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Sommario

Editoriale

Produttori agricoli, trasformatori, e reputazione dei prodotti alimentari: una relazione cruciale

L'Italia è un paese con tradizioni alimentari ineguagliabili, e si possono fare, al proposito, alcuni esempi: il formaggio Grana sembra sia nato nel 1134 nell'abbazia di Chiaravalle, a pochi chilometri da Milano. Veniva prodotto in apposite caldaie all'interno dei monasteri che possono essere considerati i primi caseifici; Giovanni Boccaccio nel *Decameron* narra che già nel 1300 il Parmigiano-Reggiano aveva raggiunto la tipizzazione odierna; del Gorgonzola si hanno alcune tracce a partire del XV secolo, nella omonima cittadina situata nei pressi di Milano; Cassiodoro, nelle sue epistole, si raccomanda di non far mancare mai alla mensa reale vini veronesi, progenitori del Soave, "soavissimi e corposi" capaci di esprimere "chiara purità....gioviale candidezza e soavità incredibile"; i primi documenti in cui con il nome Chianti si identifica una zona di produzione di vino, e anche il vino prodotto, risalgono al XIII secolo, e si riferiscono alla *Lega del Chianti*.
Questi, e tanti altri prodotti ora insigniti della DOP o dell'IGP, sono il risultato di due componenti fondamentali: la materia prima agricola e la sapienza dei trasformatori. Se in molti casi la materia prima agricola è essenziale, come nel caso del terreno e dei vitigni che su essa vivono, per assicurare al trasformatore un esito brillante al suo lavoro, in altri la competenza del trasformatore prevale, e di ciò occorre rendersi conto. Ovviamente i prodotti DOP e IGP sono assoggettati a disciplinari che vincolano rigidamente l'origine della materia prima agricola, ma gli altri alimenti non sono assoggettati a questi vincoli.
Pertanto, il richiamo fatto all'abilità dei trasformatori è diretto, prevalentemente, a chi non lavora nel campo delle DOP e IGP, e deriva dalla constatazione che talvolta si dimentica l'importanza dell'opera di chi lavora i prodotti agricoli che, per loro intrinseca caratteristica, sono variabili di anno in anno, dipendenti come sono dalle piogge, dal sole, dalla grandine, dalle brine, dai venti caldi e gelidi, dalle stesse regole della PAC, e così via. Eppure, il trasformatore deve sapere porre rimedio a queste inevitabili varianze con la sua sapienza, anche per soddisfare il consumatore che pretende, d'ordinario, stabilità nel gusto, nel sapore, nel colore e in ogni altra caratteristica del cibo che gli viene proposto.
In un tempo nel quale ci si reca nei negozi alimentari, spesso stabiliti in grandi superfici, e si comprano prodotti tutti preconfezionati, salvo qualche verdura e frutta, la invarianza del prodotto è fondamentale; solo pochi appassionati, infatti, si recano in Toscana o in Umbria per acquistare l'olio o il vino dal piccolo produttore agricolo, pronti ad apprezzare

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HANNO COLLABORATO A QUESTO FASCICOLO

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le differenze che hanno i prodotti di anno in anno, così come si comportano i consumatori di DOP e IGP. Tutti gli altri chiedono continuità nel prodotto che acquistano e, per realizzarla, i trasformatori spesso sono costretti ad approvvigionarsi in zone diverse, a compiere miscele differenti di anno in anno.
La grande reputazione degli alimenti italiani, dunque, non deriva solo dalle DOP e IGP ma anche dalla grande tradizione di competenza dei trasformatori, che occorre proteggere e rafforzare, consentendo agli stessi di operare in modo da mantenere la grande reputazione che l'alimento italiano ha nel mondo.

Luigi Costato

L'editoriale che apre il fascicolo investe un tema che sempre più di frequente si pone al centro del dibattito, politico oltre che scientifico: quello relativo all'individuazione e disciplina degli elementi che determinano la *qualità* e la *reputazione* del cibo.
In tale prospettiva, il fascicolo raccoglie contributi, che si collocano al crocevia fra disciplina della *produzione del cibo* e disciplina della *comunicazione del cibo*, nella complessa stratificazione regolatoria, che comprende regole di fonte globale, europea e nazionale.
Ulteriore elemento che caratterizza questo fascicolo – a conferma di una linea esplicitamente e costantemente perseguita sin dal primo numero della *Rivista di diritto alimentare* (pubblicato ormai undici anni fa) – è l'apertura verso la dimensione globale del diritto alimentare, sia con il crescente utilizzo della lingua inglese quale lingua veicolare, strumento di più agevole dialogo e confronto con studiosi ed operatori non domestici (tre dei lavori qui pubblicati sono redatti in lingua inglese), sia con la pubblicazione di contributi di studiosi stranieri (due degli autori che hanno contribuito a questo fascicolo).
Nella sezione dedicata alle ***Ricerche***, Luca Leone propone – appunto, in lingua inglese – un'ampia analisi delle linee evolutive in tema di utilizzazione degli Open Data al fine di accrescere le possibilità di accesso alle informazioni sui prodotti alimentari e di migliorare la protezione dei consumatori, sottolineando come il passaggio da forme di conoscenza basate sulla relazione diretta fra umani a modalità che in larga misura si risolvono in accesso a dati digitali abbia accentuato il bisogno di *fiducia*, non soltanto per quanto attiene alle misure tecniche di protezione della sicurezza dei dati, ma più in generale per quanto attiene al bisogno di trasparenza, accessibilità, affidabilità e responsabilità dei soggetti che operano in questo universo informativo. L'A. sottolinea come – a partire dal *Libro Verde* della Commissione Europea sui "Principi generali della legislazione in materia alimentare nell'Unione Europea", e nei successivi atti disciplinari, sino al Regolamento n. 1169/2011 sull'informazione al consumatore di prodotti alimentari – il tessuto normativo

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europeo abbia progressivamente valorizzato lo stabilirsi di strumenti di comunicazione bidirezionale fra consumatori ed autorità pubbliche. Il crescente ricorso, in sede sia nazionale che europea, a strumenti informatici di accesso alle informazioni sull'attività dei soggetti pubblici, ha di recente (nel novembre 2015) portato all'attivazione dello *European Data Portal* operativo in tutte le lingue dell'Unione Europea, che all'indirizzo http://www.europeandataportal.eu/en (http://www.europeandataportal.eu/it in lingua italiana) consente di ricercare dati ed informazioni in un ampio archivio suddiviso per materie. La sezione denominata "Agricoltura, pesca, silvicoltura e prodotti alimentari" comprende attualmente 721 basi di dati (712 al momento della redazione dell'articolo, a conferma della straordinaria rapidità di accrescimento ed aggiornamento di questo archivio europeo), molte delle quali relative a prodotti alimentari. In questo scenario un ruolo centrale è assegnato all'EFSA, con l'adozione di una serie di misure (analiticamente considerate nell'articolo) che mirano a garantire piena trasparenza nell'esercizio delle competenze dell'Autorità. Restano peraltro tuttora irrisolte alcune criticità, in ordine alla concreta declinazione della *fiducia* in un'area cosi delicata della relazione fra consumatori ed autorità, e l'A. conclude sottolineando come non possano essere sottovalutati i persistenti problemi legati all'operatività di un sistema di Open Data nell'area della disciplina dei prodotti alimentari, sotto i profili dell'affidabilità e chiarezza; sicché appaiono necessari ulteriori intervento del legislatore europeo in un prossimo futuro.

Valeria Paganizza e Bernd Van der Meulen commentano (anch'essi utilizzando la lingua inglese) la decisione della Corte di giustizia nel caso *Davitas* deciso nel novembre 2016 in tema di *novel foods*.

Il tema è cruciale, perché investe la stessa perimetrazione dell'area applicativa della disciplina europea in tema di novel foods, e così pone la questione se per identificare i *nuovi alimenti* il criterio cronologico che fissa un prima ed un dopo il 15 maggio 2017 possa essere assunto come unico criterio di discrimine, al di là della stessa lettera del Regolamento (CE), ovvero se ci siano taluni prodotti alimentari soggetti ad un diverso criterio, in particolare quelli – come del caso di specie – di origine minerale, e non animale o vegetale.

In termini più generali, la decisione – come ben sottolinea Valeria Paganizza – investe il problema della Corte di giustizia come *law maker*, e dunque come soggetto chiamato ad esprimere *policies* e non soltanto interpretazioni basate sulla stretta lettera della legge.

Bernd van der Meulen sottolinea come debba ritenersi tuttora non operante nell'ordinamento europeo un principio *de minimis*, in forza del quale si possa superare l'interpretazione restrittiva proposta dalla Corte di giustizia nella decisione del 2016, lasciando spazio all' *innovazione* nelle scelte di *produzione* e di *presentazione* dei prodotti alimentari.

Nei ***Commenti*** e ***Note***, Luis González Vaqué, commentando la sentenza *Superfoz* del 26 luglio 2017 della Corte di giustizia, esamina una questione assai rilevante sotto il profilo della distribuzione dei costi dei controlli dei prodotti alimentari: quella relativa ai criteri per quantificare gli importi da porre a carico dei singoli operatori della filiera. Si confrontano qui due posizioni: quella fatta propria dalla Corte di giustizia, secondo cui oneri destinati a finanziare il generale sistema dei controlli dei prodotti alimentari possono essere posti a carico dei commercianti al dettaglio di tali prodotti, senza necessità che la quantificazione di tali oneri corrisponda a quanto effettivamente speso per i controlli su tale fase della filiera, alla stregua di una prospettiva solidaristica che considera il settore nel suo insieme; e quella sostenuta dall'A., secondo il quale in esito a questa sentenza «si introduce un precedente pericoloso, che può dar luogo alla proliferazione di tasse "di origine europea", senza che esista una relazione tra il suo importo e il costo dei servizi realmente prestati.».

Nelle ***Novità***, Alice Artom commenta l'emanazione del recente Decr.leg.vo n. 27/2017 in tema di sanzioni per violazioni della disciplina sulle "indicazioni nutrizionali e sulla salute fornite sui prodotti alimentari". L' A. esamina la disciplina sanzionatoria nazionale in riferimento alle disposizioni europee e pone in evidenza le manifeste contraddizioni fra disciplina europea e disposizioni sanzionatorie nazionali, sottolineando come tale decreto legislativo, lungi dal fare chiarezza, finisca per introdurre ulteriori incertezze.

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Ricerche

Towards new "digital insights." The value of Open Data for food information in Europe

Luca Leone

1.- Introduction

In the last years there has been a groundswell of interest around the issues surrounding the new public policy of Open Data at all levels of government in Europe – and overseas as well – because the potentiality ICT technology seems to have increasingly become the glue holding public bodies and citizens together. The application of this policy in the food sector does not seem to be escaping this cutting-edge and cross-border environment.[1] As pointed out by the Global Open Data for Agriculture and Nutrition initiative,[2] there are almost three objectives Open Data might reach in this field: ‹‹enabling more efficient and effective decision making; fostering innovation that everyone can benefit from; driving organisational and sector change through transparency››. At its very core, indeed, Open Data is a digital format through which data are open, freely available, machine-readable and reusable by the public, in order to enable and enhance new forms of civic knowledge production.[3]
However, if this new digital innovation could seem at a glance a terrific tool for sharing knowledge and promoting more democratic and trusted dialogue between the EU institutions and European citizens, the overall issue is more complex than these beliefs may suggest. This is because the EU Commission framed Open Data in terms of data-driven economy, through which to pursue business and economic opportunities, as well as to create new products and services in several fields.[4] Additional reasons deal with the increasing technical problems pertaining to licensing, accessibility, interoperability and usability of data that still exist and lack uniform solutions.[5] Furthermore, the legal framework currently in force on the matter has not been completed yet, and needs to be urgently defined, in order to tackle all normative tensions arising when law has to face scientific uncertainties pertaining to technological practices and processes.[6] Therefore, a conceptual question arises: could ICT tools offered nowadays by Open Data create a perspective of communication in the food sphere as a more interactive relationship between the citizenry and public bodies?
This contribution will elaborate on the aforementioned question, by considering the normative and social aspects related to the use of Open Data in the European food domain, in order to explore how this new technology will enhance access to food information – and consumer protection, as a conse-

(1) See D. Deasy, *Food safety-the IT dimension*, in *Irish Journal of Agricultural and Food Research*, 39, 2000, pp. 343-348.
(2) Godan, *How can we improve agriculture, food and nutrition with open data*?, 2015, p. 4, http://www.godan.info/wp-content/uploads/2015/04/ODI-GODAN-paper-27-05-20152.pdf. The GODAN initiative is a growing network of 125 organisations that supports global efforts to make agricultural and nutritionally relevant data available and accessible. See more at http://www.godan.info/about/statement-of-purpose.
(3) See http://opengovdata.org/.
(4) See European Commission, *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee of the Regions, 'Open data - An engine for innovation, growth and transparent governance*, COM(2011) 882 final, Brussels, 2011, which stresses the relevance of opening up public data to pursue business and economic opportunities. See also, European Commission, *Towards a thriving data-driven economy*, COM(2011) 882 final, Brussels, 2014, where all activities related to data are considered as the drivers of the EU knowledge economy.
(5) On this issue, see J. Denis, S. Goeta, *Exploration, Extraction and Rawification. The Shaping of Transparency in the Back Rooms of Open Data*, After The Reveal. Open Questions on Closed Systems - Neil Postman Graduate Conference, New York, February 2014.
(6) P. De Filippi, L. Maurel, *The paradoxes of open data and how to get rid of it? Analysing the interplay between open data and sui-generis rights on databases*, in *International Journal of Law and Information Technology*, 23, 2015, pp. 1-22.

quence. In doing so, it will be demonstrated that Open Data might play a crucial role in generating trustworthy interactions between institutional authorities and citizens, going beyond the mere rhetoric of "data-driven economy," as strongly promoted by the European Commission with reference to Open Data.

The analysis will start from an overview on the regulatory trajectories leading to a strengthening of the preeminent role information plays in the food sector. This lens will help to sketch the genesis and the state-of-the-art on Open Data in the European food policy agenda, so as to prove that the massive cornucopia of data made available by ICT technology, and particularly by the ever-bigger Open Data, has been gradually - but radically - altering the relations among institutions, industry and the public.[7] Thanks to the opening up of knowledge possessed by the public sector, the consumer-citizen is becoming empowered in making better informed and personalized decisions, proactively oriented towards his personal interests and needs.

Taking this broad approach to answering our question will allow us, finally, to identify the reasons why institutions should encourage citizens to use Open Data in making food-related choices. This last analysis will be conducted by giving emphasis to the rich and versatile concept of trust, here understood as ‹‹the level of confidence with which an entity can entrust to another entity or entities specific services tailored for given contexts and quality››.[8] Two reasons support this choice.

Firstly, no doubt seems to exist that individuals need to feel confident towards activities carried out at institutional level[9] – even that relating to the food sector.[10] In the food sector, the ways in which knowledge, both traditional and innovative, is disseminated and shared among and with citizens are of utmost relevance and inestimable value. This is because being citizens in relation to foodstuffs means making food choices as if they were rights to protect, and through which to express oneself completely and entirely.[11] Secondly, it is true that ‹‹the passage from primarily direct and human-based relations to mostly digitalized interactions has even increased the need for trust, not only as to the technical aspects of security measures (e.g. protection of data on the web), but also as to normative issues of transparency, accountability, openness, accessibility, etc››.[12] In these terms, trust becomes a potential vehicle for building "powerful bridges" between complex digital systems and human beings.

All these reflections will lead us to argue, finally, that the use of Open Data in the food chain - regardless of the endorsement given primarily to its economic and commercial value - may open new routes between citizens and institution, by promoting and restoring trust "from farm to fork."

2.- The regulatory trajectories of food information

Food marketing is tightly related to the two fundamental interests citizens have in their relationship with the manufacturer: the interest in food safety aims at health protection and citizens' well-being; and the interest in the veracity of information received during the selection and purchase of products is

(7) B.S. Noveck, *Wiki Government: How technology can make government better, democracy stronger, and citizens more powerful,* Washington, Brookings Institution Press, 2009.

(8) I. Kounelis, G. Baldini, R. Neisse, G. Steri, M. Tallacchini, Â.G. Pereira, *Building trust in human-Internet of Things relationship*, in *IEEE Technology and Society Magazine*, 33 (4), 2014, p. 2.

(9) R. Gerald, A. Liberatore, *Democratising Expertise and Establishing Scientific Reference Systems, White Paper on Governance Work area 1, Broadening and enriching the public debate on European matters*, 2001.

(10) See E. Vos, *The EU Regulatory System on Food Safety: Between Trust and Safety*, in M. Everson, E. Vos (eds) *Uncertain Risks Regulated*, London, Routledge/Cavendish Publishing, 2009, pp. 249-267; E. Vos, Eu *Food Safety Regulation and Trust-enhancing Principles*, in W. Ellefson, L. Zach, D. Sullivan (eds), *Improving Import Food Safety*, Oxford, Wiley-Blackwell, 2012, pp. 111-133.

(11) See P. Sobbrio, *Diritto all'informazione, partecipazione democratica del consumatore e OGM*, in Agricoltura-Istituzioni-Mercati, 3, 2008, pp. 79-126; A. Germanò, *New Challenges for Agricultural Law. Innovating Food – Innovating the Law*, in F. Leonini, M. Tallacchini. M. Ferrari (eds), *Innovating Food, Innovating the Law. An interdisciplinary approach to the challenges in the agrifood sector*, Libellula, Tricase, 2014, pp. 31-46.

(12) E. Aguilar Moreno, M. Gemo, A. Rana, M. Tallacchini, *Open Data in Health: how knowledge may generate trust*, Draft booklet on the workshop held at JRC, Ispra (Italy), 18th November 2014, Luxembourg, Publications Office of the European Union, p. 3.

based on a relationship of trust between consumers and the food supplier.[13] In the first case, the citizen has the right to receive appropriate and safe food, in compliance with the correlated regulatory framework. As to the second profile, it is evident that the aspect of correct information assumes greater significance when food is the product to choose. In the global dimension technological innovation has given to the market, the selection of foodstuff embeds cultural, emotional and social meanings, which frame it in a symbolic and communicative sphere.[14]

When food safety breakdowns interested the European scene from the 90s', leading to a severe weakening of public confidence in the food industry, safety pressures arising from the marketplace led the European institutions to put in place an urgent policy intervention, bound to completely rethink and reshape their approach to food safety – and to food information as a consequence - so as to achieve the highest possible level of health protection.

Basically, the debut of the Community strategy for food safety coincided with the publication of the Green Paper on Food Law[15] in 1997, conceived as an instrument of political reflection through which to rethink the principles of food law, with the purpose of constructing a safety system capable of protecting consumers' health and environment, ex Articles 129, 129 A and 130 TEC.[16]

With specific regard to food information, the Green Paper focuses principally on food labelling and risk communication processes. Regarding the first point, the document suggests striking a balance between providing consumers with all useful and correct information and avoiding unnecessarily detailed provisions, by reinforcing the labelling rules to guarantee consumer information and fair trading. With reference to the second aspect, instead, reliable information about serious health risks arising from foodstuffs is required to be made available to the public as quickly as possible, whilst avoiding false alerts and alarmist messages. The interesting point for the issue we are discussing is when the Green Paper asks for major efforts in guaranteeing to European institutions and national authorities - as well as all interested parties, including consumers, both individuals and associations - access to information on the working procedures of the Committees and to their advice.

However, this reference remained an isolated signal, if we consider that the following White Paper on Food Safety[17] does not mention it, even though consumer information becomes the content of a specific chapter (7), being viewed as a legitimate factor relevant for protecting consumers' health and promoting fair practices in food trade. Consequently, the Commission undertook a dialogue with consumers to encourage their involvement in the new food safety policy. At the same time, information about emerging food safety concerns and the right to expect information on food quality and constituents are clearly recognised, so that informed choices can be made. All these guidelines and initiatives led, then, the way to a complete set of food regulations that, starting from the adoption of Regulation No 178/2002[18] (so called General Food Law) which established the new European Food Safety Authority (EFSA) - and going through

(13) For a broad overview on this matter, see L. Costato - F. Albisinni (eds.), *European and Global Food Law*, Padua, Cedam, 2^ ed., 2016.

(14) Not by chance in our multiethnic society, food requirements are becoming more and more diversified. Reasons can be related to religious feelings, to the sensitivity to environmental problems, or animal welfare, as well as to ethical values. Such consumers' needs, together with the increasing number of selection criteria, have made information a powerful element in the relationship between business and the citizen. Knowledge of raw materials used, techniques and methods of production plays a vital role in guaranteeing an informed choice in the food market.

(15) Commission of the European Communities, *The General Principles of Food Law in the European Union, Commission Green Paper,* COM(97) 176 final, Brussels, 1997.

(16) Ibidem, p. 11.

(17) Commission of the European Communities, *White Paper on Food Safety*, COM (1999) 719 final, 2000, Brussels.

(18) 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. For an insightful analysis of Regulation, see IDAIC (a cura di), *Commentario al Reg. (CE) N. 178/2002. La sicurezza alimentare nell'Unione europea*, in *Le nuove leggi civili commentate*, 1-2, 2003, p. 114 ss.

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several modifications of legislation on food information[19] (until the adoption of Regulation No 1169/2011[20]) - took into full account many of the aspects and problems correlated to the information exchanged in the food chain.
In particular, if articles 9 and 10 of Reg. 178/2002 prescribe specific communication and civic participation mechanisms in food regulation, so as to configure a right of the citizen-consumer to be openly informed and consulted about the choices taken in the matter, Reg. 1169/2011 deals with the establishment of the general principles, requirements and responsibilities about food information (in particular, that given through labelling), with the purpose of guaranteeing the right of consumers to information and procedures for the provision of food information (Article 2).
The normative framework thus conceived undoubtedly takes a step towards a two-way communication between consumers and public bodies. At the same time, though, it poses some general questions, three of which prove to be significant for the aim of the analysis we are conducting: how can the described food legislation be related to the use of ICT and, particularly, of Open Data? Are these general rules on access to food information in line with the idea at the core of Open Data? What are the "grey zones" of this legislation?
The next section will restrict its analysis to the above-mentioned questions, in order to keep the discussion focused.

3.- The reuse of information in the European Union: a legal focus

Promoters of ICT attribute to digital devices diverse and several benefits, ranging from the enhancement of society to encouraging and supporting more active and interactive forms of public life. In this flourishing realm of computing and information sharing, access to information came slowly to be recognised as human right to be upheld as ‹‹essential element of the […] right to freedom of expression››.[21] This new vision has expanded so conspicuously to entail legal changes worldwide, and the conceptual policy of Open Data is broadly consistent with this perspective of viewing the right to know ‹‹as an essential part of democracy››.[22]
The crucial issues surrounding the new concept of Open Data are, in fact, mostly underpinned with the idea of making certain data freely accessible and machine-reusable; of contributing valuable information about the world; of empowering citizens to make use of those data to comment, derive value, and take action in their own communities; of enabling each government, and, by and large, society, to function more efficiently.[23]
However, from a normative stance, a legal definition

(19) It found its first important regulation in Directive 79/112 (Council Directive of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer) whose horizontal nature reflects how the Community has proceeded with the creation of a common market, trying to overcome the different national mandatory rules, which could be an obstacle to the free circulation of foodstuffs. Directive lays down several rules on the labelling, presentation and advertising of foodstuffs, in order to inform and protect the consumer.
(20) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. See F. Albisinni, *The new EU Regulation on the provision of food information to consumers*, in *q. Riv.*, www.rivistadirittoalimentare.it, 2-2011, pp. 1-11; A. Iannarelli, *La fornitura di informazioni sugli alimenti ai consumatori nel nuovo Reg. n. 1169/2011 tra l'onnicomprensività dell'approccio e l'articolazione delle tecniche performative,* in *Riv.dir.agr.*, 1, 2012, pp. 38-46; A. Di Lauro, *Nuove regole per le informazioni sui prodotti alimentari e nuovi analfabetismi. La costruzione di una "responsabilità del consumatore,"* in *q. Riv.*, www.rivistadirittoalimentare.it, 2-2012, pp. 1-27; S. Bolognini, *Linee-guida della nuova normativa europea relativa alla fornitura di informazioni sugli alimenti ai consumatori*, in *Le nuove leggi civili commentate*, 4, 2012, pp. 613-678; A. Germanò, E. Rook Basile, *Manuale di diritto agrario comunitario*, III ed., Torino, 2014, p. 381.
(21) European Court of Human Rights, *Kenedi v. Hungary*, May 26, 2009, http://cmiskp.echr.coe.int/tkp197/search.asp?skin=hudoc-en.
(22) K. Janssen, *Open Government Data: right to information 2.0 or its rollback version?*, ICRI Working Paper 8, 2012, http://ssrn.com/abstract=2152566.
(23) T. Berners-Lee, *Putting Government Data Online*, 2009, http://www.w3.org/DesignIssues/GovData; T. Davies, *Open Data, Democracy and Public Sector Reform. A look at Open Government Data Use from data.gov.uk*, UK, Open Data Institute, 2010.

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explaining what essentially the term refers to has not been provided yet. In the open definition given in 2005 by Open Knowledge Foundation (OKF), a ‹‹worldwide non-profit network of people passionate about openness››,[24] Open Data is described as ‹‹data that can be freely used, re-used and redistributed by anyone - subject only, at most, to the requirement to attribute and sharealike››.[25] This explanation of what actually constitutes Open Data has, then, been enriched several times in the following years by experts and practitioners of the field. In 2014 Open Knowledge and the Open Definition Advisory Council released a new list of the essential principles defining “openness” in relation to data and content.[26] Briefly speaking, the key features of openness have been indentified with the concepts of availability, access, reuse, redistribution and universal participation, in which the idea at the heart of the doctrine of eDemocracy emerges, i.e. rethinking and reshaping dynamics and interactions between public bodies and citizens, to effectively involve the citizenry in decision-making processes, besides keeping a constant and open dialogue among administrative authorities, stakeholders and the public.[27] Even though the use of ICT to support public engagement in the institutions’ activity is still an in *fieri* field to be explored, it has been strongly attracting in recent years the interest of national governments,[28] non-profit organisations[29] and local communities.[30]

In the European Union, after the UK government launched the first web portal (www.data.gov.uk) to release information to the public, an EU internet portal aggregating national portals was developed with the purpose of creating an EU flagship initiative allowing governments, companies and citizens to easily find, understand, and re-use data created and maintained by the European institutions and Member States.[31] The core feature of the EU Open Data Portal[32] is a metadata repository providing a multi-lingual access to data published by public administrations in Member States. In November

(24) https://okfn.org/about/.
(25) http://opendatahandbook.org/guide/en/what-is-open-data/.
(26) See https://okfn.org/press/releases/open-definition-2-0-published-by-open-knowledge/.
(27) Indeed e-democracy, in its broadest mean, includes several and peculiar aspects: access to information (particularly with regard to that produced by the public, with the aim of achieving greater transparency in political decision making and give citizens the possibility to control institutions’ work); dialogue between citizens and institutions, in order to generate knowledge production; attention to the voting process (with reference to electoral lists, technical modalities of the vote or criteria for voting); the possible forms of bottom-up public engagement (C. Rabbito, *Il ruolo degli strumenti di e-participation nel processo di e-government. Il coinvolgimento dei cittadini nel policy making*, in *Informatica e diritto*, 2008, p. 441).
(28) The first 100 days of the Obama Administration, for example, showed a significant commitment aiming to entering a new era of so-called Open Government. By considering the deep role transparency might play in governmental actions, the presidency took several steps to give transparency a central role into the new reform strategy. Yet the first (then) President Obama’s action consisted in signing three presidential memos, two of which dealing with the idea of open government. If in the first one the values of transparency, participation, and collaboration are asked to be implemented by an “Open Government Directive” across executive agencies and departments, the second memo called for a new FOIA policy in order to base public authorities’ activity on the principles of openness and information disclosure. In this innovative framework, technology has been viewed as one of the most powerful tool through which opening up the government to the citizenry. By launching in 2009 the Open Government Initiative project, the Obama Administration started to pursue a path rooted in a digital culture, operating under the principles of sharing and accessibility. Technology-enabled citizen participation, thus, became a desired goal to create a new level of transparency and accountability in the American society (United States, Executive Office of the President, Office of Management and Budget, *Open Government Directive*, 2009, http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-06.pdf; United States, The White House, *Memorandum for the Heads of Executive Departments and Agencies: Transparency and Open Government*, 2009, http://www. whitehouse.gov/the_press_office/TransparencyandOpenGovernment/). See on this issue, C. Coglianese, *The Transparency President? The Obama Administration and Open Government*, in *Governance*, 22 (4), 2009, pp. 529-544; D. Robinson, H. Yu, W.P. Zeller, E.W. Felten, *Government Data and the Invisible Hand*, in *Yale JL & Tech*, 160, 2009, pp. 160-175.
(29) See, for example, the activities carried out by the Sunlight Foundation, a national, non partisan, non profit organization that uses the tools of civic tech, open data, policy analysis and journalism to make governments and politics more accountable and transparent, as well as to enable more complete, equitable and effective democratic participation, at http://sunlightfoundation.com/about/.
(30) For example, http://dadesobertes.gencat.cat, and http://dati.piemonte.it.
(31) See N. Shadbolt, *Towards a Pan EU Data portal–data.gov.eu*, 2010, http://ec.europa.eu/digital-agenda/en/open-data-portals.
(32) https://open-data.europa.eu/en/data/.

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2015, the European Commission also started funding a pan-European digital service infrastructure for Open Data, the European Data Portal.[33] Its principal objective is to create a single point of access in all 24 EU official languages for data published by public administrations at all levels of government in Europe.

Surfing on "http://www.europeandataportal.eu/en" it is possible to browse the available datasets by subject. By clicking on the "Agriculture, fisheries, forestry and foods" section, the portal shows 712 datasets[34] pertaining to the topic. With specific reference to the food sector, the data shown are related to the most different fields, spanning from food contact materials to novel food, from food additives to health claims. An example is represented by the Rapid Alert System for Food and Feed (RASFF)[35] window, which gives public access to the data on the most recently transmitted RASFF notifications, as well as search for information on any notification issued in the past. In this way constant information for institutional bodies and citizens can be assured, as well as transparency in the procedures and, consequently, control and safety.

Nonetheless, achieving these goals requires solving some difficult problems of both technical and legal nature. The former are related to the format of the data made available. The European Data Portal represents metadata references in a common format (DCAT application profile for data portals in Europe[36]) using RDF technology. However, though the DCAT has been implemented as the common vocabulary for harmonizing descriptions of the harvested datasets, its language and use are actually not easily understandable. If, on the one hand, the web tools made available by the Commission are surely remarkable and very helpful to users, on the other the challenges they pose (in terms of usability and accessibility - the reference is also to the so-called digital divide) cannot be underestimated. How can Open Data comply with the pivotal requirements food information has to have if citizens often lack the necessary background knowledge to interpret and use it? May Open Data actually assure that ‹‹food information shall not be misleading››[37], but ‹‹shall be accurate, clear and easy to understand for the consumer››?[38]

All these reflections clearly call for a balance between different interests, as well as requesting that law and technology be merged and intertwined, in order to create new forms of ICT- and food-related knowledge production.

As regards the legal stance, the main issue arising is concerned with the existing gap between legislation and Open Data. Directive 2003/98 on the re-use of Public Sector Information[39] (hereafter PSI Directive), regulates non-discrimination, charging, exclusive arrangements, transparency, licensing and practical tools to make it easy to find and re-use public documents. Inasmuch as the objective of PSI Directive is to achieve, through minimum harmonization of national rules and practices, the full potential of re-using data produced by or for the public sector, and given also that Open Data involves making data available online in universally accessible formats for any re-use without restrictions or licensing fees, this prompts the conclusion that the PSI Directive is a key instrument for all Open Data policies recently launched in Europe.

However, as shown by the European Thematic Network on Legal Aspects of Public Sector Information, ‹‹the adoption of Open Data is not what

(33) http://www.europeandataportal.eu/.
(34) Last access: 7 June 2017.
(35) As set forth by Chapter IV of Reg. No 178/2002, in Europe the "surveillance procedure" has been thought and constructed as a rapid alert mechanism (RASFF) for the notification of a direct or indirect risk to human health deriving from food or feed. That is, a sort of network involving the Member States, the Commission and EFSA, and designed on the basis of - and in accordance with - the principles of transparency, openness, participation, accountability, effectiveness and coherence. On this issue, see European Commission, *RASFF-The Rapid Alert System for Food and Feed-2015 annual report*, Luxembourg, Publications Office of the European Union, 2016.
(36) See https://joinup.ec.europa.eu/asset/dcat_application_profile/description.
(37) Article 7.1 of Reg. No 1169/2011.
(38) Article 7.2 of Reg. No 1169/2011.
(39) Directive 2003/98/EC of the European Parliament and of the Council of 17 November 2003 on the re-use of public sector information.

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PSI Directive prescribes››.[40] This is due to several reasons, such as the fact that the legal act focuses merely on the economic aspects of the re-use of information, rather than on the access of citizens to information. A second motive is related with the consideration that if the re-use is to be data protection compliant (as recognized by PSI Directive), the possibility of imposing use restrictions and conditions becomes necessarily important. Third, it has to be noted that if the re-use of government information is naturally based on the access to information, PSI Directive does not oblige Member States to provide access, presumably due to the limited legislative competences of the EU to regulate access to public sector information held by authorities in Member States.

The examination of these - and further[41] - legal problems pertaining to the aforementioned issues surely calls for a deeper and technical analysis that, however, goes beyond the purpose of this contribution. By sketching a brief picture on the matter, the intention was solely to outline that a gap still exists and needs to be addressed and overcome,[42] with the aim of reaching appropriate protection of the interests at stake. For sure, the recent Directive 2013/37,[43] adopted because of the advent of new services and applications made possible nowadays by technological innovation, tends to follow this direction. The provision obliging Member States to allow re-use of "documents" that are already publicly accessible under national rules for access to documents (Article 1.3), notably represents a big step forward to helping public sector information to be discoverable and usable.

Nevertheless, one drawback persists and cannot be underestimated. Yet the regulatory framework and non legislative measures in force at European level seem currently more focused on taking into account the economic dimension of the re-use of data, rather than giving social value potentially deriving from Open Data the legitimate attention it deserves. This consideration leads one to consider that the societal dynamics surrounding Open Data – even in its application to the food chain - be adequately supported by precise and well defined rules, able to legally structure and support the technical architecture of this innovative ICT-based model.

4.- Opening up food-related data: the role played by EFSA

In the General Food Law, references to access to food information are made by articles 40, 41 and 52, where a wide access is prescribed both to the documents possessed by EFSA, and to information relating to any potential risk to human health posed by food and feed available in the market. In both cases, the provisions claim the necessity to fully account the general principles and conditions governing the right of access to the Community institutions' documents. Despite not having been framed with regard to ICT, these provisions mirror the idea at the heart of the paradigm of Open Data, namely building bridges with the private sector and the public, by providing access to data, while creating fertile grounds for more structured processes of communication and information sharing.

However, with reference to the activity carried out by EFSA, the main issue arising from the use of Open Data is mostly linked to EFSA being an independent scientific source of advice, information and risk communication. Whether, in fact, Open Data could allow the Authority to ‹‹be an organisation

(40) LAPSI 2.0, *Position paper access to data*, LAPSI 2.0 Thematic Network D2.2, 2014, http://www.lapsi-project.eu/sites/lapsi-project.eu/files/LAPSI_D2%202.pdf, p. 13.

(41) Position papers and policy recommendations relating to PSI and Open Data produced by LAPSI 2.0 are available at http://www.lapsi-project.eu/lapsi-20. See also, A. Cerrillo-i-Martinez, *The Reuse of Public Sector Information in Europe and Its Impact on Transparency*, in *European Law Journal*, 18 (6), 2012, pp. 770-792; B. Ponti, *Open Data and Transparency: A Paradigm Shift*, in *Informatica e diritto*, 1-2, 2011, pp. 305-320.

(42) For a legal exploration of the relationship between Open Data and PSI re-use, see K. Janssen, S. Hugelier, *Open data as the standard for Europe? A critical analysis of the European Commission's proposal to amend the PSI Directive*, in *European Journal of Law and Technology*, 4 (3), 2013, pp. 1-12.

(43) Directive 2013/37/EU of the European Parliament and of the Council of 26 June 2013 amending Directive 2003/98/EC on the re-use of public sector information.

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open to contacts with consumers and other interested groups›› (Recital 56 of Reg. 178/2002), ‹‹able to communicate autonomously in the fields falling within its competence›› (Recital 54), ‹‹with a high level of transparency›› (Article 38.1), so as to ‹‹enable Member States to become more closely involved in scientific procedures›› (Recital 51), many problems might arise from publishing commercially sensitive data (formula, production methods, etc.), such as that possessed by EFSA. Since the vast majority of EFSA's data is owned by third parties, the use and access rights of the Authority regarding its data are governed by statutory and contractual obligations, while public release of data rests on the balance between public health protection and private commercial interests connected to data usage and data disclosure.[44]

For these reasons, the release of information available to EFSA is regulated by the requirement of transparency, by the principle of access to documents and by confidentiality rules bound to protect company know-how.[45]

Moreover, both PSI Directive and Commission decision 2006/291/EC[46] establishing a principle of re-use of the information available to public sector bodies do not apply to EFSA directly, though – as scholarly work pointed out – both these instruments set out a regulation that ‹‹would be coherent for the Authority to follow››.[47]

Along this line of reasoning, in 2014, for the first time, the Authority mentioned Open Data as the "policy" it should adopt, with the aim of becoming an Open Science organization, driven by the values of openness and transparency.[48] In promoting this willingness to open itself to the citizenry, by democratizing science and triggering innovation, EFSA is developing the Knowledge Junction, ‹‹an open repository for the exchange of evidence and supporting materials used in food and feed safety risk assessments››.[49] With the aim of improving transparency, reproducibility and evidence reuse, the platform's content (including reports, datasets, images, videos, laboratory outputs, software, etc.) has been catalogued to be used by EFSA's panels and working groups and any third parties when preparing for new risk assessments.

Additionally, a Data Warehouse (DWH) has been set up to publish and distribute EFSA's collected data[50] - spanning from foodborne outbreaks to chemical contaminants, from antimicrobial resistance to food consumption – so as to facilitate data analysis and data extraction, as well as harmonisation and comparisons among different type of information. In accordance with the EU Recommendation on access to and preservation of scientific information[51] and the digital agenda for Europe,[52] the Authority

(44) A deep analysis of the issue of data access and use rights in EFSA has been made by A. Kocharov, *Data Ownership and Access Rights in the European Food Safety Authority*, in *EFFL review*, 5, 2009, pp. 335-346.

(45) See EFSA, *Decision concerning access to documents*, 2003a, https://www.efsa.europa.eu/sites/default/files/assets/docsaccess.pdf; EFSA, *EFSA Code of Good Administrative Behaviour*, 2003b, https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/admincode.pdf; EFSA, *Openness, Transparency and Confidentiality*, 2003c, https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/transparencyprinciples.pdf; EFSA, *Decision of the Management Board of the EFSA concerning implementing measures of transparency and confidentiality requirements*, 2005, https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/transparencyimplementation.pdf.

(46) Commission decision of 7 April 2006 on the re-use of Commission information.

(47) A. Kocharov, *Data Ownership and Access Rights in the European Food Safety Authority*, cit., p. 345.

(48) EFSA, *Discussion Paper. Transformation to an "Open EFSA"*, 2014, http://www.efsa.europa.eu/it/corporate/doc/openefsadiscussionpaper14.pdf. This initiative has had the EU Consumer Organisation BEUC's approval, which pointed out the relevance for the Agency to guarantee more open and systematic data sharing, in order to both increase consumers' trust in EFSA work and enhance scientific scrutiny, while improving transparency and gaining legitimacy (BEUC Bureau Européen des Unions de Consommateurs, *EFSA Strategy 2020 - BEUC response to the public consultation*, 2015, p. 4, http://www.beuc.eu/publications/beuc-x-2015-117_ipa_efsa_strategy_2020_-_beuc_response_to_the_public_consultation.pdf).

(49) https://zenodo.org/communities/efsa-kj?page=1&size=20.

(50) EFSA's data collection activities – required by EU legislation (such as Directive 2003/99/EC and Regulation (EC) No 396/2005) or based on specific needs – are described in detail by EFSA, *EFSA Report on Data Collection: Future Directions*, in *EFSA Journal*, 8 (5), 2010.

(51) European Commission, *Commission Recommendation of 17.7.2012 on access to and preservation of scientific information*, C(2012) 4890 final, Brussels, 2012.

(52) Available online at http://ec.europa.eu/digital-agenda/.

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has released a technical report[53] on access to data in the DWH, in order to provide general rules for accessing data via the DWH and the persons and stakeholders who will have access to it.

In respect to these rules, two reflections appear worthy to be highlighted, pertaining to ownership of data, access to and use of the data retrieved from the DWH. With regard to aggregated data rendered public in accordance with the current EFSA DWH rules, the users accessing available datasets have to respect any applicable proprietary rule, including copyright. As regards EFSA, it is accountable for administering in the DWH the data collections, on the base of the principles of loyalty, due care and diligence, despite the ownership of most of the data collections lies with the data provider or with the third party mandating the data provider. This is the reason why, for instance, EFSA has refused so far to disclose the data supporting its scientific opinions, in spite of the several requests made for years by the not-for-profit foundation Corporate Europe Observatory (CEO),[54] with the aim of making EFSA's work available and transparent, while enabling scientific scrutiny of it.

The second relevant issue concerns the "boundaries" that DWH rules have set for both accessing and using the stored data. The different and restricted rules provided for each group of stakeholders[55] might, in fact, obstruct the full achievement of the objective 2 of EFSA's 2020 Science Strategy,[56] aimed at widening EFSA's evidence base and optimising access to its data. Certainly, some reasons find their roots in the difficulty of creating an Information Technology infrastructure that allows the assembling, exploring and sharing of datasets among an undefined number of users, so as to better support a focus on both quantity and quality of data. If, in fact, several data are expected to be available through web reporting tools via maps, tables, dashboards and graphs, some of them are static, namely not changeable by the user,i so that they do not allow the user to see the information retrieved in different ways. In this way, from a legal point of view, the "positive side" of freedom of information – that is, drawing upon ICT means and devices to take advantage of their full power of knowledge[57] – seems still far to be completely guaranteed.

Besides, in the process of opening up public data, identification, extraction and "rawification" of data are by no means mechanical operations, and they originate from several meetings, which imply crucial discussions pertaining to various and often relevant issues.[58] As recognised by EFSA itself, ‹‹the DWH may contain commercially sensitive raw data or data protected by intellectual property rights›› (i.e., chemical contaminant data originating from private

(53) EFSA, *The EFSA Data Warehouse access rules*, 2015, pp. 1-18, http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/768e.pdf.

(54) The last case concerned the request by CEO of disclosing all the possible original elements of three key scientific studies used by EFSA in assessing glyphosate. After refusing the request, because of the possible infringement of trade secrets and intellectual property rights related to the studies' owners (i.e., all industry producers of glyphosate), the Agency finally agreed to release the raw data used in the EU safety evaluation of glyphosate, as part of its commitment to open risk assessment. Nonetheless, as stressed by CEO itself, the possibility for scientific community to scrutiny EFSA's work seems still difficult to be realized. This is because, first, the documents reached CEO are scans, so that it is impossible to machine-search them, or import the data in any other software; and, second, because large sections of the data have been redacted, due to legal concerns. CEO has thus asked the EU for a solution to urgently stop relying on secret evidence for such sort of decisions (CEO, *Scientific scrutiny* on EFSA's *work, at last?*, 14 December 2016, https://corporateeurope.org/efsa/2016/12/scientific-scrutiny-efsa-work-last).

(55) The groups are the following: EFSA; members of EFSA's Scientific Committee and Scientific Panels and their Working Groups; data providers; the EFSA DWH stakeholder groups, including the general public.

(56) ‹‹EFSA aims to enhance the quality of its outputs by giving direct access to data and promoting the development of collaborative platforms in Europe and internationally, as well as fostering data re-use and innovation. EFSA will be an advocate for openness by working with data providers and organisations funding research to adopt open data concepts and standards; gaining better access to, and making better use of, data from a wider evidence base that, where possible, follow international quality standards. EFSA recognises that its efforts to make data more accessible will have to take account of data ownership, confidentiality and security issues›› (EFSA, *EFSA Strategy 2020 Trusted science for safe food Protecting consumers' health with independent scientific advice on the food chain*, 2016, p. 16, http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/strategy2020.pdf).

(57) V. Frosini, *L'orizzonte giuridico dell'Internet, in Il diritto dell'informazione e dell'informatica*, 2, 2002, p. 275.

(58) On this issue, see J. Denis, S. Goeta, *Exploration, Extraction and Rawification. The Shaping of Transparency in the Back Rooms of Open Data*, After The Reveal. Open Questions on Closed Systems - Neil Postman Graduate Conference, New York, February 2014.

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enterprises and food consumption data collection), as well as ‹‹data from which individuals may be directly identifiable in the sense of Article 2(a) of Reg. 45/2001 on personal data protection[59] applicable to EFSA››.[60]
This can explain the concerns food companies have expressed about the initiative taken by the Authority for the promotion of a new EFSA Data Access Policy; concerns that, however, the Authority seems to take into consideration, having explicitly stressed the need that the DWH be supported by a clear policy on access to the stored data,[61] and that the DWH access rules may be revised if necessary.[62]
Moreover, with reference to the need to overcome the main problems may obstruct the full implementation of Open Data in its activities, the Authority has already developed a standardised food classification system, which describes an array of individual food items, aggregated into food groups and broader food categories in a hierarchical parent-child relationship.
Furthermore, the Agency is currently committed to both ‹‹set up and implement a comprehensive and integrated information architecture framework for centralised information access management, enabling data interoperability››, and build data exchange/openness networking groups, together with innovative approaches to exploit all available sources of information.[63]
The last example of this EFSA's long-term strategy is represented by OpenFoodTox, an open source data for substance characterisation, links to the relevant Authority output, background regulations and summaries of critical toxicological endpoints, meant as instrumental support for the work of EFSA experts and staff in providing scientific advice,[64] and in disseminating information for scientific advisory bodies and stakeholders with an interest in chemical risk assessment. The new toxicological database has been also made available in a readily accessible format on the OECD's Global Portal[65] (eChemPortal) to stimulate further analysis of the data by the wider scientific community, thus generating new knowledge in the area of chemical risk assessment. In this way, the potential value linked to Open Data appears to prevail on perplexity and uncertainties surrounding it, with the view of a scientific community that is more open and inclusive.

5.- Beyond labelling

Article 12 of Reg. 1169/2011 on food information states that mandatory food information shall be available and easily accessible for all foods. In such context, surely labelling represents the most useful means through which to give food information. However, even though Reg. 1169/2011 addresses some of the most debated issues regarding labelling, so as to improve the related discipline, it concerns not only labelling, but more generally food information made available by any means, including modern technology tools (see Article 2 2, lett. a). Yet the advent of new media has led the European legislator to create a comprehensive and evolutionary approach to food information, which led to adopting rules aimed at ‹‹covering information provided also by other means than the label›› (Recital 14). This was made regardless of the ways adopted to give food information.
It is true, in fact, that an overload of information provided on the label, for example, could negatively affect the adequacy of the information itself.

(59) Regulation (EC) No 45/2001 of the European Parliament and the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.
(60) EFSA, *The EFSA Data Warehouse access rules*, cit., p. 14.
(61) Ibidem, p. 5.
(62) Ibidem, p. 1.
(63) EFSA, *EFSA Strategy 2020 Trusted science for safe food Protecting consumers' health with independent scientific advice on the food chain*, cit., p. 23.
(64) J.L. Dorne et al., *Editorial: OpenFoodTox: EFSA's open source toxicological database on chemical hazards in food and feed*, in *EFSA Journal*, 15 (1), 2017.
(65) http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en.

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Shortage of time, lack of technical skills and linguistic diversity often prevent the consumer from transforming information into real knowledge.[66] Transparency in communication of true information goes beyond the mere verification of the data reported on label.[67] Moreover, it is even more necessary that communication be effective in terms of quality. This consideration is supported by bearing in mind that Reg. 1169/2011 prescribes ‹‹sufficient flexibility to be able to keep up to date with new information requirements of consumers›› (Recital 16 and Article 1.2), both by empowering ‹‹the Commission to enable certain particulars to be made available through alternative means›› (Recital 23), and by adapting food information rules to a rapidly changing social, economic and technological environment (Recital 51). Could Open Data be a valid tool to achieve these goals?

A brief analysis of the innovative activities currently undertaken by the European Food Information Resource (EuroFIR AISBL[68]) and by Open Food Facts[69] can help us answering this question. EuroFIR is an international non profit association, whose purpose is to develop, publish and exploit food composition information, as well as to promote international cooperation and harmonisation of standards to improve data quality, storage and access. Open Food Facts is a non-profit association of volunteers that contributes to update a collaborative and free database of food products usable by anyone. Driven by the “Food knowledge is power to eat better” manifesto, the database is Open Data that, published under the Open Database Licence, can be reused in both non-commercial and commercial projects.

Both the associations, by providing food information through online tools (from databases to recipe calculators for creating food composition data) offering up-to-date and scientifically validated food information, are gradually blurring the line between experts and lay people,[70] while enhancing the awareness and understanding of the value of food composition data – for both research and commercial purposes – and its relevance for consumers in making healthier dietary choices. As a result, these activities – so as the plenty of further initiatives that could not be examined here[71] – represent relatively well-developed and successful forms of citizens-led and technology-based projects, reflecting the tendency towards ‹‹democratization of innovation››.[72] Indeed, ‹‹unrelated and even isolated citizens from different places are quickly learning how to empower themselves to become aware of, and exert, their rights by transforming knowledge and technology into civil and community life››.[73]

Certainly, the databases and web tools created and made available by the above mentioned associations are still far away from unleashing open data’s

(66) S. Bolognini, *Linee-guida della nuova normativa europea relativa alla fornitura di informazioni sugli alimenti ai consumatori*, cit., p. 675.

(67) A. Di Lauro, *Nuove regole per le informazioni sui prodotti alimentari e nuovi analfabetismi. La costruzione di una “responsabilità del consumatore*, in *q. Riv*., www.rivistadirittoalimentare.it, 2-2012, p. 4.

(68) http://www.eurofir.org/?page_id=3.

(69) http://openfoodfacts.org/.

(70) Emblematic, in this sense, is the sentence ‹‹You don't need a PhD to take part in citizen science!›› figuring on the Open Food Facts web site.

(71) In Helsinki, for instance, the National Institute for Health and Welfare has set up the food composition database Fineli Welfare, containing data on over 4000 foods and their nutrient values, with the purpose of improving software developers' possibilities to create health applications (i.e. for tracking health) specifically designed for consumers (see https://www.thl.fi/fi/web/thlfi-en/statistics/statistical-databases/open-data/thl-s-open-data-and-the-challenges). In Switzerland, Opendata.ch has launched the Business Innovation food.opendata.ch programme, with the goal of building an open and public database on food and nutrition data. The programme, funded also by the Swiss food industry, aims to both gather open data that can be re-used in applications or services and scientifically accompany the public exploitation of data in entrepreneurial projects (see https://food.opendata.ch/). In the UK, Nesta is an innovation charity that has organised, with the Open Data Institute, an open data challenge on the theme of Food, in order to encourage teams to use available open data to develop products and services to support people to make better choices with their food (see http://www.nesta.org.uk/food-open-data-challenge#sthash.g3zj1Jqw.dpuf).

(72) C. Von Hippel, *Democratizatizing innovation*, Cambridge, MA, The MIT Press, 2005.

(73) M. Tallacchini, P. Boucher, S. Nascimento, *Emerging ICT for Citizens’ Veillance. Theoretical and Practical insights,* JRC Science and Policy Reports, Luxembourg, Publications Office of the European Union, 2014, p. 18.

full potential.[74] This is due not only to the mismatch existing between the open access quality of data and the skills to adequately analyse it to provide real insights,[75] but also - as "the terms of use" state – to: first, the lack of guarantees on the accuracy of the information and data present on the sites and in the databases; second, the possible errors related to, for instance, manual input of data or data processing; third, the completeness and comprehensiveness of the provided information, as well as its conformity to any particular use and its compatibility with any third-party services. These problems may pose not a few challenges in how to best extract value from the "Open Data ecosystem." This is why further changes and improvements have been advocated[76] with regard to both harmonisation (in terms of extending data exchange format) and standardisation (in terms of developing a EU easily understandable and applicable standard for food composition data) of the on-going work on opening up food-related data in Europe.

In this ever-changing and ever-evolving scenario, the recent (2017) Digital Single Market (DSM) strategy[77] launched by the Commission has announced a dialogue with stakeholders for a possible future EU framework for data access, in order to improve, facilitate and incentivise data sharing across countries. In particular, any Member State action affecting data storage or processing has been asked to be guided by a "principle of free movement of data within the EU," thus realising the full potential of the European data economy.

Moreover, in relation to the issue of data generated by the public sector, access and reuse of Open Data have been addressed by the new European Interoperability Framework,[78] that focuses on data exchange between public sector bodies, through the inclusion of specific recommendations covering aspects such as the use of machine readable, non-proprietary formats, the use of meta-data, quality and licensing.

In this context, the so-called legal interoperability, that is ‹‹about ensuring that organisations operating under different legal frameworks, policies and strategies are able to work together››,[79] is understood by the Commission as an essential element to be guaranteed, together with the promotion and standardization of legal regimes facilitating the reuse of data (such as licences).[80]

So that, for the Open Data community to foster meaningful dialogue between citizens and civil society, the technical and legal issues inherent to data infrastructures[81] call for normative and social changes to be stated and framed as a matter of democracy and participation, able to face power asymmetry within the food chain. Indeed data protection and data stewardship can be considered as social construct, and as such subject to continuous

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([74]) See the Overseas Development Studies report for examples of the challenges at https://www.odi.org/events/4201-data-revolution-finding-missing-millions.

([75]) To this regard, Nigel Shadbolt, chair and co-founder of the Open Data Institute, has affirmed: ‹‹Too much of our data infrastructure is currently unreliable, inaccessible or only available for those who can pay. Innovators struggle to get hold of data they need, while many citizens do not feel empowered to access and use data. We must improve data skills throughout society, so policymakers, businesses and citizens can interpret and use it well›› (https://www.theguardian.com/media-network/2017/jan/06/2017-open-data-initiatives-transparency).

([76]) See http://www.eurofir.org/food-information/quality-and-standards/harmonisation-and-standardisation/.

([77]) European Commission, *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. 'Building a European Data Economy'*, COM(2017) 9 final, Brussels, 2017a.

([78]) European Commission, *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee of the Regions. European Interoperability Framework - Implementation Strategy,* COM(2017) 134 final, Brussels, 2017b.

([79]) European Commission, *Annex to Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee of the Regions - European Interoperability Framework - Implementation Strategy,* COM(2017) 134 final, Brussels, 2017c, 23.

([80]) Ibidem, p. 34.

([81]) A data infrastructure consists of data assets and the technology to store, share and use them; the organisations that operate and maintain them; the processes by which they are maintained; and guides describing how to use and manage the data (https://theodi.org/what-is-data-infrastructure).

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change.[82] As a consequence, Open Data easily appears to be listed among the means laid down by Reg. 1169/2011 ‹‹to guarantee the right of consumers to information›› (Article 1.2) - though the role played by food industries in the sharing of knowledge advocated by Open Data remains still widely marginal,[83] owing to the intricate issues related to both data ownership and market speculations. However, given that the Open Data's outstanding feature consists in its capacity to create a digital network, in which consumers can operate and take informed decisions as active citizens, what is at the stake is the need for food companies to strongly contribute with institutions to facilitate the transfer of information. Yet access to corporate data is being fervently promoted and supported as the next frontier in the development of Open Data[84] by the United Nations Global Pulse,[85] a flagship initiative encouraging for- and non-profit sectors to "donate" and exchange their own data, by anonymising their datasets and providing that data to create novel insights of digital knowledge. Although it is not yet clear what the main features of this new form of data sharing are, and what rules and standards it must comply to, research activities are gradually proving the potential lying behind the plethora of digital data currently held by industry.

As regards the food domain, a noteworthy step in this direction has been taken by FoodTrade, a social enterprise bringing together more than 1600 businesses (to date) and consumers, with the aim of mapping the food supply chain system to help people buy and sell fresh produce, so as to contribute to the creation of a fair, sustainable and local food system.

Through the creation of FoodTrade Menu, an automatic allergen labeller that uses Open Data from the Food Standards Agency, the organisation compiles information from food producers, growers and government to produce tailored menus with flagged dishes and recipes including information needed for a consumer to make an informed choice. In this way, by both providing information about food allergens in food products and enabling food businesses to connect to suppliers that match their ingredient list, the smart menu management tool helps businesses respond to the requirements of Reg. 1169/2011.[86]

What emerges from these experimental forms of connectivity mediated by the web it is that industry has been gradually commencing to focus also on contributing to knowledge production, by upholding access to information and data exchange to add value to its community and nurture fertile ground for future innovation. Whether, on one hand, embracing this viewpoint surely opens several challenges to face for small, medium and multinational commercial entities, it is true, on the other hand, that a democratic rethinking of data ownership[87] might constitute a powerful way for food players to benefit

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([82]) L. Moerel, *Big Data Protection. How to Make the Draft EU Regulation on Data Protection Future Proof*, Tilburg, Tilburg University, 2014, p. 36.

([83]) According to a research conducted by Deloitte on the distribution of data-sharing models, only 2% of companies studied make corporate data available for re-use in a more or less open manner (Deloitte, *Impact assessment support study on emerging issues of data ownership, interoperability, (re)usability and access to data and liability*, First Interim Report, cited in European Commission, *Commission Staff Working Document on the free flow of data and emerging issues of the European data economy accompanying the document Communication Building a European Data Economy*, SWD(2017) 2 final, Brussels, 2017d, p. 15).

([84]) S.G. Verhulst, *Mapping the Next Frontier of Open Data: Corporate Data Sharing,* 2014, http://www.unglobalpulse.org/mapping-corporate-data-sharing.

([85]) United Nations Global Pulse, *Responsible Data Forum on Private Sector Data Sharing – Event Summary*, 2014, http://www.unglobalpulse.org/RDF-private-sector-data-summary/.

([86]) E. Dowding, *Overview of FoodTrade Menu, a tool that helps to ensure compliance with FIRs*, in *CIEH Food*, 2014, http://food.cieh.org/food_trade_menu_a_tool_that_helps_to_ensure_compliance_with_firs.html?RequestId=b57a9838.

([87]) In relation to open farm data, for instance, the GODAN has suggested four possible strategies to pursue in sequence or combination. They embrace an interinstitutional cooperation bound to reach consensus on the terms and conditions of ownership of open data; model frameworks adopted at the local, national or regional level as examples to be emulated; a social certification scheme aimed at promoting best open data practices; and an international agreement on ownership of open data (GODAN, *Ownership of Open Data: governance options for agriculture and nutrition*, 2016, http://www.godan.info/documents/ownership-open-data-governance-options-agriculture-and-nutrition-0).

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from innovation driven by the wide and cutting-edge "Open Data movement."

6.- ICT-related food information: how knowledge may generate trust[88]

In the EU's Open Data policy, the desired objectives are almost the same as those proposed by other Open Government data programs:[89] transparency (in a democratic society, citizens should know what public bodies are doing in order to exercise public control over their work); generating economic and social value (making data open means, creating both new business opportunities and innovative services for the citizenry); providing evidence for better policy making.[90] But what is still lacking, in the author's opinion, is a clear reference to the possibility of using Open Data both to promote new forms of public engagement and to generate more trusted relations between public authorities and citizens – even in relation to the food sector.[91]
Indeed augmented transparency and public engagement have been usually considered by scholars[92] as means to boost citizens' trust. In view of the profusion of attempts scholarly work has made to define transparency, it can be said, in a nutshell, that this concept addresses the awareness of government's activities, in order to make citizens informed about public affairs, enhance accountability of institutional bodies, promote social development and democratize decision-making processes.[93] As far as participation is concerned, instead, public engagement could be defined as a spectrum of diverse organized and structured situations and activities, more or less spontaneous, in which lay people are involved and lend their support to agenda setting, decision and policy making processes.[94] It is, therefore, a vast and heterogeneous phenomenon, justified by both the need to ensure public confidence in the policy authorities, and to extend the knowledge base on which decision making takes place.
Since, as said before, the aims behind Open Data are, *inter alia*, the promotion of transparency and the support of public engagement - regardless of the endorsement given primarily to its economic and commercial value – we might argue that the practices visible in the new paradigm of Open Data are opening new routes for restoring trust.
As the US scholar Nissenbaum[95] pointed out – ‹‹trust is an extraordinary concept covering a variety of relationships, conjoining a variety of objects›› as it can refer to a relationship between one person and another, or between one person and digital information systems. In its first meaning – Nissenbaum explained – trust is a relational attitude characterized by vulnerability, being with no guarantees, no warranty. This kind of relationship between at least a trustor and a trustee leads in turn to two conceptions of trust. If in one conception trust possesses a merely instrumental value, acting ‹‹as a bridge between uncertainty and action››,[96] the other one ‹‹regards it as being an overriding value, valuable in itself››.[97] The new forms of so-called "com-

([88]) See the title of E. Aguilar Moreno, M. Gemo, A. Rana, M. Tallacchini, *Open Data in Health: how knowledge may generate trust*, Draft booklet on the workshop held at JRC, Ispra, Italy, Luxembourg, Publications Office of the European Union, 2014.
([89]) A comparison among the different initiatives and a reflection on the problems arising on the matter is presented by T. Davies, *Open Data Policies and Practice: An International Comparison*, 2014, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2492520.
([90]) N. Shadbolt, *Towards a Pan EU Data portal–data.gov.eu*, 2010, http://ec.europa.eu/digital-agenda/en/open-data-portals. https://open-data.europa.eu/en/data/; HM Government, *Open Data White Paper. Unleashing the Potential*, 2012, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/78946/CM8353_acc.pdf.
([91]) On the potential capability of Open Data to establish trust with citizens and boost democratic participation, see D. Lathrop, L. Ruma, *Open Government: Collaboration, Transparency, and Participation in Practice*, Sebastopol, CA, O'Reilly Media, 2010.
([92]) R. Gerald, A. Liberatore, *Democratising Expertise and Establishing Scientific Reference Systems, White Paper on Governance Work area 1, Broadening and enriching the public debate on European matters*, cit.
([93]) A. Florini (ed), *The Right to Know. Transparency for an Open World*, New York, Columbia University Press, 2007.
([94]) M. Bucchi, *Scegliere il mondo che vogliamo. Cittadini, politica, tecnoscienza*, Bologna, Il Mulino, 2006, p. 92.
([95]) H. Nissenbaum, *Will Security Enhance Trust Online, or Supplant It*?, in R. Kramer, K. Cook (eds), *Trust and Distrust Within Organizations: Emerging Perspectives*, Enduring Questions, Russell Sage Publications, 2004, p. 157.
([96]) Ibidem, p. 175.
([97]) Ibidem, p. 176.

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mons-based peer-production" of knowledge (socio-technical systems in which individuals cooperate to provide information or cultural goods) constitute – according to Nissenbaum's line of reasoning – a clear example of this last conception, since they can be considered valued relationships, because trust-based.

The recent application of Open Data in the food sector appears suitable to be added to this realm. This is because Open Data appears to present the contours owned by commons-based peer-production, i.e. decentralization of activities and the social nature of motivations at the base of participating people's action.[98] The new consumer-ICT interactions epitomised by Open Data have been unleashing great opportunities to upgrade the modalities of knowledge production in relation to food. These emerging citizens-based initiatives are contributing to reshaping the boundaries between private and public knowledge production in a myriad of ways: by fostering new forms of shared responsibility and accountability in aggregating, interpreting and reusing piecemeal and dispersed information; enhancing citizens' food-related knowledge; promoting freedom of information; extending and increasing deeper and trustworthy relations between institutions and the public. In these terms, Open Data reveals unknown territories, as it envisions the possibility to "stipulate" a new contract among public bodies, the business sector and society at large. This redefinition of interactions amongst social actors in their relationships with digital devices may restore trust of the citizenry in the face of institutional failures in guaranteeing the right to know.[99]

By going beyond the mere willingness to give food information, all these "life's civic spaces" are gaining momentum at virtually every level - both private and institutional – allowing people to exhibit virtuous behaviour. In this way, Open Data might also represent an innovative and helpful method to fulfil principle 3, lett. c) of the UN Guidelines on Consumer Protection,[100] that asks governments to take action to ensure ‹‹access of consumers to adequate information, to enable them to make informed choices according to individual wishes and needs››.

Particularly in the food sector, the possibility provided to individuals of acquiring a variety of data and, then, reusing them to create new forms of knowledge is able to voice the requests expressed by the General Food Law. When Reg. 178/2002 stresses the necessity ‹‹to ensure that consumers, other stakeholders and trading partners have confidence in the decision-making processes underpinning food law›› (Recital 9), and that ‹‹consumer confidence and the confidence of trading partners is secured through the open and transparent development of food law and through public authorities taking the appropriate steps to inform the public›› (Recital 22), insightful answers to these requests could arguably come from the proper use of Open Data.

Likewise, re-use of information in the framework of EFSA's activities might play a significant role in engaging the public in scientific deliberations and decisions.[101] This would be in accordance with those provisions of General Food Law requesting for ‹‹the confidence of the Community institutions, the general public and interested parties in the Authority›› (Recital 40), for openness of the Authority to contacts with consumers and other interested groups (Recital 46), as well as for an Authority capable of enabling Member States ‹‹to become more closely involved in scientific procedures›› (Recital 51). One could observe that most of these provisions belong to preambles and recitals, and whereas they do not possess binding force, they represent instead

(98) About the profiles characterizing commons-based peer-production, see Y. Benkler, H. Nissenbaum, *Commons-based Peer Production and Virtue*, in *The Journal of Political Philosophy*, 14 (4), 200, pp. 394-419.
(99) C. Jin-Hee, K.S. Chan, *Building Trust-Based Sustainable Networks*, in *IEEE Technology and Society Magazine*, 32(2), 2013, pp. 32–38; I. Kounelis, G. Baldini, R. Neisse, G. Steri, M. Tallacchini, Â.G. Pereira, *Building trust in human-Internet of Things relationship*, cit.
(100) United Nations, *United Nations Guidelines for Consumer Protection (as expanded in 1999)*, Department of Economic and Social Affairs, New York, 2003, http://www.un.org/esa/sustdev/publications/consumption_en.pdf.
(101) A. Spina, *Scientific Expertise and Open Government in the Digital Era: Some Reflections on EFSA and Other EU Agencies*, in A. Alemanno, S. Gabbi (eds), *Foundations of EU Food Law and Policy Ten Years of the European Food Safety Authority,* Aldershot, Ashgate, 2014.

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descriptive and explanatory statements aimed at clarifying the normative context. However, it has been argued that these statements have acquired an increasingly significant normative value in orienting, for instance, the interpretation of norms. From this perspective, they can be seen as "prescriptive descriptions," as they shape the seemingly factual landscape legitimizing the normative provisions.[102] In these terms, "Whereas" appear suitable, with reference to the issue we are discussing, to outline and mark the direction of EFSA's new policy.
Thus we can argue that the rapid development of ICT resulted in the birth of a new "digital insight," namely a sort of digital-social contract between the EU authorities and the citizenry, through which food and knowledge pertaining to it are becoming a vital part of shared civic initiatives. This trust-enhancing shift driven by Open Data is likely both to force interesting changes in the relations amongst social actors and to contribute to modelling the future of food sector.

7.- Concluding remarks

Individuals need to feel confident towards activities carried out at institutional level – even that relating to the food sector. In the environment of connectivity the paradigm of Open Data is creating, the real time capture and exchange of data can inspire consumer confidence by increasing the opportunities of a dialogue with the EU institutions. Untold volumes of data provided through ICT might serve to spread innovation, besides intensifying collaboration among stakeholders. By using Open Data, European citizens could gain reliable knowledge from the proactive exploitation of accessible information, given that shared data constitute public goods that can be creatively reused in many ways, so as to increase in value.
But in this picture - in spite of its prima facie attractiveness – the aforementioned technical and legal problems tightly linked to Open Data must not be neglected, if we want its civic and social value to be fully unleashed. A trust-based relationship amongst human beings – even when it is connected by digital devices - requires that expectations towards intentions and behaviors of each others be continually reaffirmed. This is particularly evident when the trustor is an institution. In this relation based on the certainty of clear and shared – or at least commonly accepted – rules, in fact, any inconsistency of communication, due to unclear or contradictory messages, is enemy of clarity and undermines trust. [103]
Facing this issue shall thus be the most preeminent challenge for the European legislator in the near future.

ABSTRACT

In the food sector, the massive plethora of data made available by the so-called Open Data has been gradually - but radically - altering the relations among institutions, industry and the public. Thanks to the opening up of knowledge possessed by the public sector, the consumer-citizen is becoming empowered in making better informed and personalized decisions, proactively oriented towards his personal interests and needs. In light of this scenario, the goal of this essay is to consider the normative and social aspects related to the use of Open Data in the food sector, with an emphasis on both its relationship with European food law and the role this new 'digital insight' might play in generating trustworthy interactions between institutional authorities and citizens.

□

([102]) M. Tallacchini, *Diritto e scienza*, in B. Montanari (a cura di), *Luoghi della filosofia del diritto. Un manuale*, Torino, Giappichelli, 2009, p. 274.
([103]) B. De Marchi, *Le origini della comunicazione del rischio nella legislazione europea*, in S. Rodotà, M. Tallacchini (a cura di), *Trattato di biodiritto, Ambito e fonti del biodiritto*, Vol I, Milano, Giuffrè, 2010, p. 478.

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"New primary molecular structure" and novel foods according to the Court: constructive or demolishing interpretation?
The EU Court Judgment in case C-448/14*

Valeria Paganizza

1.- Introduction

Either greeting the EU Court's finding in C-448/14[1] as the needed interpretation of Regulation (EC) No 258/97[2] or regarding it as a subverting reading on legal certainty might be just a question of hermeneutics[3].
As the Reader might know, Regulation (EC) No 258/97 sets two requirements – that have to coexist - to include a product in the definition of novel food. The first one is a time condition: the substance or ingredient had not been "significantly" used as food before 15 May 1997.
The second one is a class requirement: the product has to fall into one of the categories listed in the Regulation, refined over years, namely «*foods and food ingredients with a new or intentionally modified primary molecular structure*»; «*foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae*»; «*foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use*»; «*foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances*» (Article 1, paragraph 2 of Regulation (EC) No 258/97).
What if a substance or ingredient does not match or does not perfectly fit any of the groups? Shall we interpret the Regulation according to its wording, or shall we pay attention to the general *ratio*, trying to understand the legislative intent? Can we fill any gaps through an extensive interpretation? And could we make use of "by analogy reasoning"? Can we apply the general principles of the theory of interpretation to EU law, or has the Court identified different and autonomous methods to provide a meaning?
Answers to such questions are in the judgment in case C-448/14. The Court's finding is however so plain and apparent that some scholars could struggle to accept it without arguing. And this is the reason why the Author wrote this note.

2.- The case

Davitas Gmbh is a German company of the food and food supplement sector. Since 2012, it had been marketing, in Germany, a food product (called De Tox Forte) made solely of a mineral (clinoptilolite), which had never been used for human nutritional purposes within the EU. After an official control on the product composition carried out by experts, and grounding its measure on the fact that the use of clinoptilolite as food had never been significant, the municipality of Aschaffenburg prohibited the marketing of the product, until Davitas would have obtained an authorisation under the Novel Food Regulation. Davitas however argued that its product was not a "novel food", under the denotation given in the Regulation and brought an action for annulment before the Bavarian Administrative Court,

(*) The research is carried on as part of the project ValoriBio – "Valorisation of organic waste through the use of insect to obtain biomaterials for agricultural purposes" – University of Modena and Reggio Emilia - Funded Project POR FESR 2014 – 2020 – Axis 1 Research and Innovation.
(1) Judgment of the Court (Fifth Chamber) of 9 November 2016, *Davitas GmbH v Stadt Aschaffenburg*, Case C-448/14.
(2) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

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Würzburg (Bayerisches Verwaltungsgericht Würzburg), against the authority's ban.
After the rejection, Davitas appealed the judgment to the Higher Administrative Court of Bavaria (Bayerischer Verwaltungsgerichtshof). Though recognising that clinoptilolite had not been used as food significantly, within the EU, the appellant specified that it did not fall into one of the categories listed in Regulation (EC) No 258/97. Lacking therefore the second condition, the product could not be considered a novel food. In particular, Davitas specified that De Tox Forte could not fall into the category of food with a "new primary molecular structure", since its structure was the same as the one of the volcanic zeolite.
Staying the proceedings, the appellate Court, which raised some interpretative doubts on the scope of Regulation, referred two questions to the EU Court: «*1. Is the product "De Tox Forte" marketed by the appellant a food or food ingredient with a new molecular structure within the meaning of Article 1(2)(c) of Regulation No 258/97?*
2. In particular, does it suffice, in order to be able to answer this question in the affirmative, that that product, which contains the substance clinoptilolite in its particular primary molecular structure, was not yet being used as a food prior to 15 May 1997, or is it also necessary that that product is produced by means of a production process which results in a new or intentionally modified molecular structure, that is, it must be a substance which did not previously exist in nature in that form?» (point 15 of the judgment).

3.- General Advocate Opinion

A careful reading of the Opinion of Advocate General Szpunar might be functional to fully understand the judgment of the Court and its reasoning. He summarises the two questions in a single query, namely whether the category of food with a new primary molecular structure includes a substance of mineral origin having the same structure as in nature, though that structure had not been used in food or food ingredients before 15 May 1997 (point 18 of the Opinion). To answer the question, he carries on a legal reasoning that we could abridge in few points:
-Inadequacy of the literal interpretation to solve the issue;
- Possible conceptual overlapping of the conditions to qualify a food as novel, and acceptability;
- Comparison with the new EU provisions on novel foods;
- Interpretation under the general nature and purpose of the novel food Regulation;
- Historical reading;
- Reading according to practice.
Recalling some principles of EU law hermeneutics, the Advocate General suggests that the interpreter of an EU act shall not consider just the wording, but has to regard also at its context and the «*objectives pursued by the rules of which it is part*» (point 20 of the Opinion). Trying to reach a solution through the meaning of the adjective "new", the EU Officer recognises that it can refer to both a molecular structure that had been newly created and a newly used one, in food. He then draws a remarkable reasoning over the overlapping of concepts. Thinking to a "new molecular structure" as something that has not been used before as food, would superfluously replicate the first criterion that a substance has to match, to be a novel food. According to the Advocate General however such overlapping would occur only for those substances that cannot find a classification within the other categories listed in the Regulation and that could be identified in substances of mineral origin. To support his interpretation, the EU officer refers to the new regulation on novel foods that expressly includes food of mineral origin within its scope.
The main point of the Opinion concerns indeed the scope of the novel food regulation and the assertion that the general nature and purpose of the definition of novel food prevent a restrictive interpretation (point 41). The general nature – according to the Opinion – is due to the fact that the regulation covers all novel foods «*irrespective of their nature, with the exception of certain areas which are regulated by sector-specific legislation*».
The purpose consists in defining the characteristics to categorize a food as novel, with the objective of ensuring the functioning of the internal market, while protecting consumers' health. So plants, fungi, algae and microorganisms are novel foods regard-

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less of whether they are the results of human intervention, in order to protect human health. Similarly, according to the Advocate General, also food with a new primary molecular structure shall be novel food, irrespective of whether the structure is newly created or newly used within the European Union (points 43-44 of the Opinion).
Moreover, only letter c) of the Regulation could include substances of mineral origin that have not undergone a new production process giving rise to significant changes in their composition and structure.
The exclusion of an entire category of food (substances of mineral origin), that would happen through a restrictive interpretation of the Regulation, would «be contrary» to the general scope and purpose of the EU act.
As for the historical development of the wording, the Advocate General's reasoning does not give much importance to the difference between the Commission proposal - clearly including, in the Regulation, food with a primary molecular structure that had not been used before - and the text released after the Council's Common Position, where the sentence was not retained. He simply asserts that the lack in the final version of the Regulation does not necessarily mean that the Legislator intended to exclude the category from the scope of the act.
Finally, the Advocate General underlines that prior to the Davitas case, within the European Union, clinoptilolite had already been qualified as "novel food" in "practice": it was included in the EU online Novel Food Catalogue and food business operators had considered it as "novel food" while submitting applications for trade authorisation.

4.- Decision and motivation

In accordance with the Opinion of the Advocate General, the Court of Justice includes in the category of food with a new molecular structure also substances of mineral origin, considering "new" any structure that had not been used within the European Community before 1997, regardless of whether it had been newly created or just newly used.
To answer the referred questions, the Court makes use of hermeneutics topics too. We could summarise the reasoning into the following points:
- Summing-up of the questions with a focus on the meaning of "new primary molecular structure";
- Regulation (EC) No 258/97, subject and scope (the coexistence of the two conditions to classify a food as "novel");
- Comparison between the general wording of letter (c) and the detailed provisions of letters (d), (e) and (f) of paragraph 2, Article 1 of Regulation (EC) No 258/97;
- Fundamentals of EU law hermeneutics: usual meaning, context, purpose and their application to the case.
Similarly to Advocate General's reasoning, the Court starts its analysis from turning the referred questions into a single query on the meaning of "new primary molecular structure", wondering if it includes simply substances that had not been consumed significantly as food prior to 15 May 1997 (regardless of whether the structure had already been existing in nature) or if it requires also the novelty of the form, meaning that the substance underwent a process that resulted in a new or intentionally modified structure.
The EU Judge then focuses on the subject of Regulation (EC) No 258/97 (that it identifies in the placing in the market of novel food or food ingredients), and recognises that the definition of "novel food" determines by itself the scope of the Act. The Court recalls therefore the two conditions that the classification as novel food requires to this purpose, namely the use as food prior to 15 May 1997 and the referability to one of the categories listed in Article 1, paragraph 2 of the Regulation. It then analyses the content of such classes, paying particular attention to substances "with a new primary molecular structure" - the category mentioned in the referred questions - and emphasising its peculiar wording. While this class makes a general reference to the structure of a food or food ingredient, letters d), e), and f) of Article 1, paragraph 2 show more detailed provisions, the first two concerning organic substances having a particular composition and the last one encompassing food which underwent a new production process resulting in a significant change in its composition and structure.
The Court carries on its reasoning through a herme-

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neutical approach, wondering if "new molecular structure" refers only to structures that have been newly created, or simply to any substances with a structure that has not been used before as food. The usual meaning of words being insufficient to provide an unambiguous interpretation, the EU Judge perceives the need for considering the context in which the phrase is used and the purpose of the Regulation.
Although formally referring to the context, actually the Court focuses on the scope of the Act, emphasising its general nature and stating that it covers "*all novel foods or food ingredients irrespective of their nature, with the exception of certain areas regulated by sector-specific legislation*" [point 29]. On this basis, it interprets Article 1, paragraph 2, letter c) of the Regulation as referred to any substances that had not been used significantly as food prior to 15 May 1997.
The reason for such reading is the need not to exclude substances that would not otherwise fall into any of the other categories listed in the Regulation.
Also the reflection on the purpose of the novel food provisions would bring about the same result: since the Regulation aims to ensure free movement of goods, while protecting human health, a comprehensive safeguard would require the authorisation procedure set for novel foods, for any substances that had not been significantly used as food until May 1997.

5.- Comment

If we make reference to the purpose of the Regulation[3], the need to protect human health might justify the Court's findings. When a substance has not been used as food, it shall undergo a risk assessment procedure in order to evaluate its suitability and safety for human consumption.
Indeed, this is a general recurrent approach in EU Food Law, where anything that is unknown to nutrition must be assessed in order to ascertain its safety. Sometimes EU provisions require a technical independent evaluation carried out by national authorities or through EFSA intervention: this is the case of GMOs food additives, but also novel foods authorisations. For these categories, the EU regulations ask the completion of a procedure prior to the marketing of the products. Where the food belonging to this group has not undergone or has failed to pass the evaluation process, it will be considered unsafe. Such unsafety does not perfectly match what Article 14 of Regulation (EC) No 178/2002 identifies as "unsafe", that is to say a food injurious to health or a food unfit for human consumption. Abstractly a food that has not undergone an authorisation procedure might be absolutely innocuous. It might however be considered unfit for consumption, just because of the lack of the formal requirement (the successful completion of the authorisation procedure).
The unsafety of a food that has not obtained the authorisation might be inferred also through Article 14, paragraph 7, which states that «Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned».
This could be read also in the opposite: food that does not comply with specific Community provisions governing food safety shall be deemed to be unsafe.
Sometimes food business operators carry out just a self-assessment and do not have to submit any request, for instance when they simply perfect a new recipe: the product final composition is something new, while its ingredients are substances already used for human nutrition.
Even though abstractly such ingredients could interact, the safety of their use is alleged and ensured by the operator, who, under Regulation (EC) No 178/2002, has a general duty to put on the market

([3]) Several Italian Authors commented on the "old" novel food regulation, though focusing mostly on GMOs; see Germanò A., *Sui novel foods*, in *Dir. giur. agr. alim. amb.*, 2009, 9, pp. 534-535; Masini S., *Coltivazione di organismi geneticamente modificati: esigenze di sicurezza e presunzione di responsabilità*, in *Dir. giur. agr. amb.*, 2000, 11, pp. 637-644; Costato L., *Organismi biologicamente modificati e novel foods*, in *Riv. dir. agr.*, 1997, 2, I, pp. 137-164.

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only safe products[4].

The logical reasoning of the Court might however be questionable. It is undeniable that the wording of the Novel Food Regulation on substances with a "new primary molecular structure" cannot help in solving the question on the applicability to materials of mineral origin.

However we could draw several considerations, giving a hint about different perspectives. The purpose of the provisions on Novel Food is to regulate the access to the EU market of substances that have not been consumed significantly as food, in order to ensure their safety. Requiring an authorisation prior to the market is however an exception to the general principle of free movement of goods. With these elements in mind, the EC Legislator established a precise set of rules for novel foods (and only for them), thus reducing as much as possible the limitations to the free movement of goods. When focusing on the context of the Regulation, the Court states that it has a general nature, since it applies to any novel food or food ingredient, except for those products that fall into a different specific discipline (for instance, additives). The assertion of the EU Judge is accurate but it seems to disregard the fact that the definition of "novel food" comes from the Regulation itself.

As underlined in the Court's Judgment, the Regulation identifies two conditions that a food ingredient has to match to be qualified as "novel". Nevertheless, the EU Judge breaks down the structure of the act, by its interpretation of the phrase "new primary molecular structure". To the question if the expression means "any molecular structure that did not exist previously" or "any molecular structure that was not used in or as food", the Court concludes that the wording encompasses simply any substance that had not been significantly consumed as food prior to May 1997. But in doing so, the EU Judge de facto nullifies the meaning of the second condition laid down in Article 1, paragraph 2, letter c) of the Regulation, through a worthless duplication of the first condition. What is more is that such hermeneutical operation turns out to abolish entirely the need for and sense of a second condition, or at least it risks doing so. The Court reads "new primary molecular structure" as including any substances that cannot otherwise fall into any of the other categories. Sure, the Judge reasons only with regards to "clinoptilolite" and "substances of mineral origin", but the hermeneutical process is something that could be replicated for any product that cannot be assigned to the other listed categories. According to the Court's reasoning, "new primary molecular structure" becomes a residual class that could be able to cover almost any gaps in novel food categories.

There is something disturbing in this perception. If the EC Legislator had wished that any food or food ingredients that had not been used as food prior to May 1997 would be considered as "novel food", it would not have required the matching of a second condition and it would not have listed a specific set of classes. It would have simply stated that any substances that had not been used prior to 1997 as or in food should have been considered a "novel food" and should have undergone the authorisation procedure. The EC Legislator made instead something different: it considered novel food any substance that had not been significantly consumed as food prior to that moment, *provided that* it fell into one of the listed categories. We could guess that it had some reasons to do that. We could also imagine that technical developments suggested that the wording of the Regulation had to change. Indeed the new Regulation (EU) 2015/2283[5] includes also

([4]) Actually, also such certainty might falter when reading the EU Court's judgment of 15 January 2009, in case C-383/07, *M-K Europa GmbH & Co. KG v Stadt Regensburg*, according to which the fact that a food or all the individual ingredients of a food had been singularly consumed to a significant degree before 15 May 1997 is not sufficient for the Regulation (EC) No 258/97 not to apply to the food product concerned (points 30-32).

([5]) Several Authors commented on the new regulation. *Ex plurimis*, Canfora I., *Alimenti, nuovi alimenti e alimenti tradizionali nel mercato dell'Unione europea dopo il regolamento 2015/2283*, in *Diritto agroalimentare*, 2016, 1, pp. 29-46. In this review, Bonora G., *I "Novel Foods" nel Reg. (UE) n. 2015/2283 e gli insetti: una possibile evoluzione dei costumi alimentari?*, www.rivistadirittoalimentare.it, 1-2016, pp. 42-54; Volpato A., *La riforma del regolamento sui "Novel Foods": alla ricerca di un impossibile equilibrio?*, www.rivistadirittoalimentare.it, 4-2015, pp. 26-43.

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"*food consisting of, isolated from or produced from material of mineral origin*". However this does not necessarily imply – unlikely what the Advocate General argues – that the inclusion of substances of mineral origin in the new Regulation on novel foods means that also the old novel food regulation was intended to cover such substances.

Though the new Regulation declares that its scope should, in principle, remain the same as the repealed one, it also specifies that the definition of novel food needs a review, clarification and an update, "*on the basis of scientific and technological developments that have occurred since 1997*" (Whereas no 8). So we can infer that the new Regulation includes anything that was Novel Food under the last consolidated version of the previous Regulation but adds some new categories, thus clarifying also its scope. In this sense, the scope of the old regulation has survived the act, but we cannot obviously uphold the reciprocal statement, unlikely what the Advocate General did.

We cannot in other words say that the old regulation already included all that the new act describes as Novel Food. This would be irrational: the intention of the EC Legislator of 1997 could not foresee what the EU Legislator in 2015 would have done. Though not expressly mentioned in the judgment, the EU Court might have considered also this point of the Advocate General's Opinion.

The Court has however a clear and declared purpose: requiring the authorisation procedure for any substances that had not been used as food, prior to May 1997, despite the structure and the wording of the Regulation.

What is alarming in such point is that the EU Judge operates an extension of what should be considered an exception. One of the fundamentals of the European Union is the free movement of goods. The fact that the European Community (now Union) has established some restrictive rules is a peculiarity due to a specific reason (ensuring the need to protect human health, without unnecessarily limiting trade opportunities), turning to be an exception to the general freedom. The exclusion is furthermore circumstantial, being restricted to specific categories of products.

The Court's hermeneutical process cuts down these classes and seems to include in the residual one (new primary molecular structure) any substances that do not fall into other categories, for the sole reason that they would otherwise enter the EU market without a prior authorisation. To be intellectually honest, we should advice that the Author of the paper is offering a radical reading of the judgment. Someone could indeed successfully argue that this is not an automatism applicable to any substances: it would work only for those products having a new primary (and not secondary) molecular structure that – as in case of substances of mineral origin – replicates an undefined number of times. Let's think to insects. Article 1, paragraph 2 of Regulation (EC) No 258/97, letter e) includes, in the definition of novel food, "food ingredients isolated from animals", but not food or food ingredients consisting of animals. Some EU members interpreted such expression in the sense of excluding whole insects from the scope of the Regulation, while including parts of or substances extracted from these animals. According to the reading of the Court, probably whole insects would still remain outside the scope of the EC act.

The category listed in the Regulation refers to a primary molecular structure, while insects – as many other organisms - have a complex molecular structure. Should we try to identify the primary one, we will probably find several "groups" of molecular structures (for carbohydrates, for fats, for proteins or amino acids, for minerals, besides water and chitin)[6]. Moreover, should we focus on those groups, probably we will realize that they have already been used as food and this would turn to be a tricky element. We know that the old novel food regulation did not expressly include insects within its scope. If we focus on their structure, we should conclude that their primary constituents have already been part of the EU consumers' diet for centuries and therefore

([6]) A special thanks goes to dr. Sara Bortolini, University of Modena and Reggio Emilia, who explained to the Author, with a precise and thorough description, what the composition of insects is. Here there is an attempt to summarise in few everyday words the main points of her helpful speech.

there would not be any reason leading to their inclusion in novel foods[7]. However, the new regulation declaredly comprises insects in its field of application: according to the reasoning that the Advocate General carried on and that was probably considered in the judgment at stake, this would automatically mean that insects had to be included also in the scope of the old novel food regulation.

Going back to the EU Judge's analysis, it fails to consider a further detail in the wording of Article 1 (2), letter c) of the Regulation, which could help – without being determinant – to solve the hermeneutical issue. It refers to "*foods and food ingredients with a new or intentionally modified primary molecular structure*". The fact that an intentionally modified molecular structure is mentioned might suggest that the provision is referring to the result of a human manipulation or – as for the "new molecular structure" – to the result of a human activity on the substance. The novelty would thus refer to a molecular structure that was newly created and did not exist as such in nature: it might me a structure created ex novo or an existing structure deliberately adapted. In both cases, the substance will be a "novel food". If we support such reading - that the Court had not even considered - we could deem the EU Judge reasoning as having provided an extensive interpretation of an exceptional norm. This is not forbidden, but as the Court stated in past cases «*any extensive interpretation must be undertaken only with caution*»[8] and «*any derogation from or exception to a general rule must be interpreted strictly*»[9]. In the judgment at stake, the EU Court, though providing a reading that partially overthrows the regulation wording, might justify such an extensive interpretation under the attempt to fulfil the purpose of the act.

The main element of the EU Judge decision grounds on the fact that the exclusion of substances of mineral origin from the application of the novel food regulation would turn into a lack of protection for human health. Even though the wording does not expressly comprise minerals in any of the categories listed in the Regulation, considering them as not included in its scope would mean letting substances that had never been consumed as food entering the market without prior risk assessment (points 32 and 33). According to the Court, such a solution would bring to an absurd result, contrary to the ratio of the Novel Food regulation which "*aims to establish common standards […] in particular […] by introducing a single safety assessment of those foods and food ingredients through a Community procedure before they are placed on the EU market*".

As we told above, the explanation of such a solution is cogent if we consider the fundamental need to protect consumers' health, which appears to be one of the exigencies emerging from the novel food regulation.

It might be thornier trying to relate this solution also to the intention of the Legislator. As we said earlier, if it had meant to include in the regulation any substance that had not been significantly consumed as food prior to May 1997, the EC Legislator would not have provided a list of specific categories to qualify a food as novel. This should imply that the Legislator was thinking to some categories of food that, though not having been part of the EC consumers' diet prior to that date did not require an official risk assessment. In this perspective, the creative interpretation of the Court has probably gone too far.

Unfortunately, the unsoundness of such reasoning affects also the new Novel Food Regulation. We mentioned the new act some lines above, when referring to substances of mineral origin. Let's instead consider the wording of the new provision on food with a new molecular structure (the adjective primary has disappeared): "*food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997*". This is something

(7) Actually, we should also consider what the Court concluded in the Man Koso case. See note 4.
(8) Judgment of the Court (Second Chamber) of 24 November 1983, - *Hartog Cohen v Commission of the European Communities*, case C-342/82.
(9) Judgment of the General Court (Fourth Chamber, Extended Composition) of 25 January 2017, *Rusal Armenal ZAO v Council of the European Union*, case T-512/09.

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astonishing, since, while defining when a molecular structure is new, it clearly duplicates, without any reason, the first general condition that shall apply. But if a molecular structure is new when it had not been used as food or in food before 15 May 1997, why specifying also a different class for substances of mineral origin? Could not they be included in the group of substances with a molecular structure that were not used as food or in food prior to the mentioned date?

If not, this means that the category of "food with a new molecular structure" shall not encompass minerals (and also the old novel food regulation shall be interpreted in this perspective, since there are no significant changes, except for the clarification on the meaning of "new").

If otherwise the category of food with a new molecular structure shall include also minerals, the specific provision of the most recent Regulation proves to be useless. This becomes even truer when considering that the provision on food with a new molecular structure applies irrespective of the molecular level (primary or secondary structure). Any substance, either consisting of, isolated from or containing a material of mineral origin, being – as first condition applicable to any food – a food that was not used within the European Union before May 1997, would automatically be a food with a structure that had not been used before May 1997 in food.

The only means to find a sense to the provision is thus recognising that substances of mineral origin do not fall into the category of "food with a new molecular structure", either primary or not.

The wording of the new Regulation actually reflects one of the reasons beneath its adoption: it answers the scientific and technological developments occurred since 1997 (whereas No 8) which emphasises the shortcomings of the old provisions, and clarifies some of the categories listed in the previous text[10]. So, besides the mentioned changes on food of animal origin and food with a new molecular structure classes, and the inclusion of the category of substances of mineral origin, the new Regulation expressly applies to food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae; to food consisting of engineered nanomaterials and to food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements [Article 3, paragraph 2, let. a), points vi, viii, x].

The new provisions try therefore to solve some of the interpretative issues that had arisen in the past years, like the one solved by the Court in the judgment we are commenting on.

6.- Concluding remarks

After having analysed the EU Court's reasoning we could be still torn between supporting and opposing its solution[11]. The need to protect human health as ultimate goal of the Novel Food Regulation is the sole motive to approve the Judge's findings but yet there are some weaknesses on the reasoning: the nullification of the coexistence of the two conditions that characterise the definition of "novel food"; a lack on considering the whole wording of the phrase referred to food or food ingredients with a new or intentionally modified primary structure; the questionable hermeneutical process of extending an exceptional provision; the peculiar reading offered to the legislative intent. While we could share the results, the method might be debatable[12]. What cannot be easily coped with is the forced reading, wil-

([10]) The Regulation further aims to simplify the procedure for placing on the market food with a history of safe use in third countries: it requires the operator to submit a simple notification rather than starting the general authorisation procedure. In the event of reasoned safety objections by Members States or by EFSA, however, the Commission shall not authorise the placing of the market of the "new" product, but the operator may introduce a different procedure, similar to the ordinary one.

([11]) A special thanks to prof. Vito Rubino for his priceless advice on the Court's role and functions.

([12]) The international literature on the theme recognises that criticism over Court's case law is focused «on the lack of sustained reasoning» rather than on the outcomes reached by the Court. Muir E., Dawson M., De Witte B., *Introduction: the European Court of Justice as a political actor*, in Dawson M., De Witte B., Muir E. (eds.), *Judicial Activism at the European Court of Justice*, Cheltenham, 2013, pp. 3-4.

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ling to submit to authorisation any food, for the sole reason that it had not been used for nutrition prior to 1997 and irrespective of the necessary coexistence of the two conditions required by the Regulation. From the wording of the judgment, it emerges that the Court pursues the intent of submitting clinoptilolite to the authorisation procedure, in order to ensure food safety (points 31-33). It then builds its interpretation with this purpose in mind. The impression one could have is that the Judge has constructed its argumentation starting from the result it wanted to obtain, instead of reaching a solution through a step-by-step logical reasoning. The Court had the unpleasant task of making up for the gaps and the unclearness left by the Legislator but we might wonder to which extent this could be done: could the EU Judge pursue the purpose of an act, while rendering ineffective - though for a very peculiar situation - one of its fundamental provisions? This doubt recalls scholars' debate on the Court as policy maker and on its activism[13], that is to say on its role as law maker[14]: the perception that the Court had construed (and not simply interpreted) EC law according to the objective that the Judges were pursuing[15] perfectly matches the idea of a "teleological judicature" on which several scholars debated[16]. This is not a matter of integration between national legal orders and the EU one, as it was in past years, when the dispute on judicial activism was at its utmost level[17]. It is just a question on the extension of the Court's powers and on legal certainty. In the case at issue, the EU Judge pushes its interpretation till the area of legislative creation: it does not simply offer a reading of the normative text. It removes part of a constitutive provision (i.e. the need for the second condition) and adds a broader significance to the remaining words, despite the structure of the Regulation gives evidence that the Legislator intentionally formed a list of limited categories for novel foods and set two conditions for defining a food ingredient as "novel". In EU national orders, this could be perceived as a trespassing of the tripartite separation of powers, the Court having actively created a "new" provision, with the exemption of clinoptilolite from the coexistence of two conditions: it is a novel food just because it had not been used significantly as food prior to 15 May 1997. However, the role of the EU Court of Justice and the configuration of the EU legal order[18] are so peculiar that the Montesquieu doctrine might not apply[19]. As Advocate General Trstenjak stated in her opinion in case C-101/08[20], «*The institutional balance within*

(13) This is actually the same question that Ramussen H., *Between Self-Restraint and Activism: A judicial Policy for the European Court*, in *European Law Review*, 1988, pp. 28-38, tries to solve when wondering: "*How liberally may the Community judge, following his perception of the (correct) policy-orientation, which ought to prevail in judicial decision, give preference to teleology over text*", p. 33. Conway G., *The Limits of Legal Reasoning and the European Court of Justice*, Cambridge, 2012, defines the term "activism" as "*having a sometimes pejorative connotation of excessively creative interpretation or interpretation that approximates legislation*", p. 17 and p. 61. On the topic, please refer also to Sankari S., *European Court of Justice Legal Reasoning in Context*, Groningen, 2013, pp. 47 ff.

(14) The role of judges in "creating" or "shaping" law has been discussed for years. In 1968, M. Lupoi published a paper headed *Il giudice legislatore: una recente esperienza inglese*, in *Il Foro it*., 1968, vol. 91, 7-8, V, col. 546-590, focusing on the judgment of the British House of Lords in *Conway v. Rimmer.* The Author emphasised the lawmaking role (col. 550) that the Judge had to play, due to the Parliaments's inertia (col. 549), while deciding to depart from the judicial precedent. For an historical analysis from several points of view, please refer to Vv. Aa., *Giudici e giuristi. Il problema del diritto giurisprudenziale fra Otto e Novecento*, in *Quaderni fiorentini*, 2011, 40, I and II, pp. 1 ff.

(15) Albors Llorens A., *The European Court of Justice, More than a Teleological Court*, in *The Cambridge Yearbook of European Legal Studies*, 1999, 2, p. 373.

(16) Albors Llorens A., *cit.*, p. 373, makes a review of the different positions on this topic. While criticizing the selectiveness of all such studies, the Author tries to offer a comprehensive contextualised view.

(17) Lenaerts K. – Gutiérrez-Fons J.A., *To Say What the Law of the EU Is: Methods of Interpretation and the European Court of Justice*, in *Columbia Journal of European Law*, 20, 2014, 2, pp. 34 ff.

(18) Since the Van Gend en Loos case 26-62, the Court has been stressing the peculiarity of the EC legal order as something new and different from the systems of the Member States.

(19) Conway G., *The Limits of Legal Reasoning and the European Court of Justice*, Cambridge, 2012, p. 192, and *Recovering a Separation of Powers in the European Union*, in *ELJ*, 17, 3, pp. 304-322.

(20) Opinion of Advocate General Trstenjak delivered on 30 June 2009, *Audiolux SA e.a v Groupe Bruxelles Lambert SA (GBL) and Others and Bertelsmann AG and Others*, case C-101/08.

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the Community is not based on the principle of the separation of powers in the constitutional-law sense, but on a principle of the separation of functions, whereby the Community's functions are intended to be exercised by the organs which are best placed to perform them under the Treaties. Unlike the principle of the separation of powers, which seeks partly to ensure that the individual is protected by moderating state power, the principle of the separation of functions is intended to ensure that the Community's aims are effectively achieved» (point 104).

Under such assertion, if we consider the objective of food safety and health protection pursued by the European Union, the Court's findings become much more reasonable.

Yet, it is undeniable that the difficulty to accept the judgment in case C-448/14 still survives, due probably to the fact that any scholar or commentator cannot avoid to be influenced by the national legal order and tradition to which he or she belongs[21], thus seeking for the boundaries that limit the Court's function.

This becomes even more perceptible in the case at issue, where, following the judgment, a food business operator will be required to withdraw the products from the market, though he or she had started the marketing on the basis of the textual reading of the Regulation. To what extent can the EU Judge overshadow the principle of legal certainty?

Article 19 of the Treaty on European Union states that the Court shall ensure that «*in the interpretation and application of the Treaties*» (but we can extend the provision also to secondary legislation) «*law is observed*». So we could infer that the Court's judgment is not questionable as far as it complies with the law. If there had been a clear provision excluding substances of mineral origin from the novel food regulation or if the definition of "new primary molecular structure" were sufficiently determined as to clearly exclude clinoptilolite from the scope of the act, the Court's solution would have been objectionable. Where there is ground for interpretation, however, the food business operator could not claim for legitimate expectations or for the wider legal certainty recognition, since a certainty, actually, does not exist: the wording of the Regulation was not unambiguous; consequently a preventative approach pre-emptively asking for the national authority's opinion, would have been far more prudent than the direct marketing within the European Union. In balancing health protection and free movement of goods, the Court of Justice can legitimately ensure a wider shelter to the former, above all when – as in the case at issue – the effect on the food business operator's part is "just" a temporary stop on the sales, until the completion of the authorisation procedure.

The creativity of Courts' interpretation is something that is immanent in the judiciary activity: when judges rule over a case, while applying law (but this is true also with reference to judicial precedent), they do not merely mechanically implement a provision. They perform a legal reasoning that inescapably is somehow creative and discretional. The problem is to determine the limits of such creativity.

Scholars recognise that the pluralism of values has been shaping the regulatory power of law, weakening its binding capacity and turning the executive moment merely into a matter of Judges' choice[22]. The vagueness of provisions, in other words, legitimises those options implemented by the Court on the basis of the spirit of law.

Indeed, the debate over the changing role of Courts, shifting from simple execution to creation of law has been going on for years, in both common law and civil law systems.

This transformation has been perceived as the necessary consequence of modern and postmodern times, where new issues and new needs (eco-

([21]) As Tridimas T. states in *The Court of Justice and Judicial Activism, in European Law Review*, 1996, p. 200, «*Whether a decision is active or not depends on one's standpoint*». On such point, a remarkable analysis is carried out by Arnull A., *Judicial activism and the European Court of Justice: how should academics respond?*, in Dawson M., De Witte B., Muir E. eds., *Judicial Actvism at the European Court of Justice*, Cheltenham, 2013, pp. 211-232. As Tridimas T. states in *The Court of Justice and Judicial Activism*, in *European Law Review*, 1996, p. 200, «*Whether a decision is active or not depends on one's standpoint*».

([22]) Caretti P., *La giustizia arbitrale: una riflessione sulla legittimazione della giurisdizione*, in *Scritti in onore di Gaetano Silvestri*, Torino, 2016, v. I, p. 448.

nomical, political, constitutional, social)[23] arise and compel the Judge to play the role of problem-solver and policy-maker[24]. As told above, Courts do create law[25] but this does not imply that they become Legislator[26]: they simply enact - and this is more perceptible when referring to the Court of Justice of the European Union – their role of reading and implementing the law through the lens of changing times.[27] Every so often, however, they bear the burden of remedying to the «*law decadence*» and the «*fragmentation of the precept source system*», thus turning from «*judges of the single case*», to «*regulatory courts*»[28]. This happens above all in national legal orders: much has been said, in this regard, about the creative role of the Judge.

In Italy, for instance, the debate on this issue, that is still animated[29], involves almost any branch of the law (civil[30], administrative[31] and, to some extent, criminal law[32]), at different levels (from first instance Court to the Supreme Court) as well as different subjects (scholars, practitioners and judges) and becomes even more pressing when considering the «*de-statualization of the sources of law*»[33].

The main finding is however comparable: the Court's active intervention is a necessary step in contemporary legal scenario, above all in the European Union context. The novelty of some issues, the necessary generality and abstraction of law, the impossibility of acts to provide an articulated specific solution for any possible factual circum-

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([23]) Cappelletti M., *Giudici legislatori?*, Milano, 1984, p. 63.

([24]) Taruffo M., *Sui confini. Scritti sulla giustizia civile*, Bologna, 2002, pp. 153-154. On the interpreter's role and on the «*innovative power of time*», Cappelletti M., *op.cit*., p. 12. On the political features of the judiciary activity, Rodotà S., *Magistratura e politica in Italia*, in Bruti Liberati E. – Ceretti A. – Giasanti A. (eds.), *Governo dei giudici. La magistratura tra diritto e politica*, Milano, 1996, p. 23.

([25]) Lord Reid, *The Judge as Law Maker*, in *J. Soc'y Pub. Tchrs. L.*, 22, 1972-1973, pp. 22 ss.

([26]) Cappelletti M., *cit.*, p. 64.

([27]) The statement that "Judges create law" committed Italian scholars' debate for years, as recalled by Carriò G. R., «*I giudici creano diritto» (esame di una polemica giuridica)*, in Scarpelli U. (ed.), *Diritto e analisi del linguaggio*, Milano, 1976, pp. 397-406. Contrary to this interpretation, Grossi P., *La invenzione del diritto: a proposito della funzione dei giudici*, inaugural speech for the opening of the 2017 training courses at Scuola Superiore della Magistratura, par. 8, states that the Judge does not create law, since even the Legislator does not have this ability: law is something that pre-exists and has just to be found by the interpreter. The text of the speech is available at the following URL http://www.cortecostituzionale.it/documenti/interventi_presidente/Grossi_Scandicci.pdf [05.09.2017].

([28]) Albisinni F., *Prodotti alimentari o agroalimentari? Il TAR del Lazio, giudice del mercato e law maker, smentisce il MIPAAF e l'AGCM*, in this *Journal*, www.rivistadirittoalimentare.it, 3-2013, p. 39. Similarly, Pardolesi R.-Pino G., *Post-diritto e giudice legislatore. Sulla creatività della giurisprudenza*, in *Foro it*., 2017, 142, 3, p. 114.

([29]) Grossi P., *La invenzione del diritto: a proposito della funzione dei giudici, cit.*, in particular para. 6-8. Vv.Aa., *Il Giudice e la legge*, in *Questione giustizia*, 2016, 4, pp. 3 ss.

([30]) A comprehensive study on this topic started in the middle of Sixties, when G.Gorla launched an investigation on the importance of case law (or judicial activity), with a comparative research on «common law». The Author explained the reasons for such an analysis in G. Gorla, *Lo studio interno e comparativo della giurisprudenza e i suoi presupposti: le raccolte e le tecniche per la interpretazione delle sentenze*, in *Il Foro it.*, 1964, vol. 87, 7, parte V, col. 73-87 (see, in particolar, col. 73). For a contemporary overview on the role of the Judge in creating law, above all under a civil law point of view, please refer to Lipari N., *Il diritto civile tra legge e giudizio*, Milano, 2017. Please refer also to Pardolesi R.- Granieri M., *Dottrina delle corti e disimpegno dei giuristi*, in *Foro it.*, 2013, V, col. 187.

([31]) Pajno A., *Inaugurazione dell'anno giudiziario 2017*, speech held on January 31, 2017, available at-https://www.giustizia-amministrativa.it/cdsintra/cdsintra/Notiziasingola/index.html?p=NSIGA_4269449 [05.09.2017], who refers to the mobile borders among Legislator, Administration and Judge, even in civil law systems, where sources are depreciated, Laws become administrative acts and lose their characters of generality and abstraction and Judges create rules. See also Albisinni F., *Prodotti alimentari o agroalimentari? Il TAR del Lazio, giudice del mercato e law maker, smentisce il MIPAAF e l'AGCM, cit*., and Id., *Interpretazione conforme al diritto UE e diritto agrario: verso un diritto comune dell'agricoltura*, in Bernardi A. (ed), *L'interpretazione conforme al diritto dell'Unione europea. Profili e limiti di un vincolo problematico*, Napoli, 2015, p. 253, with reference to both the Italian civil and administrative Supreme Courts.

([32]) As for criminal law, the impact of the fundamental principle of "*riserva di legge*" (principle that could be summarized in the brocard «*nullum crimen nulla poena sine lege*» and which would have abstractly inhibited the "judicial creation of law") appears to have weakened, or at least changed. Borsari R., Diritto *penale*, *creatività e co-disciolinarità*. *Banchi di prova dell'esperienza giudiziale*, Padova, 2013, pp. 18 ss. See also Manes V., *Il Giudice nel labirinto. Profili delle intersezioni tra diritto penale e fonti sovranazionali*, Roma, 2012, pp. 22 ss.; Fiandaca G., *Crisi della riserva di legge e disagio della democrazia rappresentativa nell'età del protagonismo giurisdizionale*, in *Criminalia*, 2011, pp. 79-98; Donini M., *Europeismo giudiziario e scienza penale. Dalla dogmatica classica alla giurisprudenza-fonte*, Milano, 2011, pp. 53-54.

([33]) The expression is used by Lipari N., *Il diritto civile tra legge e giudizio*, Milano, 2017, p. 27, who puts emphasis on the EU Court's role as law-maker, p. 29, and on the judicial aspects that characterize EU law, p. 30.

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stances, the differences in attitudes among Member States and the need to protect health as a priority make the role of the Court an essential tool in a living and lively law system.

ABSTRACT

Shall Article 1(2)(c) of Regulation (EC) No 258/97 be interpreted as meaning that the expression 'new primary molecular structure' relates to foods or food ingredients which were not used for human consumption in the territory of the EU before 15 May 1997, or to those whose molecular structure did not exist as such in nature before that date? In case C-448/14, the EU Court opts for the first solution, thus including in the scope of the Novel Food Regulation also substances of mineral origin. This short note comments on the judgment, with an approach that, though critical, ends up in sharing the Court's findings.

L'articolo 1, paragrafo 2, lettera c del Regolamento (CE) n. 258/97 deve essere interpretato nel senso che l'espressione "struttura molecolare primaria nuova" si riferisce ad alimenti o ingredienti alimentari che non erano usati per il consumo umano nel territorio dell'Unione europea prima del 15 Maggio 1997, o a quegli alimenti o ingredienti la cui struttura molecolare non esisteva in natura prima di quella data? Nella causa C-448/14, la Corte UE adotta la prima soluzione, includendo così, nel campo di applicazione del Regolamento sui Novel Foods, anche le sostanze di origine minerale. Questa breve nota offre un commento alla sentenza, con un approccio che, pur se critico, finisce con il condividere il risultato cui è giunta la Corte.

Concurring opinion

Bernd van der Meulen

In the EU, food may not be placed on the market if it is unsafe (Article 14 of Regulation (EC) No 178/2002). A food may be unsafe due to its condition (contamination, decay, etcetera). It may also be unsafe due to its inherent characteristics. For conventional foods their inherent safety is assumed on the basis of experience. Over the twentieth century, legislators have increasingly designated categories of foods with regard to which they replaced the assumption of safety by a requirement to provide evidence of safety in an authorisation procedure. The system is that all foods fulfilling the definition of the designated category are banned from the market. This ban can be lifted by an authorisation. This authorisation usually takes the shape of inclusion of the product at issue in a positive list. In 1967 E.J. Bigwood and A. Gérard started a research series on Fundamental Principles and Objectives of a Comparative Food Law[1]. They present as core elements of structure the Principle of Abuse and the Principle of Prohibition. The former allows the production, sale and use of any food not expressly prohibited or marked on a negative list of unauthorised products. The principle of prohibition by contrast entails a general prohibition of anything not included in a positive list of authorised products, a list established and kept up to date by public authorities (p. 37). In practice countries use mixed systems applying prohibition only to foreign substances.

In the USA the prohibition principle has been introduced in 1958. Congress has chosen to apply the prohibition with authorisation requirement to the widest imaginable group of foods: 'anything added to food' (in American nomenclature these are food

(1) Bigwood É.J. - Gérard A., *Fundamental Principles and Objectives of a Comparative Food Law*, Karger, Basel-New York, 1967.

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additives). The EU by contrast has chosen a very different approach from the very beginning. Rather than requiring pre-market assessment of 'anything' the EU only brought well-defined categories of foods under such requirement (for example colouring matter in 1962 Directive 62/2645/EEC; preservatives, in 1964 Directive 64/54/EEC; antioxidants in 1970 Directive 70/357/EEC; food additives in general Directive 89/107/EEC; food supplements in Directive 2002/46/EC; GMOs in Regulation (EC) No 1829/2003).

The Novel Foods Regulation can indeed be understood as a departure from the product-category-by-product-category-approach by placing an umbrella over all the authorisation requirements covering all (other) foods not having a history of use. In fact I have advocated such reading myself[2]. In this reading, the listing of categories should not be understood as a delineation of the scope of the regulation, but rather as an attempt of the legislature to list all imaginable new foods. The obvious counter argument is that if this is what the legislature wanted, they would have followed the American approach which requires the authorisation of 'anything' rather than a listing. Indeed in listings not intended as limiting, usually an umbrella category 'any other' is included. See for example Article 2, No 4 of the Official Controls Regulation[3], listing enforcement powers.

It goes without saying that safety assessment of 'anything' is humanly impossible. Indeed we see that despite all protestations regarding supporting innovation, with the introduction of the Novel Foods Regulation all innovation at the level of food materials has come to a virtual standstill. Despite the fact that globally some 6.000 plant species[4] and 2.000 insect species[5] are consumed by humans that would classify as novel foods in the EU; despite the urgent need to broaden the EU's agro-biodiversity in the face of climate change,[6] the total number of foods authorised under the Novel Foods Regulation is less than 2 per year for the twenty years it has now been in force, less than 2 per Member State for the 28 States that are now members of the EU.

For the system to work it is vital the *de minimis* innovations are excluded for the scope of the Novel Foods Regulation. In the USA the consequence of the over-broad scope of the authorisation requirement is dealt with by excluding all substances that do not raise any concern because they are considered by experts qualified to make such assessment as GRAS (i.e. generally recognized as safe).

In EU food law, we do not find a general *de minimis* clause like the GRAS-exemption. We do, however, find some *de minimis* exceptions for example in category (e) (of Article 1(2) of the Novel Foods Regulation) "foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals". From this category exempted are "foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use". By consequence, the innovations that are achieved on a daily basis in plant and animal breeding are exempted from safety assessment and authorisation. Horticulturists and farmers have been cross-breeding species for so long, that the legislator trusts the outcome of such practices without a need for prior assessment.

In food additives we see processing aids excluded from the scope of the authorisation requirement. Processing aids are additive-like substances that are added to the process to perform a technological function. They or their residues may still be present in the final product, but they escape the authorisa-

(2) Van der Meulen B. - Van der Velde M., *European Food Law Handbook*, Wageningen Academic Publishers, 2008, pp. 292-293.
(3) 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. See also Article 3 (3)(b) of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.
(4) Knudsen I. et al., *Risk management and risk assessment of novel plant foods: concepts and principles*, in *Food Chem Toxicol*, 2008, 46, 5, pp. 1681.
(5) Van Huis et al., *Edible insects. Future prospects for food and feed security*, FAO, Rome 2013, p. xiii.
(6) See for example: JRC, *Delivering on EU Food Safety and Nutrition in 2050 - Future challenges and policy preparedness*, 2017, available at https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/delivering-eu-food-safety-and-nutrition-2050-future-challenges-and-policy-preparedness [07.09.2017].

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tion requirement if they perform no function in that final product, provided that they are safe. Food businesses are responsible that this safety requirement is met, but they are not required to submit any evidence to any authority. Indeed a prior authorisation scheme for processing aids in France was considered by the Court to constitute an unjustified barrier to trade as long as prior risk assessment by France did not show evidence of risk[7].

In the same way the category (c) in Article 1(2) of the Novel Foods Regulation "foods and food ingredients with a new or intentionally modified primary molecular structure" can be understood as exempting *de minimis* from the scope. Shockingly, the Court does not stop to reflect what the concept "primary molecular structure" means. Indeed the learned judges seem to assume – as probably only a lawyer can do – that reference is made to anything consisting of molecules. The concept "primary molecular structure" comes from structural biology. In this branch of molecular biology, it is used exclusively in relation to proteins.[8] Other substances are not usually considered having a "primary molecular structure". More specifically does the concept relate to the sequence of amino acids. Biochemistry then goes on to distinguish secondary, tertiary and quaternary structures. In biochemistry category (c) would be understood to exclude from the scope of the Novel Foods Regulation all alterations of proteins limited to the secondary, tertiary or quaternary structure and not affecting the primary structure.

The reading of the provision by the Court is dramatically different. It does not see the category as exempting, but it extends the scope of the authorisation requirements of the Novel Foods Regulation from major changes in the molecular structure of proteins to all changes in the molecular structure of proteins, to all changes in the molecular structure of any substance, indeed to the introduction of any substance consisting of molecules.

With this ruling, EU food law has reached an extreme point in application of the prohibition principle. Any molecule, indeed any arrangement of molecules, that was not consumed to a significant degree in the EU prior to 1997 is subject to authorisation (with the sole exception of new varieties of plants or animal obtained by traditional methods of breeding). What is needed now is a serious de minimis exception. Depending on how it will be applied in practice, the lighter procedure of exotic novel foods in the new Novel Foods Regulation, may be a relevant first step in that direction.

ABSTRACT

Judgement in case C-448/14 proves to be the EU food law extreme point in application of the principle of prohibition which entails a general prohibition of anything not included in a positive list of authorised products, a list established and kept up to date by public authorities.

Unlikely the biochemistry concept of "primary molecular structure", the Court does not see the category as exempting, but it extends the scope of the authorisation requirements of the Novel Foods Regulation from major changes in the molecular structure of proteins to all changes in the molecular structure of proteins, to all changes in the molecular structure of any substance, indeed to the introduction of any substance consisting of molecules.

However, for the system to work, it would be vital to exclude the de minimis innovations from the scope of the Novel Foods Regulation, similarly to the USA GRAS exemption.

□

([7]) Judgment of the Court (Third Chamber) of 28 January 2010, European Commission v French Republic, Case C-333/08. On this case, see: van der Meulen B.M.J., *Prior authorisation schemes: trade barriers in need of scientific justification, Case C-333/08 Commission v. French Republic 'processing aids'*, in *European Journal of Risk Regulation*,1, 4, pp. 465-471.

([8]) See for example Cachapa Rodrigues I., in Van der Meulen B. (ed.), *Reconciling food law to competitiveness. Report on the regulatory environment of the European food and dairy sector*, Wageningen Academic Publishers, 2009, p. 109. However, even Wikipedia provides this information. Some googling, therefore, would have provided the Court all the required background information.

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Commenti e note

La sentenza "Superfoz" relativa alla tassa sul controllo dei prodotti alimentari: un precedente pericoloso?

Luis González Vaqué

1.- Introduzione

Il 26 luglio 2017 la Corte di giustizia della UE ha emesso una sentenza[1] per dare risposta ad una domanda di pronuncia pregiudiziale sollevata dal Tribunal Administrativo e Fiscal de Coimbra (Portogallo) nell'ambito del procedimento tra *Superfoz - Supermercados Lda* e la *Fazenda Pública* (Agenzia delle entrate, Portogallo) del suddetto Stato membro. Tale domanda faceva riferimento all'interpretazione degli articoli 26 e 27 del Regolamento (CE) n. 882/2004 del Parlamento europeo e del Consiglio, del 29 aprile 2004, relativo ai controlli ufficiali intesi a verificare la conformità alla normativa in materia di mangimi e di alimenti e alle norme sulla salute e sul benessere degli animali, così come degli articoli 107 e 108 TFUE e dei principi di parità di trattamento, di non discriminazione, della libera concorrenza e della libertà d'impresa. Lo scopo di tale richiesta era chiarire la validità di una tassa destinata a finanziare i costi di esecuzione dei controlli ufficiali nell'ambito della sicurezza alimentare, della protezione e della salute degli animali e delle piante.
Vale la pena citare il fatto che *Superfoz - Supermercados Lda* è una società che in Portogallo si dedica allo sfruttamento commerciale di grandi superfici, alla distribuzione di prodotti alimentari e non alimentari e alla gestione di stazioni di servizio, come pure alla gestione di centri commerciali. Nonostante il fatto che la società usi il nome commerciale «Intermarché», nella sua decisione di rinvio il Tribunal Administrativo e Fiscal de Coimbra ha specificato che tale società possiede uno status giuridico separato sia rispetto all'affiliante *(ITMI Portogallo - Sociedade de Desenvolvimento e Investimento SA*), sia rispetto alle sue altre imprese affilianti che usano lo stesso nome commerciale. Nella decisione di rinvio si precisava inoltre che l'affiliante non raggiungeva una partecipazione nel capitale sociale di *Superfoz - Supermercados Lda* tale da conferirle poteri di gestione, di dirigenza o di amministrazione su di essa.
Nella presente nota cercheremo di chiarire in che modo la Corte abbia evitato di entrare nella vera natura delle questioni pregiudiziali di cui si parlava, al fine di chiarire i dubbi del Tribunal Administrativo e Fiscal de Coimbra su una tassa basata sull'applicazione del Regolamento (CE) n. 882/2004 che, come denunciato dai primi commenti sul caso[2], aveva l'obiettivo di raccogliere fondi, senza considerare se esistesse o meno una relazione con il costo/valore dei controlli alimentari effettivamente realizzati.

2. - La controversia principale

Con lettera del 1 luglio del 2014, la *Direção Geral de Alimentação e Veterinária* (direzione generale dell'Alimentazione e di Veterinaria, Portogallo) ha notificato a *Superfoz - Supermercados Lda* l'ingiunzione di pagamento della TSAM[3] corrispondente al

([1]) Sentenza 26 luglio 2017, causa C519/16, *Superfoz – Supermercados Lda c/ Fazenda Pública*. Si veda su questa sentenza: A. Mayoral, *Cuando lo importante es recaudar. Incoherencia y desacierto della jurisprudencia del TJUE en materia de tasas sobre los controles alimentarios*, Documento de trabajo CEEUDECO núm. 2/2017, 3-5.
([2]) Si veda A. Mayoral, *op. cit*., 1-3.
([3]) La tassa di sicurezza dei prodotti alimentari «Mais» è stata istituita dal decreto legge n. 119/2012 del 15 giugno 2012, del 15 giugno 2012; nel preambolo di tale normativa nazionale viene indicato che il diritto applicabile dell'Unione stabilisce «l'obbligo di finanziamento dei costi di esecuzione dei controlli ufficiali da parte degli Stati membri e conferisce a questi ultimi la facoltà di ottenere i mezzi finanziari

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2014, per un importo pari a 10.274,25 euro. La richiamata direzione generale ha precisato che, conformemente alla legislazione nazionale, tale importo risultava dall'applicazione della tassa (che era stata fissata a 7 euro per metro quadrato) alla superficie di vendita dello stabilimento di proprietà di *Superfoz - Supermercados Lda*, di 1.467,75 metri quadrati. La società ha contestato, dinanzi al giudice del rinvio, la legittimità delle cartelle esattoriali della TSAM a suo carico.

Va aggiunto che il *Tribunal Administrativo e Fiscal de Coimbra* ha comunicato alla Corte:

- che la tassa TSAM «si inserisce in una politica di protezione della catena alimentare e della salute dei consumatori, basata sul principio della responsabilizzazione degli agenti economici intervenienti in materia di sicurezza e di qualità alimentare»[4];
- che «siffatta tassa è diretta a finanziare il fondo della sanità e della sicurezza alimentare «Mais» (Fundo Sanitário e de Segurança Alimentar Mais) istituito dal decreto legge n. 119/2012»[5] (priva della competenza necessaria per effettuare controlli diversi da quelli previsti dal regolamento n. 882/2004);
- che «la TSAM è una tassa versata su base annuale che costituisce il corrispettivo della garanzia di sicurezza e di qualità alimentare»[6] (in questo ambito, i titolari degli stabilimenti commerciali di prodotti alimentari di origine animale e vegetale sono soggetti al pagamento di questa tassa, che viene calcolata applicando un importo unitario compreso tra 5 e 8 euro per metro quadrato della superficie di vendita dello stabilimento); e
- che la legislazione portoghese «prevede [...] una deroga al pagamento di detta tassa per gli stabilimenti che hanno una superficie inferiore a 2 000 metri quadrati o che appartengono a microimprese, a condizione che tali stabilimenti non facciano parte di un'impresa che utilizza una o più insegne e dispone a livello nazionale di una superficie di vendita complessiva uguale o superiore a 6 000 metri quadrati e che non siano integrati a un gruppo che dispone a livello nazionale di una superficie di vendita complessiva uguale o superiore a 6 000 metri quadrati. Il Tribunal Constitutional (Corte costituzionale, Portogallo) avrebbe statuito, a tal proposito, che take deroga non era contraria alla nozione costituzionale di uguaglianza»[7].

3. - Le questioni pregiudiziali

Tenendo conto dei dubbi suscitati sulla legittimità della TSAM come corretta trasposizione di quanto stabilito nel Regolamento n. 882/2004, sulla sua compatibilità con il principio di parità di trattamento e sul fatto che tale tassa potesse violare la libertà d'impresa e il dovere corrispondente di neutralità economica degli Stati membri, il Tribunal Administrativo e Fiscal de Coimbra (Portogallo) ha deciso di sospendere il procedimento e di sottoporre alla Corte di Giustizia le seguenti questioni pregiudiziali:

«1) Se l'articolo 27, paragrafo 10, del regolamento (CE) n. 882/2004, del 29 aprile 2004, o qualsiasi altra norma o principio generale del diritto dell'Unione europea che la Corte di giustizia ritenga applicabile, possa interpretarsi nel senso che osta ad una disposizione nazionale istitutiva di una tassa per il finanziamento di controlli ufficiali di sicurezza alimentare, la quale grava unicamente sui proprietari di negozi al dettaglio nel settore alimentare o misto, senza che tale tributo corrisponda ad alcun controllo ufficiale specifico realizzato a causa o a favore dei detti soggetti passivi.

2) Se la risposta alla precedente questione sarebbe

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adeguati mediante l'imposizione fiscale generale o mediante l'istituzione di diritti o tasse speciali a carico degli operatori» e che, «conformemente a tali norme, sono già state istituite varie tasse destinate a sostenere finanziariamente gli interventi di verifica e di controllo che hanno come riferimento i costi e le spese relative al personale, ossia le remunerazioni, le installazioni, gli strumenti, le attrezzature, la formazione, le missioni e le spese connesse, comprese quelle relative al prelievo e all'invio dei campioni e alle analisi in laboratorio» (si vedano i punti 11, 12, 13 e 14 della sentenza "Superfoz").

(4) Si veda il punto 19 della sentenza *"Superfoz"*.

(5) *Ibidem*.

(6) Si veda il punto 20 della sentenza *"Superfoz"*.

(7) *Ibidem*, punto 21.

diversa nel caso in cui, invece di una tassa, venisse previsto il pagamento di un contributo finanziario a favore di un ente pubblico, a carico degli stessi soggetti passivi, e che detto contributo fosse destinato a coprire i costi dei controlli di qualità alimentare, sebbene con l'unico obiettivo di estendere a tutti gli operatori della catena alimentare la responsabilità del finanziamento di tali controlli.
3) Se l'esenzione di determinati operatori economici da una tassa di sicurezza alimentare che grava unicamente su taluni dettaglianti del settore alimentare o misto (fondamentalmente le grandi imprese di commercio al dettaglio di prodotti alimentari) e che viene destinata a finanziare i costi di esecuzione dei controlli ufficiali nell'ambito della sicurezza alimentare, della protezione e della salute degli animali nonché della protezione dei vegetali e della salute delle piante, costituisca un aiuto di Stato incompatibile con il mercato interno, nei limiti in cui falsa o minaccia di falsare la concorrenza, favorendo determinate imprese o produzioni ai sensi dell'articolo 107, paragrafo 1, TFUE, o se, quanto meno, l'esenzione dalla summenzionata tassa faccia parte di un aiuto di Stato soggetto all'obbligo di comunicazione alla Commissione europea ai sensi dell'articolo 108, paragrafo 3, TFUE.
4) Se i principi di diritto dell'Unione europea, e in particolare i principi di uguaglianza, di non discriminazione, di concorrenza (incluso il divieto di discriminazione inversa – c.d. «reverse discrimination») e di libertà di impresa, ostino ad una disposizione nazionale che:
a) impone l'obbligo di pagare la tassa unicamente alle grandi imprese di commercio al dettaglio di prodotti alimentari;
b) esclude dall'ambito di applicazione della tassa gli esercizi o le microimprese con una superficie di vendita inferiore a 2 000 m2 che non siano integrati in un gruppo o non appartengano ad un'impresa che utilizza una o più insegne e che dispone, a livello nazionale, di una superficie di vendita complessiva uguale o superiore a 6 000 m2»[8].

4.- La decisione

In risposta a tali questioni, la Corte (Nona Sezione) ha dichiarato:
«Gli articoli 26 e 27 del regolamento (CE) n. 882/2004 del Parlamento europeo e del Consiglio, del 29 aprile 2004, relativo ai controlli ufficiali intesi a verificare la conformità alla normativa in materia di mangimi e di alimenti e alle norme sulla salute e sul benessere degli animali, come modificato dal regolamento (UE) n. 652/2014 del Parlamento europeo e del Consiglio, del 15 maggio 2014[9], devono essere interpretati nel senso che non ostano all'imposizione di una tassa, quale quella di cui al procedimento principale, ai soli stabilimenti commerciali al dettaglio di prodotti alimentari, senza che il gettito di tale tassa serva a finanziare specificamente i controlli ufficiali realizzati a causa o a favore di tali soggetti passivi.»[10].

5.- Commenti

5.1.- La portata delle questioni pregiudiziali e l'interpretazione della Corte

Dopo aver fatto riferimento alla giurisprudenza, secondo cui la circostanza che il giudice del rinvio abbia formulato una questione pregiudiziale facendo riferimento soltanto a talune disposizioni del diritto dell'Unione non osta a che la Corte fornisca a detto giudice tutti gli elementi di interpretazione che possano essere utili alla decisione della causa di cui è investito (indipendentemente dalla circostanza che esso vi abbia fatto riferimento o meno nella formulazione delle questioni), la Corte ha precisato: «Spetta, al riguardo, alla Corte trarre dall'insieme degli elementi forniti dal giudice nazionale, e, in par-

([8]) *Ibidem,* punto 27.
([9]) Platone è il primo ad affermare, nel Fedone, che le idee si associano per somiglianza o per contrasto. Aristotele, nel trattato sulla memoria e la riminiscenza, aggiunge un terzo elemento: la contiguità. Per Hume, l'associazione di idee viene considerata come una dolce forza, una specie di "attrazione" che egli ha mutuato dalla forza di gravità di Newton.
([10]) Così il dispositivo della sentenza "*Superfoz*", cit.

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ticolare, dalla motivazione della decisione di rinvio, gli elementi di diritto dell'Unione che richiedano un'interpretazione, tenuto conto dell'oggetto della controversia»[11].

5.2.- Sulle questioni prima e seconda

In primo luogo, il Tribunal Administrativo e Fiscal de Coimbra chiedeva se la tassa "TSAM" fosse conforme all'articolo 27.10 del Regolamento n. 882/2004, in quanto, da una parte, le spese vincolate ai controlli previsti in questo Regolamento sono coperte da altre tasse e, dall'altra, la "TSAM" grava esclusivamente sugli stabilimenti commerciali di alimenti sui quali pesano le responsabilità e i doveri stabiliti dal Regolamento n. 178/2002 e dal Regolamento n. 882/2004.
Più concretamente, la Corte di giustizia ha ritenuto che si dovesse «… intendere che, con la prima e la seconda questione, da esaminare congiuntamente, il giudice del rinvio chiede, in sostanza, se gli articoli 26 e 27 del regolamento n. 882/2004 debbano essere interpretati nel senso che ostano all'imposizione di una tassa, quale quella di cui al procedimento principale, ai soli stabilimenti commerciali al dettaglio di prodotti alimentari, *senza che il gettito di detta tassa serva a finanziare specificamente i controlli ufficiali realizzati a causa o a favore di tali soggetti passivi*»[12]. In tale contesto, la Corte ha ricordato che, ai sensi dell'articolo 3.3, del Regolamento n. 882/2004, i controlli ufficiali verranno eseguiti in una qualsiasi delle fasi di produzione, di trasformazione e di distribuzione degli alimenti interessati, e che «essi comprendono altresì, segnatamente, i controlli delle imprese del settore alimentare richiesti per il raggiungimento degli obiettivi di tale regolamento»[13].
D'altra parte, la Corte ha confermato che dai considerando 11 e 32 di tale Regolamento risulta che le autorità competenti degli Stati membri devono disporre di personale sufficiente, munito della qualifica e dell'esperienza necessarie, ed avere impianti e attrezzature adeguate per svolgere correttamente le proprie funzioni e, logicamente, a tale scopo gli Stati membri devono disporre anche delle risorse finanziarie adeguate per organizzare i controlli.
In questo senso, la Corte ha sottolineato che l'articolo 26 del Regolamento n. 882/2004 stabilisce che gli Stati membri veglieranno affinché esistano delle risorse economiche adeguate per consentire di disporre del personale e delle altre risorse necessarie a realizzare i controlli ufficiali con l'aiuto di qualsiasi mezzo si ritenga opportuno, inclusa l'imposizione generale o l'istituzione di tasse o oneri. Successivamente, si è riferita al fatto che «l'articolo 27 del predetto regolamento riguarda specificamente i diritti e le tasse»[14] e che, «ai sensi del suo paragrafo 1, gli Stati membri sono autorizzati a riscuotere tali tasse o diritti al solo scopo di coprire i costi sostenuti per i controlli ufficiali»[15].
Citando il punto 39 della sentenza "*Kødbranchens Fællesråd*"[16], ha ribadito che *le tasse e gli oneri previsti in questo articolo potranno essere destinati esclusivamente a coprire i costi degli Stati membri effettivamente derivanti dalla realizzazione dei controlli all'interno degli stabilimenti alimentari*. Inoltre, sempre secondo la stessa fonte, ai sensi dell'articolo 26 del Regolamento n. 882/2004, letto alla luce del considerando 32, gli Stati membri *dispongono di un ampio margine discrezionale quanto alla disponibilità, soprattutto nell'ambito dell'imposizione fiscale generale*, di adeguati finanziamenti per la predisposizione del personale e delle altre risorse necessarie per i controlli ufficiali: «Tale margine è per contro disciplinato dalle norme armonizzate di cui all'articolo 27 del regolamento n. 882/2004 quando gli Stati membri decidono di imporre agli operatori le tasse e i diritti previsti da tale articolo»[17].
Infine, per quanto riguarda la valutazione della

(11) Si veda il punto 28 della sentenza *"Superfoz"*.
(12) Si veda il punto 29 della sentenza "*Superfoz"*; il corsivo è nostro.
(13) *Ibidem,* punto 30.
(14) *Ibidem*, punto 33.
(15) *Ibidem*; il corsivo è nostro.
(16) Del 17 marzo 2016, causa C112/15.
(17) Si veda il punto 34 della sentenza "*Superfoz*".

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"TSAM", alla luce degli articoli 26 e 27 del Regolamento n. 882/2004, la Corte ha osservato che, dalle informazioni ad essa fornite, risulta che, f*atte salve verifiche da parte del giudice del rinvio*, questa tassa non è stata concepita come una tassa o un onere compresi nell'ambito dell'applicazione dell'articolo 27 del Regolamento citato, ma si inscrive nell'ambito di un altro tipo di risorse finanziarie che gli Stati possono ottenere in virtù dell'articolo 26 del Regolamento[18].

La Corte ha accolto quanto sostenuto dalla Commissione nelle proprie osservazioni: «la genesi di detta tassa risiede nel fatto di detenere uno stabilimento commerciale di una determinata superficie e non, come nel caso del fatto generatore di un diritto o di una tassa ai sensi dell'articolo 27 del regolamento n. 882/2204, nell'esecuzione di controlli ufficiali che sarebbero specificamene effettuati presso gli stabilimenti commerciali alimentari soggetti a detta tassa»[19].

Seguendo questi ragionamenti, la Corte è giunta alle seguenti conclusioni:

- ai sensi dell'articolo 9 del decreto legge n. 119/2012, la "TSAM" costituisce il «corrispettivo della garanzia della sicurezza e della qualità degli alimenti» e «dagli elementi forniti dal giudice del rinvio emerge, inoltre, che tale tassa ha la finalità di far gravare sugli stabilimenti commerciali del settore alimentare i costi generali connessi all'organizzazione dei controlli ufficiali, nei limiti in cui *tali stabilimenti beneficiano dei controlli effettuati a monte nella catena produttiva alimentare*»[20]; e
- i proventi riscossi grazie alla TSAM hanno come obiettivo il finanziamento del fondo sanitario e della sicurezza dei prodotti alimentari «Mais», costituito dall'insieme delle entrate destinate a finanziare i costi di esecuzione dei controlli ufficiali in materia di sicurezza alimentare: «non esiste quindi alcuna relazione diretta tra siffatta tassa e le spese che quest'ultima è diretta a coprire»[21].

5.3.- Sulle questioni terza e quarta

Anche questa volta la Corte ha fatto riferimento alla propria consolidata giurisprudenza, in virtù della quale, sempre nell'ambito della cooperazione con gli organi giurisdizionali nazionali instaurata dall'articolo 267 TFUE, la necessità di giungere ad un'interpretazione del Diritto dell'Unione che sia efficace per il giudice nazionale richiede che questo definisca il contesto fattuale e normativo in cui si inseriscono le questioni pregiudiziali che solleva o che, per lo meno, spieghi le fattispecie su cui si basano tali questioni: «la Corte, infatti, può esprimersi esclusivamente sull'interpretazione di un testo dell'Unione a partire dai fatti ad essa presentati dal giudice nazionale»[22]. Secondo la Corte, queste richieste, relative al contenuto di una domanda di pronuncia pregiudiziale, figurano in modo esplicito nell'articolo 94 del regolamento di procedura della Corte, in base al quale qualsiasi domanda di pronuncia pregiudiziale deve contenere specificatamente «un'illustrazione sommaria dell'oggetto della controversia nonché dei fatti rilevanti, quali accertati dal giudice del rinvio o, quanto meno, un'illustrazione delle circostanze di fatto sulle quali si basano le questioni» e «l'illustrazione dei motivi che hanno indotto il giudice del rinvio a interrogarsi sull'interpretazione o sulla validità di determinate disposizioni del diritto dell'Unione, nonché il collegamento che esso stabilisce tra dette disposizioni e la normativa nazionale applicabile alla causa principale». È evidente che, attraverso la sua terza questione pregiudiziale, il giudice del rinvio chiedeva se gli articoli 107.1 e 108.3 TFUE si debbano interpretare nel senso che si oppongono alla riscossione di una tassa, come la "TSAM", dal cui pagamento sono esentati gli stabilimenti di commercio al dettaglio di prodotti alimentari dalla superficie limitata. Ai fini di

(18) *Ibidem*, punto 35.
(19) *Ibidem*, punto 36.
(20) *Ibidem*, punto 37; il corsivo è nostro.
(21) *Ibidem*, punto 38.
(22) *Ibidem*, punto 44.

completezza, il Tribunal Administrativo e Fiscal de Coimbra aveva dei dubbi sulla compatibilità della TSAM con il principio di parità di trattamento, dato che questa tassa grava solo su alcuni stabilimenti commerciali di prodotti alimentari[23].
Secondo la Corte:
● anche supponendo che un'esenzione fiscale a favore di talune imprese constituisca una misura di aiuto ai sensi dell'articolo 107.1 TFUE, l'eventuale illegalità dell'aiuto non influirebbe sulla legalità della tassa da cui si esimono queste imprese: infatti, «a tal proposito, la Corte ha statuito che i debitori di una tassa, al fine di sottrarsi dal pagamento della stessa, non possono eccepire che l'esenzione di cui beneficiano altre imprese costituisce un aiuto di Stato»[24]; e
● la decisione di rinvio non contiene nessuna indicazione da cui si possa dedurre che, nonostante *Superfoz - Supermercados Lda* non otterrebbe alcun vantaggio nel caso in cui si dovesse constatare un'infrazione degli articoli 107 e 108.3. TFUE, la risposta alla terza questione pregiudiziale sia necessaria affinché il giudice del rinvio possa risolvere presso di lui la controversia in corso.
Basandosi su tali argomenti e senza esaminare approfonditamente i profili di coerenza della "TSAM" con la riscossione di fondi per i controlli alimentari, dato che viene applicata in base alla superficie di uno stabilimento, la Corte ha ritenuto che le questioni pregiudiziali terza e quarta fossero irricevibili perché: i) in tali circostanze, non sembrava che la terza questione pregiudiziale avesse una relazione con l'oggetto della controversia principale; e ii) la quarta questione pregiudiziale verteva sui principi di parità di trattamento, di non discriminazione, di libera concorrenza e di libertà d'impresa.[25]

Come segnalato da un commentatore[26], la pronuncia della Corte appare poco persuasiva, lì ove afferma al punto 51:
«Orbene, il giudice del rinvio si limita a rilevare che si potrebbe dubitare della conformità della TSAM con i principi di cui trattasi senza tuttavia fornire le ragioni per le quali detto giudice nutre tali dubbi. In particolare, la decisione di rinvio non fornisce alcun elemento che permetta di confrontare la situazione tra gli operatori debitori della TSAM e coloro che sono esenti da tale tassa. In più, un'eventuale differenza di trattamento può essere giustificata da ragioni opportune ammesse dalla giurisprudenza della Corte, ma, neppure a tal riguardo, la decisione di rinvio contiene informazioni. Pertanto, occorre constatare che la decisione di rinvio non risponde manifestamente ai requisiti richiamati al punto 45 della presente sentenza»[27].

6.- Conclusioni

Non è facile accertare quale sia la giurisprudenza della Corte di giustizia sulla questione se il Diritto comunitario consenta o meno agli Stati membri di imporre le tasse in modo arbitrario, poiché non esiste una relazione diretta tra i servizi prestati. È possibile che, come è stato segnalato da un commentatore[28], la responsabilità del fatto che si accetti questo tipo di imposte non è della Corte, quanto piuttosto del legislatore comunitario che, ad esempio, ha introdotto nelle proprie normative disposizioni ambigue come gli equivoci articoli 26 e 27 del Regolamento (CE) n. 882/2004. In ogni caso, si introduce un precedente pericoloso, che può dar luogo alla proliferazione di tasse "di origine euro-

(23) Come sottolineato al punto 24 della sentenza "*Superfoz*", il giudice del rinvio nutriva «dubbi compatibilità della TSAM con il principio di parità di trattamento in quanto tale tassa grava soltanto su taluni stabilimenti commerciali del settore alimentare».
(24) Sentenza "*Superfoz*", punto 47.
(25) V. i punti 49-52 della sentenza "*Superfoz*".
(26) Si veda A. Mayoral, *op. cit.*, 12-13.
(27) Vale la pena trascrivere quanto viene indicato nel citato punto: «tali requisiti relativi al contenuto di una domanda di pronuncia pregiudiziale sono espressamente previsti all'articolo 94 del regolamento di procedura della Corte, secondo cui ogni domanda di pronuncia pregiudiziale contiene, segnatamente, *un'illustrazione sommaria dell'oggetto della controversia nonché dei fatti rilevanti, quali accertati dal giudice del rinvio o, quanto meno, un'illustrazione delle circostanze di fatto sulle quali si basano le questioni e l'illustrazione dei motivi che hanno indotto il giudice del rinvio a interrogarsi sull'interpretazione o sulla validità di determinate disposizioni del diritto dell'Unione, nonché il collegamento che esso stabilisce tra dette disposizioni e la normativa nazionale applicabile alla causa principale*».
(28) Si veda A. Mayoral, *op. cit.*, 12-13.

pea", senza che esista una relazione tra il suo importo e il costo dei servizi realmente prestati.
Vale la pena sottolineare che la Corte, dopo aver fatto riferimento alle proprie ampie competenze quando deve dare delle risposte ad una domanda di pronuncia pregiudiziale, dichiara in modo elusivo che «la terza e la quarta questione sono irricevibili» (?). Oltretutto, non indica in modo chiaro la portata delle verifiche da parte del giudice del rinvio, oltre alla questione se la controversa tassa portoghese debba considerarsi nell'ambito dell'articolo 26 o del 27.

ABSTRACT

The European Court of Justice (Ninth Chamber) ruled that articles 26 and 27 of Regulation No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, as amended by Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014, must be interpreted as not precluding the imposition of a charge, such as a national provision that establishes a charge to finance official controls related to food safety, on retail food outlets only, where the revenue from that charge is not used specifically to finance official controls that have been caused by, or that are for the benefit of, those chargeable persons.

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Novità

Il divieto di indicazioni nutrizionali per le bevande alcoliche dopo il Decreto Legislativo 27/2017

Alice Artom

1.- Il contesto europeo

Le indicazioni nutrizionali e sulla salute sono state armonizzate a livello europeo dal Regolamento (CE) n. 1924/2006 del Parlamento europeo e del Consiglio, del 20 dicembre 2006, riguardante le indicazioni nutrizionali e sulla salute fornite sui prodotti alimentari per garantire il funzionamento del mercato interno, assicurando al contempo un livello elevato di tutela dei consumatori ("il Regolamento Claims")[1].
Tale normativa è stata successivamente modificata dal Regolamento (UE) n. 1169/2011 relativo alla fornitura di informazioni sugli alimenti ai consumatori[2] ("il Reg. Informazione ai Consumatori") che ha sostituito il primo e secondo comma dell'art. 7 del Regolamento Claims relativi all'etichettatura nutrizionale dei prodotti[3].
Per quanto riguarda gli alcolici, l'art. 4, paragrafo 3 del Regolamento Claims ha stabilito il divieto per le bevande alcoliche contenenti più dell'1,2 % di alcol in volume, dell'apposizione in etichetta di indicazioni sulla salute[4]; mentre per quanto concerne le indicazioni nutrizionali sono ammesse soltanto quelle che si riferiscono alla riduzione del tenore alcolico o alla riduzione del contenuto energetico.
Il 30 maggio del 2007, la Commissione UE ha proposto una strategia europea sugli aspetti sanitari connessi all'alimentazione, al sovrappeso e all'obesità, con il Libro bianco[5], ove ha segnalato che l'etichettatura nutrizionale è uno dei metodi principali per informare i consumatori sulla composizione degli alimenti e aiutarli ad adottare decisioni consapevoli. In particolare la conoscenza dei principi base della nutrizione e un'adeguata informazione nutrizionale sugli alimenti possono contribuire significativamente a consentire al consumatore di effettuare scelte consapevoli.
Tale principio è stato ripreso nel Considerando 10 del Regolamento sull'informazione ai Consumatori.
Nella proposta di regolamento della Commissione relativo alla fornitura di informazioni sugli alimenti ai consumatori, risalente al 2008, per le bevande alcoliche, inclusi gli "*alcopops*" (miscele di bevande alcoliche, come miscele di un soft drink di succhi di frutta con una bevanda alcolica) era previsto l'obbligo di indicare in etichetta la lista degli ingredienti e la dichiarazione nutrizionale. Tale obbligo non riguardava la birra, il vino e le bevande spiritose.
Su iniziativa del Parlamento Europeo, questa esenzione fu estesa temporaneamente a tutte le bevande alcoliche.
Di conseguenza il paragrafo 4 dell'art. 16 del Regolamento n. 1169/2011, ha stabilito che la Commissione, entro il 13 dicembre 2014, doveva presentare una relazione intesa a chiarire se alcune categorie di bevande alcoliche dovessero essere in futuro esentate dall'obbligo di fornire le informazioni relative alla dichiarazione nutrizionale, corredata da una proposta legislativa sull'elenco degli ingredienti

(1) Per l'inquadramento della materia sulle indicazioni nutrizionali e sulla salute si richiamano i Considerando 1 e 2 del Reg. (UE) n. 1924/2006 che contiene i principi ispiratori di tale Regolamento.
(2) Vedi art. 49 Reg. (UE) n. 1169/2011, Modifiche al regolamento (CE) n. 1924/2006.
(3) Il principio relativo alla tutela della salute dei consumatori e garanzia di un'adeguata informazione sugli alimenti destinati ai consumatori è contenuto nel Considerando 3 del Reg. (UE) 1169/2011, che riprende in parte il Considerando 1 del Reg. (CE) n. 1924/2006 e nel Capo II "Principi generali delle informazioni sugli alimenti" artt. 3 e 4 del Reg. (UE) n. 1169/2011.
(4) Sentenza della Corte di Giustizia Europea Sez. III, 6 settembre 2012, causa C- 544/10 *Deutsches Weintor e G c. Land Rheinland–Pfalz* sui seguenti principi contenuti nel Reg. CE 1924/2006: "Informazione e tutela dei consumatori" di cui al Considerando 1, "Nozioni di indicazioni nutrizionali e di indicazioni sulla salute" ex artt. 3 e 4, "Bevande contenenti più dell'1,2% in volume di alcol" – "Divieto di indicazioni sulla salute" ex art. 4, paragrafo 3.
(5) Commissione delle Comunità Europee, [COM (2007) 279 def.], Bruxelles 30 maggio 2007.

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e sulla dichiarazione nutrizionale obbligatoria per tali prodotti[6]. Inoltre la Commissione avrebbe dovuto valutare l'esigenza di proporre una definizione di "*alcopops*"[7]; ciò anche alla luce del principio espresso al Considerando 40 del citato regolamento.
Sugli "*alcopops*" il Considerando 40 pone in evidenza l'importanza di definire tali bevande rivolte ad un pubblico giovanile, tenuto conto dei timori sui danni provocati dall'alcol ai giovani.
Il Considerando 42 del Regolamento incoraggia gli operatori del settore alimentare a fornire su base volontaria le informazioni contenute nella dichiarazione nutrizionale per alimenti quali le bevande alcoliche[8], lasciando agli stessi la possibilità di dichiarare soltanto alcuni elementi della dichiarazione nutrizionale, ma stabilendo chiaramente quali informazioni possono essere fornite su base volontaria, onde evitare che la possibilità di scelta lasciata all'operatore del settore alimentare possa indurre in errore il consumatore.
Con grave ritardo rispetto al termine del 13 dicembre 2014[9], il 13 marzo 2017 la Commissione UE si è pronunciata con una Relazione al Parlamento europeo e al Consiglio sull'indicazione obbligatoria in etichetta dell'elenco degli ingredienti e sulla dichiarazione nutrizionale per le bevande alcoliche[10]. In tale Relazione la Commissione ha esaminato, in primo luogo, il quadro normativo di riferimento, soffermandosi in particolare sui seguenti articoli del Regolamento (UE) n. 1169/2011:
a) art. 16, paragrafo 4 che prevede, a partire dal 13 Dicembre 2016, un'esenzione temporanea per le bevande alcoliche con contenuto superiore all'1,2% in volume dall'elenco obbligatorio degli ingredienti e dalla dichiarazione nutrizionale[11];
b) art. 21 che stabilisce l'etichettatura di alcune sostanze o prodotti che provocano allergie o intolleranze con riferimento all'Allegato II. Tali requisiti si applicano anche alle bevande alcoliche;
c) art. 41, che permette agli Stati membri di mantenere in vigore disposizioni nazionali sull'indicazione in etichetta degli ingredienti delle bevande con contenuto alcolico superiore all'1,2% in volume, in attesa dell'adozione di disposizioni dell'Unione Europea armonizzate.
La Relazione tiene conto del Considerando 42 del Regolamento, che incoraggia gli operatori del settore delle bevande alcoliche a fornire su base volontaria le informazioni contenute nella dichiarazione nutrizionale, concedendo la possibilità di dichiarare in etichetta solo il valore energetico.
La Relazione richiama, inoltre, l'art. 9 lettera k) del Regolamento che stabilisce, per le bevande che contengono più dell'1,2% di alcol in volume, l'obbligo di riportare in etichetta il titolo alcolometrico volumico effettivo[12].
Per quanto riguarda le informazioni per le bevande alcoliche, la Commissione, in secondo luogo, ricorda nella Relazione le disposizioni del Regolamento Claims che stabiliscono il divieto di apporre in etichetta le indicazioni relative alla salute, consentendo i soli dati riferiti ad un basso tenore di alcol ed alla riduzione dell'alcol o del contenuto energetico, che possono essere indicati nella dichiarazione nutrizionale in etichetta.
In terzo luogo, la Commissione ha ritenuto opportuno condurre uno studio sul comportamento dei consumatori in relazione alle informazioni nutrizionali sulle bevande alcoliche da indicare in etichetta, al fine di analizzare le decisioni assunte dai consumatori stessi[13]. In questo sondaggio sono stati coinvolti otto Stati membri con lo scopo di conoscere la loro

([6]) Nel Considerando 40 il Reg. (UE) n. 1169/2011 precisa che la Commissione è stata invitata ad analizzare ulteriormente i requisiti riguardanti le informazioni sulle bevande alcoliche, proponendo, se del caso, requisiti specifici, tenuto conto delle "peculiarità" delle stesse.
([7]) Art. 16 comma 4, secondo e terzo paragrafo Reg. (UE) n. 1169/2011.
([8]) Art. 9, paragrafo 1, lettera l) e Sezione 3 del Reg. (UE) n. 1169/2011.
([9]) Fissato dall'art. 16 paragrafo 4 Reg. (UE) n. 1169/2011.
([10]) Commissione Europea COM (2017) 58 final del 13 marzo 2017.
([11]) E' bene porre in rilievo che l'esenzione temporanea dall'elenco obbligatorio degli ingredienti e dalla dichiarazione nutrizionale per le bevande con contenuto superiore all'1,2% di alcol, prevista dall'art. 16, paragrafo 4 del Reg. (UE) n. 1169/2011, riguarda anche le birre, i vini, i superalcolici e le bevande spiritose.
([12]) L'obbligo stabilito all'art. 9, lettera k) Reg. (UE) n. 1169/2011 si applica a tutte le categorie di bevande alcoliche come sopra elencate.
([13]) TNS European Behaviour Studies Consortium, Study on the impact of food information on consumers' decision making (2014).

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opinione sulle informazioni rilevanti per le bevande alcoliche.
Dal sondaggio è emerso che quasi la metà (49%) dei partecipanti avrebbe voluto ricevere informazioni sul valore energetico delle bevande alcoliche ed il 16% ha espresso l'intenzione di ridurre il proprio consumo di alcol.
Secondo uno studio svolto nel 2014 e commissionato da un'associazione di produttori di birra[14], i consumatori hanno una limitata conoscenza delle informazioni sul valore nutrizionale e sugli ingredienti delle bevande alcoliche.
In un successivo documento, alcuni rappresentanti dei consumatori hanno concluso che la differenza di disciplina tra l'etichettatura delle bevande alcoliche e quella degli altri alimenti sarebbe inaccettabile e che l'elenco degli ingredienti e la dichiarazione nutrizionale dovrebbero essere obbligatori per tutte le bevande alcoliche al fine di aiutare i consumatori a compiere scelte consapevoli[15].
Anche le associazioni della sanità pubblica si sono espresse a favore dell'indicazione obbligatoria in etichetta dell'elenco degli ingredienti e della dichiarazione nutrizionale, come parte di una strategia complessiva volta a fornire informazioni ai consumatori e a educarli sul consumo di alcol. In particolare, secondo un gruppo di organizzazioni non governative e della sanità pubblica che sostengono politiche per la prevenzione e la riduzione dei danni legati al consumo di alcol in Europa[16], i consumatori avrebbero il diritto di sapere quali ingredienti sono contenuti nelle bevande alcoliche che consumano. Inoltre dovrebbero essere fornite informazioni nutrizionali, quali il contenuto energetico, per permettere ai consumatori di controllare meglio il loro regime alimentare e agevolare uno stile di vita sano.
Recentemente il punto di vista dell'industria sull'argomento è mutato in modo significativo. Mentre in passato gli operatori del settore alimentare si opponevano a qualsiasi ulteriore prescrizione di etichettatura, oggi la maggioranza di essi riconosce che i consumatori hanno il diritto di essere informati riguardo al contenuto di ciò che bevono e gli attori di diversi settori stanno sviluppando e realizzando una serie di iniziative volontarie indipendenti o concertate volte a fornire ai consumatori informazioni supplementari.
Il settore delle bevande spiritose (es: il *brandy* o *winebrand*) ritiene che i consumatori trarrebbero vantaggio da informazioni più chiare e significative sul contenuto di ciò che bevono e che dovrebbero ricevere informazioni coerenti sul consumo responsabile di bevande spiritose per consentire loro di scegliere di adottare stili di vita più sani. Tale settore è a favore di informazioni mirate sul contenuto calorico, che possono essere fornite attraverso mezzi diversi dall'indicazione sull'etichetta: siti web, social media ed altre piattaforme[17].
Anche il settore vitivinicolo ha affermato che una dieta bilanciata è l'elemento fondamentale per condurre uno stile di vita sano e che i consumatori dovrebbero scegliere con attenzione che cosa bere e che cosa mangiare. Questo settore si è impegnato a fornire volontariamente ai consumatori le informazioni nutrizionali sulle calorie in modo adeguato al contesto ed utilizza prevalentemente supporti diversi dall'etichetta[18].
Ulteriori impegni in tal senso sono stati assunti anche nel contesto del Forum europeo "Alcol e salute"[19], piattaforma in cui gli organismi attivi a livello europeo possono discutere, confrontare approcci e prendere iniziative per contrastare i danni legati al consumo di alcol, onde consentire una maggior tutela soprattutto nei confronti dei giovani.
La Commissione UE, nella Relazione sopra richiamata, considerato positivamente quanto sopra raccomandato dai vari settori di prodotti alcolici, ha espresso sostegno ad iniziative volontarie di autodi-

(14) Consumer insights – knowledge of ingredient and nutrition information off-label information and its use –Report GfK Belgium (2014)
(15) Informed food choices for healthier consumers – European Consumer Organisation's (BEUC) position on nutrition (2015).
(16) Eurocare Reflections On Alcohol Labelling (2014).
(17) Informazioni fornite da Spirits Europe il 13 ottobre 2016.
(18) Informazioni fornite dal Comité Européen des vins il 3/6/2016.
(19) European Alcohol and Health Forum Commitment 1447949468140-1722, Provision of nutritional and ingredients information to consumers on label for all Heineken beers in Europe, Heineken International. European Alcohol and Health Forum Commitment 1446732318481 -1721, infoming consumers about beer ingredients and nutritional values, The Brewers of Europe.

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sciplina per l'indicazione in etichetta e/o su piattaforme di comunicazione informatiche (siti internet o quick response code-driven QR) dell'elenco degli ingredienti e della dichiarazione nutrizionale[20].
La Relazione ha pertanto posto in rilevo che i produttori di bevande alcoliche sono concordi nel ritenere che i nuovi requisiti sull'etichettatura riguardanti la dichiarazione nutrizionale e l'elenco degli ingredienti dovrebbero essere applicati con le stesse modalità a tutti i tipi di bevande alcoliche, perché i consumatori hanno diritto di sapere che cosa consumano.
La Relazione rammenta altresì la posizione dell'Organizzazione Mondiale della Sanità (OMS) con riguardo all'etichettatura nutrizionale delle bevande alcoliche.
Nel Piano d'Azione Europeo 2012-2020 diretto a ridurre l'uso dannoso dell'alcol[21], l'OMS ha concluso che la conoscenza degli ingredienti, incluso il contenuto di calorie, è fondamentale per la tutela della salute; sicché tali elementi dovrebbero essere indicati anche sull'etichetta degli alcolici ed, in generale, ha sostenuto che l'etichettatura nutrizionale delle bevande alcoliche debba essere la stessa di quella prevista per gli altri alimenti, al fine di consentire ai consumatori di avere accesso ad un'informazione completa sul contenuto e sulla composizione del prodotto, per la protezione della loro salute.
Questo Piano d'Azione è stato approvato da cinquantatre paesi, inclusi gli Stati membri al Comitato Regionale per l'Europa sin dal settembre 2011.
Infine l'OMS ha ritenuto che il valore energetico sia il valore nutrizionale più importante da indicare in etichetta.
La Relazione della Commissione pone in rilievo che, in mancanza di una disciplina europea dell'elenco degli ingredienti e dell'etichettatura nutrizionale degli alcolici, alcuni Stati membri hanno adottato o mantenuto in vigore disposizioni nazionali che stabiliscono un'indicazione anche parziale degli ingredienti delle bevande alcoliche, in conformità all'art. 41 del Regolamento (UE) n. 1169/2011.
Sulla dichiarazione nutrizionale la Commissione, pur rilevando che le disposizioni sono pienamente armonizzate dal citato Regolamento, evidenzia che alcuni Stati membri stanno notificando, ai sensi dell'art. 45, misure nazionali concernenti la dichiarazione nutrizionale per le bevande alcoliche. Purtroppo tali iniziative nazionali contribuiscono ad aumentare il rischio di frammentazione di mercato.
Sulla base delle informazioni assunte, la Relazione non ha identificato motivi oggettivi che giustificherebbero l'assenza in etichetta di informazione sull'elenco degli ingredienti e sulla dichiarazione nutrizionale delle bevande alcoliche o un trattamento differente per alcune bevande alcoliche, come gli "*alcopops*", pur non ravvisando per il momento, la necessità di una specifica definizione di "*alcopops*" per fini di etichettatura.
In conclusione, nella Relazione, la Commissione ritiene che le attuali iniziative volontarie, atte a fornire l'elenco degli ingredienti e la dichiarazione nutrizionale, dovrebbero essere consentite al fine di svilupparne ulteriori.
La Commissione ha pertanto invitato i produttori di bevande alcoliche a rispondere alle aspettative dei consumatori ed a presentare, entro un anno dall'adozione della Relazione (e dunque entro il 13 marzo 2018), una proposta di autoregolamentazione che dovrebbe coprire l'intero settore delle bevande alcoliche. La Commissione, nel caso in cui dovesse ritenere tale approccio autoregolamentare insufficiente, potrebbe lanciare una valutazione d'impatto per reperire ulteriori soluzioni in linea con i Better Regulation Principles[22], indicati nel documento di lavoro della Commissione del 19 maggio 2015. Questa valutazione d'impatto dovrebbe considerare opzioni normative e non, riguardanti in particolare la

([20]) Si fa riferimento in particolare alle posizioni assunte dall'Associazione europea dei produttori di birra Brewers of Europe – Second Year Report – Nov. 2014 European Beer Pledge – A package of responsibility initiatives from Europe's Brewers European Alcohol and Health Forum Commitment 1446732318481-1721 informing consumers about beer ingredients and nutritional values – The Brewers of Europe Guide to the Implementation of Regulation 1169/2011 on the provision of food information to consumers – last updated April 2015- Chapter 11 Nutritional labelling.
([21]) Piano d'azione Europeo per ridurre il consumo nocivo di alcol 2012-2020 OMS Europa.
([22]) Commission Staff working Document "Better Regulation Guidelines [COM (2015) 215 final]- [SWD (2015) 110 final] disponibile sul sito internet: www.ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm.

previsione dell'informazione sul valore energetico delle bevande alcoliche, oltre a considerare attentamente la reazione che diverse scelte potrebbero avere sul mercato interno, sulle aspettative dei consumatori in tema di efficacia di quest'informazione, così come sul commercio internazionale.

2.- Il Decreto Legislativo n. 27/2017

Il 17 marzo 2017 è entrato in vigore il Decreto Legislativo n. 27 del 7 febbraio 2017[23] recante la disciplina sanzionatoria per le violazioni delle disposizioni di cui al Regolamento (CE) n. 1924/2006 relativo alle indicazioni nutrizionali e sulla salute fornite sui prodotti alimentari.
Tale decreto, all'articolo 4, prevede il divieto di apporre un'indicazione nutrizionale o sulla salute sulle confezioni di bevande alcoliche contenenti più dell'1,2% in volume d'alcol, divieto che viene sanzionato con le seguenti sanzioni amministrative pecuniarie[24]:
a) il pagamento di una sanzione amministrativa pecuniaria da euro 5.000 a euro 20.000, nel caso in cui venga riportata sull'etichetta della bevanda alcolica l'indicazione sulla salute;
b) il pagamento di una sanzione amministrativa pecuniaria da euro 3.000 ad euro 10.000, qualora venga riportata in etichetta l'indicazione nutrizionale.
Costituiscono un'eccezione alla disciplina sanzionatoria delineata al punto b), le indicazioni nutrizionali riguardanti un basso tenore alcolico o la riduzione nel contenuto alcolico oppure la riduzione nel contenuto energetico.
Con riguardo al divieto dell'indicazione nutrizionale in etichetta sulle bevande con contenuto alcolico superiore all'1,2%, il citato Dlgs prevede, inoltre, all'art. 12 l'applicazione di una sanzione accessoria nel caso di reiterazione specifica che, ai sensi dell'art. 8-bis, comma 3 della Legge n. 689/1981, si verifica se viene violata più volte la medesima disposizione.
In caso di reiterazione specifica di tale violazione, ovvero nel caso in cui siano reperite in più Comuni confezioni di bevande alcoliche con contenuto superiore all'1,2% recanti l'indicazione nutrizionale, potrebbe essere sospeso il provvedimento dell'Autorità che consentiva lo svolgimento dell'attività che ha dato causa all'illecito amministrativo (il c.d. deposito fiscale autorizzato ex Dlgs n. 504/1995 e successive modificazioni, ovvero l'autorizzazione da parte della competente Agenzia delle Dogane alla produzione e al deposito di prodotti alcolici) per un periodo di giorni lavorativi da un minimo di dieci ad un massimo di venti.
Tale sanzione accessoria può essere disposta o dall'autorità amministrativa competente con l'ordinanza-ingiunzione[25] oppure dal giudice, con la sentenza di condanna prevista dall'art. 24 della L. n. 689/81.
Sul punto è bene ricordare che in tema di sanzioni amministrative l'art. 8-bis, comma 4 della Legge n. 689/1981 prevede un'esimente nella valutazione della reiterazione. In particolare stabilisce: "*Le violazioni amministrative successive alla prima non sono valutate, ai fini della reiterazione, quando sono commesse in tempi ravvicinati e riconducibili ad una programmazione unitaria*".
L'esimente di cui all'art. 8-bis comma 4 della L.689/81 si potrebbe applicare nel caso in cui si tratti di prodotti alcolici aventi lotti di produzione ravvicinati.
Ai sensi del combinato disposto degli artt. 2 e 13 del Dlgs n. 27/2017, ai fini dell'applicazione delle sanzioni amministrative e dei controlli ufficiali, sono rispettivamente competenti il Ministero della Salute, le Regioni, le Province Autonome di Trento e Bolzano e le A.S.L., che potranno operare anche su segnalazione delle violazioni da parte di soggetti

(23) Dlgs. 7 febbraio 2017 n. 27, Disciplina sanzionatoria per la violazione delle disposizioni di cui al regolamento (CE) n. 1924/2006 relativo alle indicazioni nutrizionali e sulla salute fornite sui prodotti alimentari.
(24) Legge 24 novembre 1981 n. 689, Modifiche al sistema penale, art. 10 Sanzione amministrativa pecuniaria e rapporto tra limite minimo e limite massimo: "*La sanzione amministrativa pecuniaria consiste nel pagamento di una somma non inferiore a euro 10 e non superiore a euro 15.000. Le sanzioni proporzionali non hanno limite massimo. Fuori dei casi espressamente stabiliti dalla legge, il limite massimo della sanzione amministrativa pecuniaria non può, per ciascuna violazione, superare il decuplo del minimo*".
(25) Ai sensi dell'art. 18 Legge 24 novembre 1981 n. 689.

privati, tutelando la riservatezza del denunciante.
E' opportuno porre in evidenza che le disposizioni relative alle autorità amministrative competenti ad applicare le sanzioni amministrative, sopra descritte, appaiono in contrasto con il contenuto della delega ricevuta dal Parlamento con la Legge di delegazione 12 agosto 2016, n. 170[26], che all'art. 5, comma 3, lettera b) richiede al Governo l'individuazione generale dell'Ispettorato centrale della tutela della qualità e della repressione frodi dei prodotti agroalimentari (ICQRF) del Ministero delle politiche agricole alimentari e forestali (MIPAAF), quale unica autorità amministrativa competente al controllo e all'irrogazione delle sanzioni, evitando sovrapposizioni con altre autorità, pur facendo salve le competenze dell'Autorità Garante della Concorrenza e del Mercato (AGCM) in tema di claims.
Come è noto, l'AGCM è competente a:
a) tutelare la concorrenza e il mercato in base alla Legge n. 287/1990[27];
b) intervenire nei confronti delle condotte dei professionisti[28] che integrano una pratica commerciale scorretta[29] a tutela del consumatore danneggiato, disponendo specifici provvedimenti, ai sensi dell'art. 27, comma 1-bis del Dlgs. n. 206/2005[30].
I provvedimenti che possono essere adottati dall'AGCM, disciplinati dall'art. 27 Dlgs. n. 206/2005, che comportano gravi conseguenze per il professionista, sono:
i) la sospensione provvisoria delle pratiche commerciali scorrette[31];
ii) il divieto di diffusione della pratica commerciale ritenuta scorretta, qualora non ancora portata a conoscenza del pubblico, o di continuazione, qualora la pratica sia già iniziata[32].
Con il provvedimento che vieta la pratica commerciale scorretta, l'AGCM può disporre inoltre l'applicazione di una sanzione amministrativa pecuniaria da € 5.000,00 ad € 5.000.000, tenuto conto della gravità e della durata della violazione[33]. Nel caso di pratiche commerciali ingannevoli, riguardanti prodotti suscettibili di porre in pericolo la salute e la sicurezza dei consumatori o di pratiche commerciali ingannevoli capaci di minacciare indirettamente la sicurezza di bambini e adolescenti[34], la sanzione non può essere inferiore a € 50.000,00.
Inoltre, a tutela del consumatore contro le pratiche commerciali scorrette, l'art. 27-ter Dlgs. n. 206/2005 prevede la possibilità che i consumatori possano rivolgersi ad organismi privati di Autodisciplina[35], prima di avviare la procedura avanti l'AGCM di cui all'art. 27 e disciplina la relativa procedura presso

(26) Legge 12 agosto 2016, n. 170, Delega al governo per l'adeguamento della normativa nazionale alle disposizioni del regolamento (UE) n. 1169/2011 del Parlamento europeo e del Consiglio, del 25 ottobre 2011, relativo alla fornitura di informazioni sugli alimenti ai consumatori, e della direttiva 2011/91/UE del Parlamento europeo e del Consiglio, del 13 dicembre 2011, relativa alle diciture o marche che consentono di identificare la partita alla quale appartiene una derrata alimentare.
(27) Legge 10 ottobre 1990, n. 287, Norme per la tutela della concorrenza e del mercato.
(28) La definizione di professionista è indicata all'art. 3, lettera c) del Dlgs. n. 206/2005, ove per professionista si intende *la persona fisica o giuridica che agisce nell'esercizio della propria attività imprenditoriale, commerciale, artigianale o professionale, ovvero un suo intermediario*.
(29) La definizione di pratica commerciale scorretta è indicata all'art. 20 del Dlgs. n. 206/2005 *Divieto di pratiche commerciali* scorrette. L'art. 20, comma 2 del Dlgs. n. 206/2005 definisce pratica commerciale scorretta: *una pratica contraria alla diligenza professionale, falsa o idonea a falsare in misura apprezzabile il comportamento economico, in relazione al prodotto del consumatore medio che essa raggiunge o al quale è diretta o del membro medio di un gruppo qualora la pratica commerciale sia diretta a un determinato gruppo di consumatori*. In base all'art. 20, comma 4 del Dlgs. n. 206/2005 sono scorrette le seguenti pratiche commerciali: a) *ingannevoli di cui agli articoli 21, 22 e 23; b) aggressive di cui agli articoli 24, 25 e 26*.
(30) Dlgs. 6 settembre 2005, n 206, Codice del Consumo: Art. 7 *Riassetto in materia di tutela dei consumatori*, L. 29 luglio 2003, n. 229, *Interventi in materia di qualità della regolazione, riassetto normativo e codificazione – Legge di semplificazione 2001*.
(31) Art. 27, comma 3 Dlgs. 206/2005 che prevede l'applicazione del provvedimento di sospensione provvisoria della pratica commerciale scorretta da parte dell'AGCM se sussiste particolare urgenza.
(32) Art. 27, comma 8 Dlgs. n. 206/2005.
(33) Art. 27, comma 9 Dlgs. n. 206/2005.
(34) Art. 21, commi 3 e 4 Dlgs. n. 206/2005.
(35) Art. 6 Direttiva (CE) 12 dicembre 2006 n. 114 del Parlamento Europeo e del Consiglio concernente la pubblicità ingannevole e comparativa che prevede l'incoraggiamento da parte degli Stati membri del controllo volontario della pubblicità ingannevole o comparativa esercitato da organismi autonomi. In Italia vedi Codice di Autodisciplina Pubblicitaria e Codice della Comunicazione Commerciale della Birra.

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detti organismi.
Alla luce di quanto fino ad ora esposto risulta che, in caso di violazione delle disposizioni sulle indicazioni nutrizionali e sulla salute di una bevanda alcolica con contenuto superiore all'1,2% in volume d'alcol, l'applicazione delle sanzioni amministrative e dei controlli ufficiali spetterà ad una "pletora" di organi amministrativi, in base al combinato disposto degli artt. 2 e 13 del Dlgs n. 27/2017, mentre per le violazioni riguardanti l'informazione pubblicitaria dei prodotti alcolici interverrà, a tutela del consumatore danneggiato, l'AGCM con i relativi provvedimenti previsti dal Dlgs. n. 206/2005, qualora ravvisi che tali condotte integrino pratiche commerciali scorrette o, su richiesta del consumatore, l'organismo di Autodisciplina competente.
Sembra di dover concludere ponendo in rilievo le seguenti criticità nel testo adottato dal legislatore delegato:
1) un rilevante errore interpretativo, poiché ha considerato come un divieto l'esenzione dall'obbligo della dichiarazione nutrizionale per le bevande alcoliche con contenuto superiore all'1,2% in volume previsto dall'art. 16, comma 4 del Regolamento (UE) n. 1169/2011, e di conseguenza ha imposto una sanzione amministrativa pecuniaria. Il divieto di apposizione dell'indicazione nutrizionale, *rectius* dichiarazione nutrizionale di cui all'art. 4 del Dlgs. n. 27/2017, seppur con l'esimente di consentire le sole indicazioni nutrizionali riguardanti un basso tenore alcolico o la riduzione nel contenuto energetico, potrebbe risultare in contrasto con le normative europee sopra richiamate e soprattutto con i principi contenuti nella Relazione, in punto di dichiarazione nutrizionale in etichetta, in tema di:
i) "consumatore consapevole";
ii) promozione di un'autoregolamentazione del settore alcolico.
Inoltre, il divieto di apposizione della dichiarazione nutrizionale sulle bevande alcoliche andrebbe a creare la frammentazione nel mercato, censurata dalla Commissione nella Relazione.
2) Il legislatore delegato, oltre ad aver male interpretato, ha anche omesso di osservare il disposto dell'art. 45 del citato Regolamento che impone la procedura di notifica preventiva alla Commissione e agli altri Stati membri in caso di adozione di una nuova normativa in materia di informazioni sugli alimenti. La notifica preventiva deve contenere i motivi che giustificano l'adozione della nuova normativa nazionale che può entrare in vigore solo dopo tre mesi dalla notifica, purché non abbia ricevuto un parere negativo dalla Commissione.
3) Il regime sanzionatorio ed il sistema dei controlli disciplinato dal Dlgs. n. 27/2017, così come strutturato dal legislatore delegato, appare in contrasto con la delega legislativa[36], che individuava l'ICQRF quale unica autorità competente al controllo ed all'irrogazione delle sanzioni e potrebbe comportare delle pesanti conseguenze sui produttori di bevande alcoliche, i quali, a seconda dell'ubicazione del/dei propri stabilimenti di produzione/depositi, potrebbero incorrere nell'irrogazione di una "pletora" di sanzioni "incongruenti" da parte di diverse autorità locali, che potrebbero applicare in modo difforme e diverso il Dlgs. n. 27/2017. Inoltre I produttori di bevande alcoliche potrebbero trovarsi di fronte ad un numero considerevole di controlli da parte di diverse autorità locali competenti e doversi difendere, con notevoli costi, di fronte a più autorità. Appare dunque auspicabile che il legislatore delegato "*melius re perpensa*" abroghi la disposizione di cui all'art. 2, comma 2 del Dlgs. N. 27/2017 e ripristini il contenuto della Legge di delegazione 12 agosto 2016, n. 170, individuando l'Ispettorato centrale della tutela della qualità e della repressione frodi dei prodotti agroalimentari (ICQRF) del Ministero delle politiche agricole alimentari e forestali (MIPAAF), quale unica autorità amministrativa competente per i controlli e la comminatoria delle sanzioni.

ABSTRACT

The principal aim of this article is to show the possible conflict between European rules, introduced by Regulation (EU) No 1169/2011 on the provision of food information to consumers and Regulation (EC)

([36]) V. supra nota 26.

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No 1924/2006 on nutrition and health claims made on food, and National rule, recently introduced by Legislative Decree No 27/2017, on nutrition and health indications concerning the alcoholic beverages. Article 16.4. of Regulation (EU) No 1169/2011 foresees a temporary exemption for the beverages containing more than 1,2% by volume of alcohol from the mandatory particulars listed in letter b) and letter e) of article 9, from December 13, 2016, date of entry into force of the nutrition declaration concerning all the foodstuffs and beverages, even though encourages the food business operators to indicate the nutrition declaration for the alcoholic beverages on a voluntary basis as foreseen by the Recitals.

The same article mentioned above has instructed the EU Commission to draw up a report on this matter. On March 13, 2017 the EU Commission has produced this report where has highlighted and supported voluntary initiatives of self-regulation for the alcoholic beverages regarding the information on the label or on other platforms such as websites or QR–code-driven applications of the list of ingredients and the nutrition declaration, inviting the industry to produce within a year of adoption of this report a self-regulatory proposal that would cover the entire sector of alcoholic beverages, reserving, in the event of unsatisfied outcome of the self-regulation approach, to evaluate other regulatory options.

The Legislative Decree No 27/2017 foresees punishment rules for the infringement of the Regulation (EC) No 1924/2006 disposals' on nutrition and health claims made on food. This Legislative Decree forbids to affix nutrition and/or health claims on the alcoholic beverages' packaging containing more than 1,2% by volume of alcohol.

The Italian legislator has implemented the EU regulations mentioned above in an opposite way as follows:

1) for the alcoholic beverages he has considered the exemption mentioned above as a prohibition punished with heavy administrative sanctions, while foreseeing the exception consisting to indicate the nutritional information about the low alcoholic degree or a reduction on energy content;

2) the Italian Legislator has forgotten that the EU rules foresee for beverages and foods information/claims on nutritional properties only.

□