SHORpCOMINGS IN ENFORCING EU FOOD LAW. WHAT DOES EU FOOD LAW STAND FOR?

FOREWORD

One billion people live in chronic hunger and financial crisis is heavily hitting EU integration. We are still tempted to consider food under the sole perspective of safety and fair trade with minor attention to the negative externalities (wastes, unbalanced chain of value, bugs in transparency and information et cetera) which the illusion of an unlimited welfare hides thanks to mechanisms tolerated or allowed by legislators. Public opinion in EU is not uniformly oriented to agree on suggestions that EU regulation is the best place to achieve consumer information and general belief that protection of national culinary traditions are weaker than (and not compatible with) a free-circulation based legal framework is increasing day-by-day. Additionally, foods consumed by Europeans are more and more a matter of international trade in agricultural, half-products and new foods from thirds countries. Despite all these important concerns, the present contribution will focus on some legal issues gathered from the Author’s Food Law Practice in an EU Member State with specific regard to interaction between EU rules on Hygiene and the enforcement at level of Member States. It will contain a set of technical and legal considerations aimed at addressing some reflections and proposals to recovery shortcomings arising from lack of certainty, misunderstandings, poor training, and contradictions between pieces of EU and National Food Law.

SUMMARY


1. EU Food Law: an introduction

In general terms EU Food Law is a distinguished case of product-law as regulations on pharmaceuticals, cosmetics, toys, machineries et cetera are. However EU Food Law has a number of peculiarities the other product regulatory frameworks rarely have: the groundbreaking tool lies on the existence of a definition of Food Law both at EU and Member State level: Nomen omen!

Definition of Food Law within EU Single Market is as follows: “the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food,
and also of feed produced for, or fed to, food-producing animals”.¹ Two elements are clearly highlighted by the mentioned provision: i) “food in general” and ii) “food safety” in particular. Such a two-fold objective is confirmed by Article 5 of GFL according to which: “food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment” (Article 5, par. 1, of GFL). It is important to bear in mind that such a definition applies to all legal acts or measures governing foodstuffs adopted at both the Community and national levels. Consequently, public authorities and private operators should pay attention to both elements: safety management and the other legal issues enclosed in the definition of Food Law, namely: protection of consumers interests, fair practices and, where appropriate, the protection of animal health and welfare, plant health and the environment.²

Secondly, EU Food Law is based upon general principles specifically governing the food market: risk analysis and precautionary principle, consumer protection and transparency.

Thirdly, the complex regulatory organization and the establishment of an Independent Authority play for an increased distinction of food (and feed) regulations from the other sister – regulations.

Fourthly, EU regulation on food calls for a more stringent integration within national systems for control of conformity.³

Since its very beginning, European legal acts in the domain of food trade called for more integration, mutual cooperation and assistance between public authorities. EU Food Law dates back to 1960s as veterinary activities in the EEC Commission were first formalised in 1963, when Directorate-General VI – Agriculture – established a new Directorate F – Agricultural Legislation – with Division F.3 in charge of harmonisation of the legislative, regulatory and administrative matters in the Member States. The year before (1962) the plan for a Common Agricultural Policy

³ It is to be noted that the mentioned features are given in respect of pharmaceutical, from one side, and substances covered by REACH as well, but a lower level of integration in respect of Food Law.
was adopted. As the demand for fresh meat increased dramatically in Europe in the 1950s and 1960s it was decided to harmonise the veterinary requirements for trade in live cattle and swine and in fresh meat, between the Member States: in 1964 the Council adopted the Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine and the Directive 64/433/EEC on health conditions for granting temporary and limited derogations from Community health rules on the production and marketing of fresh meat. This piece of legislation harmonised veterinary legislation in the Member States based upon the following principles: the responsibility of the exporting Member State, the control procedure, the importance of certification, the safety clause. Its scope was “partial harmonisation”, i.e. the rules were limited to products traded between the Member States.4

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (hereinafter, also General Food Law, GFL) gave rise to a number of innovations: i) general principles of Food Law (Risk Analysis, Precautionary Principle, Protection of consumers’ interests and principles of transparency); ii) general framework on risk assessment and risk management and the establishment of an Independent Authority dealing with risk assessment (the European Food Safety Authority, EFSA); iii) new and general obligations for food business operators (general safety requirements, duty of compliance, traceability, withdrawn of unsafe foods, and product presentation); iv) general outline on food control within the Single Market, including importing and exporting foodstuffs.

Such a general set of rules has to be integrated with a number of sectoral legislations laying down rules for specific products (baby foods, supplements, products of animal origin et cetera) or aspects (Food Hygiene, for example), specific product safety and quality requirements, presentation

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5 Article 14 of GFL.
6 Article 17.1 of GFL.
7 Article 18 of GFL.
8 Article 19 of GFL.
9 Article 16 of GFL.
10 Article 17.2 of GFL.
11 Articles 11 to 13 of GFL.
rules (labelling and promotion), and other aspects. As of today, European Union has a well planned food policy involving Community and National Level and an intensive training programme, managed by the Commission Services.

Objectives of EU food Law as addressed by General Food Law are to ensure a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment; and to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements of EU law. Other ground principle is proportionality as set out in Article 5 of the Treaty, according to which EU Regulation should not go beyond what is necessary in order to achieve the objectives pursued; also principle of subsidiarity applies, according to which where objectives cannot be sufficiently achieved by the Member States and would therefore, by reason of their complexity, trans-border character and, with regard to food imports, international character, be better achieved at Community level, the Community may adopt measures. These objectives have been inserted within the Lisbon Strategy addressing the aim at promoting better regulation and maintain/support competitiveness.

These objectives have been implemented by means of the Hygiene Package which consists of a number of EU legal acts laying down main provisions as regards food hygiene meaning “the

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measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use” (Article 2, litt. a) of Reg. (EC) No 852/2004.

One of the key concepts in the EU Food Law is that Food Business Operators (hereinafter, FBOs) at all stages of production, processing and distribution within the business “are responsible for ensuring the fulfilment of food law which are relevant to their activities”\textsuperscript{13}. This is one of the cornerstones in EU regulation since the involvement of public authorities in food safety assurance was a key point in the first phase of harmonisation in the EEC food market. On the other side, Public Authorities (rectius, Competent Authorities) are called to test compliance of products marketed within the Single Market. EU Hygiene Laws requires a radical change of mind for civil servants operating within the framework of official control for foodstuffs as it is reported under paragraph 2 of this contribution.

2. Modern EU Food Law and Challenges for the Systems of Official Control

Article 17, par. 2, of Regulation (EC) No 178/02 requires Member States to enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. For that purpose, they must maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution. Additionally Member States are required to lay down the rules on measures and penalties applicable to infringements of food law, which must be effective, proportionate and dissuasive.

General requirements for Official Control on foodstuffs are addressed today by the already mentioned Reg. (EC) No 882/04 whose broad scope gives the ground to consider it as the twin-regulation to GFL. Reg. (EC) No 882/04 contains the general obligations Member States have to comply with in carrying out official control of food. As long as control of conformity is under the

\textsuperscript{13} Article 17.1 of GFL.
Member States’ competence, national enforcement is the main critical point in evaluating real impact of food related legislation adopted by EU Institutions.

A number of authorities are entitled to carry out control activities on foods both at national and EU level.

EU level is involved as regards to control in Member States (Article 45 of Reg. EC No 882/04); Controls in Third Countries (Article 46 of Reg. EC No 882/04); Safeguard measures (Article 56 of Reg. EC No 882/04); Import Conditions (Article 47 of Reg. EC No 882/04); and Training of control Staff (Article 51 of Reg. EC No 882/04). Another important target for the Community is to develop a comprehensive, integrated approach to the operation of controls in order to have a global and uniform approach with regard to official controls by means of broad guidelines drawn up at Community level, promoting coherent national strategies, and identify risk-based priorities and the most effective control procedures.

As regards Member States, they are requested to enforce Food Law and to organize the official control on their territories accordingly to principles, rules and requirements including specific procedures as regards to Multi-annual Control Plans, Crisis Management, Financing, Recover Measures and Penalties, as addressed by EU Food laws, notably the Reg. (EC) No 882/04 and Reg. (EC) No 854/04, and other specific acts.

With reference to the organisation of the official control by Member States, Reg. (EC) No 882/04 requires official controls are carried out regularly, on a risk basis and with the appropriate frequency (Article 3 of Reg. (EC) No. 882/04).

Risk and Risk Analysis got confirmed as marking tools of the whole EU Food Law. Article 6, par. 1, of GFL establishes that, in order to achieve the general objective of a high level of protection of human health and life, food law is “based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure”. As a result, risk analysis plays as the Grundnorm role as of law-making process but it also has an increasing role in the control of verification of compliance process. Confirmation to this assumption is given by Council Regulation (EC) No

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15 Pisanello D., Obblighi di sicurezza alimentare nel mercato unico europeo tra gestione del rischio e responsabilità d’impresa, Diritto Comunitario e degli Scambi Internazionali, 4/2008.
834/2007 on organic production and labelling of organic products where it arranges that “the nature and frequency of the controls shall be determined on the basis of an assessment of the risk of occurrence of irregularities and infringements as regards compliance with the requirements laid down in this Regulation”.

Secondly, Official Control must be carried out regularly and consistently with an “appropriate frequency of control” (i.e. according to an adequate planning). The frequency should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or quality assurance programmes, where such programmes are designed to meet requirements of feed and food law, animal health and animal welfare rules. Ad hoc controls should be carried out in case of suspicion of non-compliance. Additionally ad hoc controls could be carried out at any time, even where there is no suspicion of non-compliance.

Member States are requested to perform control of conformity on foodstuffs consistently with principle of risk analysis, and also with appropriateness and other requirements (no discriminatory checks; same care in checking compliance with no regard to final market, no prior warning golden rule (audit is excepted) and appropriate measures to be adopted with reference to a “non compliance”, adequate financial resources and appropriate training activities). A number of general standards in enforcing EU law on official control are addressed with specific reference to these tools: Transparency and Confidentiality; Control and verification procedures (investigation, methods and techniques, sampling and analysis, reporting, follow-up, necessary actions, Penalties, Contingency plans). Compliance with such a set of requirements should be assured by means of the Multi-Annual National Control Plan (MANCP) which is intended by Reg. (EC) No 882/04 as the

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17 Article 4 of Reg. (EC) No 882/04.
18 Audit is a control technique introduced by Reg. EC No 882/04 and Reg. EC No 854/04. Audit means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives. Other appropriate techniques for official control purpose include: routine surveillance checks and more intensive controls such as inspections, verifications, sampling and the testing of samples.
19 Article 54 of Reg. (EC) No 882/04.
20 Articles 26 to 28 of Reg. (EC) No 882/04.
main implementing measure of the obligation settled out by Article 17, par. 2 of GFL.\textsuperscript{21} According to Articles 41 and 42 of the Reg. (EC) No. 882/04, Member States are required to prepare and implement a single integrated multi-annual national control plan and to provide the Commission with an up-to-date copy upon request. Every year, Member States are requested to submit to the Commission a report indicating any amendment of the MANCPs, the results of controls and audits, the type and number of cases of non-compliance and the actions taking to ensure effective operation and enforcement\textsuperscript{22}. Despite the Regulation (EC) No 882/04 and the effort of EU Commission, “it is not known how many Member States have drawn Multi-Annual National Control Plans or how many Member States have submitted those to the Commission”.\textsuperscript{23}

Capacity building in complying with requirements relating to food control activities depends on a number of drivers, notably the financial resources available. It is to note that Reg. (EC) No 882/04 contains provisions laying down financing of official control (Articles 26 to 29) reflecting the rationale of EU Food Law: the more the compliance, the lower the fees and the charges on Food Business Operator.

The financial rules on official control are a very complex issue so that the Commission called for an external evaluation aimed at providing a better understanding of the functioning of the inspections fees systems as currently implemented by the Member States on the basis of the relevant provisions of the Reg. (EC) No 882/04.\textsuperscript{24}

The study confirmed that there is a significant degree of variation in the enforcement of the financing provisions of the Reg. (EC) No 882/04 by the Member States and a significant lack of clarity and transparency of the various national fee systems as currently implemented. On the basis of the findings reported by the study, Commission is near to launch discussion on a range of policy

\textsuperscript{21} Article 41 Reg. EC No 882/04 reads: “In order to ensure the effective implementation of Article 17(2) of Regulation (EC) No 178/2002, of animal health and animal welfare rules and of Article 45 of this Regulation, each Member State shall prepare a single integrated multi-annual national control plan”.

\textsuperscript{22} Article 44 of Reg. (EC) No 882/04.

\textsuperscript{23} Food Chain Evaluation Consortium (FCEC), Study on fees or charges collected by the Member States to cover the costs occasioned by official controls, Framework Contract for evaluation and evaluation related services - Lot 3: Food Chain (awarded through tender no 2004/S 243-208899). The study is available on-line at the following webpage: http://ec.europa.eu/food/food/controls/inspection_fees/index_en.htm.

options: a) “full subsidiarity”, which would imply the repeal of most of the constraints laid down in the existing legal framework, as regards in particular the calculation of the fees and the scope of the mandatory fees; Member States would be free to decide on the best way to finance their official control services; b) “full harmonisation”, with fees fixed at the same level across the whole European Union and for all the sectors concerned (identified by Community legislation).

Under an operative ground, Member States have to designate and conferring of competencies to one or more authorities complying with the standards addressed by the UE. Contrary to the Commission’s expectations, more than one CA is involved in most cases, which creates lack of transparency and of central/overall responsibility. In Member States with decentralised management, the central Competent Authority is not always in control and efficient/effective coordination is not always ensured.25 The multiple authorities approach is still a common (a problematic) issue also in other countries as China26, Turkey27, India28 and Israel29.

Designated Member States’ Competent Authorities (CAs) are obliged to perform official controls consistently with compulsory standards consisting in the following: Effectiveness and appropriateness of the performed controls; Experience and qualification; Appropriate and properly maintained facilities and equipments; Absence of conflict of interest; Legal powers to carry out the control and to take the necessary measures in case of non compliance (i.e. measures under Article 54 of Reg. (EC) No 882/04); Penalties if so provided by national legal framework; Adequate planning and documented procedures; Periodically examination whether activities and related results comply with planned arrangements; Multi-Annual Control Planning; Efficient and effective coordination and cooperation between the units and CAs.

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25 Food Chain Evaluation Consortium (FCEC), Study mentioned under footnote 23.
26 DG(SANCO) 2009-8187, Final report of a mission carried out in China from 26 October to 05 November 2009 in order to evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products.
27 DG(SANCO) 2008-7644, Final report of a mission carried out in Turkey from 20 October to 29 October 2008 in order to evaluate the control systems in place governing the production of fishery and aquaculture products intended for export to the European Union.
28 DG(SANCO) 2009-8190 - Final report of a mission carried out in India from 16 to 24 September 2009 in order to evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products.
29 DG(SANCO) 2009-8341, Final report of a mission carried out in Israel from 18 to 22 October 2009 in order to evaluate the control systems in place governing the production of aquaculture fishery products intended for export to the European Union and DG(SANCO) 2009-8219, Final report of a mission carried out in Israel from 23 November to 03 December 2009 in order to evaluate the operation of controls over the production of milk, heat treated milk and milk based products for human consumption destined for export to the European Union.
In conferring competence to the internal authority or authorities, Member States should not ignore the scope of the Reg. (EC) No 882/04 which is clearly highlighted by Article 1: “general rules for the performance of official controls to verify compliance with rules aiming, in particular, at: (a) preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment; and (b) guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information”. In other terms, implementation of Reg. (EC) No 882/04 should not be exclusively devoted to the food safety and hygiene rules.

Article 1 of Reg. (EC) No 882/04 is not a novelty ex se: the previous Directive (Directive EEC No. 89/397 on the official control of foodstuffs) had a similar provision on the scope of the law. The very huge difference in respect of earlier legal system lies on the powers the CAs are entitled vis-à-vis non compliance: unlike Directive (EEC) No 89/397, Reg. (EC) 882/04 expressis verbis requires, inter alia, CAs to address “administrative actions”, effective, dissuasive and proportionate, in order to resolve the non compliance.

Few doubts on the meaning of non compliance: all breaches of compliance “with rules aiming, in particular, at: (a) preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment; and (b) guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information” (Article 1 of Reg. (EC) No 882/04). Such situations should be subject to recover measures accordingly to Article 54 of Reg. (EC) No 882/04 or Article 19 of Reg. (EC) No 854/04.

Despite such a certainty, legal interpretation as regards multifunctionality of Food Law is sometimes denied by judicial approach and national enforcement shows weak awareness of the real extent of the scope of EU Food Law, as it is highlighted in the following paragraphs.

30 According to Article 1 of Directive (EEC) No 89/397, “official control of foodstuffs” consisted of inspections by the competent authorities of the compliance of foodstuffs “with provisions aimed at preventing risks to public health, guaranteeing fair commercial transactions or protecting consumer interests, including provisions on consumer information”.

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3. Shortcomings in assessing EU Food Law Requirements

As above mentioned, Official Controls on foodstuffs under the meaning of Reg. (EC) No 882/04 should not be exclusively devoted to the food safety and hygiene rules. Additionally it should be borne in mind that, according to Articles 3.1 and 5 of GFL, there should be no doubt that FBOs are obliged to comply both with safety and other rules governing its foodstuff and food producing process. It should be undisputed that the general conformity duty, as ruled by Article 17 GFL, relates to safety requirements (Articles 14, 18 and 19 of GFL)31 and presentation requirements (Article 16 of GFL)32 as well.

In assessing the proper scope of EU Food Law it should not be ignored the scope of the Regulation (EC) No 882/2004 which is clearly highlighted to cover both “rules aiming, in particular, at: (a) preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment”; and “guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information” (Art. 1 of Reg. (EC) No 882/04).

This issue seems to be alternatively accepted/dismissed by the EC Court of Justice which ruled upon the question in a tentative and precarious manner.

In a first case (Lidl Italia case33), the question submitted to the EC Court was about who can be made responsible under criminal and administrative Law if the particulars of the label of a pre-packed foodstuff are not consistent with labelling requirements. In the initial case, the indication of the alcoholic strength by volume of an herbal liqueur denominated with “Amaro alle erbe” marketed by the Company Lidl Italia did not comply with the value established by the analysis carried out by the Italian food control authority. Consequently the Competent Authority

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31 Article 14 of GFL provides for the general safety requirements by means of the definition of unsafe product. Other requirements established for safety purposes are traceability and safety management under Articles 18 and 19 of GFL respectively.
32 Article 16 of GFL reads: Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.
(Municipality of Arcole), ordered Lidl Italia to pay a fine. The sanctioned company challenged that decision before the competent court (Giudice di Pace of Monselice) contending that the infringement at issue could not be imputed to it since it did not manufacture the product at issue, but merely distributed it in its stores.

EC Court, after establishing that it is for Member State to determine the sanctioning system and penalties for breaches of Food Labelling rules, strongly affirmed that “even if Regulation No 178/2002 does not apply ratione temporis to the facts of the main proceedings, it follows from Article 17(1) of that regulation, entitled ‘Responsibilities’, that operators in the food sector are to ensure at every stage of production, processing and distribution in the undertakings under their control that the foodstuffs comply with the requirements of the foodstuff legislation applicable to their operations and are to check that those requirements are fulfilled”\(^{34}\).

This statement was ictu oculi backed by taking into account the two-fold content of the compliance duty as ruled by Article 17 of GFL: food safety and consumer protection.

In a second case, EC Court adopted a different approach and ruled in a very different way: in the judgement of 26 February 2008, in the case C-132/05 (Commission v. Germany)\(^{35}\), the Court ruled on the Commission request to declare that, by formally refusing to proceed against the use, on its territory, of the name “Parmesan” on the labelling of products which do not comply with the requirements of the specification for the protected designation of origin (PDO) “Parmigiano Reggiano”, thereby favouring the appropriation of the reputation of the genuine, Community-wide protected product, the Federal Republic of Germany has failed to fulfil its obligations under Article 13(1)(b) of Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs\(^{36}\). In this case, three questions were discussed at the Court: extension of legal protection of compound designations, infringement of the PDO “Parmigiano Reggiano” and obligation on the Federal Republic of Germany to proceed against infringements of Article 13(1) of Regulation (EEC) No

\(^{34}\) Judgment of the Court of 23 November 2006, in Case C-315/05, par. 53.
2081/92. The previous two questions were a sequel of an earlier case, where the third one represented the spotless core of the judgement.

EU Commission tried to contend that the Federal Republic of Germany was bound to take action against the unlawful business but its arguments were based under Articles 10 and 13 of Regulation (EEC) No 2081/92. According to the Commission, Member State intervention should include administrative and penal measures such as to enable the objectives referred to in that regulation concerning the protection of designations of origin to be achieved. Products which do not comply with the requirements of the regulation should be not marketed. It is important to note that no reference to Reg. (EC) No. 882/04 was submitted by the Commission application nor by the Czech Republic and Italian Republic which supported the applicant.

As defendant, Germany claimed that numerous legislative provisions enabling action to be taken against the unlawful use of a PDO, in particular the Law against unfair competition (Gesetz gegen den unlauteren Wettbewerb) of 7 June 1909 and the Law on trade marks and other distinctive signs (Gesetz über den Schutz von Marken und sonstigen Kennzeichen) of 25 October 1994 have been adopted. In the view of Germany defence, by granting those civil law rights, the Federal Republic of Germany has taken all the measures necessary to guarantee full application of Article 13(1) of Regulation (EEC) No 2081/92. According to the Federal Republic of Germany, it was not necessary for the public authorities to take administrative action on their own initiative against infringements of rights granted by Regulation on protection of protected designation of origin for foodstuffs. And the Court gently followed by declaring that “the Commission has not demonstrated that the Federal Republic of Germany has failed to comply with the obligations under Regulation No 2081/92, and it has not furnished proof that measures such as those referred to in paragraph 63 above were not taken or were not such as to protect the PDO ‘Parmigiano Reggiano’. And the action was dismissed.

In so ruling, the Court entered in an interpretation of the “control of verification of compliance” which is totally restricted to the Reg. (EEC) 2081/92 and inconsistent with the general legal framework of EU rules on official control for foodstuffs.

37 Judgement of the Court of Justice of European Communities, 25 June 2002, case C-66/00 (Bigi).
38 Paragraph 69 of the Parmesan Case Judgement.
The main reason of blame claims that the judgement issued on the Parmesan Case was grounded on an incorrect meaning of “control of verification”. Indeed, by following Germany suggestions, the Court mixed up the system of control of compliance (with the rules on fair practice and protection of consumer interests) for the national structure for accreditation and control as ruled by Article 10 of Regulation (EEC) No 2081/92.\(^{39}\) It is evident that verification of compliance with to the registered specification, carried out in order to obtain the right to use the protected designation of origin, is something different to the verification of compliance of a product with food regulations under the ruling of Regulation (EC) No 882/04.

Additionally such a judgement seems to be not consistent with the rationale of Regulation (EC) No 510/06 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs according to which “the designations of origin and geographical indications protected on Community territory should be subject to a monitoring system of official controls, based on a system of checks in line with Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, including a system of checks to ensure compliance with the specification of the agricultural products and foodstuffs concerned”.\(^{40}\)

It is to be noted that Reg. (EC) No. 882/04 expressly recalls the legislation related to the protection of designation of origin and organic foods under the Recital 9: “Council Regulations (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, and (EEC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs contain specific measures for the verification of compliance with the requirements contained therein. The requirements of this Regulation should be flexible enough so as to take account of the specificity of these areas”.

\(^{39}\) Paragraphs 73 – 77 of the Parmesan Case Judgement which clearly demonstrate the *trompe d’oeil*.

These languages are clearly oriented to include the legislation on the protection of geographical indications and designations of origin for agricultural products and foodstuffs into the scope of Reg. (EC) No 882/04 even if in a flexible way.

So, what flexibility should mean as regards interaction between general rules on official control of conformity for foodstuffs and sectoral rules for denominations of origin?

Flexibility may affect the multi-annual planning of control activities as well as the training of civil servants involved in carrying out official control but, in accordance with the reasons above expressed, it seems quite undisputable that Article 54 of Reg. (EC) No 882/04 should apply to situations of breach to rights conferred by the Regulation on the protection of geographical indications and designations of origin for agricultural products and foodstuffs or on organic production.

Of course, Reg. (EC) No 882/04 (which entered in force on 1 January 2006) and Reg. (EC) No 510/06 (which entered in force 31 March 2006) did not apply *ratione temporis* to the facts of the proceeding but this is not a sufficient reason to accept the *ratio decidendi* applied by the Judgment on the Parmesan Case.

By means of a recently filed reference for a preliminary ruling from the *Giudice di Pace di Varese* (Italy)\(^{41}\) the EC Court has now room to review previous (and partially contradictory) judgements on the relationship between regulation on Official Control (Reg. (EC) No 882/2004) and EU Rules on Food Labelling (Directive (EC) No 2000/13).

It would be a good opportunity to define the matter. According to above mentioned consideration EC Court should adopt an integrated approach taking into account the whole scope of EU Food Law and finally dismiss Parmesan Case law case and the related decoupling based approach in the form of safety vs. other (and minor) legitimate objectives: as it will be shown in the following paragraphs such an approach breaches general rules on control of conformity for (all) foodstuffs and seriously risks to give rooms to Member States to enforce EU Food Law inconsistently with EU Food Law.

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\(^{41}\) Reference for a preliminary ruling from the Giudice di Pace di Varese (Italy) lodged on 17 December 2009 - Mohammed Mohiuddin Siddiquee v Azienda Sanitaria Locale Provincia di Varese (Case C-541/09).
4. Additional shortcomings in achieving the claimed top level safety protection

With specific regard to safety obligations imposed on FBOs other shortcomings may arise from practice.

First duty for FBO is to be known by the competent authority/authorities since only registered or approved establishments are entitled to place food products on the EU market.42 As experience indicates in a number of food alerts, bugs in registration of FBOs lead to serious deficiencies in performing crisis management procedures. This is a common issue with reference to traders, warehouses and other facilities. Despite EU Food Law obliges all FBOs to be registered/approved, it is for National competent authorities to enforce this obligation: on this way, where national enforcement has weak results, grey area lies and deprive effectiveness of capacity building of crisis management skills.

For example, such an inconsistent situation has been detected in Netherlands, where “the system for the registration of the FBOs (including traders, warehouses and storage facilities) is not clearly defined and not uniformly applied”.43

It is a very common issue since, despite DG Sanco’s perspective, a number of Member States do interpret the term “supply” as the mere physical delivery of the food/feed or food producing animal. According to the view of Commission as recently highlighted by EU Standing Committee on the Food Chain and Animal Health, this term “supply” “refers more to the transfer of ownership of the food/feed or food producing animal”. Additionally, brokers must be considered as a form of supplier for the purposes of some safety obligations (as traceability) “whether or not they take physical possession of the goods”.44

Food business operators must also provide the competent authority with evidence of their compliance with HACCP based procedure obligation45, and to ensure that any documents

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43 DG(SANCO) 2009-8222, Final report of a mission carried out in the Netherlands from 09 to 20 March 2009 in order to evaluate the official controls over infant formulae, follow-on formulae and baby foods, including the supply chain. The report observed that “businesses, which were registered but not operating as FBOs and on the other hand, some storage facilities from which export takes place were not listed as registered establishments and consequently never inspected. One of the registered facilities did not fulfil the basic hygienic requirements”.
44 EU Standing Committee on the Food Chain and Animal Health, Guidance quoted under footnote 44.
45 Hazard Analysis and Critical Control Point (HACCP) is a methodology to achieve safe and suitable for consumption. Accordingly to the Recommended international code of practice general principles of food hygiene, adopted by the
describing the procedures developed in accordance with hygiene and safety regulations are up-to-date at all times\(^{46}\). They are also obliged to retain any other documents and records for an appropriate period. Detailed arrangements for the implementation of this obligation have been adopted at EU and National levels in order to facilitate the implementation of this obligation.\(^{47}\)

Food business operators are also requested to ensure that the competent authority always has up-to-date information on establishments, “including by notifying any significant change in activities and any closure of an existing establishment”.\(^{48}\)

**Quid iuris**: what “significant changes” are? Practice shows that, where guidelines, procedures or instructions are not issued by the competent authority to the FBOs, civil servants involved in official control are tempted to apply such a provision in an authoritative manner.

This is an important shortcoming since it reverses the balanced responsibilities between FBO and Official Control as ruled by GFL. From a second point of view, the highlighted shortcoming may lead to sanction, where it is so provided by the National legal order, which is inconsistent with the aim at promoting competitiveness of food industry. It is the case of the Italian enforcement of the Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004. Indeed, according to the Decree No 193/2007\(^{49}\), an administrative fine from € 5,000.00 to € 30,000.00 applies to the FBO which failed to provide up-to-date information on new activities carried out in approved, including notification of any significant change in activities and any closure of an existing establishment (Italian Legislative Decree No 193, Article 6.2). Where Competent Authority is not adequately trained on the new legal framework on food safety it would be common issue that the question

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\(^{47}\) EU Standing Committee on the Food Chain and Animal Health, Guidance quoted under footnote 44.


gives raise to uncertainty and trial to the Court which is a time and cost spending for food industry. In order to resolve this shortcoming it should be considered to limit the compulsory up-to-date information to changes which lead to modification in the recipe, process, or internal organisation; in other terms those changes which should be reflected on the HACCP based procedure.

FBOs, other than those operating at the level of primary production, have also to meet general hygiene requirements laid down in Annex II of Regulation (EC) No 852/2004 and any specific requirements provided for in Regulation (EC) No 853/2004. It is also to be noted that a third set of measures are binding for FBO, but they are addressed in a flexible manner: Article 4, paragraph 3, of Regulation (EC) No 852/2004 requires Food Business Operators to adopt “as appropriate” the following specific hygiene measures under the meaning of Article 4 of Regulation No 852/2004: (a) compliance with microbiological criteria for foodstuffs; (b) procedures necessary to meet targets set to achieve the objectives of this Regulation; (c) compliance with temperature control requirements for foodstuffs; (d) maintenance of the cold chain; (e) sampling and analysis. Sometimes EU and/or national Regulations may provide for implementing measures or guidelines, as it is the case of microbiological criteria as ruled by Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, but uncertainties lie where no specific provision is addressed nor at Communitarian neither at the National Level. In this case, do FBOs reasonably risk to be deemed inconsistent with general safety clause as ruled by Regulation (EC) No 178/02, Article 14? It depends on the degree and quality of knowledge of EU legal framework on foodstuffs the civil servants apply in performing Control activities. In my view, considering that FBO is the primary responsible, it is for the latter to decide what specific measure to be undertaken and how to enforce them within its business. In other terms where specific measures are not clearly addressed by legislation or regulation, FBOs must be given the right to demonstrate to the Competent Authority that its procedures offer equivalent results in terms of safety. It goes without saying that such an evaluation has to be carried out on a science-based ground as long as food law is based on risk analysis (Art. 6, GFL). Disputes and problems may arise where the Competent Authority fails to properly address such evaluation on equivalence: civil servants operating within the framework of official controls would be tempted to require “sameness” rather then equivalence.

The same difficult in enforcing EU Food Hygiene Laws at National level deprive the implementation of permanent procedure or procedures based on the HACCP principles which Food
Business Operators, other than those operating at the primary production level, must put in place, implement and maintain.\(^{50}\)

Other safety requirements are addressed with reference to other specific tools and may give raise to uncertainty as well. In this respect it is important to consider that under Article 18 of GFL laying down traceability obligation, FBOs must have in place “systems and procedures” which allow to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed and to identify the other businesses to which their products have been supplied. It is well known that such an obligation is intended to facilitate product recalls.

Food crises in the past have shown that tracing the commercial flow of a product by keeping invoices was not sufficient to follow the physical flow of the products, as food/feed could be, for example, sent for storage. Therefore, it is essential that the traceability system of each food/feed business operator is designed to follow the physical flow of the products.\(^{51}\)

At the same, it is important to highlight that Article 19 of GFL, laying down recall obligation of unsafe products, does not provide for a similar stringent obligation: the latter article only requires that, if a foodstuff is supposed to be inconsistent “with the food safety requirements”, FBO must “immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof”\(^{52}\). What exactly the provision requires to FBO is to recall the product which has a divergent content from the obligation of putting in place, implementing and maintaining a

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\(^{50}\) HACCP principles are listed under article 5 of Regulation (EC) No 852/04 as follows: (a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels; (b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels; (c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; (d) establishing and implementing effective monitoring procedures at critical control points; (e) establishing corrective actions when monitoring indicates that a critical control point is not under control; (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

\(^{51}\) EU Standing Committee on the Food Chain and Animal Health, Guidance quoted under footnote 44.

\(^{52}\) Article 19.1 of Regulation (EC) No 178/2002 reads as follows: “If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection”.

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permanent procedure to apply in case of unsafe product is on the market which must be withdrawn. This shaded framework clearly gives ground to FBOs to stay far from adopting stringent crisis management plans because they have no obligation nor interest in doing the opposite.

Additionally, the mentioned situation has a result in enhancing disarticulation between traceability procedures and effectiveness in recall plans. As any food lawyer knows well, in a number of situations the evidence of lack safety can be detected only days after the product has been supplied or consumed! This is a common situation in products of animal original which are required to comply with microbiological criteria: analysis of conformity are commonly delivered days or weeks after the concerned batch as been delivered.

On this way, safety and crisis management oriented procedures stays on the distance.

5. **Shaded legal framework as regards consequences of lack of conformity**

As above mentioned, Food Business Operator are the primary responsible of legal compliance with standard relating to safety and fair trade as ruled by EU and/or Member States.

The Article 17 of GFL lies within the objective that was set in the White Paper on Food Safety to define the roles of competent Member States authorities and all categories of stakeholders in the food chains (i.e. farmers, food manufacturers, importers, brokers, distributors, public and private catering businesses…). Considering that a FBO is best placed to devise a safe system for supplying food/feed and ensuring that the food it supplies is safe, it holds primary legal responsibility for ensuring compliance with food law and in particular (but not exclusively) food safety.

In respect of the meaning and extent of FBO’s responsibilities, it should be considered that, according to GFL and Reg. (EC) No. 882/04, a number of legal consequences for the FBO can be addressed when a lack of compliance with Food Law is detected.

A first set of consequences affects the market access: the Competent Authority (CA), as established at the National level, has in some circumstance the power to determine whether a food is marketable or not: this would be the case of Border Inspection Posts for food entering EC

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53 Council Directive EC No 97/78 of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries.
customs or the case of inconsistency with microbiological criteria addressed by Reg. (EC) No 2073/05⁵⁴.

From a regulatory point of view, other consequences relate to a number of legal issues linked to the detection of breaches to food law:

i) Sanctions in the form of administrative fines and/or criminal offences, according to National legal system;

ii) Recovery/corrective measures in accordance to Regulation (EC) No 882/04, Article 54;

iii) Additional control activities and increased level of control;

It is clear that the liability of food business operators should flow in practice from the breach of a specific food law requirement (and from the rules for civil or criminal liability which can be found in the national legal order of each Member state). According to the EU Standing Committee on the Food Chain and Animal Health, the liability proceedings will not be based on Article 17 of GFL but on a legal basis to be found in the national legal order and in the specific infringed legislation; in other terms this Article does not have the effect of introducing a Community regime regulating the allocation of liability among the different links of the food chain. Determining the facts and circumstances which may render an operator liable to criminal penalties and/or civil liability is a complex matter which depends very much on the structure of the different national legal systems.⁵⁵

Nevertheless, it is to be noted that compliance with EU requirements have to be considered in any legal proceedings dealing with breach to food law, as any discussion related to matters of responsibility should take into account the fact that interactions between producers, manufacturers and distributors under the point of view of legal and contractual requirements. On this way national enforcement has top role: quality in training staff (both at private and public sectors) regarding allocation of liabilities is a conditio sine qua non for the appropriate execution of Article 17 of GFL.

From a sanction oriented perspective, as already mentioned it is to Member States to lay down the rules on sanctions applicable to infringements of food law and take all measures necessary to ensure that they are implemented. In other terms it is to Member States to provide for sanctions with

⁵⁵ EU Standing Committee on the Food Chain and Animal Health, Guidance quoted under footnote 44.
the sole limitation arising from EC Law.\textsuperscript{56} In doing so, effectiveness, proportionality and
dissuasiveness are legal requirements Member States are bound to respect as ruled by Article 55 of
Regulation (EC) No 882/04.\textsuperscript{57} In this field, applicable law is the result of a number of acts:

1) Legal acts adopted at Communitarian Level which provides for obligations and
   requirements but not sanctions;

2) National legal acts adopted to transpose and/or enforce EU laws, including sanctions;

Difficulties in enhancing a coordinated relationship between EU Food regulations and national
previously adopted legal acts, laying down food safety and/or food in general, is a very common
issue since food is a matter of culture and market regulation from long time in a number of Member
States. This aspect should explain why some Member States fails to enforce EU regulation on food
hygiene: for example French legal order does not provide for a system of sanctions for breaches to
EU Hygiene rules settled out by so called Hygiene Package. It is of important concern since this
lack \textquotedblleft hampers the proper monitoring of anomalies/deficiencies/infringements detected by the
competent authorities\textquotedblright.\textsuperscript{58}

Other Member States’ legal systems show different shortcomings: co-existence between EU
Food regulations and national previously adopted food related legal acts is a feature of Italian Food
Law where enforcement of Hygiene Package has been assured by Legislative Decree No 193/2007,
which coexist with other pieces of legislation dealing with food safety (Law No 283/1962, on
hygiene and safety requirements on producing and retailing foodstuffs and beverages, and its
implementing rules addressed by Decree No 327 of the President of the Republic). Such a situation
sometimes reduces the certainty of law since coordination between EU and national regulation is a
matter of interpretation and legal interpretation rarely plays for certainty. Additionally schemes of
legislation under Law of 283 (dating back to 1960s) heavily differ from the ground upon which
safety and compliance management for foodstuffs has been drafted by new EU Food Law. Such a
situation is also detrimental for effective penalty system to be put in place and it also deprives

\textsuperscript{56} Judgment of the Court of 23 November 2006, in Case C-315/05, Lidl Italia Srl v Comune di Arcole (VR).
\textsuperscript{57} Article 55 of Regulation (EC) No 882/2004.
\textsuperscript{58} DG(SANCO)/2009-8231 - Rapport final concernant une mission effectuée en France du 15 au 26 juin 2009 en vue
d’évaluer les contrôles officiels relatifs a la sécurité des denrées alimentaires d’origine animale, en particulier la viande,
le lait et leurs produits.
dissuasive impact for FBOs which have minor stimulation in applying a compliance oriented approach.

From the point of view of criminal law (or administrative fines), the relation between Food Law and the final punitive decision depends on the role of the fault within each National legal order. For example, where criminal prosecution is based on the fault, an EC oriented judicial approach should require a careful evaluation of the degree of FBO’s consistency with hygiene rules (HACCP and Good Manufacturing Practices) and food safety management standards (traceability and crisis management). Such evaluation should be the base for assessing the fault and then to state for the conviction or the dismissal. Nevertheless some judgments issued at the Italian level are not uniformly oriented to apply such a rule with the consequence that the fault is not a matter of compliance with EU food requirements.59

From another point of view, national enforcement is a critical point with reference to a third requirement addressed by Regulation (EC) No 882/2004, Article 55, laying down sanctions: where sanctions adopted for breaches to Food Safety Regulations result in very low fines with no reference to the importance of the food business involved, it is obvious to observe a detrimental impact on effectiveness, dissuasiveness and proportionality of the penalty system.

Some examples may help to target the point: Italian legal system provides for an administrative fine to apply in case of breaches to general hygiene requirements as ruled by Regulation No 852/2004/EC, Annex II and/or to specific hygiene requirements as ruled by Regulation No 853/2004/EC: the administrative fine in this case is from € 500.00 to € 3,000.00 (Decree No 193, Article 6.5). How seriously someone can consider such a penalty as dissuasive? The same applies for the lack of permanent procedure or procedures based on the HACCP principles, including procedures for controlling compliance with Regulation 2073/2005/EC on microbiological criteria for foodstuffs and procedures regarding the chain of information: administrative fine from € 1,000.00 to € 6,000.00 (Decree No 193, Article 6.6). Is this legal framework adequate to the mission to create a system of sanctions commensurate with the seriousness of the deficiencies/infringements detected?

59 This seems to be the ground upon which Judgement No 25122 of 2 April 2008 issued by Cassazione Penale (Italian High Court) is based.
Sanction based system has been a common issue among Member States as regards Food regulation. Nevertheless Hygiene Package introduced new instrument for conformity control: according to Article 54 of Regulation (EC) No 882/2004 and Article 19 of regulation (EC) No 854/2004, when the CA identifies non-compliance, it must take action to ensure that the operator remedies the situation. Decision on which action to be taken having regard to the nature of the non-compliance and that operator’s past record with regard to non-compliance.

Article 54 of Reg. (EC) No 882/2004 and Article 19 of Reg. (EC) No 854/2004 provide for a not exhaustive list of actions to be addressed, where appropriate. Such list includes the following measures: (a) the imposition of sanitation procedures or any other action deemed necessary to ensure the safety of feed or food or compliance with feed or food law, animal health or animal welfare rules; (b) the restriction or prohibition of the placing on the market, import or export of feed, food or animals; (c) monitoring and, if necessary, ordering the recall, withdrawal and/or destruction of feed or food; (d) the authorisation to use feed or food for purposes other than those for which they were originally intended; (e) the suspension of operation or closure of all or part of the business concerned for an appropriate period of time; (f) the suspension or withdrawal of the establishment's approval; (g) the measures referred to in Article 19 on consignments from third countries; (h) any other measure the competent authority deems appropriate. It is important to remember that rights are granted to FBO: indeed the CA must provide the FBO concerned, or a representative, with written notification of its decision concerning the action to be taken together with the reasons for the decision. Additionally CA must inform FBO concerned on rights of appeal against such decisions and on the applicable procedure and time limits.

Corrective measures are one of keys of EU Food Safety System as their ground is a command and control system where highly qualified staff is necessary since addressing a corrective measure needs at least the following:

a) the civil servant must be trained to understand the technical and legal issues involved in the detected lack of conformity;

b) the staff involved in Official control to be trained in order to choose the adequate solution (measure) on a case-by-case basis (flexibility);

c) the competent authority to have the legal powers to address an authoritative order to be implemented and respected by the FBO.
It is no surprise that national competent authorities often fail to comply with this requirements. Reports issued by FVO as regards findings and recommendation on official control systems are plenty of cases.

- UK legal system on the protective measures against Bovine Spongiform Encephalopathy (BSE) enables Meat Hygiene Service (MHS), Animal Health (AH) and Department of Agriculture and Rural Development (DARD) staff to implement recovery measures in case of non-compliance. The measures which can be imposed comprise powers to issue warnings, as well as suspend, amend or revoke authorisations, licences or registrations. During the mission carried out by the Food and Veterinary Office (FVO) between 19 to 29 January 2010, which formed part of the general audit 2009 of the United Kingdom conducted under the provisions of Regulation (EC) No 882/2004, the FVO team noted that: In Northern Ireland, several incidents involving contamination of feed with feather meal used as OF/SI had occurred at the end of 2007. Follow up inspections and sampling had been carried out by DARD at some of the operators where such problems were identified. However, no sanctions were imposed on the farmer which admitted he had deliberately fed feather meal to his animals (pigs). The enforcement actions which were imposed upon him only consisted in a warning letter and a cautioned interview. Similarly, no enforcement actions nor sanctions were imposed on an intermediary which supplied to a cattle farm some feed contaminated with feather meal (and which was unfit to be used as feed as consisting of burnt soya)\textsuperscript{60};

- Also Finland demonstrated low level of enforcement as regards corrective measures where lack of conformity is detected: following the findings of the audit carried out by FVO with regard to official controls related to the safety of food of animal origin, in particular meat, milk and their products,\textsuperscript{61} Finnish Competent Authority was requested to “take measures in order to ensure that deficiencies

\textsuperscript{60} DG(SANCO) 2010-8344, Final report of a mission carried out in the United Kingdom from 19 to 29 January 2010 in order to evaluate measures concerning bovine spongiform encephalopathy (BSE).
\textsuperscript{61} DG(SANCO) 2009-8229, Final report of a specific audit carried out in Finland from 08 to 18 September 2009 in order to evaluate the follow-up action taken by the competent authorities with regard to official controls related to the safety of food of animal origin, in particular meat, milk and their products in the context of a general audit.
related to the general hygiene requirements as laid down in Annex II of Regulation (EC) No 852/2004, in particular in red meat establishments, are identified by the Municipal Food Control Authorities (MFCAs) and that corrective action is taken by the FBOs in all establishments under the supervision of the Evira (Finnish Food Safety Authority) as well as the MFCAs and “to take measures to ensure that deficiencies related to specific hygiene requirements as laid down in Annexes II and III to Regulation (EC) No 853/2004 are identified and addressed, in particular with regard to facilities and operations in red meat establishments”.

In a comparative ground it should be noted that enhancing of capacity in terms of active reaction to breach to regulation is a problem also in Third countries:

- According the FVO report of a mission carried out in India from 16 to 24 September 2009 in order to evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products, follow-up investigations of non-compliant results are not existing and, as regards to contaminant control, unable to identify the actual source of detected residues. Corrective actions at the level of the primary producers (farms) are delegated by the competent authority to the exporting establishments which clearly stays as a breach to requirement issues by Article 5 of Reg. (EC) 882/2004 according to which: “the activities referred to in Article 54 shall not be the subject of such a delegation”.

- The mechanism for follow-up of non-compliant results was the subject of a number of recommendations addressed by FVO to China’s Competent Authorities on 2003 and 2006. According to the 2009 report of FVO on control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products.

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62 DG(SANCO) 2009-8229, Recommendation No 2.
63 DG(SANCO) 2009-8229, Recommendation No 3.
64 DG(SANCO) 2009-8190, Final report of a mission carried out in India from 16 to 24 September 2009 in order to evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products.
65 DG(SANCO)/9046/2003, Final report of a mission carried out in the People's Republic of China from 15 to 25 September 2003 in order to evaluate the controls of residues in live animals and animal products and of poultry meat hygiene.
66 DG(SANCO)/8294/2006, Final report of a mission carried out in China from 22 March to 30 March 2006 concerning the evaluation of the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products.
contaminants in live animals and animal products “Chinese competent authorities operate a comprehensive control system for residues in food of animal origin and the use of veterinary medicinal products in food producing animals. This system is underpinned by a well equipped laboratory network, well defined quality control standards and, in the case of the export establishments, comprehensive own-checks which are complemented by strict supervision by the competent authorities. Notwithstanding some of the shortcomings identified during the course of the inspection, for example in relation to the follow-up of non-compliant results and incomplete validation of some analytical methods, it is clear that considerable improvements have been made relative to the findings of previous FVO residues inspections”.

As already mentioned, Reg. (EC) No 882/04 contains provisions laying down financing of official control (Articles 26 to 29) reflecting the rationale of EU Food Law: the more the compliance, the lower the fees and the charges on Food Business Operator. Indeed Article 27.6 of Reg. (EC) No 882/04 reads: “when, in view of own-check and tracing systems implemented by the feed or food business as well as of the level of compliance found during official controls, for a certain type of feed or food or activities, official controls are carried out with a reduced frequency or to take account of the criteria referred to in paragraph 5(b) to (d), Member States may set the official control fee below the minimum rates referred to in paragraph 4(b), provided that the Member State concerned provides the Commission with a report specifying: (a) the type of feed or food or activity concerned; (b) the controls performed in the feed and food business concerned; and (c) the method for calculating the reduction of the fee”.

The same rule is the ground for Article 28 of Reg. (EC) No 882/04, laying down expenses arising from additional official controls: “when the detection of non-compliance leads to official controls that exceed the competent authority's normal control activities, the competent authority shall charge the operators responsible for the non-compliance, or may charge the operator owning or keeping the goods at the time when the additional official controls are carried out, for the

67 DG(SANCO) 2009-8187, Final report of a mission carried out in China from 26 October to 05 November 2009 in order to evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products.
expenses arising from the additional official controls”. It is to bear in mind that “normal control activities” are the routine control activities required under Community or national law and, in particular, those described in the Multi-annual National Control Plan (MANCP). It results that activities exceeding normal control activities include the taking and analysis of samples as well as other controls that are required to check the extent of a problem, to verify whether corrective action has been taken, or to detect and/or substantiate non-compliance.

The *regula aurea* is that the less the compliance, the more the controls and the costs. Beyond this simple rule, legal framework on financing official controls on foodstuffs is a very complex matter: a better understanding of the functioning of the inspections fees systems as currently implemented by the Member States on the basis of the relevant provisions of the Regulation (EC) No 882/2004 (Articles 26 to 29) is needed by the Commission which called for an external evaluation aimed at providing a survey addressed to competent authorities in all Member States, an in-depth analysis (case studies) in relation to six Member States representing a variety of fee regimes, interviews with key experts and stakeholders at EU level, extensive analysis of existing literature and data review.  

The study⁶⁹ established that there is a significant degree of variation in the enforcement of the financing provisions of the Official Control Systems by the Member States and a significant lack of clarity and transparency of the various national fee systems as currently implemented. As a result, direct comparison of actual fee levels across the EU (and between sectors) is extremely difficult.⁷⁰

The study results also suggest that, due to the very broad definition of cost categories in Annex VI to the Regulation and to the reported lack of transparency of the calculation methods, it is quite unclear whether cost-based fees truly reflect actual costs incurred by the competent authorities of the Member States for the performance of the inspections for which the fees are collected. Significant differences in the organisation, structure and staffing (number and profiles of staff) between Member States have important financial implications for the cost of official controls.

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⁶⁹ Food Chain Evaluation Consortium (FCEC), Study mentioned under footnote 23.

⁷⁰ The study results also suggest that, due to the very broad definition of cost categories in Annex VI to the Regulation (EC) No 882/04 and to the reported lack of transparency of the calculation methods, it is quite unclear whether cost-based fees truly reflect actual costs incurred by the competent authorities of the Member States for the performance of the inspections for which the fees are collected.
6. Safe, complaint and not defective foods?

Compliance with EU standard and requirements is of concern for business transactions since marketability of foodstuff may be hampered by lack of consistency with certain standards. From another point of view, the right of citizens to be supplied with safe food may be the ground for civil action.

As long as civil liability is based on the proof of the fault, compliance with food standards and requirements is a defense claim at the Court in a civil trial. On the contrary, where legal order provides for no fault liability system, as it is the case for civil action under product liability regime, compliance with food law has a minor role. From this point of view, it is to remember that Article 21 of GFL establishes that the provisions of Chapter II (General Food Law, articles 4 to 20) “shall be without prejudice to Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products”. In other terms, food, even if processed consistently with the best safety practices, may be challenged as defective where it is assumed as cause of a damage or injure to the consumer. Article 21 GFL is clearly oriented to avoid any interference of the business compliance with Food Law on the civil trail held to settle a product liability claim under the Directive EEC No 85/374. As a consequence, product safety standards seem to have different meaning and diverse impact according to the several piece of legislation considered from time to time. It is to be borne in mind that under the meaning of Article 6 of Dir. 85/374 a product is defective “when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation”. From a logical point of view, the safety which is expected should be gathered by the legal standards at least. Additionally, EU Food regulation introduces standards aimed at assuring a high level of safe consumption by assessing safety performance of products, binding procedures on FBOs et cetera. Are the standards addressed by Food Law of such to conform the definition of “defect” as relevant under the Dir. EEC No 85/374? According to Article 21 of Reg. EC No 178/02 the answer is the
negative. The paradox is that a product, deemed safe under the meaning of GFL, may be held as ground for a civil suit (product-liability).

Notwithstanding the radical separation of the two mentioned pieces of legislation, product liability law, from one side, and Food regulation, on the other, may be affected by some cross-contamination hypothesis.

Firstly, the identification of the producer: as everybody knows, for a number of food products the indication of the “genuine” producer is mandatory; a very stringent provision requiring the exact identification of the producer is for products of animal origin, accordingly to Article 5 of Reg. 853/2004 establishing that a product of animal origin can be marketed only if it bears a health mark applied in accordance with Regulation (EC) No 854/2004 or an identification mark applied in accordance with Annex II, Section I, of the Regulation (EC) No 853/2004. Also EU Legislation on Food Labelling (Directive (EC) No 2000/13) requires the name or business name and address of the manufacturer or packager, or of a seller established within the Community to be labelled on the product.

Secondly, EU Food Law may impact the defence claims as ruled by Article 7 of Dir. EEC No 85/374 according to which “the producer shall not be liable as a result of the Directive if he proves:

(a) that he did not put the product into circulation; or

(b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards; or

(c) that the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business; or

(d) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities; or

(e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered; or

(f) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.
An interesting point stays on the defence claim under Article 7 (a) according to which producer liability is excluded where the manufacturer proved that he did not put the product into circulation. The question is to consider whether the food recall, launched under the meaning of Article 19 of GFL, may give rise to consider such a recalled product “out of the market” or not. Additionally, where a producer ordered the withdrawn, by alerting all the clients supplied with the defective/unsafe bunch, is he to be held liable under the Dir. EEC No 85/374 for the sole finding that one of his clients failed to withdrawn the 100% of recalled products?

Traceability and product control, as applied by the food industry, may play a role in the view of Article 7(b) defence claim. Producer shall not be held liable if he proves that “having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards”. This is the case of a number of food contamination or tampering cases. In these cases, traceability and product control may help the defendant: Article 7 (b) is clearly relating to the probable assumption (not certitude) that the defect, as claimed by the plaintiff, was not originated within the producer process. The effectiveness of such defence will depend greatly on the judges’ interpretation of the burden of proof and notably what degree of probability he will require in order to assess whether the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards.

Defence claim ruled by litt. (d) is of interest as it states that when the defect is due to compliance of the product with mandatory regulations issued by the public authorities, produced shall not be deemed liable under the meaning of Directive (EC) No 374/1985. It is important to note that the opposite case is out of the scope of this provision: in other terms, compliance with Food regulation is of not impact on the civil trial under the ruling of Directive 1985/374!

Since compliance with regulatory framework has no direct consequence on product liability because of Article 21 of GFL, cost-benefit analysis of a compliance with Food Law will be adversely impacted in the FBO’s view as costs (capital expenditure for enhancing compliance with Food Law) are not balanced by benefits (reduction or elimination of risk of recovery of damages). It is also of primary importance to consider that, in such a scenario, costs may be higher for industry as insurance programmes covering civil liability will be not fully affected by a righteous approach to food business.
7. Final remarks: seeking the key to enter the baroque cathedral

Being aimed at pursuing a number of different objectives, a high level of protection of human life and health, the protection of consumers' interests, including fair practices in food trade, modern EU Food Law is a very impressive set of rules covering a large number of aspects of the food chain and of activities of public authorities. It seems like a great baroque cathedral whose entry is hide.

In particular such big legal structure may risk to be shattered by a decoupling based overview (safety vs. other legitimate objectives; regulation vs. enforcement; European level vs. national level) where the whole scope of Food Law risks to be not properly understood by the entire circle of stakeholders and Competent Authorities and Food Business Operators gets addicted to an esoteric legal system.\footnote{Pisanello D., What do Food Safety and Fair Trade stand for? Reconciling the twofold objective of EU Food Law, European Food and Feed Law Review, 5/2009.}

The analysis carried out in this contribution has shown a number of difficulties and shortcomings related to the enforcement of EU Food Law which seem related to different reasons.

A first set of grounds shares difficulties which affect EU integration in general: food legislation is an old-dated (but not necessarily obsolete\footnote{As it is demonstrated by Pellicano C.M. as regards Italian food related criminal law in his contribution to Pisanello D, Biglia C., Pellicano C.M., Guida alla Legislazione Alimentare, EPC Libri, Roma, 2010.}) matter, touching upon economical and cultural interests: this point could partially explain the reluctance opposed by some Member States in enforcing EU Food Law and the important differences between Member States which still are at stake as regards enforcement and execution.

Secondly, coexistence between EU legislation and National legal acts laying down food safety and consumer information rules is a current issue in more than one Member State: as Italian case proves well, national legal framework shows important differences in the approach to regulation of food market, which necessarily lead to difficulties in achieving full conformity to EU requirements for compliance-requested party (national competent authorities): uncertainty about legal status of norms in case of contrast between national and EU provisions, lack of knowledge about legal interpretation of regulations, and poor awareness of remedies and legal proceedings for ensuring the respect of EU legislation can be qualified as major critical points.
Member States are requested to perform official controls consistently with the standards of excellence accordingly to EU Food Law: where EU standards in these fields aim at top-quality in organisation of control activities (planning, performing and monitoring, at least) the point is: are Member States and Public Authorities ready to achieve these objectives? This question is more urgent these days as financial crisis is drawing down resources.

Grounds for positive answer are rare.

The radical change in mind which is pursued by EU Food Law as regards organisation and performing of official controls for foodstuffs, requires important training activities of staff dealing with controls of conformity. At the same time, it is arguable that young staff would be more sensitive and reactive to modify their know-how and procedures vis-à-vis new legal framework than senior colleagues. It has not minor relevance the fact that top management positions are filled by senior officers.

Nevertheless, the analysis demonstrates that only a part of shortcomings in enforcing EU Food Law are “in re ipsa” since they are due to ineluctable drivers which affect any sector covered by EU integration. Other difficulties relates closer to the way EU norms are drafted and/or implemented by competent authorities and/or interpreted by Courts.

With reference to the language of EU norms of food regulation, attention should be paid on rules laying down financing mechanisms for Official controls (see paragraphs 2 and 5) and relationship between compliance with Food Law (as defined by Article 3, 1) of GFL) and civil liability (see paragraph 6). Where the system of financing official control is under evaluation, there is no evidence that a comparable re-evaluation will be addressed as regards the system of civil liability for FBO.

Interaction between norms à la carte and concrete implementation gives ground for additional shortcomings. A top example is detectable with regard to flexibility approach, which stands as a major tool within the Hygiene Package: the lack of stringent procedures and/or implementing guidelines, and weak financial resources for training, seriously risk to hamper the enforcement of the key-concept of flexibility as regards conformity evaluation of FBOs as carried out by staff of Official Control. In other terms, as long as flexibility is not backed by adequate implementing guidelines and appropriate training, it may stand as a no-effective tool, at least in those areas where
the primary responsibility for Food Business Operator and the new role of Competent Authority are not properly understood consistently with EU Food Law.

According to the analysis carried out in this contribution, diaphragm between the EU level, entitled to set the rules, and the National level, which is charged with control of conformity and sanctions for breaches, stands as another major critical point: proportionality, effectiveness and dissuasive oriented penalty system (Article 55 of Regulation (EC) No 882/2004) should be investigated in a more stringent way which seems to be not the case.

Finally, it seems that almost shortcomings share a common root: the multiple authorities approach. It seems that multifunctionality of EU Food Law leads to involve more than one authority despite EU Commission’s preference for one national competent authority. Nevertheless, multiple authorities approach seems to be common issue in a number of Member States. Particularly, but not exclusively, where one sole competent authority has not been settled up, allocation of competence within the single Member State leads to an increased dilution of public responsibility (local - regional - if any - and national) which seriously reduce the performances of Official Control system and the level of legal certainty for FBO. In such a scenario, it is not rare to observe authorities dealing with some aspects regulated by EU Food Law which are not trained according to Regulation (EC) No 882/2004 and which act irrespectively of EU Food Regulations.

Having regard to this situation, one could be tempted to see centralisation of enforcement of EU Food Law as the solution. But it is a questionable matter. Also Re-Nationalization is a solution but it has no serious chances to be implemented.

EU institutions are aware of the need of higher uniformity for conformity control in the field of foodstuffs and devoted important financial resources to enhance a standardized approach to the enforcement of EU Food Law, notably - but not exclusively - by means of the programme “Better Training for Safer Food”. Training is an important tool but highlighted shortcomings show the need of further activities, efforts and solutions.

It is important to observe that there is no serious and stringent evaluation carried out the Services of Commission over the training activities performed by National Competent Authorities for the staff involved in official control for foods. On the contrary, it could be arguable that Services of DG Sanco should carry out a severe examination of these activities as they are crucial for recovering shortcomings. Regulation (EC) No 882/2004 stresses this point but enforcement is required to reverse the current situation where training of national staff is more a market issue than a quality oriented activity.

It would be of interest to observe that training is usually intended as just a on-the-spot action (one day or more) with no activity of follow-up. On the contrary needs of staff performing official control activities are bigger and more complex. Civil servants need to be supported on their day-by-day activity as complexity of legal framework, uncertainty as regards obligations and rights have to be managed in a proper way. Such a support programme may be based on a network of qualified experts which provide legal counsel in the field of controls of conformity to food law, feed law, animal health, animal welfare and/or plant protection. This support service should be designed for the entire public authorities dealing with Official Control. This feature should permit to achieve two objectives: i) economies of scale assuring low costs for public authorities as lack of financial austerity is a key-factor; ii) an EU coordinated approach since “Food Law” always is the result of National and EU legal and administrative acts governing food. Additionally each request of counselling should be processed by a team of qualified experts: two or three advisors: one competent for National Food Law, the second competent for the EU related issues, and the third, where necessary, as an expert in technical matters (veterinary, biologist, food sciences).

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Bibliography


ARBOUR M.-E., Sicurezza alimentare e prodotti difettosi dopo Lidl e Bilka: un binomio sfasato?, in Danno e Responsabilità, 2007, p. 989


BEVILACQUA D., The Codex Alimentarius Commission and its Influence on European and National Food Policy, in European Food and Feed Law review, 2006, p. 3.

BLIND K. et a., Standards in the service sectors. An explanatory study, Aprile, 2003, Study committed by EU Comm. CE, Enterprise Directorate-General, contract n. 20010671

BUNDESINSTITUT FÜR RISIKOBWEERTUNG (FEDERAL INSTITUTE FOR RISK ASSESSMENT), EU Food Safety Almanac 2009

BLUMANN C. – ADAM V., La politiche agricole commune dans la tourmente: la crise de la “vache folle”, in Rev. trim. dr. eur., 1997, p. 270,

CARREÑO GARCÍA J.I., Agricultural in WTO Law, in B. O’Connor, TBT and Agriculture, London, Cameron and May, 2005


CHITI M.P., Il rischio sanitario e l’evoluzione dall’amministrazione dell’emergenza all’amministrazione precauzionale, in Rivista italiana di diritto pubblico comunitario, 2006, p. 1


COURT OF JUSTICE OF THE EUROPEAN COMMUNITIES, Judgment of 23 November 2006, Case C-315/05, Lidl Italia Srl v Comune di Arcole (VR)
COURT OF JUSTICE OF THE EUROPEAN COMMUNITIES, Judgement of 26 February 2008, Case C-132/05 (Commission v. Germany)

COURT OF JUSTICE OF THE EUROPEAN COMMUNITIES, Judgement of 25 June 2002, Case C-66/00 (Bigi)

EUROPEAN COMMISSION, Discussion paper on strategy for setting microbiological criteria for foodstuffs in Community legislation, SANCO/1252/2001, 8 March 2005


EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, Guidance document on the implementation of procedures based on the HACCP principles, and on the facilitation of the implementation of the HACCP principles in certain food businesses, 16 November 2005

EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, DG(SANCO) 2009-8187, Final report of a mission carried out in China from 26 October to 05 November 2009 in order to evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products

EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, DG(SANCO)/ 2008-7644, Final report of a mission carried out in Turkey from 20 October to 29 October 2008 in order to evaluate the control systems in place governing the production of fishery and aquaculture products intended for export to the European Union

EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, DG(SANCO) 2009-8190, Final report of a mission carried out in India from 16 to 24 September 2009 in order to evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products

EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, DG(SANCO) 2009-8341, Final report of a mission carried out in Israel from 18 to 22 October 2009 in order to evaluate the control systems in place governing the production of aquaculture fishery products intended for export to the European Union
EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, DG(SANCO) 2009-8219, Final report of a mission carried out in Israel from 23 November to 03 December 2009 in order to evaluate the operation of controls over the production of milk, heat treated milk and milk based products for human consumption destined for export to the European Union

EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, DG(SANCO) 2009-8222, Final report of a mission carried out in the Netherlands from 09 to 20 March 2009 in order to evaluate the official controls over infant formulae, follow-on formulae and baby foods, including the supply chain

EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, DG(SANCO) 2010-8344, Final report of a mission carried out in the United Kingdom from 19 to 29 January 2010 in order to evaluate measures concerning bovine spongiform encephalopathy (BSE)

EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, DG(SANCO) 2009-8229, Final report of a specific audit carried out in Finland from 08 to 18 September 2009 in order to evaluate the follow-up action taken by the competent authorities with regard to official controls related to the safety of food of animal origin, in particular meat, milk and their products in the context of a general audit

EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, DG(SANCO) 2009-8190, Final report of a mission carried out in India from 16 to 24 September 2009 in order to evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products

EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, DG(SANCO)/9046/2003, Final report of a mission carried out in the People's Republic of China from 15 to 25 September 2003 in order to evaluate the controls of residues in live animals and animal products and of poultry meat hygiene

EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, DG(SANCO)/8294/2006, Final report of a mission carried out in China from 22 March to 30 March 2006 concerning the evaluation of the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products

EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, DG(SANCO) 2009-8187, Final report of a mission carried out in China from 26 October to
05 November 2009 in order to evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products.

EU Standing Committee on the Food Chain and Animal Health, Guidance on the implementation of articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) n° 178/2002 on general food law conclusions of the standing committee on the food chain and animal health, 26 January 2010.

European Food Safety Authority - EFSA, Opinion of the Scientific Panel on Biological Hazards on microbiological criteria and targets based on risk analysis, EFSA Journal (2007), 462, 1-29.

Food Chain Evaluation Consortium (FCEC), Study on fees or charges collected by the Member States to cover the costs occasioned by official controls, Framework Contract for evaluation and evaluation related services - Lot 3: Food Chain (awarded through tender no 2004/S 243-208899).


Maljean-Dubois S., Biodiversité, biotechnologies, biosécurité: Le droit international désarticulé, in Journal de droit international, 2000, p. 948.


PISANELLO D., What do Food Safety and Fair Trade stand for? Reconciling the twofold objective of EU Food Law, European Food and Feed Law Review, 5/2009

PISANELLO D., Update of Italian Guidelines on Rapid Alert System for Food and Feed: some explanation in a shaded internal legislative framework, European Food and Feed Law Review 1/2009

PISANELLO D., Obblighi di sicurezza alimentare nel mercato unico tra gestione del rischio e responsabilità d’impresa, Diritto Comunitario e degli Scambi Internazionali 4/2008

PISANELLO D., Denominazioni di origine ed indicazioni geografiche protette tra diritto industriale e diritto alimentare: il caso Parmesan II, Contratto e Impresa/Europa 1/2008

PISANELLO D., Applicazione della sentenza “Lidl” all’interno degli Stati membri: legislazione interna e normativa comunitaria a confronto, Diritto Comunitario e degli Scambi Internazionali, 3/2007


PISANELLO D., Italy’s ‘Swan Song’ for pure chocolate?, Coffee & Cocoa International's August/September 2006

PISANELLO D., L’accordo tra la Comunità europea e gli Stati uniti d’America sul commercio del vino, Contratto e Impresa/Europa 1/2006

PISANELLO D., The challenges of implementing EC food law in Italy, Foodnavigator.com, 08 August 2006

PISANELLO D., La riforma del sistema comunitario delle denominazioni di origine e delle indicazioni geografiche dei prodotti agricoli e alimentari, Contratto e Impresa/Europa n. 1/2006

PISANELLO D., Italian chocolate sector stuck in political deadlock, Foodnavigator.com, 19 April 2006

RIEDEL R. –RIEDEL C., Shortcomings of the new European Food Hygiene Legislation from the Viewpoint of a Competent Authority, in in European Food and Feed Law review, 2/2008, p. 64


F. TRIMARCHI, Principio di precauzione e qualità dell’azione amministrativa, Rivista italiana di diritto pubblico comunitario, 2005, p. 1673

VAN DER MEULEN B., The Function of Food Law, On the objectives of food law, legitimate factors and interests taken into account, Food and Feed Law Review 2/2010