popular legitimacy of a body is, the lower objective legitimacy is required and *vice versa* [ROMANO TASSONE, 2007, 261 f.]. In one end of this ideal scale there is parliamentary legislator [ROMANO TASSONE, 2007, 262], on the other end there is public administration: the lack of democratic legitimacy (or at the most the indirect democratic legitimacy) of the latter makes the objective legitimacy of administrative decisions more relevant; the democratic legitimacy of the former lightens (but does not eliminate) the relevance of the objective legitimacy of decisions. In other words, objective and subjective legitimacy combines differently, but every public decision needs them both [ROMANO TASSONE, 2013, 572].

Our legal systems (that is national legal system and EU legal system) emphasize the role of objective legitimacy. As seen above, legitimacy effects on validity of decision. A subjectively legitimated decision cannot be reviewed by jurisdiction: at the most, only the qualification of the decision-maker can be judicially reviewed. So the judicial review on legislation and administration by constitutional, administrative and civil Courts proves that every decision ought to be objectively legitimated too [G. CORSO, 2014, 426].

There is no doubt that the most powerful objective legitimacy for a discretionary public decision is reasonableness. For this reason, every judicial review

on public decisions implements reasonableness (or proportionality or costs-benefits analysis) standard, with a degree depending on subjective legitimacy of the body who adopted the measure. Precautionary measures are widely discretionary. Nevertheless, precaution compels public authorities to decide without reasonableness guarantee: because it imposes to decide without certainty, it implies the “reasonableness failure”. So precautionary measures do not have the most powerful objective legitimacy of discretionary measures: at the moment of its adoption, you cannot say whether or not a precautionary measure is reasonable.

In this framework, the compulsory respect to precautionary decisions grounds on precaution itself. First of all, precaution weighs down procedural commitments (participation and transparency), so it increases the relevance of procedure in objective legitimacy [FRACCHIA, 2010, 121 f.] in order to balance the lack of reasonableness guarantee. But overall, precaution is the “legal translation” for fear for others. Since Ancient Greeks, who fears for himself is a coward, shall be despised. Rather who fears for others is morally righteous [G. CORSO, 2014, 162]. Fear for others is a virtue (in the moral sense): prudence [FRACCHIA, 2010, 123]. And this virtue legitimate precautionary decisions, as many other environmental policies and decisions [LUHMANN, 1988, 223 ff.]. It is an aretaic legitimacy (where ‘aretaic’ means grounded on virtue – “ἀρετή” in ancient Greek).

It means however that precaution does not suit traditional standards (of legitimacy and validity) of liberal *Rechtsstat*. *Rechtsstat* can be summed up in the following sentence: individual freedom is in principle unlimited; public authority is in principle limited [SCHMITT, 1928, 173]. For this reason, *Rechtsstat* demands that restriction to individual freedoms ought to be warranted and legitimated by rational/reasonable justifications (as well as ruled by law, that is in keeping with *Vorberhalt des Gesetzes* and *Vorrang des Gesetzes*) [about precaution and rule of Law, see ALLENA, 2016, § 3 and 4]. Precautionary measures instead are ethically warranted and legitimated, because of their lack of reasonableness guarantee.

So there is also a worse risk of risk decisions than second level risk: risk decisions call into question the basis of our legal systems (EU legal system and national legal system) – the *Rechtsstat* as we know it. Is it an acceptable risk? Once precaution is laid down by “constitution” (articles 191 TFEU, 9 TFEU and 11 TFEU) [on constitutional value of EU primary law, see VON BOGDANDY, 2011, 20 ff.], legal science cannot answer this question.

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III. Food Safety between European and National Authorities

Scilla Vernile

CONTENTS: 1. Introduction: the multi-level organization for food safety. – 2. The institution of the European Food Safety Authority. – 3. The division of functions between the European Food Safety Authority and the European Commission: risk assessment v. risk management. – 4. The Risk Management: the Commission's Procedures. – 5. National Authorities: a network model to protect the food safety. Dissemination of information. – 6. The Italian experience. The opportunity of establishing a national independent authority for food safety.

1. Introduction: the multi-level organization for food safety

Food safety is guaranteed through a multi-level approach. The import and export of food requires the coordination of the rules in force in the countries of origin and destination, in order to ensure, at least in the European territory, the free movement of goods.

The economic interest of the market cannot, in fact, override the safety requirements imposed by the seriousness of the risks to human health, therefore, it is necessary to organize a network of all competent authorities to ensure respect of the rules for food safety.

Nevertheless, the protection of health is certainly the main purpose, but not the only one.

Other interests come into consideration, such as consumer and environmental protection or, the already mentioned, free trade in the European market. The coordination between the different territorial levels is, then, necessary to ensure uniform regulation in order to guarantee the free movement of goods while safeguarding food security.

European policies on food safety, in fact, have always been the result of the intent of national institutions to overcome any EU restrictions, in order to achieve the common market of products, while maintaining a high level of protection. For this purpose, it was decisive, on one hand, the contribution of the Court of Justice, which has repeatedly intervened to censor the restrictive practices of the Member States, basing their decisions mainly on the principle of mutual

recognition and proportionality of any limit established at the National level to guarantee interests such as protection of health or consumer; on the other hand, the harmonization of the various National provisions in the field, with particular reference to the discipline of the components of food such as additives, preservatives, colorings, sweeteners, flavors and solvents, as well as of the modalities used to mark products [COSTATO - BOLOGNINI, 2003].

In particular, in order to make the regulation consistent across all European territories, the regulatory power of every member State has been significantly reduced, due to the increasingly pervasive European legislation [GENESIN, 2009], able to ensure a uniform discipline throughout Europe [LEIBOVITCH, 2008]. From the point of view of the application of rules, instead, functions are shared between European and national authorities according to a network model.

Competence in the area of food safety, in fact, is distributed on two levels, European and national. The first level is competent for functions requiring a unitary exercise, such as the management of situations of alarm, emergency and crisis. The national level, instead, is responsible for monitoring compliance with legislation, in order to ensure proper and uniform application of the rules in force within the Union.

Administrative functions for the protection of food security are, therefore, shared between European and national authorities: the first involves when there is no agreement among the second or when the possible health risk requires the exercise of unitary functions, such as in cases of alarm, emergency and crisis; national authorities, instead, verify the respect of obligations to protect food safety and are competent in the first instance for the authorization to place products in the market, with some sectoral exceptions (such as, for example, the marketing of GMOs). However, in case of actual or potential disagreements between the authorities of two or more Member States, the power of authorization is drawn at European level, in order to ensure a shared and uniform decision throughout the European Union [SAVINO, 2007].

The division of functions is not, therefore, so clear, but all the powers in the field of food safety are interwoven and sometimes overlap at the two levels, as is typical of network structures [CASSESE, 1999]. Competence is, in fact, shared between Member States and European institutions and, although their respective tasks are defined, there is frequently a mingling, justified by the need to ensure a uniform level of protection.

2. The institution of the European Food Safety Authority.

European policies on food safety, already expressed by the publication, in 1997, of the Commission Green Paper on «The General Principles of Food Law in the European Union» (later merged into the Treaty of Amsterdam in 1999) and, in 2000, of the White Paper on food safety, were further articulated in EC Regulation no. 178/2002 of 28 January 2002. Within the text, there is the identification of general principles and requirements of food law, the description of procedures to apply in case of alarm, emergency and crisis, and, above all, the institution of the European Food Safety Authority, defined as «independent scientific point of reference», responsible for the coordination of all the other authorities that deal with food safety at national level.

In the wake of events which in previous years had hit Europe, not only threatening the food safety but also engendering panic situations due to significant media effects, the European institutions have felt the need to intervene in a decisive manner, not just confirming and strengthening the general principles within a normative act immediately binding, but also by establishing an authority, having specific scientific competence, in order to objectively assess risks related to food and provide clear and truthful information, not influenced by interests of different types and made available to the competent national authorities - to ensure more informed decisions - and to the consumers, to reassure them with regard to the products circulating in the EU territory.

The creation of EFSA has been, therefore, an important signal of the attention reserved by the European institutions to the issue of food safety [GABBI, 2008], as well as the Authority seems to be a useful reference point for the various national authorities which are entrusted with the care of food safety.

The coordination of the national authorities is, however, only one of the tasks assigned to the Authority, having in the first place to point out its active role in research and promotion of food security. As we shall see further, indeed, the Authority is the scientific advisory body at the central level and, for this reason, on the one hand, it is the main center for research and scientific advice, on the other, it acts as a «reference point» for organizations that deal with food safety in the different member states [ALEMANNO, 2008].

The Authority, based in Parma, is made by the Executive Director, the Management Board, whose members are mandated to act in the public interest, without representing governments, organizations or sectors, and groups of experts and scientific departments [SILANO, 2009], composed of highly independent scientists, with functions of scientific advisory for decision-makers.

The Authority shows a particular structure, very different from the one that normally characterizes the European agencies, since the Management board is

not composed of representatives of the Member States. Coordination with Member States is ensured, in fact, by means of another organ, the Advisory Forum [LONGOBARDI, 2009], «composed of representatives from competent bodies in the Member States which undertake tasks similar to those of the Authority, on the basis of one representative designated by each Member State».

The aim of the European legislator, therefore, is to ensure a strong partnership between the Member States and the concentration of the relevant information and knowledge needed for proper risk assessment [CAPELLI - KLAUS - SILANO, 2006]. In accordance with Regulation no. 178/2002, in fact, the institution of an Advisory Forum helps to avoid overlaps between scientific studies and, consequently, waste of resources, and to iron out any differences between the various national agencies.

However, the distinguishing feature of the Authority is detected in its nature as an independent authority, with its own legal personality and subtracted both to political directives as to the control of other European institutions, more than in the particular conformation of the Authority [LOSAVIO, 2003]. All members of the Authority have proven experienced and their independence is ensured by the nomination and the impossibility of removing them in advance.

The Authority is responsible for assessing the risks related to foodstuffs, by collecting, analyzing and processing the data available, and for providing both the European and national institutions with scientific advice on security of food and feed, nutrition, animal health and welfare, protection and plant health [SMITH - TERRY - DETKEN, 2012].

Instead, the Authority doesn't have any regulatory power on the food market, coming to light an important difference between this one and the classical model of independent authorities. EFSA, indeed, is exclusively responsible for the risk assessment, while its management is left to the European Commission.

The reason of the absence of regulatory power is explained by the multiplicity of relevant interests, which has prompted the European Union to maintain separate risk assessment and risk management, the first object of a scientific investigation, the second of the comparison of all the interests involved.

This does not exclude, in any case, a strong influence of the Authority on the formulation and implementation of food law, which should find its scientific basis on opinions issued by the Authority in relation to the different areas of interest.

As a consequence of the absence of decision-making powers in the hands of EFSA, its decisions cannot be appealed, presenting the nature of scientific advice not immediately able to affect the subjective legal situations [ALEMANNO - MAHIEU, 2008]. And in fact, it may be subject to legal protection only the act

coming from the organ with decision-making powers – in this case the Commission – that acquires the opinion expressed by the Authority by adopting a measure scientifically based on the assessment issued by EFSA.

The scientific risk analysis can, therefore, be censored only indirectly, i.e. by contesting the act having a content based on the scientific opinion. Notwithstanding that, albeit indirectly, the scientific evaluation can be criticized only in the case of manifest lack of logic, recognizing broad discretion to the complex assessment of the possible risks to human health from food and feed products.

3. The division of functions between the European Food Safety Authority and the European Commission: risk assessment v. risk management.

As anticipated, the institution of a dedicated European agency for food safety has not completely ousted the jurisdiction of the European Commission on the matter.

The creation of an independent body has indeed responded to the need to ensure a scientific evaluation of the risks associated to food, headed by a structure with the necessary technical skills for an objective assessment. EFSA, instead, is not responsible for risk management, regarding the decisions related to face situations of alarm, emergency and crisis, returned to the discretion of the Commission.

The European Food Safety Authority and the Commission are placed, therefore, on two different levels, which we can name the first scientific, the second discretionary.

The independent authority, in fact, is competent for assessing the dangerousness of food products relying on scientific experts specialized in the field, while the Commission, once known the potential risks, establish how to intervene and manage the information received.

The first step at the base of the food safety policy consists, then, of the assessment of risk, that is the evaluation of the possible harmful effects of a product or a food process and the seriousness of the consequences. All in accordance with the principles of excellence, independence and transparency, requiring that the assessment is carried out by highly qualified experts, independent of political and economic influences, through transparent procedures, able to highlight also the eventual gaps in scientific knowledge. Moreover, in order to allow understanding of the scientific findings, the results achieved must be accompanied by an explanatory statement from which it could be possible to trace back to the rea-

sons upon which scientists have based their reasoning and any remaining uncertainties [CAPELLI- KLAUS - SILANO, 2006].

At the stage of risk assessment follows that of management, that is based, however, on entirely different criteria. If, in fact, the Authority must verify whether or not a product is dangerous, independently and solely on the basis of the scientific evidence available, the Commission has to decide how to manage the Authority's results transmitted and how to act in case of a manifest health risk also taking into account all the possible conflicting interests.

The Commission, indeed, called upon to intervene whenever a situation of alarm, emergency or crisis appears, has to choose among those possible the most appropriate measure, in light of all other interests that are important, always respecting the precautionary principle [POTO, 2005; s. *supra* FOLLIERI], but also the principles of proportionality and reasonableness with which the former must always be balanced.

The decisions concerning risk management are, therefore, the result of high discretion, although European legislation, however, requires a high level of protection of human health.

The identification of the most appropriate intervention measures then must take into account some aspects such as the duration of the consequences, reversibility of the effects, but also the suitability of the measure in the light of cost-benefit analysis. The higher level of protection must, in fact, always be pursued by resorting to the least onerous possible, even because the European Court has clarified that also in the food sector the risk can be reduced, but it is impossible to totally eliminate it. It follows that eventual absolute prohibitions based on a strict application of the precautionary principle can only be allowed where they are truly warranted by specific circumstances.

4. *The Risk Management: the Commission's Procedures.*

The procedures followed by the Commission for risk management are described in the Regulation n. 178/2002 in three specific sections: Rapid Alert System, Emergencies and Crisis Management. However, the applicable discipline has been since expanded and in particular it has been more precisely specified by subsequent regulations (for example, by the Regulation no. 16 of 10 January 2011 laying down implementing provisions in relation to the system of rapid alert for food and feed).

By starting the analysis of the procedures from the Rapid Alert System [MACCIONI, 2011] it should be noted first that it is not a novelty brought by the

Regulation no. 178/2002, which, indeed, only replaced the system already introduced by Council Directive 92/59 / EEC on products general safety. However, it has not changed the fundamental nature of the system as an information dissemination measure about possible risks connected to food in order to allow possible early intervention and awareness.

The system has, in fact, a primarily informational purpose, not just to permit both the European and national authorities to react in an appropriate manner, but also to prevent possible emergency situations [PETRELLI, 2003]. The information, circulated through the rapid alert system, moreover, does not only cover the possible risks, direct and indirect, to human health deriving from food and feed, but also the measures taken by individual States to face the problem, in order to standardize the reaction interventions. Through the rapid alert system, therefore, all the competent authorities are able to know promptly, possible situations of danger to human health and to prepare a targeted intervention, timely and appropriately.

The system consists of a network involving the Member States, the European Food Safety Authority and the Commission and of which the latter is the management entity. It is the Commission, in fact, to which are transmitted all the relevant information from both Member States and the Authority, that may, however, supplement the notification with any scientific or technical data capable of allowing more aware of risk analysis .

The model described is in line with the classical distribution of functions between the European and national levels, according to which the national authorities must act to ensure food security, instead the European level is competent for the task of disseminating information on risks and measures taken within the whole EU territory.

The situation, however, changes in the presence of emergency situations which may constitute a serious risk to human health. In this case, if the intervention of the national agency is not adequate, the Commission acquires the competence to act to face the dangerous situation.

Under Articles 53 and 54 of Regulation no. 178/2002, the Commission may, in fact, intervene on its own initiative or at the request of a Member State, by resorting to measures of varying intensity depending on the severity of the situation, including the suspension of the circulation of the products in the market.

The second procedure described in the Regulation relates, in fact, to the direct intervention of the Commission where a risk for human health deriving from food or feed has been verified. This is an important case of direct administration, in which the European institution does not only influence the activity of the authorities of each Member State or at least confirm the need for national inter-

vention, leaving it to the discretion of Member States the choice about the concrete ways, but intervenes in the first person, regardless of any national initiative.

Only in the case of the Commission's inaction, in fact, every State can intervene autonomously, configuring a kind of subsidiarity on the contrary, since the responsibility lies in the first instance at the central level and, only in the case of inaction, to individual national authorities [ALBISINNI, 2003].

Finally, regarding the third procedure, it is characterized by close cooperation between European and national authorities with preventive function. Regulation no. 178/2002, in fact, deals with the theme of crisis management, by requiring the Commission, EFSA and Member States to draw up a general plan, in which are marked «the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54».

The provision is clearly the result of the many crises faced by the European Union prior to the adoption of Regulation no. 178/2002, such as the well-known case «Mad Cow» which, together with others, led the European institutions to take on the need to ensure appropriate measures to overcome any similar unpredictable phenomena. On the other hand, the generality of situations that may be considered in the plan and the vagueness of the rules seem to confirm that it is a general disposal applicable where the risk could not be avoided on the basis of legislation in force or with the emergency measures [BOLOGNINI, 2003].

However, although the content of the plan is not specified in detail, the European legislator has clarified that, within the text, they should be indicated «the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy». Regulation highlights, therefore, two important needs which the plan must answer over the identification of the necessary measures to address the crisis: the need to ensure transparency of procedures and a communication system.

The provision has the distinct aim of protecting consumers. The various information must not, in fact, simply be made accessible, but should be, also, understandable for consumers in order to avoid any unfounded concerns [BOLOGNINI, 2003].

Finally, the Regulation also rules the tasks of the Commission in the case a crisis occurs. In accordance with art. 56, the Commission, where identifies a situation that cannot be addressed solely with the applicable provisions or with the emergency measures, «shall immediately notify the Member States and the Authority». Simultaneously, «the Commission shall set up a crisis unit immediately, in which the Authority shall participate, and provide scientific and technical assistance if necessary».

The immediate setting up of a crisis unit is an extremely important issue for the management of the crisis. Through the unit, in fact, first of all, it becomes easier to coordinate with any of crisis units constituted at the national level, second, it is made available to consumers a subject, highly qualified, with the task of providing adequately information in order to avoid panic situations. The following art. 57, paragraph 3, confirms, in fact, that «the crisis unit shall keep the public informed of the risks involved and the measures taken».

As for the cases in which should be set up a crisis unit, the Regulation refers to any «situation involving a serious direct or indirect risk to human health deriving from food and feed, and the risk cannot be prevented, eliminated or reduced by existing provisions or cannot adequately be managed solely by way of the application of Articles 53 and 54». The rule confirms, then, what already mentioned for the preparation of the general crisis plan, although it has been interpreted by some scholars as implying a subset of crisis situations, for which the plan would not be sufficient, but that would also require a unit crisis [BOLOGNINI, 2003].

Anyway, it seems certain that the Regulation establishes a kind of hierarchy of actions that the Commission, supported by EFSA and national authorities, should take to manage the risk for health food. At first, in fact, it must apply the existing legislation, in the second round the Commission can resort to emergency measures and when they are both not able to overcome the dangerous situation, it is necessary to use a plan and a unit crisis specially set.

All three procedures as outlined in the Regulation enable, then, or at least should enable the Commission, responsible for risk management and supported by EFSA and Member States, to overcome any situation of alarm, emergency or crisis, by using flexible procedural models, therefore also applicable to unpredictable situations. The discipline of procedures is, in fact, sufficiently generic and indeterminate, confirming the possibility for the Commission to adopt not typical measures, however adequate to overcome the alarm, emergency or crisis. After all, also in the Italian administrative law there is an attenuation of the principle of typicality in case of emergency powers [SAVINO, 2007].

How, then, to the recipients of these measures, they are the Member States and not immediately private people, with important consequences in terms of protection. Indeed, both the fact that emergency actions are addressed to the Member States, as their nature of general acts, make difficult to access to judicial protection.

If, therefore, Member States implement the measures established at the European level, individuals can appeal the domestic acts and, then, through a preliminary ruling, the matter could be referred to the European court. Where,

however, is not adopted an act of implementation, individuals may try to appeal to the supranational court, proving that the decision affects them directly [SAVINO, 2007].

5. National Authorities: a network model to protect the food safety. Dissemination of information.

National authorities in the field of food security do not constitute a common experience for all member States, in the sense that only some of them have established independent agencies dedicated to the control of food safety. In others, including Italy, there is not a specific independent authority, but the task of ensuring compliance with the rules in this area is entrusted to internal organs to other national institutions.

And indeed, the European discipline, as well by requiring Member States to identify a body for controlling the implementation of European provisions, doesn't impose the establishment of a special independent authority, since it is sufficient, but at the same time necessary, to entrust a functionally independent body for the food risk assessment. The EC Regulation no. 2230 of 23 December 2004, containing the rules for the application of the previous Regulation no. 178 of 2002, made clear the need to ensure an independent organ in charge of the scientific risk assessment, without, however, limits the legal form that can be chosen.

Regardless, then, of whether it is independent authorities, which have an autonomous and separate structure, or incardinated organs within other institutions, the common profile is represented by the responsibility of ensuring the application of legislation on food safety. It is up to the national level, in fact, the task of monitoring compliance with the obligations to protect food security and providing data and information to EFSA, that acts as the network coordinator of the competent national authorities.

It is possible, therefore, distinguish two spheres of action of the national authorities: the first primarily internal, the second aimed to the coordination with the European level.

From the internal point of view, in fact, every national authority or body responsible for food safety must ensure compliance with current regulations, exercising authorization, control and sanction powers. From a supranational perspective, instead, the national authorities have responsibility to provide EFSA with all information necessary for risks evaluation and, at the same time, to apply the instructions from the same authority on the criteria that should be considered in check the safety of food products.

The construction of a network system guarantees, in fact, the standardization of the assessment methods, especially in order to prevent that differences in the criteria used will result in illegal competitive obstacles [COSTATO - BOLOGNINI, 2003]. And indeed, European intervention for the assessment and management of risks takes over, as already mentioned, only in the absence of agreement between the national authorities, or where any situation of alarm, crisis or emergency requires uniform action in all the territory.

In conclusion, food security is protected by a network system, in which EFSA, Commission and national authorities share functions and are coordinated in order to ensure the proper implementation of rules governing the matter and a high level of protection.

The first subdivision covers, then, the type of intervention, ordinary or emergency: in the first case, the national authorities are competent, in the other European authorities have power, especially in light of the subsidiarity principle on which is based in general the allocation of administrative functions within the Union and that gives the Member States the task of ensuring the implementation of standards, except where it is appropriate the supranational intervention for a uniform implementation of the rules or for the inadequacy of national measures, as in the case of alarm, emergency and crisis.

The second division, however, is actually a sub-allocation, since it can be found at both European and national level. It regards the distinction between risk assessment and risk management activities, kept separate, as seen talking about the European Union institutions, and with different degrees of separation, as, for instance, we will see for Italy, in order to ensure, objective, independent and impartial evaluation.

6. The Italian experience. The opportunity of establishing a national independent authority for food safety.

According to art. 117, c. 3, of the Italian Constitution, nutrition is one of the concurrent legislation subjects. At the regulatory level, therefore, the State must define the general principles of the sector, while the regions are called to lay down the detailed regulations.

Regarding, however, the administrative functions, they shall be distributed among the different levels of government in accordance with the principles of subsidiarity, differentiation and adequacy, so, at the national level, administrative skills are divided between State, regions and local autonomies, depending on the type and the required degree of intervention.

Focusing only on the state level, here are several organs that perform functions in some way connected to the issue of food security. However, more attention should be paid to the independent risk assessment organ that was established in order to comply with the commitments coming from the European Union.

With D.L. n. 202 of 1 October 2005, in fact, it has been established, into the Ministry of Health, the National Committee for Food Security, whose activity was ruled only later with D.M. n. 27799 of 26 July 2007 that defined the Committee in terms of «technical and advisory body on matters referred to in Regulation (EC) No. 178/2002».

The Committee is divided into two sections: the first with functions of risk assessment and protection of food safety; the second with advisory competence for consumer and producer associations in the field of food safety. The committee, as well as being the scientific body of reference at national level, is the competent authority to deal and coordinate with the European authority, participating to the Advisory Forum through its own representative.

The Committee is, therefore, the body responsible at national level for the evaluation of food safety risks, but despite being independent, having to provide scientifically objective assessments, it must comply with the directives coming from the Strategic Committee, which determines, also on the light of instances of consumer and producer associations, the priorities of the scientific Committee, through the preparation of an annual and multi-annual technical and scientific plan.

There has never faded, however, the debate on the desirability of establishing a special independent authority to protect a sector in which many critical interests converge. And indeed, the art. 2 of Law 24 December 2007, n. 244, provided that the National Committee for Food Security assumes the name of «National Authority for Food Safety», transferring the authority headquarters in the city of Foggia, although without changing from a substantive point of view the structure, remaining the incardination within the ministry of health.

The next D.L. n. 248 of 2007 set, however, a further change of name to «National Agency for Food Safety», leaving to a special regulation the task of disciplining in detail the functioning, organization and administration of the Agency. Regulation, however, has never been adopted, with the result that the agency has never gone into action. In fact, the food safety functions are still handled by the National Committee for Food Security hinged at the Ministry of Health, a fact which raises some concerns about the compliance of national legislation with that of Europe.

As already mentioned, indeed, the European Union, while not limiting the choice of the individual Member States to the legal form of the organism respon-

sible for the protection of human security, has, however, made it clear that this should be an independent organ, precisely in order to keep separate risk assessment from risk management.

In the Italian experience, however, independence seems threatened by the incardination of the committee within the ministry of health, so that the person in charge of risk assessment is part of the one responsible for managing [LONGOBARDI, 2009]. It would be more appropriate, therefore, the establishment of an effectively independent authority, with technical competence, as well as it occurs at the European level.

Moreover, the creation of a specific authority in matters of food safety would promote, also, the incorporation of all the functions in some way related in the hands of a single subject. If it is true, in fact, that the National Committee is, at the moment, the national equivalent of the European authority and our independent agency in matters covered by Regulation no. 178/2002, it is also true that other functions related to the subject of food security are distributed among various public entities.

After all, the complexity of the national system, due to the multiplicity of subjects to some extent involved in the food safety area, both with advisory and decision-making capacity (think, for example, to the Ministry of Agriculture and Forestry, the internal commissions of the two Chambers, the Superior Council of Health, the ASL), is a reflection of the delay with which, even in Europe, has been given attention to the issue of food security.

Already before the establishment of a European authority and the obligation for Member States to put special independent bodies in charge of the protection of food safety, numerous functions in the field of agriculture, health and hygiene, joined in recent years by consumer and producer protection, were attributed to public entities. All interests which together make up the macro interest to food security that today should find a single and independent reference point [FIORENZA - FIORENZA, 2002].

The establishment of an independent authority responsible for the protection of the entire food sector would, then, lead to combine the different functions in a single entity, highly competent and independent and able to reconcile the interests of food security with other equally important interests, first of all the competition in the market in full compliance with European legislation.

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IV. Brief Considerations on the Regulation of Food Labelling

Letterio Donato

CONTENTS: 1. Labels as a means of communication and food as a form of expression.- 2. objectives of European labelling legislation: 2a. consumer protection.- 2b. free movement of products.- 2c. informed and ethically oriented choice.- 3. scope: new elements concerning mass caterers contained in Regulation (EU) No 1169/2011.- 4. mandatory and voluntary information;- 5. labelling for direct sale.- 6. conclusions

1. *Labels as a means of communication and food as a form of expression.*

The labelling of food products has grown in importance over time, fulfilling a duty to inform consumers.

In the context of the food market, in which exchange between product and price is characterised by the anonymity of the purchaser and the fact that the agreement concerns an object, labels become an essential and principal tool for the exchange of information between seller and buyer.

The label is the main means of communication through which the producer passes on the legally required information relating to the product, as well as any other information deemed appropriate, within certain limits. Thus, from the label, consumers obtain the necessary information that allows them to exercise their right to a fully informed choice [LATTANZI P., 383 ff.; GIROLAMI M., 1 ff.; SAJA R. - TOMMASINI A., 494 ff.].

The importance of labels grows according to the type of information they contain. This is often in the form of so-called *credence attributes*, in relation to which information is structurally asymmetrical, since it cannot be obtained through direct consumer experience [APRILE M.C. - ANNUNZIATA A., 111].

For this reason labels become incorporated with products and circulate with them becoming “commodities” in their own right [GERMANÒ A., 146], since they are capable of transferring knowledge, understood as “objective” acquisition (intersubjective *rectius*) of data [PUGLIATTI S., 251], of hidden elements that could potentially influence consumers’ choices.

The circulation of labelled products therefore affects market rules, the harmonisation of which is one of the fundamental objectives of European treaties.

EU legislators altered labelling rules through Regulation (EU) No 1169/2011, which sets out the regulatory framework and expressly repeals all previous Regulations and Directives on this subject. It is a “horizontal” Regulation, with other related “vertical” rules concerning specific products.

The legislative framework is interesting in that it systematically refers to annexes, drawn up and updated by the European Commission, allowing flexibility (within certain quantitative and time limits) regarding the information that labels must contain. This allows the basic regulations to be kept up to date and better able to cope with changing consumer and market requirements.

As this paper will attempt to demonstrate, labels also appear to be an important litmus test of the complex values that influence consumers’ choices, conveying the concept of food being accepted into modern affluent society. Indeed, there seems to be widespread support for the idea that food is not just an indispensable resource for survival, but a means by which people express themselves, protect the environment and contribute to the sustainable development of the planet and the protection of wildlife.

2. Objectives of European labelling legislation: 2a. consumer protection.- 2b. free movement of products.- 2c. informed and ethically oriented choice.

A clear indication of the abovementioned trend can be found in the way food information legislation objectives have developed over the years:

2a. The first premise of the Regulation sets out the primary aim of food labelling regulations: consumer protection.

European and domestic legislation has pursued this objective ever since the so-called “mad cow” scandal and this pursuit has now been strengthened by a considerable widening of mandatory information and stricter rules protecting against allergens;

The guidelines contained in the white paper on food safety that preceded Regulation (EC) No 178/2002 already made consumer protection an absolute priority of food information.

The need for consumer protection is certainly heightened by the globalisation of the food market, which requires rules guaranteeing adequate health and safety standards for food products within the EU.

2b. The second and most long standing objective pursued by the Regulation is undoubtedly free movement of products, to be achieved through legislative harmonisation.

European legislators and case law have always attempted to harmonise food market regulations in order to guarantee free movement of goods within the EU.

The second premise of the Regulation identifies the need to guarantee the free movement of safe and wholesome food in the interest of citizens and food business operators.

The principle of free movement has a dual role. It requires the establishment of a uniform package of mandatory information but, at the same time, it represents an extrinsic limit to the determination of voluntary information or to the widening by member states of the amount of mandatory information; in other words every time further information may have the effect of limiting or obstructing the market for no specific reason [COSTANTINO L.].

As many have observed, the label ends up becoming a “technical rule” that affects competition and constitutes a non-tariff barrier to the movement of goods. [GERMANÒ A. - RAGIONIERI M.P. - ROOK BASILE E., 84; SAJA R. - TOMMASINI A., 495].

The new rules concerning distance selling, the limitations of information on the origins of products (see, *infra*, A. Guerrini) and of voluntary information (see, *infra*, P. Pantalone) all seem to be directly linked to the pursuit of this objective.

2c. On reading the Regulation it is possible to identify another objective pursued by European legislators, that of guaranteeing consumers’ right to an informed choice.

This is a new element that has always been lacking in domestic and European food information legislation but is now officially recognised in European regulations.

Labelling becomes a tool capable of allowing consumers to make an informed choice, not only on the basis of considerations strictly tied to survival or the need to feed oneself, but rather by giving importance to fundamental aspects of human development. People use food to express themselves, their ethical convictions and participate in the pursuit of common interests.

For the first time European legislators lay down labelling regulations aimed at supplying all necessary information of an environmental, social and ethical nature, in the knowledge that these considerations are capable of influencing consumer choice more than others.

It is no coincidence that economic studies show how consumer dynamics are increasingly detached from spending power; it is no longer just price that determines choice of foods, but more complex and noble considerations that require the supply of adequate information [ANNUNZIATA A., 178]. (this can be seen from the regulations requiring indications concerning the appropriateness of specific foods for vegetarians or vegans, or those supplying information on the environmental impact of a particular food, the distance of place of production from that of sale, method of production, and numerous others).

The choices made by ever more attentive and better informed consumers are increasingly based on the quality of products, not only in terms of food safety (especially health and nutritional considerations), but also as regards eco-sustainability in terms of prevalent use of local and renewable resources, maintenance of soil fertility, use of natural products and procedures and respect for the living conditions of livestock [GIUCA S., 75].

In the same vein, European legislators demonstrate renewed attention for the productive function of agriculture through life-cycle management, since there is a close link between food policy choices and exploitation of resources [NAPOLITANO G., 302].

3. Scope: new elements concerning mass caterers contained in Regulation (EU) No 1169/2011.

A further element in support of the hypothesis that Regulation (EU) No 1169/2011 is part of a partially new approach to food information can be deduced from the scope of the new regulations, which is considerably widened.

The Regulation applies to food business operators at all stages of the food chain, where their activities concern the provision of food information to consumers and applies to all foods intended for the final consumer, including those delivered by mass caterers and those intended for supply to mass caterers (art.1, par.3).

This regulation represents a new element in European food labelling law as it extends the rules and principles concerning food labelling to all food business operators.

In the light of this extension of food information rules to the entire food chain, art.8 regulates the responsibility of food business operators with regard to the provision of food information to consumers.

This article also represents a new element in European law and forms part of the strengthened system of responsibility throughout the food chain, laid down

initially in the white paper on food safety, and then in Regulation (EC) No 178/2002, in articles 17, 18 and 19, which contain the basic rules concerning the responsibilities of food businesses [COSTANTINO L., 131; GIROLAMI M., 3].

The supranational regulation incorporates the principle of “integrated approach to the whole food chain” set out in the white paper on food safety, providing incentives for forms of self-regulation by businesses and allowing for the traceability of every stage of production [SPOTO G., 1077].

The wider scope of the Regulation clearly indicates that European legislators intended to use it not only to compensate for the weaker contractual bargaining position of certain subjects, but also to guarantee the absolute right to accurate and complete information [GIROLAMI M., 3; BOLOGNINI S., 635].

The Regulation even applies to transport undertakings when the place of departure is within the territory of one of the member states.

It is also applied to mass caterers, who become both subjects to whom information must be provided by the producer on the pre-packaging label and subjects responsible for providing information to the final consumer, without prejudice to the responsibility of the producer unless the distributor decides to alter the content.

4. Mandatory and voluntary information.

4a. The new approach to food information can also be seen from the central part of the Regulation, which sets out in concrete terms which information producers have to supply to consumers on the product label.

As was pointed out earlier, the Regulation guarantees that rules will be updated through the provision of a recurring regulatory framework.

A series of categories of information are specified as being mandatory for inclusion on labels, largely concerning: a) identity, composition and properties of the food product; b) information on consumer protection and safe use of the food, including any ingredients that may have harmful effects for certain categories of consumers or any further elements that could impact consumers' health (allergies and intolerances art. 21); c) information on nutritional aspects. Alongside this information, certain other types of information are specified as being mandatory according to the type of food, the latter being altered from time to time through updating of the annexes to the Regulation by the European Commission.

The aim is to provide a systematic framework for food information in order to guarantee consumers' right to be informed. Consumers must be put in a posi-

tion to be able to make informed choices and receive relevant information concerning consumer protection and environmental, social, religious and ethical considerations that may be of importance to them [LOSAVIO C.].

Indications concerning possible allergies or intolerances are particularly important and it is a requirement for the presence of any of a series of substances included in the list of allergens to be shown in such a way as to be immediately perceptible to the consumer [SAJA R. - TOMMASINI A., 508].

However, the Regulation does not adopt a position with regard to so-called precautionary labels, in other words labels that allow the producer to warn of the possible presence of certain substances that may cause allergies and intolerances, when these substances may be present only in trace quantities.

The decision by member states to increase the amount of mandatory information, on the other hand, is necessarily subject to the pursuit of objectives clearly defined by European law and to the commission's notification procedure (protection of public health; consumer protection; fraud prevention; protection of industrial and commercial rights; repression of unfair competition), without prejudice, obviously, to the limitation that individual domestic interventions cannot limit or prohibit the free movement of goods that conform to EU regulations [SPOTO G., 1071].

4b. Labels may contain information other than mandatory information. This may be the subjective expression of a quality of the product that helps orient consumers' choices.

Voluntary information includes information that may ethically orient consumers' choices or information relating to the suitability of the food for vegetarians and vegans or for specific groups of consumers.

Voluntary information, however, can only be provided within certain limits, striking a balance balancing between the operator's choice to provide it with the need to guarantee clear information and fair presentation of the food (Premise 47).

Food business operators are not free to determine the information to include if the information provided could create confusion for consumers. If there is too much information this may hide crucially important facts, weakening or even nullifying consumers' capacity to read and use it, also considering the time factor involved in making a purchase [SPOTO G., 1080].

In the end, the fact that information is true is not enough to make it useful; it needs to be relevant and provided in an appropriate quantity [LUCIFERO N., 144 ff.]. For this reason, the Regulation makes the determination of voluntary information subject to approval by the European Commission.

4c. Right from the premises the Regulation sets out the principles regulating the way in which food information must be provided on labels.

Consumers not only have the right to receive truthful and accurate information, but they also have the right to receive it in such a way and in such a form that it does not represent reality differently to what it actually is [COSTANTINO L., 137 ff.].

It is explicitly prohibited to include information on the label that may mislead consumers (on the characteristics of the food with regard to its nature, identity, properties, composition, quantity, period of conservation, country or place of origin, or method of production). This includes the prohibition to emphasise characteristics that a product actually possesses but which are common to all products of the same kind.

5. Labelling for direct sale.

Finally, the regulation of direct sale set out by European legislators is of significant interest.

In this case, direct human contact is considered sufficient in itself to guarantee a fully informed choice by consumers and thus eliminates the need for most of the mandatory information included on the label.

Indeed, for direct sale there is an explicit exemption from the rules governing labelling, the only mandatory information being that which concerns possible allergies and intolerances.

All further information becomes voluntary and the added value of the product is tied to the communicative abilities of the food business operator. The consumer's choice is informed because there is the opportunity to communicate directly with the food business operator.

6. Conclusions.

As well as compensating for the information gap between consumers and producers, information requirements in the food market seem to be increasingly used to pursue general interests concerning the free movement of goods [SPOTO G., 1073] and full personal development, in protection of common interests.

Labels provide citizens (rather than just consumers) with a complex collection of information that allows them to understand the quality of the food they intend to buy and to make their choice based on considerations that are not nec-

essarily limited to the logic of food security, but are oriented towards the overall concept of food safety [RAMAJOLI M., 277].

In this context, a prominent role is played by consumer advertising protection, which nowadays mostly takes the form of setting up administrative systems and regulatory instruments of a general nature [G. NAPOLITANO, 310].

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V. Responsibility and Penalties under Regulation 1169/2011 on Food Information

Lorenzo Cuocolo and Francesco Gallarati

CONTENTS: 1. Introduction. – 2. The responsibilities of food business operators with respect to food information before Regulation 1169/2011. – 3. The responsibilities of food business operators with respect to food information after Regulation 1169/2011. – 4. The lack of penalties applicable to the infringement of food information law. The Italian case.

1. *Introduction.*

Regulation 1169/2011, the new General Regulation on food labeling, went into effect more than two years ago, on December, 13th 2014.

The Regulation was intended to reorganize the European legislation on food information, amending and repealing many of the acts that, in the previous years, had been adopted on the matter. Among others, the Regulation repealed Directive 2000/13/EC, which previously laid down Union rules relating to the labeling, presentation and advertising of foodstuffs.

The main aim pursued by the Regulation was to update the rules on food labeling provided by Directive 2000/13/EC – which, for the most part, dated back to 1978, more precisely to Directive 79/112/EEC – and thus to resolve some of the issues that had been raised under the previous legislation.

In particular, one of the issues that Regulation 1169/2011 aimed to tackle was that of the responsibilities of food business operators with respect to food information. Indeed, the Regulation intended to put an end to the fragmentation of national measures that, in the decade before, had constituted an obstacle to the proper functioning of the internal market as well as a cause of distortion of the competition between food operators located in different Member States.

In this respect, on the one hand, it must be said that the Regulation represents a significant step forward in the direction of the implementation of a complete harmonization of the subject. On the other hand, though, it must also be observed that some problematic issues are still unresolved. This paper will focus in particular on two of them.

In the first part of the paper, the analysis will concentrate on the problem of the allocation of responsibilities along the food supply chain. Before the adoption of Regulation 1169/2011, the lack of harmonization caused great uncertainty as well as disparities between operators located in different Member States. In this regard, art. 8 of the Regulation tries to lay down a simpler and more complete legislation on the matter. Yet, there are still some problems of interpretation that must be faced.

The second part of the paper will concentrate on the lack of penalties applicable to the infringements of the Regulation's rules. In fact, the Regulation doesn't provide any rule concerning the penalties that must be applied for the infringement of food information law, thus leaving to the Member States to lay down the legislation on the matter.

Clearly the two aspects are strictly connected, since the liability system laid down by the Regulation won't be operative as long as the Member States won't provide effective, proportionate and dissuasive measures and penalties to apply to the food business operators who don't respect the rules on the food information. This means that Member States' inactivity can prevent the Regulation from producing its effects, in spite of the complete harmonization provided by the European legislation. This last issue will be analyzed with specific reference to the Italian case.

2. The responsibilities of food business operators with respect to food information before Regulation 1169/2011.

Before the adoption of Regulation 1169/2011, no specific rule was provided by European law about the distribution of responsibilities among food business operators.

In fact, Directive No 2000/13/CE, which previously laid down Union legislation on food labeling, contained no express rule on the matter. As a consequence, each Member State could lay down its own rules. In particular, although the principle of responsibility of food business operators existed in some Member States and areas of food law, in other areas this was either not explicit or else responsibility was assumed by the competent authorities of the Member States through the control activities they carried out. The lack of harmonization caused great disparities, which were liable to create barriers to trade and distort competition between food business operators in different Member States.

A first response to this issue was given by Regulation 178/2002, which established the general principle of the responsibility of food business operators.

In particular, art. 17(1) set forth that food business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

According to the 30th recital of Regulation 178/2002, this provision was based on the consideration that food business operators were best placed to devise a safe system for supplying food and ensuring that the food they supplied was safe; thus, they should have primary legal responsibility for ensuring food safety.

In short, by article 17(1), in conjunction with the 30th recital of Regulation 178/2002, the European legislator established the principle of the responsibility of food business operators for the infringement of food law, thus preventing Member States from implementing or maintaining other kinds of responsibility systems.

Still, Regulation 178/2002 didn't provide a complete harmonization of national responsibility systems relating to food law. In fact, article 17(1) didn't expressly mention which food operator was to be considered responsible for the breach of single provisions, and in particular for the infringement of the rules on food labeling. On the contrary, it was extremely vague on the point, simply establishing the responsibility of all food business operators «at all stages of production, processing and distribution». In this respect, it is important to highlight that article 3, number 16, of Regulation 178/2002 gives an extremely broad definition of «stages of production, processing and distribution». According to that provision, in fact, the expression encompasses any stage of the food supply chain, from the primary production of a food to its storage, transport, sale or supply to the final consumer, as well as its importation.

In conclusion, before the adoption of Regulation 1169/2011, although the principle of the responsibility of the food business operators was established by Regulation 178/2002, Member States still had the jurisdiction to adopt national measures in this area. The result was a high fragmentation of rules, which constituted an obstacle to the proper functioning of the internal market and led to a distorted competition between food operators located in different Member States.

Prime example of this fragmentation is the judgment given by the European Court of Justice on the case *Lidl Italia v. Comune di Arcole* (C-315/05), on November, 23th 2006.

In that case, the Italian competent health authorities took some samples of an alcoholic beverage produced in Germany and distributed in Italy by Lidl Italia. Thanks to the laboratory analysis carried out on the samples, the health authorities found out that the actual alcoholic strength of the beverage was lower

than that stated on the product label. Thus, the Italian authorities charged Lidl Italia with an infringement of the Italian Legislative Decree n. 109/1992, which implemented the European Directives on the matter.

Lidl Italia appealed the administrative decision before the national courts, alleging in particular that the European provisions on the labeling of pre-packed foodstuffs were addressed not to traders who merely marketed the food product, but exclusively to the producer of the food product itself. Unlike the producer, in fact, the distributor could not know whether the information indicated on the label affixed on the food packaging was correct or not.

In those circumstances, the Italian court referred to the European Court of Justice for a preliminary ruling on the question whether Directive 2000/13/CE was to be interpreted as establishing the principle of liability of the producer for the infringement of the legislation on food labeling. In other words, the question was whether the European legislation was to be interpreted as precluding a Member State's legislation, such as the Italian, which made it possible for a distributor to be held responsible for an infringement of the food labeling legislation, resulting from the inaccuracy of an information given by the producer on the product label.

The Court of Justice held that, since Directive 2000/13/CE hadn't provided a complete harmonization of the subject, therefore Member States remained responsible for the provision of the rules in that regard, provided that those rules did not seriously compromise the achievement of the results pursued by the Directive. According to the Court, the Italian legislation, giving a wide definition of the range of operators which may be held responsible for the breach of the European provisions, not only did not compromise, but on the contrary contributed to the achievement of the goals prescribed by the Directive.

In addition, the Court of Justice stated that no general principle of exclusive liability of the producer with regard to the exactitude of the particulars appearing on the labeling of the pre-packaged products was established by the European legislation. On the contrary, the Luxembourg judges stated that, following the above-mentioned Art. 17(1) of Regulation 178/2002, all the food business operators were to ensure the compliance of the foodstuffs with the food legislation applicable to their activities and to check that those requirements were met.

The *Lidl Italia* judgment highlighted, if necessary, all the failings of the European system of responsibility with respect to food information. In fact, by allowing the food distributor to be held responsible, while no penalty was applied to the subject to whom the inaccuracy was ascribable, this ruling showed to what paradoxical outcomes the fragmentation of the European legislation could lead.

It is in view of these failings that Regulation 1169/2011 must be read.

3. *The responsibilities of food business operators with respect to food information after Regulation 1169/2011.*

The 21st recital of the preamble of Regulation 1169/2011, probably having in mind the *Lidl Italia* judgment, states that in order to prevent a fragmentation of the rules concerning the responsibility of food business operators with respect to food information, it is appropriate to clarify the responsibilities of food business operators in this area. In addition, it states that the clarification should be in accordance with the responsibilities regarding the consumer referred to in Article 17 of Regulation 178/2002.

Implementing the provision of the 21st recital, art. 8 of the Regulation establishes which subjects are to be held responsible for the infringement of food information law. Particularly relevant for our purposes are paragraphs 1 to 5.

Paragraph 1 lays down the general principle that the food business operator responsible for the food information shall be the operator under whose name or business name the food is marketed or, if that operator is not established in the Union, the importer into the Union market. This is the subject who, according to paragraph 2, shall ensure the presence and accuracy of the food information in accordance with the applicable food information law and requirements of relevant national provisions.

For the definition of ‘food business operator’ the Regulation refers to the definition given by article 3 of Regulation 178/2002, according to which it is the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control. As for the definition of ‘food business’, we must also refer to the definition given by Regulation 178/2002, following which ‘food business’ means 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.

In other words, article 8(1) and (2) of Regulation 1169/2011, in conjunction with article 3(2) and (3) of Regulation 178/2002, provide that the responsibility for the presence and the accuracy of the food information weighs in the first instance on the producer – if it markets the product under its name –, on the customer – in case of outsourcing –, or on the importer in the Union market – if the producer and the customer are not established in the EU.

In short, these are the subjects whom the Regulation holds as generally responsible for the violation of food information law, and on whom weighs the obligation to ensure that the information indicated on the food label is correct and in compliance with the European and national relevant legislation.

Besides the general responsibility of the producer/importer, the Regulation lays down other forms of liability. Indeed, the following paragraphs of art. 8 regulate the obligations of the other operators located along the food supply chain.

In particular, paragraph 3, with regard to food business operators who do not affect food information, states that they shall not supply food which they know or presume, on the basis of the information in their possession as professionals, to be non-compliant with the applicable food information law and requirements of relevant national provisions.

In addition, paragraph 4 establishes that food business operators, within the business under their control, shall not modify the information accompanying a food if such modification would mislead the final consumer or otherwise reduce the level of consumer protection and the possibilities for the final consumer to make informed choices. Furthermore, it provides that, if the food business operators modify the information accompanying a food, they are to be held responsible for that.

In other words, article 8(3) and (4) establish a limited responsibility for the food business operators others than those concerned by paragraphs 1 and 2. Indeed, these subjects' liability is limited to certain specific cases. In particular, under paragraph 3 they will answer when they know or presume that the information indicated on the label of the food product they supply is inaccurate or lacks of some of the necessary requirements under the relevant legislation. According to paragraph 4, in addition, the food business operators respond if the lack or the inaccuracy of the information indicated on the label is due to the modifications made by the operator itself.

The *ratio* of these provisions is quite clear: it is logical to hold the food business operators (others than those considered by paragraphs 1 and 2) liable only for the information they know or presume to be inaccurate or absent, or for having contributed to the inaccuracy or to the absence of the information.

Following these provisions, for example, in the *Lidl Italia* case, the distributor wouldn't have been held responsible for the inaccuracy of the information indicated on the label, since that inaccuracy was out of its sphere of control.

More difficult to interpret is the rule provided by art. 8, paragraph 5, according to which «without prejudice to paragraphs 2 to 4, food business operators, within the businesses under their control, shall ensure compliance with the requirements of food information law and relevant national provisions which are relevant to their activities and shall verify that such requirements are met».

This provision clearly echoes that of art. 17(1), Regulation 178/2002, i.e. the provision which regulated the distribution of responsibilities before the adoption of Regulation 1169/2011. Indeed, it seems to recall the responsibility system

laid down under the previous legislation, following which every food business operators, at all stages of production, processing and distribution had to «ensure» and «verify» the compliance of the food products with the requirements of food information law.

Therefore, the question is how to reconcile this provision with what provided by the preceding paragraphs, and in particular by paragraphs 3 and 4.

The solution is probably to be found by emphasizing the part of the provision where it is said: «which are relevant to their activities». This expression, in fact, could either refer to the «provisions» or to the «requirements». Indeed, this last solution is to be preferred.

In the first place, in fact, this solution is more coherent with the *intentiono legis*, as it emerges from the analysis of the preparatory works, and in particular of the drafts of the provision that have been scrutinized by the European Commission, by the European Parliament and by the Council, before the adoption of the final text of the Regulation. Secondly, as it will be better explained below, it allows to better reconcile the provision of paragraph 5 with those of the preceding paragraphs. Lastly, it is more consistent with the text of the provision, where the word «relevant» is written twice, one in connection with the «national provisions» and one with the «requirements» («shall ensure compliance with the requirements of food information law and *relevant* national provisions which are *relevant* to their activities»).

In this last respect, the English version of the provision differs substantially from other linguistic versions, such as the French or the Italian.

With specific reference to the French version, it can be observed that art. 8(5) states that the food business operators «*assurent et vérifient la conformité avec les exigences de la législation concernant l'information sur les denrées alimentaires et avec les dispositions nationales qui sont pertinentes dans leurs activités*». As it can be easily noted, the expression «*qui sont pertinentes dans leurs activités*», which corresponds with the English «which are relevant to their activities», in the French version seems to refer to the «national provisions» (*les dispositions nationales*), also because the word «*pertinentes*» appears only once in the French version.

In other words, because of the imperfect translation of art. 8(5), and the incoherence between the English and the French versions, it is not clear whether the expression «which are relevant to their activities» is to be referred to the provisions or to the requirements.

As it has already been said, though, this last solution is to be preferred because it leads to a more logical interpretation of article 8.

By emphasizing the link between the expression «which relevant to their activities» and the word «requirements», in fact, we can conclude that the food

business operators others than those concerned by art. 8(1) and (2), within the business under their control, have to ensure and verify the compliance only with those requirements of food information law which are relevant to their activities.

In other words, following this interpretation, every food business operator along the food supply chain has to ensure and verify the compliance of the food information with the requirements which are relevant to their activities. In addition, every food business operator is responsible if it supplies food which it knows or presumes, on the basis of the information in its possession as professional, to be non-compliant with the applicable food information law, or which it has contributed to make non-compliant, by modifying the information accompanying the food.

At the same time, besides this form of responsibility weighing on every food business operator, art. 8(1) and (2) establish the general responsibility of the food business operator under whose name or business name the food is marketed or, if that operator is not established in the Union, the importer into the Union market. Differently from the operators concerned by paragraphs 3 to 5, these subjects are responsible also for the infringement of food information law occurring out of their sphere of control.

4. The lack of penalties applicable to the infringement of food information law. The Italian case.

As already said, Regulation 1169/2011, while on the one hand lays down a general discipline on the food information harmonizing the Member States' legislation, on the other hand though doesn't provide any rule regarding the measures and penalties applicable to the infringement of food information law.

Conversely, Regulation 178/2002, laying down the general principles and requirements of food law, at article 17(2) states that it is up to the Member States to lay down the rules on measures and penalties applicable to infringements of food and feed law, which shall be effective, proportionate and dissuasive.

In Italy, the rules on measures and penalties applicable to the infringement of food information law are laid down by Legislative Decree n. 109/1992, implementing Directives 89/395/CEE and 89/396/CEE. Even if, in the last decades, this act has been repeatedly modified in order to update its discipline to Directive 2000/13/CE, many of its provisions still date back to 1992.

In the last years some attempts have been made to adopt a new legislation on the matter, in order to update the Italian legislation to Regulation 1169/2011. Yet, so far these attempts haven't achieved their goal.

In particular, Law n. 96/2013 delegated the Government to adopt, in the following two years, a Legislative Decree laying down the measures and penalties applicable to the infringement of many European legislative acts, among which, in particular, Regulation 1169/2011. On the basis of this mandate, the Italian Ministry for the Economic Development prepared a draft of Legislative Decree, implementing a reorganization of the national legislation on the matter. Yet, that Decree has never been adopted and, in the meanwhile, the time has expired and the delegation has lost effect.

More recently, on August 2016 the Italian Parliament adopted Law n. 170/2016, which delegates the Government to adopt, within twelve months, one or more Legislative Decrees in order to conform the Italian legislation to the provisions of Regulation 1169/2011. In particular, art. 5(2) demands the adoption of effective, proportionate and dissuasive penalties. Furthermore, the Law confers competence on the Central Inspectorate for Quality Protection and Fraud repression (ICQRF) to inflict the penalties for the infringement of food information law.

In the meanwhile, as long as a new legislation won't be adopted, the only measures and penalties applicable to the infringement of the Regulation are the ones laid down by Legislative Decree n. 109/1992.

Legislative Decree 109/1992 is organized as follows: on the one hand, articles 2 to 17 of Legislative Decree 109/1992 set forth the rules on the information that must be indicated on food labels; on the other hand, article 18 lays down the penalties applicable to the infringement of the rules provided by articles 2 to 17.

Since Regulation 1169/2011 entered into effect, deeply modifying the previous legislation on food information, a problem of coordination between the rules laid down by the European Regulation and the national provisions has been raised. In particular, the question is whether the measures and penalties provided by the Italian Legislative Decree can be applied to the infringement of the rules laid down by the Regulation.

The problem is that, following the principle of the rule of law, penalties can only be applied on the basis of a law provision gone into effect previously. This means that, since no application by analogy is allowed, the penalties provided by the Italian Legislative Decree can't be applied to the infringement of the new rules laid down by the Regulation.

Recently, the Italian Ministry of the Economic Development tried to solve this problem by the means of a Circulaire dated March, 6th 2015, sent to the competent Public Administrations, in order to clarify which orientation shall be adopted on this matter. With specific reference to the interpretation of article 18, the Ministry in its letter classified three categories of provisions:

in the first place, some provisions of Legislative Decree 109/1992 regulate matters which are not considered by the Regulation. For these matters, no harmonization is implemented, therefore the national legislation remains effective;

in the second place, on some matters the Regulation confirms the provisions of Legislative Decree 109/1992. On these matters, the principle of rule of law isn't affected. Indeed, the Regulation simply gives a new legal basis to already existing rules. Therefore, for the infringement of these rules, the penalties provided by the Italian legislation can still be applied. In this regard, it is important to notice that recently the Italian Ministry has sent a new *Circulaire* (dated December, 14th 2016), containing some clarification provided by the European Commission on the coordination of Regulation 1169/2011 with the provisions of Legislative Decree 109/1992;

lastly, the Regulation lays down some new rules, which were not provided under the previous Italian legislation. For these rules, following the principle of rule of law, the penalties provided by national legislation cannot be applied.

Eventually, the Ministry alleged to the *circulaire* a chart in which it illustrated the concurrences between the European and the Italian legislation on the matter, matching each provision of the Regulation with one or more provisions of the Italian Legislative Decree and vice-versa.

In conclusion, by the means of the *Circulaire*, the Ministry has tried to provide a transitional regime applicable pending the adoption of the new legislation. Still, it must be observed that the *Circulaire* is not legally binding. Indeed, it doesn't produce any legal effect outside the Public Administration. Therefore, it doesn't prevent the Italian courts from following a different interpretation of the national food information law.

VI. Foodstuffs Traceability and Fraud

Andrea Guerrini

CONTENTS: 1. The origin of food products and ingredients: general considerations on foodstuffs. – 1.1. In-depth examination. – 1.2. Ingredients present in foodstuffs. – 1.3. The responsibility of the manufacturer and the supplier. – 2. Civil remedies against the duty of information in the food market. – 3. Remedies against Food frauds. – 3.1. European definition of food fraud. – 3.2. The safeguard of “Made in Italy”. – 3.3. Trading and purchasing of forgery products. – 3.4. Trade frauds. – 3.5. Selling of industrial products with mendacious signs. – 3.6. Frauds.

1. The origin of food products and ingredients: general considerations on foodstuffs.

The European rules on advertising and presentation of food stated in the EC Directive n. 2000/13, which is still in force, contains two provisions regarding the origin and provenance of foodstuffs.

The art. 2, par. 1, letter. “I” of the aforementioned Directive establishes that the labelling must not mislead the purchaser, particularly with regards to the origin or provenance of the products. The art. 3, par. 1, n. 8 of the Directive determines that the place of origin or provenance is included among the mandatory information on the label of food products in case this omission could mislead the consumer as to the origin or provenance of the food product.

Of the two provisions examined above, concerning the origin and provenance of foodstuffs in the EC Directive n. 2000/13 only the first one, namely the Article. 2, par. 1, letter. point “I”, is adopted, without substantial changes, in the art. 7, par. 1, letter. a. of the European Regulation n. 1169/2011.

The consequence is that in Regulation 1169/2011 the ban imposed on the food business operator to mislead consumers with regard to the country of origin or place of provenance of food remains substantially unchanged.

It’s important to point out how in the new writing of the provision introduced by Regulation 1169/2011, the European legislator uses the words “Country of origin” instead of “origin” and the expression “place of origin” instead of “provenance”.

Differently from the first of the two provisions that, as we have seen, didn’t suffer any substantial change, the second provision, that is the article. 3, par. 1,

point n. 8, of Directive 2000/13 EC, which requires the food business operator to indicate the place of origin or provenance of the foodstuff, where this lack could mislead the consumer regarding the country of origin or place of actual provenance, was complemented with a final sentence which has clarified and strengthened the effectiveness of the rule.

In this framework it's important to clarify some aspects.

According to art. 9, par. 1, letter. "I", of Regulation (EU) No. 1169/2011, the indication of the country of origin or place of provenance of food is mandatory foreseen by art. 26 of the Regulation.

Art. 26 of the Regulation decree, clarifies that the obligation to indicate the country of origin or place of origin must be observed in particular when the information accompanying the food or the labelling could induce the consumer to think that the food has a different country of origin or place of provenance.

The new formulation aims to tackle attempts to mislead consumers regarding the origin or place of provenance of a product by means of pictures, photographs or any type of images properly presented with the colours of the national flag of the country⁸.

For the rest, the Regulation 1169/2011 doesn't make special modifications to the notions of country of origin and place of origin.

With regard to the concept of place of origin the article. 2, par. 2, letter. g., of the Regulation 1169/2011, highlights that the place of origin of a food product is any place indicated as the one the food comes from but it's not the "country of origin" as determined in accordance with articles. 23-24-25-26 of the Regulation n. 2913/92, namely the Custom Code.

1.1. *In-depth examination.*

Although the notions of country of origin and place of origin are still linked to the provisions of the Community Customs Code, Regulation 1169/2011 introduces specific rules regarding the indication of the country of origin or place of origin of certain products.

Article. 26, par. 2, letter. b., makes it mandatory to indicate of the country of origin or place of provenance for certain types of meat, but the European Commission has to adopt appropriate implementing acts.

⁸ Regarding food different from foodstuffs above mentioned (with the exception of course, of products with PDO and PGI under Regulation (EU) No. 1151/201243) there are no European standards setting specific obligations for operators in the field of indications of the origin or source of the goods. For these products apply the general rules of origin contained in the European Customs Code.

In this respect, according to par. 8 of article. 26 of Regulation 1169/2011, the Commission has adopted Regulation (EU) No. 1337/201348, which determines the mandatory indication of the country of origin or place of provenance for sheep meat, goat meat, pig meat and birds meat.

For other foodstuffs as, for example, meat of a different type from those previously listed, for milk and other unprocessed foods, par. 5 of Regulation 1169/2011 establishes that the European Commission presents to the European Parliament and the Council by 14 December 2014, specific reports regarding the mandatory country of origin or place of provenance.

Furthermore, the European Commission, in accordance with par. 6 of the regulation 1169/2011, has presented to the European Parliament and the Council a report on the mandatory indication on country of origin or place of provenance for meat used as an ingredient.

1.2. Ingredients present in foodstuffs.

Par. 3 art. 26 of Regulation 1169/2011 introduces an entirely new discipline on the indication of the country of origin or place of origin of a food product in case that the country of origin or the place of origin of the product is different from the origin of its primary ingredient.

In this case, according to that provision, it's mandatory to indicate the country of origin or place of provenance of the primary ingredient.

Alternatively, the operator must indicate that the country of origin or place of provenance of the primary ingredient is different from that of the food product.

These provisions could have been put into place by the Commission by means of the adoption of implementing acts by 13 December 2013, according to par. 8 of art. 26 of Regulation (EU) No. 1169/2011 but, unfortunately, the Commission didn't operate in this way.

With reference to the milk used as an ingredient in dairy products, the products based on a single ingredient and ingredients that represent more than 50% of the foodstuff, par. 5 of art. 26 of Regulation 1169/2011 requires the Commission to submit, by 14 December 2014, to the European Parliament and the Council a report on the indication of the country of origin or place of provenance (the Commission has presented the final report on the 25 May 2015).

1.3. *The responsibility of the manufacturer and the supplier.*

The choice of the European Legislator⁹ with regard to the topic of the responsibility is not a joint but an alternative responsibility between the manufacturer and the importer.

In this respect, for instance, the responsibility related to the information on pre-packaged foodstuffs is generally attributed to the manufacturer but it could also happen, for instance in case of an incomplete label, that the responsibility lies with the distributor.

In this context, on one hand Member States have lost the power to establish, with proper provisions, responsibilities which are different or alternative to the fully regulated in art. 8, and on the other hand for inspection should be easier to identify the subjects to sanction.

Nevertheless, with the exception of the presence of potential allergens, the rules of the Regulation n. 1169/11 don't apply to:

- Non-prepackaged food
- Food packaged at the store on specific request of the consumer
- Pre-packaged for direct sale

The consequence is that Member States have to regulate these cases.

The reason of this choice is that for this type of food there are no problems with regard to intra-Community trade and so the European legislator, observing the principle of subsidiarity, has preferred to give to Member States the opportunity to adopt the preferred standards.

However, with regard to the information concerning not-prepackaged foods, it's clear that distributors could have a key role considering the lack of a packaging.

⁹ Article 8, Reg. 1169/2011, entitled "responsibility", establishes: the person responsible for the food information is the manufacturer or, if the product is manufactured outside the EU, the importer; people who are in charge of ensuring the information must guarantee the presence and the accuracy of the information; the food business operators don't supply foodstuffs that they think or presume are breaching the information rules or requirements of relevant national provisions; food business operators, within the businesses under their control, can't rectify the information accompanying food if such modification misleads the final consumer or, in any case, reduces the level of consumer protection and the possibilities for the final consumer to make informed choices – for this reason they are responsible of any change –; food business operators, within the businesses under their control, have to ensure compliance with the requirements of food information law and relevant national provisions which have a key role into their activities, verifying that such requirements are met; food business operators, within the businesses under their control, shall ensure that information relating to not pre-packed food intended for the final consumer or for supply to mass caterers shall be transmitted to the food business operator receiving the food, in order to enable, when required, the provision of mandatory food information to the final consumer; food business operators that supply to other food business operators food not intended for the final consumer must ensure that those other food business operators are provided with sufficient information to enable them to verify their obligations.

It's really difficult to understand the reason why the European legislator has been opting for a differentiation between packaged and prepackaged products, in the first place because the consumer should access the same information with regard to foodstuffs to avoid the phenomenon of misleading regardless of the fact that foodstuffs are pre-packaged or not, and in the second place because in this way there is a sort of distinction between first class and second class products.

All said and done without forgetting, on one hand that European legislation appears incoherent and inconsistent, and on the other hand the regulations of art. 8 regarding the position of the distributor is substantially weakened because it is related to the choice of Member States to adopt the rules on prepacked products as well as for the non-prepacked products.

2. Civil remedies against the duty of information in the food market.

Art. 9 of Reg. 1169/2011 establishes the list of the mandatory particulars¹⁰.

Nevertheless, the Regulation without defining them, mentions certain types of information consumers can find on the label of food products because the producer has decided to list it and not because that type of information is mandatory *ex. art.* 9.

The information mentioned above is really important both in the pre-contractual and in the contractual stage.

In the pre-contractual stage, the information is directed to the market and for this reason in case of lack/omission of some information mandatory by law or in case of incorrect or inaccurate information, whether mandatory or voluntary, on the label or in the advertisement, the suitable reaction should be to file a complaint to the Competition and Market Authority to inhibit the prohibited conduct and at the same time ask the operator to comply with the rules.

It's important to highlight that the Italian legislation recognizes penal and administrative relevance to the omissions qualified as mandatory or their presentation in an unclear, unintelligible or ambiguous formulation.

¹⁰ Pursuant to art. 9 the mandatory particulars are: the name of the food; the list of ingredients; any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; the quantity of certain ingredients or categories of ingredients; the net quantity of the food; the date of minimum durability or the 'use by' date; any special storage conditions and/or conditions of use; the name or business name and address of the food business operator referred to in Article 8; the country of origin or place of provenance where provided for in Article 26; instructions for use when it would be difficult to make appropriate use of the food in the absence of such instructions; with respect to beverages containing more than 1,2 % of alcohol by volume, the actual alcoholic strength by volume; a nutrition declaration.

In the contractual stage, before the entering into force of the Reg. 1169/2011, the doctrine sustained that the information contained on the label should be divided in “essential information”, namely the price and the “*nomen*” of the food product and “not essential information” that is all the other information. In case a contract had been concluded with the absence of the essential information, that contract would be null and void. Differently, if a contract had been concluded with the absence of the non-essential information the only consequence would be the annulment of that contract for malice if the consumer proved the decisiveness of the scam.

Surely, despite this is an opinion that can be shared, it's not enough to ensure to the consumer an adequate protection considering the evident difficulty in proving regard the decisiveness of the scam.

A solution closer to the spirit of the Regulation 1169/2011 could be the following one.

If all the particulars included in art. 9 were considered as “essential information”, because they are necessary to describe the object pursuant art. 1346 c.c., the consequence is that in case of omission, incorrect or inaccurate information, the contract is null and void, as it would lack the requirement of the definiteness of the object since it's not possible to identify the item to whom the contract is related.

In this framework, it is important to understand the fate of a contract that has a label containing false voluntary particulars.

It's useful to recall that pursuant to the art. 7, Regulation 1169/2011, voluntary particulars mustn't mislead the consumer.

In theory, we have four possible remedies:

1) The consumer, pursuant to art. 130 of the Consumer Code, in case of deficiency of compliance, has the right of reinstatement of the good without charge by mean of the fixing or reparation, he also has the right to a suitable reduction of the price or to the termination of the contract.

2) Pursuant to art. 11 of the Consumer it's forbidden the trade on the national territory of any product or product packaging that doesn't show in a clearly and legible form the information included in Articles 6, 7 and 9.

- Nevertheless it seems that the consumer code is unable to provide a definitive answer with regard to the label and its requirements because Chapter II, after specifying the minimum content, the mode of indication and the languages of the information, at art. 8 specifies that the regulation does not apply to products subject to specific provisions contained in Directives or other Community provisions and related national transpositions. This provision includes even foodstuffs that are regulated by-Regulation 1169/2011 -

3) Another possible solution is the annulment of the contract because that it's signed error.

However, it would be really difficult to prove the requirement of essentiality because the purchaser should demonstrate that the error has been determinant for the consensus. In this respect, it was decided that it is irrelevant the erroneous and incomplete description of the goods made in the contract, where if it's not prove the purchaser has addressed to purchase an asset instead of another. In addition, the discipline could have a difficult enforcement because of the special rules for the conclusion of contracts for foodstuffs that would make it difficult to recover the additional requirement of recognisability that postulates the existence of a negotiation and of a consumer behaviour estimable from the other part.

4) Another possible remedy could be the annulment of the contract for malice. The use of this institute would be reasonable because if the label contains voluntary false information, it appears objectively intended to mislead the consumer: however, it could be difficult to prove the malice. Indeed, the malice, like the error, is a fault of the consent that causes the annulment of the contract only if the false representation of reality generated by it has been essential to the completion of the legal transaction: in other words, the malice has to be decisive in influencing the choice of the purchaser.

Furthermore, it's important to notice that, on one hand the manufacturer or seller could sustain the lack of the needed diligence of the consumer (he consumer is required to prove the "normal diligence" or a "not guilty ignorance"), plaintiff in a possible action for annulment, and on the other hand that the success of the action of annulment is linked to the presence of a scam suitable to surprise a person with a normal diligence, a simple lie or omission not being enough.

In conclusion we can observe that all the remedies existing in the Italian law have a high degree of risk and for this reason they are not a safe harbour for consumers.

3. Remedies against food frauds.

3.1. European definition of food fraud.

In the EU legislation there is no definition of "food fraud".

Each EU Member State provides various definitions for facts that represent a certain type of violation of statutory agri-food chain requirements.

The food fraud is committed when foodstuffs are deliberately placed on the market, for financial gain, with the intention of deceiving the consumer. In a number of Member States those facts may be relevant for the application of criminal penalties and of procedural rules on criminal prosecution.

Although there are many kinds of food fraud, the two main types are:

- a) the sale of food which is unfit and potentially harmful, such as:
 - Recycling of animal by-products back into the food chain.
 - Packing and selling of beef and poultry with an unknown origin.
 - Knowingly selling goods which are past their 'use by' date.
- b) the deliberate misdescription of food, such as:
 - Products substituted with a cheaper alternative, for example, farmed salmon sold as wild, and Basmati rice adulterated with cheaper varieties.
 - Making false statements about the source of ingredients, i.e. their geographic, plant or animal origin.

Food fraud may also involve the sale of meat from animals that have been stolen and/or illegally slaughtered, as well as wild game animals like deer that may have been poached.

3.2. *The safeguard of "Made in Italy".*

The Italian legislator, with the law. 350/2003 art. 4, paragraph 49, complemented and amended by legislative decree, law n. 35/2005, law n. 99/2009 and legislative decree n. 135/2009, has adopted measures for the protection of the "Made in Italy" brand, with the primary aim of protecting consumers and provide precise information regarding the origin of sold product.

For this reason, each product must be identified with brands and labels that guarantee the origin, provenance, place and method of production. The Decree Law n. 135/2009, converted with amendments by law n. 223/2009, art. 16, paragraph 1, stated that it's classified as "Made in Italy" a product made entirely in Italy and for which the drawing, the design, the processing and the packaging, are exclusively made in Italy. The products with the same characteristics can be classified and labelled with the words "100% Made in Italy", "100% Italian", "all-Italian".

The following paragraph 4 states that the use of such information outside the limits described before, which can be misleading, is sanctioned by art. 517 of the Criminal Code.

Furthermore, the paragraph 6, art. 4 of Law n. 350/2003, has introduced, paragraphs 49-*bis* and 49-*ter* administrative fines and the confiscation of goods in case of misuse of these brands.

Finally, and still on the subject of brand protection in Italy, the recent legislative decree n. 83/2012, converted with amendments by Law n. 134/2012, art. 43, paragraph 1, added to the aforementioned article. 4 of Law n. 350/2003 paragraph 49-*quarter* which establishes that Chambers of Commerce, responsi-

ble for their territory, are the competent body to receive the report for the imposition of administrative fines for violations of paragraph 49-*bis*.

The next paragraph 1-*bis* of the same article identified the organoleptic values required for extra virgin olive oils to be labelled with the word “Italy” or “Italian”, in order to provide correct information to protect consumers and to prevent fraud in the oils area.

As indicted by paragraph 1-*ter* the checking of these values will be entrusted to a panel of tasters authorized by the Ministry of Agriculture and Forestry, as established by article. 5 of the Decree of 28 February 2012.

Lastly, paragraph 1-*quater* has determined that the “real origin” of food is the place of cultivation or breeding of agricultural material that is used for the production and preparation of products, as well as the place where the effective transformation took place.

The forgery or alteration of DOC, DOP, IGP, DOCG brands is punished by the art. 517-*quater* of the criminal code because, in general, that kind of brands are used to identify a specific area, region, and sometimes even a single country designating an agricultural product or a foodstuff as originating in that territory and not to distinguish products of a company from products of another company.

3.3. *Trading and purchasing of forgery products.*

People who buy or accept counterfeit products, without having first checked the legitimate origin, are prosecuted, pursuant to art. 1, paragraph 7, Decree n. 35/2005, converted with modification by law 80/2005, complemented by art. 17 paragraph 2, law n. 99/2009, with a fine between € 100.00 to € 7,000.00, with the application of the additional sanction of administrative requisition pursuant to art. 13 Law no. 689/1981.

Nevertheless, this behaviour is even punished by art. 712 of the Criminal Code which states that “any person who acquires, without having first ascertained the legitimate origin, or in any case receives for any reason items that, for their quality, condition of the person who offers them or price, can be suspected to relate to crime, is punished with imprisonment up to six months or a fine no less than € 10,000. People who push someone to buy or receive things, without having ascertained the legitimate origin are punished in the same way.

In this case there is one issue, which is the overlapping of rules considering that both art. 712 of the Criminal code and art. 1. Paragraph 7 above mentioned punish the same behaviour.

In this respect, art. 9 of Law no. 689/1981 on the principle of speciality, states that when the same offense is punished by a penal provision and a provision establishing an administrative penalty, or by a number of provisions which provide for administrative sanctions, the special provision will be applied.

In this case art. 1, paragraph 7 over mentioned applies instead of art. 712 of the Criminal Code, but only for goods that are subject to intellectual property protection. Art. 712 applies in all other cases when goods are purchased from other crimes.

Paragraph 3 of the same article also requires the administrative requisition of the building where the counterfeit goods are produced, stored, held for sale or sold.

It's really important to underline that art. 1, paragraph 7 of Decree n. 35/2005 also states that, if the purchase is made by a trader or importer or any other person different from the purchaser, an administrative penalty from € 20,000 to € 1,000,000 is established.

3.4. *Trade frauds.*

The operator who in connection with a trade or administration activity, transfers to the purchaser an asset different from the negotiated asset, incurs in the crime of fraud on the market (art. 515 Criminal Code).

This kind of crime can also occur with the simple exposure on the shelves of products with false signs that can mislead consumers.

The same type of crime occurs when the expiration date on the label of food products is incorrect, materializing in this way the hypothesis of attempted fraud on the market.

It's worthwhile to point out that in case of conviction for fraud on the market, the sanctions are extremely heavy.

Indeed, article. 515 of the Criminal Code, in case of conviction, provides the imprisonment up to two years or a fine of up to 2065,83 €.

The accessory punishment for this type of offense is the loss of moral requirements for the exercise of a commercial activity pursuant article. 71, Legislative Decree n. 59/2010.

3.5. *Selling of industrial products with mendacious signs.*

If someone puts on the market industrial products, with names, trademarks and national or foreign identifying signs to mislead the purchaser about the origin, provenance or quality of the manufacturing process or the product itself, he is punished pursuant article 517 of Criminal Code.

For the configuration of this crime it is not required the registration or recognition of a brand or its actual forgery or concrete misleading of the purchaser on the product, being enough the mere attitude to mislead the consumer regarding the essential characteristics of the product.

Article 517, in case of conviction, provides the imprisonment up to two years or a fine of up to 20.000 €.

3.6. *Frauds.*

The operator incurs in the crime of fraud pursuant art. 640 of the Criminal Code if, in connection with a commercial activity, with artifice and deceit, he misleads consumers, convincing the commercial activity to buy a different product from the product object of their agreement, assuring them or other people an unjust profit and causing at the same time damage to the consumer.

The crime is punished with the imprisonment from 6 months to 3 years or a fine from 51 € to 1032 €.

The penalty is the imprisonment from 1 to 5 years and a fine from 309 € to 1,549 €:

- 1) if the offense is committed against the State or another public body or on the pretext of exempting someone from military service;
- 2) if the offense is committed in the victim engendering fear of an imaginary danger or the erroneous belief of having to carry out an order of the Authority.

The scam is the typical fraudulent crime against property.

The main feature of this crime is in the deception operated by the crook that induced the person to perform an act which can be both positive and negative that determines a reduction of the assets of the “victim”, with an enrichment of the deceiver.

In the scam, the doer, operates through artifice or deception; in this way the victim is damaged by itself, performing an act of disposition that is detrimental to its heritage and beneficial for the crook.

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VII. The Authorisation Procedure of Health Claims made on Foods under EC Regulation no. 1924/2006

Pasquale Pantalone

CONTENTS: 1. The objectives of EC Regulation no. 1924/2006. – 2. (*following*)... and its scope. – 3. The definition of health claims according to EC Regulation no. 1924/2006. – 4. The “general” and “specific” requirements. – 5. The authorisation procedure. – 6. Conclusions.

1. *The objectives of EC Regulation no. 1924/2006.*

The aim of this paper is to provide a general overview of the authorisation procedure of health claims made on food products under EC Regulation no. 1924/2006 and to examine its most relevant and critical legal aspects.

Specifically, this Regulation, as Recital 3 points out, complements the general principles in EC Directive 2000/13/EC (on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs) and lays down specific provisions concerning the use of nutrition and health claims concerning foods to be delivered to the consumer [for a brief overview of the legal context in which Reg. no. 1924/2006 has been implemented, see RUBINO V., 2013; FERRARI M., IZZO U., 2012; PETRELLI L., 2009].

Three of the most important objectives pursued by EC Regulation no. 1924/2006 on nutrition and health claims made on foods are: 1) the effective functioning of the internal market; 2) the attainment of a high level of consumer protection; and 3) the safeguard of financial investments on research and development within the agri-food industry.

Because the objectives of the Regulation could not be sufficiently achieved by the Member States, the European Community (now “European Union” after the Lisbon Treaty) decided to set, in accordance with principles of subsidiarity and proportionality, a common legal framework on nutrition and health claims made on foods to avoid that differences between national provisions that might impede the free movement of goods and create unequal conditions of competition in the internal market of agri-food products. Therefore, the EC acted under art. 95 of ECT (now art. 114 of TFEU), according to which «(t)he European

Parliament and the Council shall (...) adopt 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». The result of that “approximation” of the national provisions is Regulation no. 1924/2006.

On the other hand, the products put on the market must be safe and adequately labelled in order to ensure a high level of consumer protection, to give the consumer the necessary information to make choices in full knowledge of the facts: this consumer’s awareness is considered even more fundamental by the European legislator when foods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantages over similar products to which such nutrients and other substances are not added [on the importance of the “intelligibility” of those claims, see VAQUÉ L.G., 2014; see also GERMANÒ A., RAGIONIERI M.P., ROOK BASILE E., 2014]. In this sense, it is no accident that Regulation n. 1924/2006 highlighted that scientific substantiation should be the main requirement for the use of nutrition and health claims (Recital n. 16 of the Regulation).

Focusing specifically on “health claims”, one must add that Recital 22 states that such claims should only be authorised for use in the European Union after a scientific assessment «of the highest possible standard» carried out by the European Food Safety Authority [on EFSA’s role in implementing Regulation no. 1924/2006, see VALTUENA S., LENG L. ET AL., 2007; for a general overview of EFSA, see VERNILE S. in this publication]. This strict scientific assessment is justified by the fact that an health claim may encourage consumers to make choices which directly influence their total intake of individual nutrients or other substances in a way that would run counter to scientific advice (see Recital 9 of the Regulation).

Thus, the Regulation aims at safeguarding truthfulness, clarity, reliability and usefulness of the information, taking as a benchmark the “average consumer”, namely one «who is reasonably well-informed and reasonably observant and circumspect» (Recital n. 15 of the Regulation).

Lastly, the Recital n. 31 stresses the importance of the third objective mentioned above, that is the protection of the investment (even though limited in time) made by innovators in gathering the information and data supporting an application pursuant to Regulation n. 1924/2006 in order to stimulate research and development within the agri-food industry.

2. (Following)...and its scope.

Having briefly mentioned the main objectives of the Regulation n. 1924/2006, it is now necessary to pinpoint the scope of the regulation.

Under art. 1, para. 2, this Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered to the final consumer. Then, any communication which is functional to the sale of a food product shall comply with the provisions of the Reg. n. 1924/2006. This means that the same Regulation should not be applied, according to Recital 4, to claims which are made in non-commercial communications, «such as dietary guidelines or advice issued by health authorities and bodies».

An important limit of the scope of the Reg. n. 1924/2006 can be found in the definition of “claim” in accordance with art. 2, para. 2, n. 1) of the Regulation [HABER B., MEISTERERNST A., 2007], which states that the Regulation only applies to “voluntary claims”, namely any message or representation «which is not mandatory under Community or national legislation».

There are also specific exemptions to the application of the Reg. n. 1924/2006, which are expressly mentioned in art. 1, para. 5: in certain sectors regulated by special provisions (such as dietetic foods, mineral waters, water intended for human consumption, food supplements), the Regulation shall apply «without prejudice» to these provisions. This means that, in those sectors, the Reg. n. 1924/2006 is generally applicable to the extent that there are not special aspects regulated. In addition, according to Recital 5 of the Regulation, generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health, such as “digestive” or “cough drops”, should be exempted from the application of the Regulation.

Another aspect to be considered in examining the scope of the Reg. n. 1924/2006 is the potential intersection with other legislation, principally the Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs [on labelling of food products and on the specific provisions included in the Regulation n. 1169/2011, see CUOCOLO L. and DONATO L., in this publication]. Specifically, as already mentioned above [see para. 1], the Reg. n. 1924/2006 has to be read in a relationship of complementarity to the Directive 2000/13/EC, since it introduced specific provisions concerning the use of nutrition and health claims concerning food to be delivered as such to the consumer (Recital 3 of the Regulation).

3. *The definition of health claims according to EC Regulation no. 1924/2006.*

Health and nutrition claims are properly defined differently by Reg. no. 1924/2006.

Under art. 2, para. 2, n. 4) of the Regulation, «“nutrition claim” means any claim which states, suggests or implies that a food has a particular beneficial nutritional properties (...)».

Otherwise, «“health claim” means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health» (art. 2, para. 2, n. 5 of the Regulation).

Health claims can be primarily distinguished through the physiological effect they state, suggest or imply in: (a) reduction of disease risk claims and (b) health claims other than those referring to the reduction of disease risk (so called “functional claims”). In addition, health claims can be also classified through the type of consumer they refer to (i.e. children’s development or health claims).

According to art. 2, para. 2, n. 6 of the Regulation, reduction of disease risk claims are health claims that state, suggest or imply that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease (for instance, «the regular intake of calcium prevents the risk of osteoporosis»).

Health claims other than those referring to the reduction of disease risk (“functional claims”) are described in art. 13 of the Regulation. Generally speaking, such claims are characterised by additional effects due to the presence of components that interact with one or more physiological functions of the human organism by making positive effects on health status. Specifically, “functional claims” are claims that describe or refer to: (a) the role of a nutrient or other substance in growth, development and the functions of the body, or (b) psychological and behavioural functions, or (c) slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

One must accept that the definition of health claims given by Reg. n. 1924/2006 is very wide, since it only focuses on the “relationship” that must exist between a food, or one of its constituents, and health. One must also consider that the term “health” is not defined in the Regulation.

The European Court of Justice confirmed that the term “relationship” must be understood in a broad sense, as «(it) provides no information as to whether that relationship must be direct or indirect, or as to its intensity or duration» [ECJ], 6 September 2012, *Deutsches Weintor eG v. Land Rheinland-Pfalz*,

C-544/2010; see also the Opinion of Advocate General Mazak on the same case delivered on 29 March 2012].

Thus, according to ECJ, «the concept of a “health claim” must cover not only a relationship implying an improvement in health as a result of the consumption of a food, but also any relationship which implies the absence or reduction of effects that are adverse or harmful to health and which would otherwise accompany or follow such consumption, and, therefore, the mere preservation of a good state of health despite that potentially harmful consumption». Moreover, the ECJ added that «the concept of a “health claim” is deemed to refer not only to the effects of the consumption – in a specific instance – of a precise quantity of a food which is likely, normally, to have only temporary or fleeting effects, but also to those of the repeated, regular, even frequent consumption of such a food, the effects of which are, by contrast, not necessarily only temporary and fleeting».

Due to that broad interpretation being adopted by ECJ, it is extremely challenging for jurists to pinpoint clear boundaries between: (a) health claims and nutrition claims, in the case of the lasts have indirect beneficial effects on health (for instance, the presence of probiotics has positive effects on health); (b) reduction of disease risk claims and functional claims; (c) children’s development and health claims and other health claims.

With regard to lett. (b) and (c), the Standing Committee on the Food Chain and Animal Health tried to add some clarifications [see Guidance on the implementation of Regulation n° 1924/2006 on nutrition and health claims made on foods, 14 December 2007].

Specifically, when the claim mentions a disease risk factor generally recognised by scientific evidence, it should be considered a reduction of disease claim only to the extent that a reduction of this risk factor is stated, suggested or implied; other cases are to be considered as “functional claims”. With regard to children’s development and health claims, the Standing Committee pointed out that the term “children”, which is not defined in the Regulation, should be understood as reaching the end of the growth period. In addition, it specifies that children’s development and health claims, unlike other health claims, are the ones solely referring to the development and health of children, and where the scientific substantiation is only valid for children.

4. The “general” and “specific” requirements.

Art. 10, para. 1 of the Regulation no. 1924/2006 bans fundamentally the use of health claims for the labelling, presentation and advertising of foods,

unless they comply with the “general requirements” in Chapter II and the “specific requirements” in Chapter IV and they are authorised and included in the required lists provided for in art. 13 and 14 of the Regulation.

The general requirements apply to both nutrition and health claims.

First of all, the use of such claims shall primarily not be false, ambiguous or misleading. In that sense, it is banned, for instance, for any foodstuff to give rise to doubt about the safety and/or the nutritional adequacy of other foods or encourage (or condone) excess consumption of a food (see art. 3, para 2. of the Regulation).

Secondly, the use of nutrition and health claims shall comply with specific nutrient profiles established for food and/or certain categories of food by the European Commission (art. 4 of the Regulation). In other words, it is not permitted to use a health claim if the food product exceeds certain maximum values of fat, sugar and salt.

The foodstuff's correspondence with specific nutrient profiles considered virtuous aims at avoiding a certain food product with a nutrition or a health claim being sold easier (because of the claim) rather than other similar food products with no claim, even though its nutrient profile is not generally acceptable by the scientific community. In other terms, the purpose of this provision is to avoid the concealment of the overall nutritional value of a food product with a nutrition or a health claim.

These specific nutrient profiles should have been established by European Commission within 19 January 2009 (art. 4, para. 1 of the Regulation). Due to the absence of an agreement among the Member States, this provision is not yet implemented [see para. 6].

Other general requirements for the use of both nutrition and health claims are provided for in art. 5 to 7 of the Regulation; in summary, those provisions required: (a) the truthfulness of food product's beneficial effects as expressed in the claim and their understanding by the average consumer (art. 5); (b) the scientific substantiation for both nutrition and health claims (art. 6); (c) the mandatory presence (with the exception of generic advertising) of nutrition labelling of products on which a nutrition and/or health claim is made (art. 7; in this case, the information to be provided shall consist of that specified in art. 30, para. 1 of Regulation no. 1169/2011 on the provision of food information to consumers).

After having summarized the general requirements, one may note that only health claims shall meet additional “specific requirements” in order to be authorised and included in the lists provided for in art. 13 and 14 of the Regulation.

Firstly, according to art. 10, para. 2 of the Regulation, health claims shall only be permitted if some “complementary” information is included in the labelling or in the presentation and advertising.

Specifically, this “complementary” information shall refer to: (a) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle; (b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effects; (c) where appropriate, a statement addressed to persons who should avoid using the food; (d) an appropriate warning for products that are likely to present a health risk if consumed to excess [see the Commission Implementing Decision no. 2013/63/EU of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in art. 10 of Regulation no. 1924/2006].

Secondly, certain references to advantages of a nutrient or food for overall good health or health-related well-being are permissible to the extent they are accompanied by an authorised specific health claim included in the lists provided for in artt. 13 or 14 of the Regulation (art. 10, para. 3 of the Regulation).

Thirdly, the Regulation established some restrictions on the use of certain health claims, such as (a) claims which suggest that health could be affected by not consuming the food; (b) claims which make reference to the rate or amount of weight loss; (c) claims which make reference to recommendations of individual doctors or health professionals and other associations.

In addition to the general and specific requirements, there are other special requirements for the reduction of disease risk claims, namely: «the labelling or, if no such labelling exists, the presentation or advertising shall also bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect» (art. 14, para. 2 of the Regulation).

5. The authorisation procedure.

The authorisation procedure differs depending on the type of the health claim.

Health claims other than those referring to the reduction of disease risk and to children’s development and health may be made without undergoing the “individual” authorisation procedure laid down in artt. 15, 16, 17 and 19, if they are based on generally accepted scientific data and well understood by the average consumer (art. 13, para. 1 of the Regulation).

Those claims refer to: (a) the role of a nutrient or other substance in growth, development and the functions of the body, or (b) psychological and behavioural functions, or (c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

With regard to claims on growth, development and functions of the body, one may note that such claims might generally refer to children. However, it remains true that claims concerning the development and health of children are subject to the “individual” authorisation procedure laid down by artt. 15, 16, 17 and 19 of the Regulation. Therefore, they cannot be included in the list provided for in art. 13, para. 3 of the Regulation. The difference between “functional claims” according to art. 13 and claims referring to children pursuant to art. 14 is substantially based on scientific substantiation: «proof in case of a claim referring to children in the sense of art. 14 would be a study on the effects that was conducted solely with children» [THRON M., MEYER A.H., 2009; see also para. 3].

“Functional claims” provided for in art. 13, para. 1 of the the Regulation are subject to the “collective” authorisation procedure laid down in art. 13, para. 2 and 3.

Art. 13, para 2 states that Member States provide the Commission with lists of such claims by 31 January 2008 at the latest accompanied by the conditions applying to them and by references to the relevant scientific justification [see THRON M., MEYER A.H., 2009]. Thus, the Commission shall adopt, in accordance with the procedure referred to in art. 25, para. 3 of the Regulation and after consulting the European Food Safety Authority, a list of permitted health claims other than those referring to the reduction of disease risk (and all necessary conditions for the use of these claims) by 31 January 2010 at the latest (art. 13, para. 3 of the Regulation).

However, the list has been adopted by the Commission with Regulation no. 432/2012 after the conclusion of the “collective” procedure in July 2011 [for a general analysis of this Regulation, see RUBINO V., 2013].

Nevertheless, Regulation no. 1924/2006 specifies that any addition of claims to this list based on newly development scientific data and/or which include a request for the protection of proprietary data shall be adopted following the “individual” and “accelerated” authorisation procedure laid down in art. 18, except for claims referring to children’s development and health, which shall be authorised in accordance with the procedure laid down in art. 15, 16, 17 and 19 (art. 13, para. 5 of the Regulation).

According to art. 18 of the Regulation, this procedure can be started by any food business operator intending to use a health claim not included in the list provided for in art. 13, para 3 of the same Regulation.

The application for the inclusion of such a claim shall be submitted to the national competent authority of a Member State, which in turn it sends it to EFSA for a scientific assessment as well as to the Commission and the Member States for information. The Authority issues its opinion within a time limit of five

months from the date of receipt of the request. Where the Authority, following scientific assessment, issues an opinion in favour of the inclusion of the claim in the list provided for in art. 13, para 3 of the Regulation, the Commission takes a decision on the application, after having consulted the Member States and within two months of receiving the opinion of the Authority.

On the other hand – notwithstanding what it is clearly stated in art. 2, para. 1, lett. b) of Directive 2000/13/EC (according to which «(t)he labelling and methods used must not (...) attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties») – reduction of disease risk claims and claims referring to children’s development and health may be made where they have been authorised, in accordance with the “individual” authorisation procedure provided for in artt. 15, 16, 17 and 19 of the Regulation, for inclusion in an European list of such permitted claims with all the necessary conditions for the use of them (art. 14 of the Regulation). According to this provision, it might be confirmed that the basic rule of a wide-ranging ban of disease-related advertising should remain in force, with the exceptions laid down in Reg. no. 1924/2006 [HABER B., MEISTERERENST A., cit.; see also art. 7, para. 3 of the Regulation no. 1169/2011, according to which «food information shall not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties»].

The “individual” authorisation procedure of reduction of disease risk claims and children’s development and health claims begins with the sending of the application to the national competent authority of a Member State (which is, in Italy, the Ministry of Health). The application shall include specific information laid down in art. 15, para. 3 of the Regulation: specifically, it is important to highlight that the health claim shall include a copy of the studies which have been carried out to demonstrate that the health claim complies with the criteria provided for in this Regulation.

After having received the application, the national competent authority informs EFSA and makes available to it the entire application. Thus, the EFSA informs “without delay” the other Member States and the Commission of the application and makes the application available to them.

The EFSA gives its obligatory (but non-binding) opinion within five months from the date of receipt of a valid application (art. 16, para. 1 of the Regulation). The opinion aims at verifying that the health claim is based on scientific substantiation and meets the requirements provided for in Regulation no. 1924/2006 [for an analysis of the structure of EFSA opinions, see FROHNWIESER K., MEYER A.H., 2013; THRON M., MEYER A.H., 2009; EFSA published several guidance documents in order to give to applicants examples of assessments of appli-

cations regarding one same subject area: see, for instance, the EFSA Guidance on the scientific requirements for health claims related to gut and immune functions or to functions of the nervous system or to physical performance]. Therefore, the opinion is sent to the Commission, the Member States and the applicant and it is afterwards made public. The applicant or member of the public may address comments to the Commission within 30 days from such publication.

Within two months after receiving the opinion of the EFSA, the Commission submits to the Standing Committee on the Food Chain and Animal Health a draft decision on the lists of permitted health claims. Where the draft decision is not in accordance with the opinion of the Authority, the Commission provides an explanation for the differences.

In accordance with the regulatory procedure and with the scrutiny referred to in art. 25, para. 3 of the Regulation, the Commission adopts the final decision on the application; it, then, informs the applicant of the decision taken and it publishes details of the same decision in the Official Journal of the European Union.

All health claims that were authorised are included in specific lists: the list of health claims other than those referring to the reduction of disease risk and the list of reduction of disease risk claims. Those claims may be used, in conformity with the conditions applying to them, by any food business operator, if they are not restricted for use in accordance with data protection reasons (art. 17, para. 5 of the Regulation).

According to art. 20 of the Regulation, the Commission establishes and maintains a «Community Register of nutrition and health claims made on food». The Register includes, among others, the nutrition and authorised health claims; it also contains a list of rejected health claims and the reasons for their rejection. Health claims authorised on the basis of proprietary data are recorded in a separate Annex to the Register.

The Register aims at ensuring the transparency of the information published on it and at avoiding the risk for potential applicants to make applications for a health claim authorisation which was already assessed by the Commission.

In order to pursue the third objective mentioned above, that is the safeguarding of financial investments on research and development within the agri-food industry (see para. 1), art. 21 of the Regulation states that the scientific data and other information in the application may not be used for the benefit of a subsequent applicant for a period of five years from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used according to the conditions provided for in art. 21, para. 1 of the Regulation.

With regard to data protection, one of the main issues is whether a proprietary study can be legally protected although it was published before application: in the decision 2009/980/EU of 17 December 2009, the Commission decided, for instance, not to grant data protection to studies that had already been published [HABER B., MEISTERERNST A., 2011].

6. *Conclusions.*

There are some critical aspects to be highlighted about the authorisation of health claims under Reg. n. 1624/2006.

Firstly, there was a big debate on the power of the Commission to establish specific nutrient profiles for food and/or certain categories of food.

In fact, the definition of specific nutrient profiles might create discrimination between the food products that do comply with its specific nutrient profile and the ones that do not. It is no accident that this provision was one of the most disputed points in the legislative process, as it consequently led to a distinction – which is not based on scientific substantiation – between “good” and “bad” foods [HABER B., MEISTERERNST A., *cit.*]. This distinction might also be perceived as misleading by the average consumer, in violation of one of the main objectives of Regulation no. 1924/2006 [see para. 2].

One also added that there might be a problem of competence in exercising the power of establishing the specific nutrient profiles. In fact, if this power is ascribable to the matter of public health, the EU would have no competence to harmonize national legislation, but only a coordinating or complementary competence (see art. 6, TFEU).

Moreover, one should not underestimate that the establishing of specific nutrient profiles for food and/or certain categories of food might constitute a violation of the proportionality principle due to the exclusion of certain food products from the “good foods list”, that is to say, the list of the products which may have nutrition or health claims [for these critics, see GENCARELLI F., 2014]. The exclusion of some food products may be much “disproportionate” if those food products have a significant role on the diet of certain Member States.

Another risk of the establishing of specific nutrient profiles can be the standardization of diet models. This may cause a prejudice for diet habits and traditions within the Member States.

The debatable power to establish specific nutrient profiles for food and/or certain categories of food may be considered obsolete after the entry into force of Regulation no. 1169/2011 [this is the same conclusion of European Parliament

in a recent plenary session on 12 April 2016, in which it backed proposals to scrap the concept of nutrient profiles]. Regulation no. 1169/2011 aims at ensuring clear and complete information on the food's nutritional values in order to allow the consumer to know the overall nutritional value of a food product; Thus, if the aim of establishing specific nutrient profiles is to give truthfully information about food products, the same aim may be reached by Reg. no. 1169/2011 [GENCARELLI F., 2014].

In addition to those critical aspects, the authorisation procedure for the inclusion of health claims in the specific lists seems to operate far too ponderously.

Generally speaking one noted that this procedure tends to assimilate food products with health claims to medicinal products. For instance, applicants shall provide real clinical human studies in order to demonstrate, with a high standard of evidence, the scientific substantiation of the food product's beneficial effects on health. In addition to that, certain products can be differently qualified in various Member States as foods and medicinal products.

However, one stated that EFSA has basically no competence for the delimitation of foods and medicinal products [HABER B., MEISTERERNST A., cit.]. In any case, the demarcation between medicinal and food products should be based on the pharmacological properties of the products [EC], 15 January 2009, *Hecht Pharma v. Staatliches Gewerbeaufsichtsamt Lüneburg*, C-140/2007; see also the definition of medicinal product given by art. 1, para. 2 of the EC Directive 2001/83/EC] and the decision as to whether or not a product should be judged as medicinal remains within the competence of the Member States [EC], 5 March 2009, *Commission v. Kingdom of Spain*, C-88/2007] and

As some authors have highlighted [GENCARELLI F., 2014; RUBINO V., 2013], the use by EFSA of very strict assessment criteria for the scientific evaluation of health claims explains the overdue and the disappointing result of the authorisation procedure of "functional claims" (on 44.000 applications, only 222 of them were approved). Another problem of the EFSA assessment might be the uniform treatment of all types of claims: as some authors have underlined [HABER B., MEISTERERNST A., 2011], EFSA uses the highest possible standard in the evaluation of all health claims irrespective of the type of claim.

In conclusion, it cannot be denied that the ponderous authorisation procedure and the high costs of scientific studies might put a brake on research, development and innovation and might represent a barrier to access to the market for small and medium-sized enterprises. In the light of this result, a modification of Regulation no. 1924/2006 – especially in the parts referring to the procedures – would be highly desirable.

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VIII. Geographical Indications as Public (and Private?) Rights

Bernard O'Connor and Miriam Hamdan

CONTENTS: 1. The main features of GIs. - 2. The property of GIs. - 3. The public/private nature of GIs in the EU. - 4. The control system- 5. Conclusion.

1. *The main features of GIs.*

GIs are a form of intellectual property (IP) defined in Article 22(1) of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) as « Indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographic origin».

Their protection in the EU is based on a *sui generis* system in which GIs are considered a distinct form of IP and different, in particular, from Trade Marks. The basic European idea of GIs is that the use of a public name (e.g. the town of Parma) can be restricted in relation to a particular product. When protected, the State gives the exclusive right to use this public name in relation to a food product so long as the producers produce the product within the defined geographical area and comply with certain production specifications set out in public law.

GIs guarantee a quality, characteristic or reputation of the product on the market: consumers rely on the given qualities, characteristics or reputation guaranteed by the GI as registered and are prepared to pay a premium for such products. In addition land within the defined geographical area defined for a specific GI can often have a higher value than land lying outside this area.

The law requires that there must be a specific link between a GI and its place of origin. The TRIPs definition makes clear that the link is not merely a reference to the soil or place, known in French as 'terroir' but also, from an anthropological point of view, including the idea of reputation which is formed by collective production skills and knowledge built up over time by people located in a specific area [Peñalver, 2009].

Based on European and Italian experience, this note is a first attempt to examine the interplay between the public and the private nature of GIs. It first

looks at the main features of GIs in EU and Italian law and then it explores some practical aspects which deal with the interests of both the State and individual producers related to GIs.

2. *GIs as property.*

The inclusion of intangible property rights, in particular GIs, in the basket of property rights has not been easy, especially for Civil Law countries, where there is no distinction between personal and real property. Since GIs are now included in the TRIPs Agreement there can be no doubt that they are property rights. However, doubts about the ownership of GIs have not yet been resolved: even though it is inherent in the idea of GIs that they have substance prior to registration and normally a single producer cannot seek protection, the basic EU rules on GIs (Regulation (EU) No 1151/2012) do not contain any provision as to who holds the right to the property of a GI. The fact that it is not possible to transfer the right to use a registered name, and existing producers cannot oppose the use of the name by new producers producing according to the specifications, indicates that GIs do not fall within established ideas of intellectual property which tend to promote the defence of ownership. The fact that the State must ensure that operators complying with the specifications are entitled to be covered by the verification of compliance and have the right to use the protected name shows that reference is made to the state and not to existing producers or groups of producers.

Some authors [MANTROV, 2014], hold that there is no formal right holder of a GI in the sense that private parties cannot exclude others from using a GI: each operator located in the geographical area that complies with the product specification has a right to use the registered name. Others [TINLOT, 1987], recognize a collective right to use the name linked to the property of the soil. Others [ALMEIDA, 2014], promote the idea that GIs are similar to the German type of common property, according to which it is an indivisible right that belongs to all the producers of the demarcated region whose products comply with a specification [FERRARI, 2015]. Others consider GIs as a special type of collective trade mark [AUBOUIN, 1951] or as a *sui generis* right protected by unfair competition rules, a right to participate in a public society [PIATTI, 1999], a co-ownership between the State and producers and a State right *tout court* [MANTROV, 2014].

The debate on ownership is relevant to such questions as: who has the right to use a GI? And more prosaically, how can the improper or deceptive use of GIs be avoided and punished and what is the role producers can play in seeking to enforce the rights inherent in the GI?

3. The public/private nature of GIs in the EU.

The provisions of Regulation 1151/2012 on quality schemes for agricultural products and foodstuffs which attempt to capture in law the European idea of GIs reflect both the private and public features of GI protection in the EU.

A GI is regulated by public law and the State is intimately involved in the registration of the GI, in ensuring that those using the GI do so according to the specifications laid down by the State in public law, and in insuring that there is no misuse of the name in the market place.

However, the presence of private applicants, gathered into producer groups, is an implicit condition [BARHAM & SYLVANDER, 2011] that European Law recognises both to register a product as a GI and subsequently in the market place.

The reasons why producers decide to gather into producer groups in order to coordinate production and sales of food products are mainly economic. Small farmers have a weak bargaining power with respect to retailers. Competition in the food supply chain is high. And in relation to GIs a further economic reason for grouping together and defending interests is because GIs are usually produced in small quantities, with special production requirements increasing production costs.

The economic imperative to combine into groups is only beginning to be recognized specifically in EU GI law. Article 45 of Regulation 1151/2012 provides that a producer group is an association, irrespective of its legal form, constituted by those who work with the product the name of which is capable of registration. However this definition does not just include primary producers but also allows for others in the value chain to participate and thus there is a distinction between GI groups and traditional farmer producer organisations. To the extent that members of a GI group are producers they cooperate to pursue a public interest linked to the GI. At the same time they pursue the private interest of the single operators working with the registered product: they cooperate and compete with each other at the same time.

The synergy of public and private becomes apparent during the main phases of the registration process.

The product specification is a public document with a central role in the GI system: it is the main document for the registration but also defines the way a GI can be produced, packaged and even distributed and is guarantee of the quality of the products for consumers.

Unlike in relation to trade marks which are designed and promoted for private interest, public authorities are involved in the development of the content of the product specification. This is particularly so where there is disagreement

between different producers as to the correct traditional method of production or the geographical area in which the product is made. The public authority seeks to get agreement between all parties. But, at the end of the day, it can in practice impose solutions. This happens when there is no agreement between producers in the opposition procedure that precedes any registration.

The opposition procedure in itself reflects the collective nature of GIs. After the public authority has determined that a name meets the basic criteria for registration as a GI it opens the application to review by interested parties through the opposition procedure. Two opposition procedures are foreseen. The first, during the national procedure, and the second at the EU level. The details of the application are published in the national or EU official journal so as to ensure the widest circulation. It is common that opponents are less concerned about objecting to the registration, unless the object of the opposition is to claim that the name is generic, but more about the details of the application such as the definition of the geographic scope of the origin of the product or the traditional methods of production. Should the applicants and the opponents not reach agreement during the different opposition periods, then the competent authorities have a strong role in determining the exact nature of the specifications in that it can find that some of the grounds of opposition are valid and the specification must be amended if the GI is to be registered.

In conclusion, the role of the public authorities is a strong indication of the public nature of the GI and that it is not merely a reflection of the private interests of producers: the content of the product specification that defines the daily operation of GIs is the outcome of public procedure involving all interested parties.

Registration of a GI is not the end of the process. EU law recognizes that traditions are not static and that specifications may need to change: any non minor modification to the product must follow the same procedure required for the approval of the first product specification and producer groups have a specific role in amendments to the specifications under the terms of Article 49 of Regulation 1151/2012.

4. *Public controls on GIs.*

Based on Regulation 1151/2012 Member States are obliged to carry out controls both at the stage of production and in the market place. These are the so-called *ex officio* controls. The controls are designed to ensure that the producers comply with the production specifications and that there is no fraud in the market place.

Member States must designate the competent authorities for performing official controls, offering adequate guarantees of objectivity and impartiality, and ensuring that they have at their disposal the qualified staff and resources necessary to carry out their functions.

Competent Authorities can delegate specific tasks to private or public control bodies certified by an accreditation body that ensures that these entities are independent third parties free from any conflict of interest as regards the exercise of its tasks.

However, the authorisation does not release competent authorities from their overall responsibility and the need to monitor the performance of control bodies. Audits of inspections are organised on the delegated body and, if it turns out that control bodies are failing to carry out properly the tasks delegated to them, the delegating competent authority may withdraw the delegation if the control body fails to take appropriate and timely remedial action. However, doubts regarding the sufficient protection of GIs have been raised. If the State delegates the certification function to a free market of certification bodies, the concern arises that commercial considerations may distort the independence of the controllers and, consequently, damage the quality of GIs as well as the level of control that is demanded.

Because of the need for independence, producer groups themselves cannot participate in the certification and verification process even if those same groups have a strong interest in ensuring that the specifications are met and that all producers are complying with the GI requirements (particularly where production costs are higher than they might otherwise be for similar products not benefiting from the GI).

There are two kinds of verification of compliance. A first control is a prerequisite to allow a producer to use the GI. Costs of the verification of compliance with the specifications may be borne by the operators that are subject to the controls but Member States may also contribute to cover the costs: it is a further indicator of the public nature of GIs and of the interest that even European Union has in protecting them. There are also, in some cases, on-going controls on the production process to ensure that the compliance is consistent.

With respect to controls in market place, it is usually producers themselves who are the first to identify problems and the first to feel the commercial impact of fraud. Thus they have a private interest in ensuring compliance. However competence to control the market place lies with the competent authorities nominated by the Member States. Thus the controls remain public as GIs are part of public law even if strong private interests can be at stake. This double interest has been addressed for the first time in Article 45 of Regulation 1151/2012 giv-

ing powers to producer groups aimed to protect and promote the quality, reputation and authenticity of a GI. As a result, groups can monitor the market and ensure that other products not covered by the registration are not misleading (the famous example of Parmesan and Parmigiano Reggiano) and they can take action to protect the GI.

Private and public interests are clearly mixed. On one hand, producer groups are undertaking a public function. This can be seen most clearly in Italy where inspectors from the producer groups themselves may be recognised as public security agents. On the other hand, producer groups are made up of producers exercising a business activity seeking to protect their private interests. Accordingly, the delegation of tasks to private control bodies and to producer groups needs to be monitored with attention by the public authority in order to ensure that the public element is not swamped by the private.

A recent ruling of the Italian Supreme Court (Cass., Sez. I, 10 January 2008, n. 355, in *GCM*, 2008, I, 21 ff.) found that the activities performed by the Consortium and the control body generally represent private exercise of public functions because they implement the institutional purpose of protecting public interest of genuineness and loyalty in the agri-food market. However, it is necessary to verify case-by-case the activity they perform and whether they move away from the functions conferred on them by the law.

The increasing role of producer groups raises further questions that will need to be the object of a deeper analysis. Can producer groups control production volumes? Can these groups (also known as Consortia in Italy) ask for compensation if there is fraud on the GI by third parties? Can producer groups ask for the patrimonial losses suffered by the producers using the registered name? These questions are beyond the scope of this brief introduction to the problem. It is clear however that the questions raise issues not only on the cusp between private and public law but also the public interest in protecting fair competition in the market place.

5. Conclusion.

The protection of GIs in the EU has both private and public elements. The concept of *Terroir* is not only limited to topography. It also encompasses the skills and the determination of farmers and producers who have kept traditions alive. This is the reason why producer groups are given a significant role in relation to GIs and in particular their protection in the market place. EU GI law has evolved over the last 25 or so years to give these groups the compe-

tence to perform both private and, increasingly, quasi-public functions. Competition authorities and courts circumscribe and monitor this competence without restricting it too much.

Although GIs are public in nature, they are intellectual property rights raising the question of the nature of the right. Private and public elements weave together: in most cases they are in complementary relationship, in others, the private tries to penetrate where the public has (or shall have) an exclusive role.

Given the recent changes to EU GI law recognising the interests of producers groups it can be seen that the legislator appears willing to recognise the rights of those who produce and market GIs and who have maintained the traditions over time.

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IX. The European System of Protection of the Qualified Geographical Indications

Alice Villari

CONTENTS: 1. Introduction.– 2. The evolution of the rules governing the protection of geographical indications. – 3. The issues investigated by the European case law: a) limits of the protection granted by the European system to PDO and PGI and generic names – 4. (*Follows*) b) The relationship between European and national protection system. – 5. Conclusions.

1. *Introduction.*

The geographical names (*i.e.*: any name suitable to indicate a place certainly identified and to indicate an origin or promise a quality of a product, exercising or evoking charm on consumers) have a particular influence on the choices of consumers and are widely used in economic and competitive activities for their particular significance. Among them, the main distinction concerns the categories of “simple geographical indications”, which indicate only the origin of the product without disclosing the existence of a specific link between its characteristics and the geographical area expressed in the name, and “qualified geographical indications”, which, in addition to the origin of the product, attest specific standards of quality of the products, justified on environmental factors (e.g., climate and soil) or human factors (traditional processing). For an overview of the different geographical indications please refer to the distinction inferred from the judgement *Budvar* (Court of Justice, 18 November 2003, C-216/01, *Budvar* available at <http://eur-lex.europa.eu>) which also identifies “direct geographical indications”, consisting in the precise and exact name of the geographic location where the product is produced, “indirect geographical indications”, that does not recall the name but still evoke the geographical place where the product is produced, “geographical indications of absolute protection”, which preclude the use of the name by producers in other regions, even when the name is used with the addition of expressions such as “like”, “similar”, “imitation” and “geographical indications of relative protection”, which, for protection, require the evidence

that the geographical name used is able to cause confusion and to mislead consumers.

In particular, the category of “qualified geographical indications” are the following:

- “Protected Designation of Origin” (PDO): trademark protection assigned by EU to food products considered particularly valuable, originating in a specific place, region or, in exceptional cases, in a country, whose quality or characteristics are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors and which all production steps take place in the defined geographical area (such as “*Parmigiano Reggiano*” and “*Prosciutto di Parma*”);

- “Protected Geographical Indication” (PGI): trademark protection granted by the EU to the typical products based on less stringent criteria than those of the PDO, because it is sufficient that only a certain quality or characteristic of the product is tied to a specific geographical area and that at least one of its production steps takes place in the defined geographical area (such as “*Salame Felino*”, “*Aceto balsamico di Modena*”);

- “Traditional Speciality Guaranteed” (TSG): trademark protection concerning products that meet a traditional typical recipe and therefore it is not the origin but the method of production or processing that distinguishes the product (for example “*Mozzarella*” and “*Pizza Napoletana*”). To use the mark TSG it is sufficient that the place of production and the origin of the raw material is within the EU territory. Under Article 3, n. 3 of Reg. 1151/2012, to register a name as “traditional” is necessary that proven usage on the domestic market for at least a 30-year period.

2. *The evolution of the rules governing the protection of geographical indications.*

Initially geographical indications found their discipline in some international agreements and in numerous bilateral agreements between states, mainly based on the mutual recognition of protected designations of origin, provided that they were protected in the country which was party to the agreement.

European case law, however, was initially suspicious in relation to the use of geographical indications, as they were deemed as a tool of restraint to imports and a way of protection of domestic sectors in difficulty, against the principle of Article 28 of the Treaty of Rome, stating that the Member States are banned to introduce restrictions to the of free movement of goods or measures equivalent to quantitative restrictions. In this respect Court of Justice in its judgment *Sekt*

of 1975 (Court of Justice, 20 February 1975, C-12/74) about the protection of geographical indications stated that designation of origin and geographical indications shall be protected only in the case that, under national applicable laws, such indications designate a product whose characteristics are closely linked to the production area; otherwise, if national rules do not provide for such a link, the use of indications of origin would be against the prohibition of introducing measures equivalent to quantitative restrictions to the free movement of goods.

Later, the case law has taken a less intransigent attitude towards the use of geographical names, based on Article 32 of the Treaty of Rome, admitting the specificity of agriculture against the antitrust regulation. In fact, the particular nature of some food products and the regime of special attention shown by the EU regulation, led to discover that often the information that the consumer receives through the brand are not sufficient. Consequently, for certain sectors (especially wine, cereals and cheese) was drafted a specific discipline about the use of special signs of recognition, having not only a distinctive function of the product through the indication of the manufacturer, but also a qualificative function of the product itself, assuring consumers that to a certain denomination corresponds a certain quality of the product, resulting from a particular relationship with a territory.

In order to overcome the fragmentation of rules and to establish a system of protection for qualified geographical indications, which may be uniform and centralized at Community level, the European Community issued the Reg. 2081/1992 on the protection of geographical indications and designations of origin for agricultural products and food. In particular, the registration system, allowing to protect at Community level geographical names which have been nationally registered, meets both the requirements of consumer protection (fourth recital Reg. 2081/1992) and those to ensure competition between producers (seventh recital). The registration, in fact, grants the establishment of an ownership right that can be enforced in all the Member States by each operator in the geographical area defined in the specification.

The object of Reg. 2081/1992 is limited to names that relate to products for which there is a specific link between their characteristics and the geographical area from which they originate. Therefore the indications that simply highlight the geographical origin of the product regardless of any particular characteristics are excluded from the scope of the Regulation. The limited scope of the Regulation is the result of an interpretation of the European Court which clarified that the scope of Reg. 2081/1992 only covers products for which there is an “agro-environmental” link between characteristics of the food and the place of origin

(so-called “quality products”) (see Court of Justice, judgment 7 November 2000, C-312/98, *Warsteiner*).

In 2006, with Reg. 509/2006, on the traditional specialties guaranteed for agricultural products and food (TSG), and Reg. 510/2006, on food and agricultural registered as “Protected Designation of Origin” (PDO) and “Protected Geographical Indication” (PGI), the European Union simplifies and clarifies the procedures for registration of local products names, even accepting the requests of the World Trade Organization (WTO) to eliminate, at least in part, the obstacles for competition.

The process of strengthening of the European quality policy goes on with the Reg. 1151/2012 published on 15 December 2012 and in force from 3 January 2013, on quality regimes for agricultural products and food in relation to PDO, PGI and TSG. Such Regulation, together with the Delegated Regulation no. 664 of 18 December 2013 and Implementing Regulation no. 668 of 13 June 2014, composes the so-called Quality Package [RAGIONIERI, GRUNER, ZOLLA, 2011 e ARFINI, 2013]. Reg. 1151/2012, replacing the former Reg. 2081/1992, Reg. 509/2006 and Reg. 510/2006, is based on Article 43 of the Treaty on the Functioning of the European Union about agriculture matters and on Article 118, concerning the harmonization of national laws.

The main changes made by the new legislation can be summarized as follows:

1. simplification of registration procedures - in particular in relation to the opposition period, which has been halved from six to three months (Article 51);
2. introduction, in addition to the existing quality indications (PDO PGI and TSG), of a second class of quality regimes, *i.e.* the indications “mountain product” and “product of island farming”, that can be used only for the internal market and on a voluntary basis (Articles 31 and 32);
3. recognition of the role of consortiums, which may help in exercising control of the legitimate use of the names on the market by taking the appropriate measures to ensure adequate legal protection and taking initiatives to counter actions potentially affecting protected names (Article 45);
4. inclusion of new products eligible for certification of quality under IGP and DOP (such as chocolate and derived products, salt, cotton, leather, hides, feathers) (Annex 1);
5. possibility to ensure to further geographical names the same level of protection of the PDO, even if the relevant raw material comes from a larger area than the defined geographical area, provided that also the production area of the raw materials is defined, and there are special conditions for the production of the raw material beside the presence of a control system (Article 5, par. 3);

6. increase in the protection, extended also to the products used as “ingredients” for products which do not require the registration (Article 13);

7. introduction of the obligation by the Member States to protect such indications not only by the initiative of a party, but also *ex officio*, on the basis of specific action plans (Article 13) [RUBINO, 2013; F. CAPELLI, 2014].

It is now interesting to investigate how the European case-law reads and applies the aforementioned legislation. Vicissitudes of the Salame Felino are emblematic to answer to two critical questions: (a) which are the limits of the European protection?, and (b) how indications which have not been registered can be protected?

3. The issues addressed by the Community case-law: a) limits of the protection granted by the European system to PDO and PGI and the generic names

For the protection of PDO and PGI the juridical system refers to the discipline of the exclusive of the brand name. Such protection granted to the holder of a trademark gives the opportunity for the owner to apply legal mechanisms, established *ad hoc* by the legislature by means of special laws, in order to claim the exclusive use of a brand name against third parties who might use them illegally.

The judgment of the Court First Instance “*Grana Biraghi*” (First Instance Tribunal, judgement 12 September 2007, T- 291/03, *Consorzio per la tutela del formaggio Grana Padano vs U.A.M.I. and Biraghi S.p.A.*) [RUBINO, *www.diritto.it*], confirming the principle stated in the decision of the Court of Justice “*Parmesan*” (Court of Justice, judgment 25 June 2002, C-66/00), provides clarification in relation to the wideness of the exclusive right for the geographical indications: according to the European Court the exclusive right referred to geographical indications has to be limited only to the “most significant” part of the name, being excluded the protection for generic terms.

The concept of generic nature is also the focus of another issue analyzed by the case-law that, in application of the principle deriving from Article 3 of the Reg. 2081/1992 and article 6 of Reg. 1151/2012, stated that names that have become generic cannot be registered. A geographical name becomes generic when an expression, which also refers to a link with a place, has become in the everyday language the common name of an agricultural or food product. The issue has recently been dealt by the Court of Justice in its judgment dated 10 September 2009, case C-446/07.

The Court expressed as a consequence of the preliminary ruling by the Court of Modena about the interpretation of Article 2 of Directive 2000/13/

EC on labeling and presentation of food and advertising and Reg. 2081/1992. The national court, by means of the ordinance dated 26 September 2007, specifically raised the following preliminary question: whether a geographical name, for which the application for registration as a PDO or PGI has been rejected or blocked at national level, is generic, at least for the period that the effects of the rejection/block remain valid. According to the Court of Justice, the legal value of the geographical name, in particular its generic nature, is one of the elements which, without being decisive, may be usefully taken into account in the assessment on whether the labeling is misleading. However, given that only the Commission is ultimately responsible to decide on applications for registration, the fact that the application is rejected or blocked by the national authorities does not affect assessments of the generic nature of a geographical name not yet protected. In its reasoning, the Court refers to Article 13, n. 3 of Directive 2000/13, according to which the names already protected cannot become generic. Instead, names not yet protected may become generic only in case of absence of obstacles provided by a protection already in place. This involves the mere possibility and not the legal presumption that such names are to be deemed as generic while the recording is pending. A name, in fact, becomes generic as a result of an objective process at the end of which, although it contains the reference to the geographical location in which the product was originally produced or marketed, it becomes the common name of such product. Therefore, in order to consider a name as generic, it is necessary a specific decision of the Court about the application to register the name, in the sense that the registration is rejected on the grounds that the name has become generic (see also Court of Justice, judgment 25 October 2005, C-465 e 466/2002, and Court of Justice, judgment 26 February 2008, C-132/05).

In addition, the European Court provided also clarifications to guide the national court in its decision. In order to assess the suitability of misleading indication on the label, the national court should take into account the alleged expectation of an average consumer informed and reasonably careful about the origin, provenance and quality of food because it is essential that consumers are not misled and lead to consider that the product has origins, provenance and quality other than the real ones. The duration of use of the name by other manufacturers is an objective element that can change the expectations of the reasonable consumer, while the good faith of a manufacturer/dealer is a subjective element that has no effect on these evaluations.

In conclusion, (i) the generic nature of a name cannot be presumed until the Commission has ruled on the application for registration, rejecting it, where appropriate, because the name has become generic, as a result of an objective pro-

cess at the end of which it has become the common name of a product, and (ii) the name of a food product containing geographical references that is not registered as PDO and PGI may legitimately be used by third parties, provided that the labeling of the product so named does not mislead an average consumer.

4. (Follows) *b) The relationship between the system of protection in Europe and national protection regime.*

Recently, the Court of Justice has solved the problem of the relationship and the interrelationship between the system of protection for qualified geographical indications established at Community level and the national systems relating to the same geographical indications.

The Court has recognized that the European system of protection does not exclude that simple geographical indications can benefit from the protection at national level. Orientation inferred from *Bud II* (Court of Justice, judgment 9 August 2007, C-478/07 *Budějovický Budvar*), ruling that the system of European protection has a comprehensive nature, because Reg. 510/2006 did not intend to implement a system of protection which is complementary to the national legislation – such as that one established by Reg. 40/1094 for the trade mark – but a uniform system that intends to apply with the exclusion of any national systems of protection, in order to overcome the heterogeneous practices of recognition and protection existing in the various Member States. Instead it was uncertain, until the judgment “*Salame Felino*” of 2014, the fate of geographical indications which would abstractly fall within the scope of the European discipline concerning qualified geographical indications, because they express a link between quality, features and reputation of the product and the geographical area of origin, but have not been (yet) registered in the Community Register.

The facts of the dispute go back to 1998 when the Association for the Protection of the *Salame Felino* sued Kraft Jacobs Suchard S.p.A. (actually Kraft Food) before the Court of Parma for unfair competition, alleging that the defendant had marketed a product having the name “*Salame Felino*” although produced in Cremona and, therefore, in a region different from the Parma one. At that time, the name “*Salame Felino*” had not been yet registered at Community level neither as a PDO nor as a PGI, because the registration as a PGI only occurred in March 2013, as a result of a long and troubled proceeding that began in 1997, during which the Court of Justice was called upon to express about generic nature of the name (judgment 10 September 2009, Case C-446/07) [PRETE, 2014]. Kraft, who was sentenced at first instance of unfair competition, appealed the judgment

– which was rejected – and then proposed appeal to the Supreme Court, stating that the system of protection of origin names set under Reg. 2081/1992 precludes national legislations from granting exclusive right to use a protected name of origin with no Community registration. In January 2013, the Supreme Court stayed the proceedings and referred to the Court of Justice about the following questions: a) if the Reg. 2081/1992 has to be interpreted in the sense that it authorizes the exclusive right to use a geographical name even without a legally binding measure establishing the boundaries of the geographical area and product requirements; b) what is the protection regime applicable to geographic names not registered.

The Court, in its judgment of 8 May 2014, C-35/13 [FALCONI, 2014], reiterated the comprehensive nature of the European system of protection, whereby a name can benefit from the protection regime of Reg. 2081/1992 only in case of enrollment in the register of the Commission. The compulsory nature of the registration pursuant to Art. 5 Reg. 2081/1992 was already been stated by the Court of Justice, judgment. 9 June 1998, C-129/97 and C-130/97, *Chiciack and Fol*, in Racc., 1998. Moreover the Court acknowledged the possibility that geographical indications which have not been (yet) registered at the European register, even if they do not have protection at European level, may, however, be protected at national level, within the limits and conditions that national rules do not compromise the free movement of goods. Therefore, with regard to simple geographical indications, the Court, confirming its guidance on the point, rules in the sense that the European legislation does not prevent Member States from protecting this type of geographical indications outside the cases covered by Reg. 2081/1992 (and in particular in misleading advertising and unfair competition) (Court of Justice, judgment 10 November 1992, C-3/91, *Exportur*; Court of Justice, judgment 7 November 2000, C-321/98, *Warsteiner*) [VALLETTA, 2002, MONTELIBONE, 2001, CAPELLI, 2001].

The most significant passage of the judgment is, however, represented by the evaluations expressed by the Court in relation to the rules applicable to geographical indications which, while being abstractly within the scope of Reg. 2081/1992, have not been registered in the Community Register. For the first time the Court accepts that such indications can be protected at the national level under the same system of protection provided for the simple geographical indications (*i.e.* geographical indications relating to products for which there is not any specific link between their characteristics and their geographical origin), provided that the following two conditions:

1. that the national system of protection granted to them does not compromise the objectives of Reg. 2081/1992, since the national legislation should have the effect of ensuring that the products actually originate from the geographical area indicated; is

2. that the national system of protection is not in breach of the free movement of goods.

It has instead remitted to the national court to verify whether the system of protection offered by the applicable national legislation (for Italy it is the Legislative Decree no. 30/2005, *i.e.* the Industrial Property Code, and formerly the Legislative Decree no. 198/1996) is compatible with the guidelines on the protection of qualified geographical indications and the free movement of goods.

Based on this ruling, the Italian Supreme Court, which had raised the questions before the European Court, by means of judgment dated 12 February 2015, overturned the decision on the merits which had condemned the Kraft for unfair competition, since, according to the Supreme Court, Article 31, par. 1 of Legislative Decree no. 198/1996 provides a definition of geographical indication that – based on a link between geographical origin and characteristics of the products – is not outside of the scope of Reg. 2081/1992: therefore the national court could not have applied the national rule of Art. 31, par. 1), for a geographical indication not registered at a European level.

However, the Court observed that Article 31 of Legislative Decree no. 198/1996 envisages two distinct cases of unfair competition: the first, consisting in the false attribution to products of qualities linked to a given geographical origin (Art. 31, par. 1); the other which makes reference to a geographical origin other than the actual place of origin, regardless of any reference to the quality of the products originating from that place (Art. 31, par. 2). Only the latter of these two hypotheses is not included within the scope of the European Regulation and, therefore, can still operate in our system because it *«protects the mere geographical name, preventing its use for products coming outside of the area to which the name refers, without any connection to quality and characteristics of the products»*. In the case analyzed by the Court, however, the form of unfair competition covered by Art. 31, par. 2 was not challenged, because the Producers Association of the Salame Felino had linked the unfair business conduct exclusively to the violation of use of the geographical name in connection with the quality of product deriving from the place of production.

5. Conclusions.

From the above analysis, it is clear that the *ratio* of a European system of protection of indications is that the typical and/or traditional food, that can reach a large spread on the European and international markets and, therefore, run the risk of being imitated and counterfeited in these markets, require a much more effective protection than the one offered by national law.

However, the current system of protection appears not self-sufficient and imperfect, because it is unable to respond to problems reported by doctrine and in part also highlighted by the ambiguity of the European case-law. In this respect some authors speak of “lights and shadows” [CAPELLI, 2014], indicating a degree of indecision of discipline on geographical names of food products, which may lead to a position of weakness for the European Union in the negotiations for the implementation of the TRIPs Agreement to the Treaty of Marrakesh on the WTO.

The two main aspects in relation to which it would be desirable to rethink the European legislation both depend on the inadequacies of European law itself, leaving space for a referral to national rules. In particular, on one hand, the European legislation on geographical indications only deals about the content of the protection but do not regulates remediations and sanctions, whose enforcement takes place only at national level. The second aspect concerns the protection of geographical indications that do not fall within the scope of European legislation, first of all the simple geographical indications. In this regard, it is worth noting that, based on lessons arising from the case “*Salame Felino*”, it is likely that the national laws, entering into force in a period prior to the effectiveness of the European laws, can have a scope substantially coincident with that of the European regulations, where grant protection to names which have any link between origin and quality of products. It follows that, at the presence of a jurisprudence that allows no national regulation for the protection of situations already subject to protection by the European law, any residual space of action for national legislators (for example, the protection of simple geographical indications) ends up being lands threatened by a total legal *vacuum* for the absence of protection, because no rule is dealing with. Then, it would be the case to imagine, either a European system with a wider scope, in order to include also the spaces that currently would be a matter of national legislators, or to rewrite national rules in the light of the new European law.

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X. Private and Public Organizations in the Protection of Typical Foodstuffs

Miriam Allena

Contents: 1. Introduction.- 2. Different systems for the protection of geographical indications: general overview.- 3. The evolution of the role of groups of producers and *Consortia* in the European and Italian legislation.- 4. Groups of producers and *Consortia* as 'private bodies exercising functions of a public nature'.

1. Introduction.

This article focuses on the relationships between public and private bodies in the promotion and protection of agricultural products or foodstuffs of a certain nature, quality and reputation which are essentially or exclusively due to their geographical origin [HUGHES J., 2006; TREGEAR A., 2001; CARLI C.C., 1999].

In particular, it addresses the role of Italian Private *Consortia* in the protection of geographical indications (GIs) registered as PDO (Protected Designation of Origin), PGI (Protected Geographical Indications) and TSG (Traditional Specialities Guaranteed) under the EU Regulation No 1151/2012 of 21 November 2012, on quality schemes for agricultural products and foodstuffs (see Alice Villari's paper above).

As Bernard O'Connor and Miriam Hamdan pointed out in their paper (see above), in the EU GIs are protected as a separate form of intellectual property, under a *sui generis* system of protection and registration specifically dedicated to the safeguard of agricultural products and foodstuffs. Moreover, the EU scheme has been grounded on a strong public oversight: public authorities play an important role in guaranteeing the economic interests of producers using the GIs logo against fraud or deceptive business practises as well as in protecting consumers who associate certain products with specific areas, processes and traditions. The system reflects the nature of agricultural GIs within the EU whom rationale is not only to secure «*a fair return for farmers and producers for the qualities and characteristics of a given product, or of its mode of production*» and to provide «*clear information on products with specific characteristics linked to geographi-*

cal origin» (see Recital 18 of the EU Reg. No 1151/2012), but also to contribute to the achievement of broader policy objectives such as, for instance, the safeguard of the quality, the diversity and the tradition of the agricultural production, the development of rural areas, the protection of the environment (see Art. 1 of the EU Reg. No. 1151/2012). This is the reason why the public administration is variously involved in the protection process of GIs and it covers many of the costs associated with securing and enforcing them [JOSLING T., 2006, 4 ss.]. In other words, it could be argued that the involvement of public or quasi-public bodies is required by the public policy interests which GIs are meant to serve [RAMAJOLI M., 2016, 397 ss.].

Nevertheless, under the EU regulation, also private or semi-public organizations play a role in the protection process of GIs: for instance, very often private bodies take responsibility for (or collaborate in) carrying out official controls and for maintaining the quality of agricultural products and foodstuffs in general. This phenomenon raises the question of the nature of the powers exercised by these entities and of the regulatory regime applicable to them.

Drawing on the above, this article is structured as follows: after an illustration (at para. 2) of the two main institutional approaches to GIs protection, the EU *sui generis* system of protection of quality signs is considered. Thus, para. 3 provides an analysis of the gradual evolution of the role played by groups of producers, while para. 4 addresses the broader question of which legal regime should govern the activities of those groups of producers and of the others private bodies when they are involved in the promotion and protection process of quality signs.

2. Different systems for the protection of geographical indications: general overview.

EU is the world's main proponent of *sui generis* protection for GIs and has elaborated a complete and refined regulation to safeguard agricultural products and foodstuffs whose qualities are influenced by specific local and geographical factors such as climate and soil. Other examples of countries which have embraced a similar *sui generis* scheme of protection are Southern countries such as India or Mozambique [BRAMLEY C., BIÉNABLE E., KIRSTEN J. (eds.), 2013].

The EU scheme provides for a distinct registration system for GIs specifically tailored to the unique attributes of these intellectual property rights and characterised by a strong public law enforcement: the aim is to ensure that users of GIs comply with the agreed standards of production and that the use of a given GI does not mislead consumers as to the true origin of the product and does not embody unfair market practises. To these ends, the EU Regulation

No 1151/2012 provides that Member States are responsible for putting in place an integrated system of official controls (in accordance with EC Regulation 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) to verify the compliance of agricultural GIs with the product specification and to monitor the use of registered names when products are placed on the market (Arts. 36 and 38). Furthermore, public authorities can take, *ex officio*, appropriate administrative and judicial measures «to prevent or stop the unlawful use of protected designation of origin and protected geographical indications» that are produced or marketed in their territory (Art. 13, par. 3).

Overall, the *sui generis* approach tends to put the burden of costs on the public administration or on producers/processors (represented by a group or a *Consortium*) who benefit from the protection: this may prove to be very convenient especially for small producers who would otherwise not be able to bear the costs which are necessary to protect their products.

Where a *sui generis* approach is not adopted (as, for example, in USA, Canada, Australia and Japan), the trademark system provides the legal framework for the protection of quality requirements of all products, including agricultural ones and foodstuffs.

In this case, the holder of a mark must set the relevant standards of quality, safety and other desirable characteristics which can, but do not necessarily have to, be reconnected to a certain geographical origin. The holder is also responsible for exercising controls over the use of the mark by certified parties (ensuring compliance with the defined standards) and for imposing sanctions in case the products fail to meet the given standards [GIOVANNUCCI D.-JOSLING T.-KERR W.- O'CONNOR B.- YEUNG M.T., 2009]. Overall, the protection is based on a private initiative (the Government or the Public Administration being involved only when the interested private parties file an application to a national trade mark registrar that, nevertheless, does not have the power to examine the merit of the request) and the private sector bears most of the costs associated with the management and the enforcement of the protection (for instance, the owner of the mark needs to carry out a regular monitoring of the markets where the trademark is protected and he has to launch the necessary legal actions to protect its intellectual property right).

In terms of substance, the two mentioned schemes appear similar: both safeguard the interests of producers against unfair competition (giving them the possibility to distinguish their products from similar but not identical products which may cost less) while, at the same time, protect consumers against mislead-

ing information. Of course, while *sui generis* GIs regimes indicate geographical origin [see Recital 15 of the Reg. No. 1151/2012], trademarks indicate a commercial origin (so that products can be made anywhere), but both of them can serve as guarantees of quality and as valuable commercial brands, though trademarks do not automatically embed a quality offering [GANGJEE D., 2006, 112 ss., 113; LANDES W.M. and POSNER R., 2003].

Nevertheless, the level of protection of the EU *sui generis* regime is higher than the one of trademarks: for instance, since GIs certify a certain origin or a local manufacturing tradition which grants the good at stake specific status or reputation, the registered name is protected against any direct or indirect commercial use and against any evocation of the name, even if the true origin of the product is indicated and consumer would not be confused [see Art. 13 of the Reg. n. 1151/2012]. On the contrary, in trade mark law, the protection is only against the goods sufficiently similar to cause confusion among consumers: thus, third parties using a protected name would not be sanctionable if the name is translated or accompanied by expressions such as “style”, “type”, “method” or similar and the true origin of the product is clearly shown on the label [EVANS G.E., 2013].

Furthermore, in the EU *sui generis* regime the scope of protection is generally broader since GIs give effect to specific policy interests which overcome the traditional market-related benefit of trademark law: in fact, as referred to above (para. 1) they are means of addressing social and environmental development objectives such as the diversification of agricultural production, the preservation of the cultural heritage of the territories as well as the protection of natural resources, the development of rural areas and the reduction of the exodus from them (see Recital 4 and Art. 1(1) of Council Regulation No 1151/2012). In this perspective, they are instruments of public policy [RUBINO, V., 2013].

The subject-matter of this work makes it impossible to give a complete overview of the different institutional approaches to GIs but it should be noted, at least, that another common way to protect GIs are collective marks and certification marks: they belong to the trademark family, but are subject to a special regime.

Collective marks indicate the affiliation of different enterprises simultaneously using the collective mark [RICOLFI M., 2009, 231 ss.]: the members of the group using the collective mark must fulfil certain requirements set out in a specific regulation (though they are not necessarily quality requirements) and the owner of the mark, who may be either a private association or a public body, supervises the use of it and can exclude others private subjects or enterprises from the same use. Thus, from this point of view, the protection accorded is different

from the EU *sui generis* regime where each producer located in a given area can join the quality sign as long as his products comply with the prescribed quality standards. Again, this is a consequence of the circumstance that the purpose of GIs registered under the EU Regulation No 1151/2012 is not to ensure an ownership right (significantly, there is no owner of these GIs) but to certify the unicity/genuineness of some products resulting from their organoleptic characteristics and from environmental or cultural factors such as the provenience from a specific area, the use of certain raw materials and of specific production methods, the '*savoir faire*' of the people living in that area, etc. (it is the concept of '*terroir*' which includes both physical components of the environment and human factors [PARISIO V., 2015, 83 ss., 91]).

As to the certification marks, they are used to show the compliance of a product with certain defined standards of quality, materials, mode of manufacture or to certify that goods or services originate in a specific geographic area [O'CONNOR B., 2007, 72 ss.]. The certification authority (which owns the mark) has to identify and publish all the criteria under which a designation can be protected and the control bodies in charge of certify whether the relevant criteria are met. Thus, since they are signs of supervised quality, they contrast with collective marks (which do not necessarily imply a claim of quality) and appear in some way more similar to the EU *sui generis* system of protection: significantly, all the producers of a certain region are entitled to join the quality sign as long as their products comply with the prescribed quality standards [ZAPPAGLIO A., 2015].

3. The evolution of the Role of Groups of Producers and Consortia in the European and Italian legislation.

The EU regulation No 1151/2012 strengthens the role of representative organizations of producers (*«groups»*) and specifies their functions in protecting and safeguarding GIs for agricultural products.

According to the former EC Regulation No 2081/1992 of 14 July 1992 (*i.e.* the first regulation providing a unitary system of protection of PDO and PGI within the EU) and the subsequent Regulation n. 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, a group was meant to consist of *«any association of producers or processors working with the same agricultural product or foodstuff»* (Art. 5, par. 1) and its task consisted solely in the presentation of the application at a national level to register a product under a quality scheme or, after the regis-

tration, to amend the product specification in the light of scientific and technical progresses [COSTATO L., 2012; DEVENYI P., 2011]¹¹.

The fact that groups are formed by producers (and are representative of producers' interests) was probably at the basis of the EU initial choice to limit their role in order to avoid any possible conflict of interests [see ECHOLS M.A., 2008, 162, who undelines that «[f]rom a commercial perspective, they (the groups) are similar to the guilds of medieval times. From a social perspective they might be considered representatives of the community and the local tradition – the guardians of the communal property interest»]. From this point of view, it should be noted that the very first EU regulation on geographical indications overcame the tradition of countries with a long history of GIs protection, such as France and Italy, where local producers' groups had always been largely involved in the monitoring process of quality signs.

Anyway, the EC Regulation No 2081/1992 outsourced the system of official controls to independent and external bodies designated by Member States. These inspection bodies could be public or private (in which case they were required to be accredited to European standards) and had to offer adequate guarantees of objectivity and impartiality towards all producers and processors subjected to their control. Their main task consisted in verifying that the requirements of the registered specification were met and their control could result in the exclusion of producers and operators within the defined area who did not fulfil those requirements.

Regulation No 2081/1992 was implemented into the Italian legal system by Law No 128 of 24 April 1998, whose Art. 53, par. 1, requires that for every registered product there must be an inspection body formally authorised by the Ministry of Agricultural Policy and in charge of ensuring that the requirements of the registered specifications are met. A specific Division of the Ministry of Agricultural Policy (the *Ispettorato centrale della tutela della qualità e repressione frodi*) and the relevant local authorities oversee the inspection work conducted by the control independent bodies. Furthermore, the Ministry of Agriculture is in charge of coordinating all the inspection activities.

¹¹ The specification is the document that contains all the technical information necessary to describe the product: the conditions indicated herein are binding on producers intending to use the registered name (only products which comply with the specification can be marketed under the PDO, PGI or TSG registered name). According to the EU regulation, groups of producers have to file the application to the competent public authority designated by each Member State. After a reasonable period of time, if no objections are raised and if all the requirements seem to be met, that authority has to forward the application to the Commission who will scrutinise it again to ensure that there are no manifest errors and that Union law and the interests of stakeholders outside the Member States of application have been taken into account: see EU Reg. No. 1151/2012, Recital 58).

Conversely, Art. 53, par. 15¹², specifies that *consortia* (i.e., voluntary non-profit associations of producers in the same value chain set up in accordance with Art. 2602 of the Italian civil code) recognised by the Ministry of Agriculture¹³ serve the purpose of promoting and protecting GIs. In particular, they can: (i) bring forward regulatory proposals and perform advisory tasks to promote the product concerned; (ii) contribute to the improvement of the quality and authenticity of their products (in terms of food safety, chemical, physical, organoleptic and nutritional characteristics); (iii) achieve agreements, for a limited period of time, on the provisional and coordinated planning of the production of PDO, PGI and TSG; (iv) contribute to the supervision and the safeguard of PDO, PGI and TSG from unfair competition, misuse and imitation. To this end, *consortia* can employ a corps of qualified agents, with the title of public security agents (*agenti di pubblica sicurezza*), in charge of controlling the implementation of the provisions laid down by laws and regulations at all levels (farms, producers and traders). The Ministerial Decree of 12 April 2000 provides for the rules on cooperation between private *consortia* for the protection of PDO, PGI and TSG with the *Ispettorato centrale della tutela della qualità e repressione frodi*.

In other words, notwithstanding that the EC Regulation No 2081/1992 and the subsequent EU Regulation 510/2006 did not contain specific rules for groups of producers (apart from their explicit involvement in the registration process of PDO and PGI) and attempted to outsource all the control activities to independent bodies, *consortia* have continued to play a fundamental role under Italian law. Indeed, not only they have carried out activities such as consumers' information and promotion activities in general, but they have continued to cooperate with the independent control bodies in verifying compliance of the products with the specifications and, above all, in monitoring the use of the names in trade (in particular by checking whether similar products, produced or marketed in the EU with false indication of origin, qualities and characteristics, could lead to confusion among consumers and therefore damage the PDO and PGI products).

In fact, at an operational level, *consortia* have played a major role in the enforcement of the product specifications: therefore, in many cases they informed control bodies and national authorities of unauthorised uses or practices and have commenced private legal actions in the courts of Member States to protect registered names against unfair commercial uses.

¹² As modified by Art. 14 of the Community Law No 526 of 21 December 1999.

¹³ According to the Italian regulation, an association of producers (or a *consortium*), in order to obtain Ministerial recognition has to represent at least 2/3 of the certified production calculated over a given period of time.

It is worth noting that, over the past years, the European Court of Justice (ECJ) has gradually recognised the importance of the role played by producers' groups in safeguarding -and therefore in monitoring- the characteristics and the qualities of GIs, on the contention that they are *«those who have the necessary knowledge and know-how and a fundamental interest in preserving the reputation acquired»*. On this basis, the ECJ held, for instance, that the rules governing the Rioja wine *“denominación de origen calificada”*, by ensuring that operators in the wine sector of the Rioja region controlled bottling as well, pursued the aim of better safeguarding the quality of the product and the reputation of the designation for which they (the operators) were to be regarded as having *«full and collective responsibility»* [see ECJ, Judgment of 16.05.2000, Case C-388/95, *Kingdom of Belgium v. Kingdom of Spain*].

Similarly, a few years later, in the *Parma Ham* case, the ECJ established that, by requiring the slicing and packaging to be carried out in the region of production, the specification of the PDO *Prosciutto di Parma* was intended to allow the association of producer representatives (the *Consorzio del Prosciutto di Parma*) to safeguard the quality and authenticity of the product (by keeping under their control one of the ways in which the ham appeared in the market) and, consequently, *«the reputation of the PDO, for which those who are entitled to use it assume full and collective responsibility»* [see ECJ, 20 May 2003, case C-108/01, *Consorzio del Prosciutto di Parma v. Asda Stores Ltd*].

In this scenario, it is not surprising that the EU regulation No 1151/2012 finally fully acknowledged the importance of groups of producers and of their role non only in defining the content of the products specifications but, more generally, in the day- to-day management of the GIs [see Recital 57 that, after stating that: *«Groups play an essential role in the application process for the registration of names of designations of origin and geographical indications and traditional specialities guaranteed, as well as in the amendment of specifications and cancellation requests»*, specifies that: *«The group can also develop activities related to the surveillance of the enforcement of the protection of the registered names, the compliance of the production with the product specification, the information and promotion of the registered name as well as, in general, any activity aimed at improving the value of the registered names and effectiveness of the quality schemes. Moreover, it should monitor the position of the products on the market»*].

In particular, Art. 45 of this Regulation enumerates in some detail the role and responsibility of producer's groups and explicitly states that they are responsible not only for the advertising, promoting, labelling and packaging of the product, but also for ensuring compliance of a given product with its specification and for enforcing the use of the name in trade by taking appropriate measure

to ensure legal protection and, more in general, to counter potentially negative impacts on protected names. Due to this fundamental role of groups, according to the para. 2 of the same Article, Member States shall encourage their formation and their activities by administrative means [*«A group is entitled to: (a) contribute to ensuring that the quality, reputation and authenticity of their products are guaranteed on the market by monitoring the use of the name in trade and, if necessary, by informing competent authorities; (b) take action to ensure adequate legal protection of the protected designation of origin or protected geographical indication and of the intellectual property rights that are directly connected with them; (c) develop information and promotion activities aiming at communicating the value-adding attributes of the product to consumers; (d) develop activities related to ensuring compliance of a product with its specification; (e) take action to improve the performance of the scheme, including developing economic expertise, carrying out economic analyses, disseminating economic information on the scheme and providing advice to producers; (f) take measures to enhance the value of products and, where necessary, take steps to prevent or counter any measures which are, or risk being, detrimental to the image of those products»*].

4. *Groups of producers and consortia as 'private bodies exercising functions of a public nature'*

The EU regulation has explicitly recognised that groups of producers now play a leading role in the protection of PDO, PGI and TSG: as referred to above, their broad competence extends from the definition of production methods or operating standards and packaging rules to the protection of registered names against any direct or indirect commercial use. In some ways, this evolution has been consistent with the role that has always been played by groups of producers in countries with a strong tradition in protecting and promoting regional food products such as Italy or France¹⁴. Furthermore, the increasing relevance of these private bodies (groups or producers or *consortia*) within the EU reflects a more general trend of reduction of public intervention in economic activities since 1980s: this process has taken the two principal forms of privatization and contractualization of functions and public activities [on this topic see ELLIOTT M., 2012].

It is beyond the purpose of this paper to investigate the reasons underpinning the so called “hollowing-out” phenomenon entailing a transfer (to some

¹⁴ Think, for instance, that in France the first regulation of “Roquefort” by a parliamentary decree dates back to 1411, while the delimitation and regulation of the “Port” wine in Portugal started in 1756.

degree) from the public to the private sector. On the contrary, the present work shall be limited to an outline of some remarks on the nature of the activities of groups of producers and *consortia* for the protection of GIs.

There is no doubt that these private bodies (together with private independent control bodies mentioned to above) are viewed with favour by the European and Italian legislation as they usually are ‘closer’ to the local community (as well as to the local traditions) and, therefore, likely to be more effective in enforcing GIs in a given territory. At the same time, their involvement in the protection and promotion of GIs is in line with the principle of horizontal subsidiarity (which is also formally recognised in Art. 118 of the Italian Constitution): according to this principle, public authorities shall abstain from intervening in those activities in which the action of non-state actors and civil society in general can accomplish the same end.

Nonetheless, it is also true that said private entities, when dealing with many of the above mentioned activities, exercise functions which are *de facto* ‘public in nature’: indeed, the monitoring over the quality, reputation and authenticity of agricultural products and foodstuffs is exercised not only in the interest of producers and consumers, but can also constitute a means to support public policies in a broader social and economic perspective [PERFETTI L.R., 2014, 3 ss., 18]. Significantly, as mentioned, people employed by *consortia* and responsible for overseeing GIs are qualified as “public security agents” under the Italian legislation.

The exercise of functions of a public nature by bodies which are private in substance is not a new phenomenon: in Italy, the first study on this topic was Guido Zanobini’s influential book *L’Esercizio privato delle funzioni e dei servizi pubblici* published in 1935 in the *Primo trattato completo di diritto amministrativo* (First Comprehensive Treaty of Administrative Law) edited by Emanuele Orlando (the founder of the so called “Italian School of Public Law”. However, there is no doubt that this phenomenon has considerably increased over the last decades [SESSA V., 2007].

Nonetheless, for the purposes of this article it is especially interesting to underline that the decisions taken by said private bodies -not unlike the ones taken by public bodies- can sometimes heavily affect the individuals involved: for instance, the imposition of a specific package or of a new labelling system can entail significant additional costs for producers. Therefore, producers should be granted access to all the relevant data of the decision making process and at least be given the possibility of participating, of being heard, of knowing the rationale behind each decision. At the same time, the power of *consortia* to impose restric-

tions of business activities should be clearly regulated in advance by the law in order to prevent any unjust interference with entrepreneurial freedom.

However, practical experience shows that *consortia* very often tend to impose rules that do not have a clear legislative basis and do not put in place fair procedures when adopting actions capable of affecting members of the *consortium* or, more generally, the other producers included in the promotion/protection system. As a result, the engagement of private entities in the EU and national protection policy of GIs risk to result in a general reduction of substantial and procedural guarantees that are usually connected with the exercise of the administrative action. Indeed, the right to be heard, the right to have access to all the documents of a public procedure in which citizens are involved, as well as the duty of the authority to give reason, are guarantees commonly recognised within administrative procedures [Galligan D., 1997]. Furthermore, any individual who is affected by a decision taken by a public body can invoke administrative law and judicial review to vindicate his/her rights against the exercise of the public power: this is particularly important since judicial review not only constitutes a remedy against unlawful use of public powers, but also allows third parties to challenge administrative decisions taken by public bodies. On the contrary, as is well known, under corporate law only a company member may judicially appeal a resolution of the shareholders, since the system is aimed at protecting the personal interest of shareholders and not the general (public) interest.

The perspective of applying all the guarantees connected with the right of a fair administrative procedure to the activities carried out by private bodies exercising public functions is therefore in line with Feliciano Benvenuti's doctrine of the so called 'objectivised administration' (*amministrazione oggettivata*), *i.e.* the idea of administration identified not by looking at the subjective nature of the bodies involved (whether private or public), but looking at the very (public) nature of the functions exercised [BENVENUTI F., 1978, I, 6 ss.; *Id.*, 1952, 118 ss.].

At the same time, this approach also seems consistent with the European Convention of Human Rights (ECHR) doctrine: indeed, pursuant to the Strasbourg jurisprudence, a body involved in the discharge of the State's obligations or exercises coercive or special powers delegated by the State, should be regarded as a public entity and, as a consequence, when performing those functions, it should ensure the guarantees laid down in Art. 6 of the ECHR and in Art. 1 of the First Protocol of the ECHR (see ECtHR, 8 June 2006, *Wos v. Poland*, Applicatio No. 22860/02) [QUANE H., 2006, 106 ss.; GOISIS F., 2014, 1 ss.]. Art. 6 ECHR, which codifies the 'right to a fair trial' principle, provides for a number of procedural guarantees which, according to the European Court of Human Rights (ECtHR) jurisprudence, shall be applied whenever the position of a citizen is

substantially affected, regardless of the formal nature of the procedure at stake (see ALLENA M., 2012 and ID., 2014). Art. 1, First Protocol of ECHR, requires that any interference with the peaceful enjoyment of possession should be lawful, i.e. it should respect the conditions provided for by law: this provision, clearly intended as a safeguard against arbitrary measures, provides defence also to intellectual property rights (such GIs) which, according to the settled ECtHR jurisprudence, can be described as possessions (see Eur. Comm. HR, decision of 16 December 1974, Müller v. Austria, Appl. No 5849/72).

Moreover, the same substantial perspective is now confirmed by the Italian Administrative Procedure act of 1990 (Law No. 241/1990), i.e. the first legislation in Italy that set out general principles aiming at protecting citizens when facing administrative action (before the entry into force of the Law No. 241/1990, Giorgio Pastori's book, *La procedura amministrativa*, published in 1964, has been the first study in Italy looking at the administrative procedure as an instrument for the improvement of the relationships between the administration and the public, recognising to the latter several rights towards the exercise of the administrative power) [PASTORI G., 2010,81 ss.]. Indeed, according to Art. 1, para. 1-ter (text modified in 2005), private bodies exercising administrative functions are subject to the principles governing administrative functions and are due to ensure a level of protection for citizens which shall not be lower than the one guaranteed by the public administration [for a complete historical and comparative analysis of the Italian law on administrative procedure see the essays collected in *Italian Journal of Public Law*, vol. 2 No 2/2010]. Symmetrically, Art. 7, para. 2, of the Italian Administrative Trial Code (Law No. 104/2010) provides that "public administration" is any entity whose activity is subject to the principles of administrative procedures. Thus, this provision shows that, also for the purposes of administrative judicial protection, what is relevant is not the formal nature of the bodies involved but the (public) substance of the activities put in place.

In conclusion, there is no doubt that nowadays public law, as an instrument aiming at regulating the exercise of the power of governants over society offers to citizens a higher degree of substantial and procedural protection than private law. Therefore, the principles of administrative law enforced via judicial review should be applicable whenever the power exercised is characterised as imperative in nature and, more in general, whenever it is capable of heavily affecting individual rights.

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XI. EU Regulation on Food Waste: A New Challenge?

Rocco Steffenoni

CONTENTS: 1. Introduction. – 2. EU regulation on food waste: setting pathways of convergence. – 2.1 Framing a preliminary definition and a harmonised regulation of bio-waste. – 2.2 The evolution of food waste as a self-standing concept. – 2.3 The new Circular Economy Package (2015) and the revised legislative proposals on waste: an analysis on food waste. – 3. The vexed debate around an EU definition of food waste. – 4. Food donation: brief remarks about Italy, France, and the United Kingdom. – 5. Conclusions.

1. *Introduction.*

Following the EU Commission meeting of the 23rd July 2008 about the repeal of fruit and vegetable marketing standards, Mariann Fischer Boel, the former EU Commissioner for Agriculture and Rural Development stated that «in this era of high prices and growing demand, it makes no sense to throw these products away or destroy them». Such a quote might be regarded as a new course of action about the distortive effects of EU regulation on food. Later that year, indeed, Regulation (EC) No 1221/08 abolished 26 out of 36 existing marketing standards and, as a result, allowed the sale of many edible foodstuffs that otherwise would not have been sold within the EU.

Food waste is a worldwide phenomenon. Figures show that the consumer food waste alone amounts to more than US\$400 billion per year (WRAP-NCE). Yet this trend is not expected to decline. By roughly 2050 the global population is estimated to reach 9 billion people (+30%) and many of these people may become increasingly better off, doubling up to 5 billion people by 2030, with relevant impacts in terms of consumption patterns (KHARAS, FAO 2011). Therefore, as opposed to the maximization in food production that in a century led to a considerable reduction of the proportion of hungry on global scale, the role of food regulation should now pursue the optimization of the raw materials and food production (CHARLES). In this respect, an analysis of policies put in place to tackle and reduce food waste, which accounts for US\$600 billion a year, might play a vital role.

Along this line, the Universal Exposition hosted in Italy (Expo 2015) focused on the right to healthy, secure and sufficient food. In particular, during

the event the «Milan Charter» was drafted which explicitly considers *unacceptable* that «each year, 1.3 billion tonnes of food produced for human consumption is wasted or lost in the food supply chain». Similarly, in a recent Resolution adopted by the UN General Assembly on 25 September 2015 it has been pledged to «halve per capita global food waste at the retail and consumer levels and reduce food losses along production and supply chains, including post-harvest losses».

This article proceeds in five parts. Section 2 covers the institutional debate on bio-waste, and consequently on food waste, within the EU waste management policy. Section 3 concerns the complexities around the wording of the term «food waste». Section 4 addresses food donation as a means of reducing food waste in light of the circular economy. In particular, it briefly analyses some best practices on food donation in Italy, France, and the United Kingdom. Section 5 draws the conclusions putting forward proposals to better regulate food waste depending on the food chain stage.

2. EU regulation on food waste: setting pathways of convergence.

Prior to addressing food waste as a stand-alone topic, it is worth analysing in brief the EU legislation and policy favouring bio-waste recovery as an alternative to its landfilling.

The European Commission (EC) has paid particular attention to bio-waste for a number of reasons. As an example, upon being landfilled, bio-waste «produces methane, a greenhouse gas which is 21 times more potent than carbon dioxide» (EUROPEAN COMMISSION 2005). Moreover, since the greenhouse gas emissions caused by «the production, packaging and transportation of food that is thrown away are needless additional emissions», the improvement of efficiency of «the food supply chain, so as to prevent food waste and eliminate edible food waste, is a key step towards climate change mitigation» (EUROPEAN PARLIAMENT 2012). Furthermore, even though municipal waste, which constitutes a large proportion of biodegradable waste, accounts only for 7-10% of the total waste produced in the EU, this waste stream is «amongst the most complex ones to manage, and the way it is managed gives a good indication of the quality of the overall waste management system in a country» (EUROPEAN COMMISSION 2014).

2.1 Framing a preliminary definition and a harmonised regulation of bio-waste.

During the '90s, EU regulators became far more aware of the inherent connection between waste management and the processes of recovering/recycling,

especially to the extent that it averts the exploitation of virgin materials. In 1996 the Community Strategy for Waste Management reviewed its previous '89 version and reiterated its targets to promote a more sustainable waste management on the basis of the precautionary and preventive principles. Therefore, it confirms the hierarchy principle, as mitigated by economic and social costs considerations, whereby «the prevention of the generation of waste shall remain the first priority, followed by the recovery of waste and finally by the safe disposal of waste». Consequently, the unavoidable waste should be primarily recovered (via re-use, recycle, and energy recovery) and eventually landfilled in the event of no possibility of recovery.

In order to reduce the landfill of biodegradable waste, Directive 1999/31/EC on the landfill of waste encourages «the separate collection of biodegradable waste, sorting in general, recovery and recycling» (Recital No 17). To this end, it prescribes that Member States must undertake a national strategy «for the implementation of the reduction of biodegradable waste going to landfills» (Art. 5, par. 1).

Since 2003 the EU has been increasingly engaged in laying the foundations for a strategic approach to the prevention and recycling of waste. As an example, the management of bio-waste in the EU is the subject of a Green Paper in 2008. Whereas under Directive 1999/31/EC biodegradable waste was defined as «any waste that is capable of undergoing anaerobic or aerobic decomposition, such as food and garden waste, and paper and paperboard» (art. 1, par. 1), according to the Green Paper bio-waste does not include all the biodegradable waste (e.g. natural textiles, paper or processed wood) but only «biodegradable garden and park waste, food and kitchen waste from households, restaurants, caterers and retail premises, and comparable waste from food processing plants». Particularly, the bio-waste definition excludes also «those by-products of food production that never become waste».

A turning point within the EU policy on waste management is Directive 2008/98/EC, which lays down the main legal framework. It aims at «reducing the use of resources, and favour[ing] the practical application of the waste hierarchy» (Recital No 6), and encourages a general rethinking of the production, distribution and consumption/use phases. Establishing a EU *recycling society* is certainly among one of the most ambitious objectives of the Directive in «seeking to avoid waste generation and to use waste as a resource» (Recital No 28). Because of that, while drafting the prevention programmes, Member States are mandated to «break the link between economic growth and the environmental impacts associated with the generation of waste» (Art. 29, par. 2).

Nevertheless, Directive 2008/98/EC confirms the historical definition of waste as «any substance or object which the holder discards or intends or is required to discard» (Art. 3), which was already adopted by Directive 75/442/

EEC, and it embraces reasonably the Green Paper's stance on bio-waste. Yet, it fails to provide any legal definition of food waste. Finally, in the light of the Community Strategy for Waste Management, according to Article 4 the waste hierarchy (prevention, preparing for re-use, recycling, other recovery, and disposal) applies a priority order not only in waste prevention but also in management legislation and policy.

2.2 *The evolution of food waste as a self-standing concept.*

In the wake of the EU strategies, the European Commission drew up a new roadmap (2011) for a sustainable future «to further develop our wealth and well-being, whilst reducing the levels and impact of our resource use» up to 20% by 2020. A major issue that concerns the EU is the impact of the food sector to the greenhouse gas emissions (17%) and to material resource use (28%), especially because 90 million tonnes (180kg per person) of food (without considering agricultural food waste) are wasted daily and because much of this food would have been suitable for human consumption. To this end, Member States are invited to increasingly address food wastage within National Waste Prevention Programs.

According to its Communication, the Commission should have taken steps by 2013 to issue a Communication on sustainable food in order to better assess «how best to limit waste throughout the food supply chain, and consider ways to lower the environmental impact of food production and consumption patterns». Nevertheless, the Barroso Presidency of the European Commission postponed repeatedly the date for completion (EU FOOD SENSE; HOUSE OF LORDS 2014). Eventually, with a delay of almost two years the Communication (*Closing the loop - An EU action plan for the Circular Economy*) was published in December 2015 (*infra* par 2.3).

Before addressing the recent developments that took place in December 2015, it is worth analysing the pathway that led to consideration of food waste regulation as a self-standing concept. In this respect, the EU Parliament published in 2012 a Resolution specifically on how to avoid food wastage on the basis of relevant studies (*inter alia*, FAO 2011) and to tackle food waste as both an environmental and ethical problem, and an economic and social cost. In particular, the Food and Agriculture Organization of the United Nations (FAO) provides figures showing that reducing food waste (by 1/3 globally) is «a significant preliminary step in combating hunger in the world».

Furthermore, the Resolution points out that «there is no harmonised definition of food waste in Europe» and therefore the Commission should embark

upon its promoting role in setting a legislative proposal on the definition of food waste and its distinction from food residuals for biofuels or bio-waste reutilised for energy purposes. Moreover, within its Resolution the EU Parliament also puts forward that, in order to favour «consumers with a lower disposable income to buy high-quality food at cheaper prices», Member States should allow retailers to reduce «the price of fresh food to below the cost of production when it is close to its sell-before date». Finally, according to the Resolution consumers should be encouraged to buy fresh fruit and vegetables with uncommon size and shape, which are the cause of too many avoidable discards; similarly, consumers should be informed about the different meaning of date labels (*best before*, *expiry date* and *use by*) so as to «reduce consumers' uncertainty regarding food edibility». Indeed, whereas the rationale of *use by* date is safety, *best before* date is merely associated with quality.

Taking a similar stance, the EU Parliament stressed in 2013 its own position while passing with the Council the Decision No 1386/2013/EU on the 7th Environment Action Programme, whereby it singled out the European Commission's priority to «present a comprehensive strategy to combat unnecessary food waste and work with Member States in the fight against excessive food waste generation».

Instead, the European Commission took a wrong turn in 2014. In fact, shortly before holding the EU elections, the European Commission published a Communication (*Towards a circular economy: A zero waste programme for Europe*) and a proposal for a Directive on waste (COM (2014)397) amending Directive 2008/98/EC that purported to cover most of the waste management sector. However, the proposal was later repealed on the 25th February 2015 due to the European Commission's purpose to see the wider picture on the phenomenon exploring synergies with other policies (e.g. markets for secondary raw materials) and to gain a better knowledge on the EU countries' specificities.

On the one hand, the 2014 European Commission's Communication took a stance against a linear economic model «based on the assumption that resources are abundant, available, easy to source and cheap to dispose of». Conversely, it favoured a circular approach whereby waste disposal (landfilling and incineration without energy recovery) is the last resort choice and resources are productively reused to the extent that they can keep providing an added value.

On the other hand, the proposal for a Directive acknowledges the vital role of a common and comprehensive policy on food waste, notably by proposing the first EU normative definition of *food waste* (*infra* par. 3). For this purpose, Member States were required within the waste prevention programmes to reduce by at least 30% between 1 January 2017 and 31 December 2025 the food waste gener-

ation across the food supply chain (manufacturing, retail/distribution, food service/hospitality and household sectors). Similarly, as an implementation of the waste hierarchy Member States should take into consideration within their programmes «as to whether and for which categories of food waste donation as well as the possible use of former foodstuffs in animal feed should be given priority over composting, creation of renewable energy and landfill» (Recital No 25).

Even though it was already mentioned that such a proposal was lately repealed, it is of some interest to look critically at Recital No 25 in the light of *food versus fuel* concerns (HARTMAN). Indeed, by analysing its wording it seems that the European Commission mission took a neutral stance in terms of prioritising food donation. After all, the EU policies start from antinomic premises: the unequal distribution of resources against a growing number of underfed and malnourished people with scarce access to healthy and edible food (EUROPEAN PARLIAMENT 2012), and a «prudent and rational utilisation of natural resources» (Directive proposal COM(2014)397).

In other words, by virtue of provisions laid down by the proposal for the Directive it does not necessarily follow that across Member States an apple, that for any reason flows from the food supply chain, should be primarily allocated through food donation in stead of being used for compost and digestate from bio-waste. In this respect, as a response to ethical and social concerns, Netherlands advocates that «food intended for human consumption is actually used for this purpose» (DUTCH POSITION PAPER 2015). It suggests thus a two-stage process (optimum utilisation) whereby, upon prevention of food loss for human consumption, the principles set forth in the *Moerman Ladder* have to be followed. According to this scale of values, use for human food (e.g. food banks) and conversion to human food (processing and reprocessing) have to be preferred to use in animal feed, further, compost and energy, and, as *extrema ratio*, burning/dumping.

Besides, the French National Assembly has recently unanimously voted for a Law (No 632/2015) which sets forth a special hierarchy for food waste policy: 1° prevention of food wastage; 2° allocation of the unsold products for the human consumption by way of food donation or food-processing; 3° distribution for animal consumption; 4° allocation for compost or energy purposes, notably for anaerobic digestion (Article L. 541-15-4 Code of Environment). As a consequence of this ladder, there is a clear overriding preference in France for food donation against allocation for compost or energy purposes.

Taking the same approach, the UK Government stated that «if food waste cannot be prevented then the waste hierarchy would support first the redistribution of surplus food to humans, and if not suitable for that purpose then used for animal feed (under strict conditions). There will always be unavoidable food

waste and Government support reflects the value of Anaerobic Digestion (AD) in diverting waste from landfill to generate biogas» (HM GOVERNMENT 2014).

For instance, if the European Commission had followed the WRAP proposal (advanced by the UK WRAP - Waste & Resources Action Programme) to distinguish between *avoidable waste*, *possibly avoidable waste* and *unavoidable waste* (WRAP 2008), whereby *unavoidable waste* is «food that could not have been eaten and includes items such as teabags, bones and hard fruit and vegetable peel», it could have been easier at least for this latter category to set a normative preference for compost and energy purposes. Consequently, the EU strategy against food waste, as laid down in the COM (2014) 397 proposal of Directive, seems at least to be flawed with regard to the previous considerations. Therefore, the decision of the European Commission to repeal the proposal and to publish in December 2015 a new comprehensive package on food waste has to be welcomed.

2.3 The new Circular Economy Package (2015) and the revised legislative proposals on waste: an analysis on food waste.

The new Circular Economy Package, recently published by the European Commission on the 2nd December 2015, consists of a Communication (*Closing the loop - An EU action plan for the Circular Economy*) and four legislative proposals for Directives to support the transition towards a circular economy. That is to say an economic system where «the value of products, materials and resources is maintained in the economy for as long as possible, and the generation of waste minimised». In line with the theme of this paper, only the significant parts of this package regarding food waste will be analysed.

Within the Communication, the European Commission deploys its priorities on food waste. In particular, in order to reach the Sustainable Development Goals (SDGs) by 2030, it commits itself not only to develop a common methodology and indicators to measure the food wastage phenomenon, but also to review the relevant EU legislation related to waste, food and feed to favour food donation and the use of foodstuff for animal feed (by 2016). Moreover, it suggests exploring the “current date” marking in order to enhance the understanding by actors in the food chain as well as by consumers (by 2017).

With regard to the new proposal for a Directive amending Directive 2008/98/EC (COM(2015)595), the issue becomes more complicated. Indeed, despite the high expectations on a more comprehensive stance of the European Commission on food waste, it seems that the new proposal has not yet met these expectations; it could be argued that it has even lowered them.

Indeed, if compared with the previous Work Programme 2014-2015 within the Horizon 2020 and also with the new Circular Economy Communication, this proposal appears to address food wastage only incidentally. For instance, under Article 9 it lays down generically that Member States have to take measures to «reduce the generation of food waste in primary production, in processing and manufacturing, in retail and other distribution of food, in restaurants and food services as well as in households». Thus, the proposal seems to postpone any relevant action upon defined uniform methodologies, through a delegated act, for the assessment of prevention and progress in food waste reduction. Besides, as a matter of interpretation, according to Recitals No 12 Member States *should* take these measures, whereas Article 9 states *shall*.

This being so, within the new proposal the normative definition of food waste disappears, which by contrast featured in the previous repealed proposal (*infra* par. 2.3). Likewise, the new proposal also fails to provide any reference to the aspirational objective to reduce food waste by 30% by 2025, which, in fact, was mentioned in Recital No 24 of the previous proposal. Furthermore, the European Commission removes any reference to the hierarchical waste management within the national waste prevention programmes on food waste, on which doubts about its appropriateness had been previously raised (*supra* par. 2.2).

Therefore, in order to draw a *prima facie* conclusion, the new proposal for Directive seems not to have addressed properly, so far, the concerns that a comprehensive EU policy on food waste should have required. Yet, at the same time several national Parliaments (HOUSE OF LORDS 2014) have shown a clear preference to tackle most of the food waste issues at the EU level. However, from these considerations it does not necessarily follow that a further implementation might not take place during the ensuing dialogues with the EU Parliament, Council, EESC, CoR, and national parliaments according to the legislative procedure for the enactment of the proposal.

3. *The vexed debate around an EU definition of food waste.*

From the very beginning of the debate around a common EU strategy on food waste, defining, measuring and distinguishing the phenomenon has represented one of the greatest obstacles. After all, setting down a common definition is a crucial precondition to set out and develop the most suited policies.

A first normative definition of food waste was contained in the proposal for a Directive (COM(2014)397) which was later repealed. Nevertheless, its wording is worth considering, especially given the fact that, as stated above (*supra* par. 2.3), the following European Commission's proposal expunged such a normative definition.

According to that, *food waste* means «food (including inedible parts) lost from the food supply chain, not including food diverted to material uses such as bio-based products, animal feed, or sent for redistribution». Such a definition forms part of a much wider debate, which involved FAO, the EU FUSIONS project and the UK funded body WRAP (Waste & Resources Action Programme), along with academia (PARFITT 2010).

For instance, the European Commission's definition differs from those put forward by FAO in 2011, whereby it distinguished between *food loss* and *food waste*. In accordance with this definition, indeed, the former is «decrease in edible food mass throughout the part of the supply chain that specifically leads to edible food for human consumption», the latter is «occurring at the end of the food chain (retail and final consumption) [...], which relates to retailers' and consumers' behaviour». Moreover, under the FAO definition both *food loss* and *food waste* concern only those «products that are directed to human consumption, excluding feed and parts of products which are not edible»; therefore, a wasted banana peel should never be regarded as a source of food waste. Furthermore, while “*planned*” *non-food uses* can not be accounted under losses, because were bound to get out from the supply chain, on the contrary, food that was originally meant for human consumption but accidentally flows from the human food chain and which ends up being processed as biomass and bio-waste is considered as “*unplanned*” *non-food uses* and it forms part of food losses.

In 2014 the EU FUSION project, supported by the European Commission, shaped another definition whereby the final destination of all food is emphasised. Particularly, the term food waste refers to those flowed resources that could not be efficiently reused in a different way. So, it stems clearly from a different point of view: influenced by the circular economy's precepts, as well as a clear EU perception of food waste as part of bio-waste.

More precisely, food waste is thus «any food, and inedible parts of food, removed from the food supply chain to be recovered or disposed (including composted, crops ploughed in/not harvested, anaerobic digestion, bio-energy production, co-generation, incineration, disposal to sewer, landfill or discarded to sea)». It stands out that it includes both food and drink waste, as well as both edible and inedible parts of food, so that «the overall resource efficiency of the food system is taken into account when assessing its sustainability»; therefore, a wasted banana peel increases the food waste figures. Moreover, since food donation of the surplus to charities is considered as a redistributive destination, it does not count as food waste. Indeed, in this case the foodstuff is nonetheless consumed, «although the logistics and distribution activities are different from that originally planned».

In addition to that, the WRAP (2015) proposal termed as food waste «any food that had the potential to be eaten, together with any unavoidable waste, which is lost from the human food supply chain, at any point along that chain». It is, to a certain extent, a broader definition than the others referred to above; yet, at the same time, it provides a very clear and self-explanatory wording. Interestingly, it removes any reference to *edible* and *inedible* because these are too culturally specific concepts.

Finally, the World Resource Institute (WRI), a multi-stakeholder research organization, has recently published in March 2015 a draft version of its report *Food Loss and Waste Protocol* aiming at developing a global accounting and reporting standard for measuring food as well as associated inedible parts flowed from the supply chain. In spite of being in its infancy and an on-going project, it seems that it might lend support to better understanding the difference between *food loss* and *food waste*.

4. *Food donation: brief remarks about Italy, France, and United Kingdom.*

The donation of food plays a crucial role in preventing food wastage and combining it with ethical concerns, especially in light of the new EU Circular Economy Package. As stated in the «Milan Charter», published during Expo Milan 2015 in order to raise attention to the topic, priority should be given to «identifying and reporting the critical issues in legislation governing the donation of unsold food, so that we can actively commit to salvaging and redistributing the surplus». Accordingly, it bears mentioning that the European Commission committed itself, within the Annex to Communication on Circular Economy, to facilitate food donation by 2016.

Nonetheless, relevant legislation at the EU and national level that can ease the donation of food is still to be clarified. In this respect, the national best practices represent a fundamental regulatory training ground, which the EU regulator should take advantage of. To this end, some best practices of three EU Member States will be briefly highlighted: Italy, France, and the United Kingdom.

Across the Italian legislation, Law No 155/2003 is particularly relevant. Following on from the US Bill Emerson Good Samaritan Act of 1996, this law exonerates retailers who donate foodstuffs to food banks from legal responsibility, so as to incentivise them to such a good practice. Moreover, a recent proposal for a Law (A.C. No 3057 by the MP Gadda et al) has been discussed in the Parliament, whereby the administrative and fiscal aspects of food donation would be eased and the reuse of food surpluses to the human consumption prioritised

accordingly. Particularly, the proposal extends the concept of green procurement by considering food donation as criterion when the award is made to the most economically advantageous tender.

With reference to the French law, the awareness raised by the report of the *député* Garot published in 2013 culminated in an unanimous parliamentary vote on Law No 632/2015 (due to be finalised with a vote in the French Senate in early 2016). In addition to what has already been mentioned above (*supra* par. 2.2), retailers over a certain size are obliged to conclude agreements with food banks to facilitate food donation.

The analysis of the UK model shows that, despite the large amount of studies and data collected over the years, a legislative action is far from being proposed. On the contrary, the UK approach to food waste has preferred a horizontal subsidiarity approach via voluntary agreement promoted by the government sponsored Waste Resources Action Plan (WRAP). Through a non-legislative approach the UK Government favours voluntary initiatives where stakeholders sign up to subsequent prevention targets to deliver reductions in food waste. The main lines of actions have been the Courtauld Commitment (CC) within the UK grocery sector, the Hospitality and Food Service Agreement (HaFSA) in the UK's hospitality and food service sector, as well as an education campaign Love Food Hate Waste (LFHW).

5. Conclusions.

The European Union has become definitely aware of the relevance of food waste as an autonomous issue. Despite of that, the number of concerns hovering around the EU regulation on food wastage is still high. For instance, in absence of a common methodology to measure food waste in close cooperation with Member States and stakeholders, as well as without a normative definition of food waste at the EU level, a practical step towards a EU regulation is out of sight.

In order to resolve the current deadlock, the European Commission should take advantage of the manifold best practices that Member States have undertaken over the years. To name but a few, the Italian, French, and UK cases have been highlighted. In this regard, an implementation at the EU level of such best practices, with particular emphasis on food donation, should harmonize in light of the circular economy such positive effects across Member States. Food donation could increasingly lower the amount of edible foodstuff that, without priority to human, might have been definitely flowed from the food chain and therefore shifted to energy or wasted in landfills.

In conclusion, depending on the food chain stage it is preferable to embark upon a different regulatory approach. For instance, regulators should encourage, or even oblige with command and control techniques, industry representatives to conclude voluntary agreement, whilst they should opt for behavioural and user-friendly regulations at the consuming phase where cultural, emotional and bounded rational behaviours are more likely to take place.

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XII. Safety, risk, opportunity. A sociological framework from the point of view of social system theory

Matteo Finco

CONTENTS: 1. Selecting the theme. – 2. Sociological background. – 3. Opportunities: analysis of a concept. – 4. The risk. – 5. Decision makers and those affected. – 6. Food as a fundamental right: bind/opportunity? – 7. Conclusions.

1. *Selecting the theme.*

An investigation about interests and opportunities for Italy concerning the regulation of the food law in Europe means having to do with law, economy, politics, but also with science and technology, health and nutrition, ecology, culture; a sensitive matter of universal interest. Therefore, the interdisciplinary and manifold nature of the subject involves a wide spectrum of issues and obligates to take into account numerous requests from individuals and society as a whole. In this sense, elements for orientation can be provided by sociology, specifically from social systems theory.

2. *Sociological background.*

The starting point is here the concept of *differentiation*. Briefly, the main presupposition of General System Theory: we live in a society that is no longer, like those archaic, organized as segmental (clans and tribes), according to a center/periphery (like the empires), or hierarchically (in strata, with the nobility in a favored position compared to common people). The current form is the one of *functional differentiation*, which emerged in the Eighteenth century: now the society is structured by *functions* (not to be confused with purposes, consisting of goals temporally specified). Therefore, modern society is internally divided into subsystems, each one called upon to solve a specific problem. These are structural, unavoidable issues: economy has the task of managing the problem of access

to scarce resources (not everyone can have everything at the same time); law provides generalized normative expectations, effective even when they are violated (law does not prevent offence, but indicates what to do when it happens), science produces knowledge, and so on. Each *system* – which never occurs regardless of its *environment*, meaning what is external to its borders and represents a source of *irritation* for the system (distinction *system/environment*) – is thus characterized by a specific, irreducible perspective (even if conditioning between systems is not excluded), operating on the basis of their function and their *code* [BARALDI C., CORSI G., ESPOSITO E., 2002], which determine the internal logic followed by the system: for law it is right/wrong; for economy have/have-not and therefore pay/don't pay. From this necessarily follows conflict, which thus represents a physiological element, intrinsic to the contemporary reality, and that increasingly stands out in a more and more unified and global (in many fields: economic, legal, political, cultural, communicative, and so on) society, in which the territorial boundaries tend to lose importance.

Food, then, is an «object» which is «conceived» in different ways in the various subsystems of society: it is a commodity for the economy (and therefore regards trades, consumption, employment); law and ethic generally understood it as a fundamental right, a good for humanity to which everyone should have a broad, and according to many, indiscriminate access; it is a cultural product (taking into account culinary traditions, local history and identity) and a theme for mass media (just think about the impressive number of television broadcasts and websites dealing with gastronomy); it is central to the interests of science and technology (both as nourishment – now it is even possible to produce meat in a lab without killing animals – and for the effects that production, collection and distribution of food have on the ecosystem).

Conflicts originating from the irreducibility of the perspective of each system are particularly sharp in a sensitive area as the one of food: for example, not only the «fundamental right to food» clashes with the economic perspective and the liberalization of markets has repercussions over the individual dietary habits; today's ecological (land use, biodiversity protection, pollution problems, etc.) and health issues (and therefore safety) represent a permanent emergency, impossible to be solved once and for all. In a world increasingly interconnected and complex at the same time, on whose stage are acting increasingly multifaceted and less definable, always mutable [Bauman, 1998] identities, on the one hand it is difficult to harmonize the variety of values, norms and rights regionally recognized, despite the need for uniformity (perhaps claimed more by economic and law); on the other hand, claims of individuals about guarantees related to personal self-determination and integrity are becoming more and more urgent: it is

the so-called *claims inflation*, i.e. the request for increasing protection and performances [LUHMANN N., 2015].

Conflicts and quarrels, in order to be solved, require *decisions* to be made.

3. *Opportunities: analysis of a concept.*

The link between the concept of decision and the one of opportunity is already easily detectable. However, it is appropriate to analyze it more closely. At the same time, regarding the topic in question, it is sociologically interesting, besides the analysis of the content (*which* opportunities), the one of the conditions of their identification (*how* it is possible to identify certain opportunities rather than others). It is, in systemic-constructivist terms, the so-called *second-order observation* [BARALDI C., CORSI G., ESPOSITO E., 2002]. That is, the attempt to see *how* someone observes. To understand how (in other words, by virtue of which *distinction*) the (first order) observer addresses a specific theme, what he is able to see, and what remains precluded to him. This is possible since the second observer is located at a different level (he observes on the basis of a different distinction), meaning a different perspective that allows him to grasp what the first order observer can not see. For example: a first observer tries to determine whether an hypothesis is correct or not, and is able to do that thanks to the 'pattern' (distinction) right/wrong. A second order observer, who observes the first one, can in turn try to see if the distinction used by him (right/wrong) is right or not. Therefore, one wonders about the conditions of possibility of the first observer. Applying this to our case, the question is: *how* do we identify opportunities for Italy in the field of food law?

According to the dictionary Treccani, *opportunity* comes from the Latin *opportunitas*, meaning «being opportune; quality, condition of what is or is deemed appropriate» and therefore «being convenient, beneficial», an «opportune circumstance, a suitable, favorable situation». *Opportunus*, composed by *portus* (harbor) and the prefix *ob* (towards, to), refers to the wind «that leads towards the port», which is thus *favorable*. This term is also indicated in the English vocabulary Merriam-Webster under the heading *opportunity*: «a favorable juncture of circumstances», «a good chance for advancement or progress». Opportunity then indicates hypothetical gains, possible improvements, a variance that makes a difference.

A first consideration concerns the regionalist perspective (that of *a specific* country: Italy), inherent in the issue in question. It is necessary to consider that today's society is an increasingly global society: the German sociologist Niklas

Luhmann spoke in this sense of *world society* (*Weltgesellschaft*) [LUHMANN N., 1997], as a reality characterized, on a global level, by increasing interdependence of economic and financial, as much as socio-cultural processes, with the resulting emergence of a communication network of global dimensions. If the local/regional factor plays a predominant role in the subsystems of law and politics (sovereignty and national constitutions) [LUHMANN N., 2012], undoubtedly in other areas it tends to lose importance. This leads, in relation to a matter regulated at a European level (thus international or transnational), to relativize any perspective limited to a national context: would it perhaps make more sense to consider opportunities for Europe, rather than for Italy?

Anyway, considering the regionalist perspective, it is important to clarify from which specific point of view – in other words, from which system – we are observing. Functions and interests, and consequently purposes and programs will differ. If we follow the idea of functional differentiation, we can not consider Italy as an undifferentiated system: economic opportunities will be different from opportunities related to other areas, and may conflict with them. Politics, in particular, should take this into consideration, being called to plan and realize interventions. Remembering it to people who work in the political system, is a task for those who produce knowledge. If, let's say, on one hand guarantees of brand protection and local production could be an advantage for the promotion of local products, and produce a positive impact beyond the economic system (for example in the connection between a specific territory and its social and cultural traditions), on the other hand norms about the liberalization of the market could encourage exports, but also facilitate the introduction of low quality foods in our country, influencing consumer choices with negative effects for nutrition.

Within the system of science devoted to the production of knowledge, it is also important to reflect on disciplinary divisions: even if they are addressing the same issue, different disciplines have different perspectives, more directly related to a specific system (law for jurists, economy for economists, and so on). In addition to interdisciplinary evaluations, scientists from any field will wonder about the consequences of the distinctions they are using, and will ask what they preclude; whether they are able to consider different points of view, beyond the limits marked by the tradition of the discipline; whether, in addition to determining opportunities, they are able to take account of the critical issues that emerge from other points of view.

4. *The risk*

Opportunities mean *occasion* or possibility, not certainty, but *uncertainty*. In pursuing an opportunity, we can succeed or not. Sociology, in recent years, largely devoted itself to illustrate the concept of *risk* and the link between risk and modernity: especially Anthony Giddens [GIDDENS A., 1990], Ulrich Beck [BECK U., 2011; 2003a; 2001] and Niklas Luhmann [LUHMANN N., 2013; 1996; 1993].

Beck developed the concept of *risk society* where risk is depicted as an effect of modernization: we observe the enormous development of productive and, at the same time, destructive forces; we claim for more and more security, but science and technology, which make us hope to get it, open new, and sometimes disturbing, scenarios, generating dangers and disasters potentially irreparable. Moreover, the risks are now global, rather simultaneously global and local: they concern men, animals and plants, and affect not only limited portions of territories and populations, but the whole world. This, again, makes us doubt any regionalist perspective: if a catastrophic failure (possible epidemics, food contamination) has effects far beyond individual States, maybe – as Beck suggested – it is convenient to think more and more according to transnational perspective, calling into question the sovereignty and local governments and opening to a concrete cosmopolitan perspective [BECK U., 2003b].

Luhmann analyzed the evolution of the concept between premodern and modern times, and its impact on the structure of society. The term appeared at the turn of the Seventeenth century, when it was possible to observe a switch from thinking in terms of *fortune*, of prudence as «the capacity of humans [...] to choose between reasonable expectations» [LUHMANN N., 1996], to the idea that some benefits can not be achieved if one doesn't put something into play [LUHMANN N., 1993]. If, at first, the idea of *security* (*securitas*) switched from «freedom from care» to search of «a secure basis for the making of decisions», then it lost its strength: it is now clear that absolute security does not exist, because something unexpected can always happen. Security only exists in the present moment: only insecurity and uncertainty can be represented as something lasting. If one do not accept this, not only disasters don't disappear, but the agitation produces damages that could be avoided [LUHMANN N., 2013].

It is the *decision*, according to Luhmann, to mark the transition to the modern concept of risk, which is not opposed to security anymore, but to *danger*: assuming that future damages are always possible, we can distinguish between those that arise from chosen decisions (within any perspective, that is, any system) – in this case we talk about risks – and those arising from external, environ-

mental factors – these are called dangers. Dangers are unavoidable, they don't depend by men: there is always the danger that a tree falls due to lightning. Risks instead are selected: I risk to be hit by a tree fallen because of lightning, only if I decide to go out. One is always exposed to dangers, while risks are chosen, they are faced in view of certain possible advantages. Herein lies the connection with the opportunity, thanks to the concept of decision: if I want to try to seize an opportunity, I have to risk. By risking, I expose myself not only to the possibility of not having success and not improving my condition, but also to that of making it worse: in case of failure one does not necessarily go back to the starting point. For example, not seizing certain opportunities that the market offers may mean, in perspective, the failure of a company. This happens because, if an attempt was made or not, on one hand one can fall behind others, and this produces a difference that is hard or impossible to fill; on the other hand, because if one tried, he brought into play resources and energies that are now exhausted.

Decision, risk and opportunities therefore seem to form a single block in the semantics of contemporary society. They have to do with uncertainty, with a complex world, with the determination of the future. In fact, with the risk, and therefore through the decisions taken in the present, one tries to bind the future: to control, or at least to limit, the possible future, to prevent some of the damages already conceivable. The future remains unknown, but at least one has tried to direct it, to control it. This is an attempt to plan, to establish a connection between present and future: risk is one of these strategies. Another is *trust*, that is, the ability to rely on their own expectations, thus reducing complexity through decisions [LUHMANN N., 2002b].

Therefore, we are always called upon to decide. To risk. To realize prospects that a contingent world, seemingly full of opportunities, of possibilities for self-determination, offers to us. More decisions thus involve an increasing number of risks. We can not, indeed, avoid to make decisions: even not deciding is a decision; even not wanting to take a risk exposes to a risk: the one of not perceiving opportunities that may be advantageous. Any risk, then, leads to generate further risks: if I insure myself against an adverse event, I run the risk of paying unnecessarily, if that event does not occur (and it is exactly in the maritime field-trade that, in the Eighteenth century, insurance and the concept of risk were produced [CEVOLINI A., 2013]). Also the decisions taken will affect in a decisive way further decisions in the future, which in turn will produce other risks.

This undermines the idea of *progress* and, at the same time, raises the awareness of the limits of knowledge: the more our knowledge increases, the more we attempt a rational calculation, the more we know that we do not know. After all, how could we know that a communitarian regulation will improve the state of

affairs, both in general and according to various national perspectives? Indeed, we can be almost certain that pitfalls and problems that are currently invisible will emerge.

If we talk about *opportunities*, therefore is at stake much more than what may appear at first glance. We risk a secure present, for a future that is not secure at all. We implement strategies whose consequences, especially in the case of failure, are not always predictable. In other words: there's no turning back. If new rules are declared on a European scale, replacing or completing the national ones, maybe then it becomes necessary – and here the term is not chosen at random – to think about what we may lose before, or at least at the same time, that we think about the possible new benefits.

5. Decision makers and those affected.

Decisions are always taken from a partial point of view: important is thus to establish who decides and who is affected by these decisions. It is therefore necessary to distinguish between *decision makers* and *those affected* by the decision: between systems that decide and their observers in the environment of the system. Who assesses risks, and who, in addition, is affected? Depending on the point of view – the *decision maker* or *those affected* – we talk about risks or dangers. Who is affected, it is so in an unpredictable way, because the dangers are arising from the decisions of others [LUHMANN N., 1993]. In fact, we accept more easily damages caused by our behavior, than those who depend by external situations, over which we have no control (for example: we prefer to die due to a poor diet rather than due the effects of food chemistry [LUHMANN N., 2013]).

On the one hand it is necessary to consider that the distinction between decision makers and those affected by the decision is not always easy to notice [LUHMANN N., 1993]), taking into consideration that individuals are included (with different degrees of involvement and freedom of action) in a different way for each functional system (this situation is described by the concept of *inclusion* [BARALDI C., CORSI G., ESPOSITO E., 2002]). On the other hand, it is not possible to take part in all the decisions affecting ourselves (for this reason one should be cautious talking about participation, which means multiplication of decisions and then bureaucracy [LUHMANN N., 1996]): it is necessary to acknowledge that decisions are increasingly dependent by organizations (we could complain about the «decisions taken from the top»). Big financial groups, authorities of economic governance, political institutions are always embedded in organizations that hold shares of power and that are basically perceived by individuals as distant. In the

European context an example is the so-called «Troika» (European Central Bank, International Monetary Fund, European Commission). It is not less important the fact that more and more organizations are supranational entities: once again, a regionalist outlook displays its limits, especially from an economic perspective.

So, as Luhmann writes, the fact that decision-making processes with effects on a global scale depend by organizations, produces a situation where everyone feels excluded and at the same time involved in every decision [LUHMANN N., 2013]. This also affects the concept of «social solidarity»: if in the past the dangers used to hit indiscriminately and pushed individuals to cope collectively (thus encouraging solidarity), risks and the distinction between decision makers and those involved by decisions open the way to a loss of trust and the emergence of conflicts [LUHMANN N., 2013; 1993; CORSI G., 2015]. Therefore, looking at possible future benefits and damages and considering the perspective of those involved can make the difference.

6. *Food as a fundamental right: bind or opportunity?*

Article 25 of the *The Universal Declaration of Human Rights* of 1948 states that «Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food». In light of this proclaimed right the European institutions, in recent years, worked to produce documents and regulations as the *White Paper on Food Safety, Food Security*, and the *General Food Law Regulation* (Regulation (EC) No 178/2002) adopted by the European Parliament and the Council of Europe; also institutions were created such as the *European Food Safety Authority* (EFSA) and the *Rapid Alert System for Food and Feed* (RASFF). All in order to ensure – in addition to the protection of the market – rights to food and food security.

One might ask how the fact that food is considered a fundamental right influences the attempt to seize certain opportunities. From the point of view of ethics, there is an opportunity to strengthen and extend rights to a greater number of individuals who can claim in case of alleged violations.

In the terms of general systems theory [LUHMANN N., 2002a], fundamental rights are *institutions*, which protect individual autonomy from state interference, ensure the differentiation of the political system and its separation from other systems keep open communication possibilities and the individual's inclusion in functional systems. Fundamental rights are therefore not only *values*: unlike values, they have binding force. The right to a secure and quantitatively sufficient

nutrition constitutes an obligation – that’s the point – for all systems that have to do with food.

Obligation is synonymous for obstacle. This is clear in the market, whose players have to face the need to fulfill obligations that involve cost, safety procedures, etc. Even politics should consider that fundamental rights are important in the future possible reforms of regulations about that matter: it is thus necessary to produce norms that are compatible with the fundamental right to food, and that are effectively applicable. A significant commitment is imposed because we have to move between values (such as health and safety) designed to protect individuals (whether conceived as human beings, citizens or consumers), guaranteeing them «protection» (for example with laws that encourage the increase of standards of food quality and requiring a strengthening of controls) on the one hand, and values inspired by other principles (e.g.: free market, competition, right to doing business), on the other.

Food law, in other words, has to act between a series of principles and values that are hard to balance and are likely to contradict each other; concepts (which represent values, ideals, and sometimes rights) as nutrition, health, safety, are difficult to be implemented individually but trying to guarantee all of them at the same time could be problematic (it is hard, for example, to think about ordering them in a hierarchy; and it is also hard to design norms and find points of balance, e.g. between the need to ensure that a product meets a high standard of safety and, at the same time, guarantees an adequate nutritional supply).

7. Conclusions.

If one wonders about which opportunities Italy has in the light of the current law of the European food, it is necessary to:

- keep in mind the inevitability of conflicts imposed by the peculiarity of the object «food», because of the various meanings that it assumes and the different dimensions where it plays a central role (market, work, health, safety, environment, etc.);
- establish the perspective of the observer and of which system he defines limits and possibilities (scientists must ask which distinctions they use, and whether it is possible a dialogue between different disciplines);
- wonder whether is convenient to maintain a regionalist perspective and define the limits it imposes in an increasingly global world;

- once the opportunities are identified, accept the fact that pursuing them exposes to a potential damage (risk), which however is not always to be determined in advance:
 - take into account of the fact that risks expose to possible regressions in comparison with the starting positions (one not only risks to gain nothing, but also to lose what he has) and elaborate hypothesis in this direction;
 - identify case by case – in a scientific way– who are the decision-makers and the other individuals involved;
 - from a legal perspective: establish norms in order to prevent and neutralize conflicts; norms that are compatible with the fundamental right to food and that could ensure compliance with other rights and values considered essential; above all: norms and other forms, not strictly legal, for the protection of people involved;
 - recall politics its duty to decide, and provide it with traditional and new tools.

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XIII. Conclusions

Aristide Police

There is a common feature in the works collected in this volume: the two principles to which the various papers refer to – security and certainty – are in conflict with each other and with other principles.

Four papers address the topic of labelling and its function of giving certainty, but in each of them labelling has a different function in terms of certainty and safety. For instance, Letterio Donato's paper focuses on labelling as a way to protect the market, whereas in Pasquale Pantalone's paper labelling (and in particular health claims) is seen as a measure to ensure a high level of consumers' protection within the market. Furthermore, Andrea Guerrini stresses the issue of traceability as a way to guarantee the certainty of legal relationships between buyers and sellers as well as between sellers and their competitors (who which could instrumentally use labelling to mislead the rational behavior of the market). Finally, Lorenzo Cuocolo and Francesco Gallarati investigate the system of sanctions in case of violations of rules laid down in the European regulation on food labelling.

Miriam Hamdan, Bernard O'Connor, Alice Villari and Miriam Allena's papers focus on geographical indications as instruments of protection within the market but, again, from different perspectives. In particular, international and European regulation on geographical indications aims at protecting the market, while in the Italian context private entities such as *Consortia* protect interests of local producers against the market: indeed, the *Consortium* of Parma ham or the *Consortium* of Parmigiano Reggiano represent the need of protection of a geographical area against the whole market of ham or of hard cheeses.

On a different point of view, there is also a conflict between guarantees of certainty and guarantees of security.

Guarantees of certainty are in line with the market since they make consumers' choices more informed and, as consequence, producers will try to adapt supply to demand. On the contrary, security can be perceived as a principle "against" the market. Think for instance of security policies based on the precautionary principle: said principle introduces uncertainty and instability in public-private and in private-private economic relations (and, as it is known, uncertainty and instability make market efficiency weaker). This argument does not want to deny

the necessity of precaution, but it states that the more precaution is not based on scientific knowledge, the more a given decision is not a precautionary one but it becomes a political one capable of affecting liberties: indeed, freedom of trade implies that products must be bought and sold on the market without any political or administrative obstacle. For this reason, I think the principle of precaution should be applied carefully.

A good example is provided by GMOs: so far, there is no scientific evidence that GMOs can be dangerous for human health. As a consequence, a decision of the Italian Government to ban GMOs would be a political decision against the market and it would be incompatible with economic liberties. This is all the more so as in Italy GMOs can be marketed, so that a ban on their production would be unreasonable (the only result would be that Italians would buy GMOs from foreign enterprises causing a general situation of inequality and irrationality).

Taking a step back, and continuing the analysis of the papers collected in the volume, Scilla Vernile's work concerns the regulation and organization of risk management: the separation between the subjects making rules and the organs that carry out the relevant functions comes out from the above mentioned remarks on the safety requirements and the principle of legal certainty.

With regard to European controls, they can be distinguished in two different types: *ex ante* or preventive controls and successive or repressive ones, resulting in penalties that have been touched upon by Andrea Guerrini with regard to the profiles concerning traceability, and by Lorenzo Cuocolo and Francesco Gallarati more in details. With respect to both these types of controls, it is necessary to focus on the problem of risk assessment (faced by Scilla Vernile, especially when it comes to European and national authorities that distinguish functions of risk assessment and risk management), that is very weakly perceived if the evaluation is carried out after the adoption of the relevant rules. Risk assessment is, indeed, an activity that cannot be carried out during the stage of controls (either preventive or successive), but it should be accomplished before, at the time of rule making.

The problem of the time of the risk assessment derives from the variety of the competent authorities and from the complexity of the administrative organization. At the European level, the distinction between the activities of risk assessment and risk management is very clear, since it is shared between the two competent authorities: the EFSA, based in Parma, and the Commission, based in Bruxelles.

At the domestic level the situation is totally different: there are eleven different systems of national competences which result from a very fragmented regulation, made step by step, for progressive achievements of territories, in order

to implement European law in the domestic legal order. Besides this, said eleven systems of competences are not exclusively Italian, as they are partly shared with the European level and exercised in a fragmented way. In fact, food safety regulation has never been harmonized, especially when it comes to controls and safety, compatibility between safety and legal certainty, homogeneity of the systems of controls, uniformity of sanctions and of the guarantees of the sanctioning systems (for this reason, the complexity of the organization is not only a failure of Italy, but it derives also from the fragmentation of the European legal framework).

On the other side, as to food waste, the responsibility is entirely European. The report of Rocco Steffenoni highlights the myopia of the food safety system and the fact that, even if decisions are taken by institutions, they are not necessarily rational.

Yet, the circumstance that both the EU and national legal systems are concerned with labelling, but don't care about the fact that by 2050 world population will rise from 6 to 9 billions, should lead us to think that maybe food safety is a larger problem that requires additional guarantees to the ones related to labels, traceability or the prohibitions that national rules pose to those systems. In particular, it is clear that the food farming production should be improved (for instance, through GMOs, but the same should be said for other circuits that increase the production capacity), in order to face this dramatic increase in demand.

