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Food Traceability in Europe, the US and China: Comparative Law and Regulatory Technology

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ABSTRACT: The issue of traceability in the food sector lies within the framework of a multiplicity of principles ranging from product identification to data recording, information integration, and accessibility. Traceability responds to a recent need for market and consumer protection which has driven and is still driving policies of major world powers in the food industry and beyond such as the European Union, the United States of America and the People's Republic of China. In a comparative and multidisciplinary perspective, food regulation poses scientific, economic, legal and technological challenges. Thus, on the one hand, food regulation builds upon the concepts of coexistence, right to know, and precautionary principle. On the other hand, innovation through emerging technologies such as blockchain foreshadows new organizational and regulatory models for a more effective management of traceability systems within the food supply chain.

KEYWORDS: Food regulation; Traceability; GMOs; RegTech; Blockchain

SUMMARY: 1. World's food supply and traceability – 2. Traceability principles within the food supply chain – 3. European Union: Legal and biotechnological framework in the traceability system – 4. United States: Food law & policy to trace the food supply chain – 5. People's Republic of China: Enhancing food safety through traceability regulation and innovation – 6. Blockchain for the food supply: An innovative and decentralized register for a better FTS

1. World's food supply and traceability

Food represents a physiological necessity for the survival of every human being. This relationship between food and survival has determined the need across the world to adopt effective measures to ensure food safety.[1]

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[1] Although the present paper does not intend to analyze the issue of food security, it is appropriate to mention one of its definitions in order to distinguish it from food safety. "*Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food*

This must be intended: as hygienic-sanitary safety, in order to avoid any physical, chemical or biological pathogenic hazard;[2] and as information security, aimed to provide complete transparency in the communication to the consumer in relation to the characteristics of food as well as to its mode or quantity of consumption.

To give a broad idea of the importance of food safety, as stressed by the World Health Organization (WHO), each year worldwide, unsafe food causes 600 million cases of foodborne diseases and 420,000 deaths.[3] The global dimension of the food phenomenon has led, especially during the 20th century, to the birth of new institutions at a national, supranational, and international[4] level, and to the development of strict regulations on food safety and consumer protection.

Nevertheless, the broad topic of food safety must include efficient management of the food supply chain.[5] In fact, food supply systems are under increasing pressure from human activity and consumer

preferences for an active and healthy life" (World Food Summit 1996, *Rome Declaration on World Food Security*, available on: http://www.fao.org/).

[2] In this regard, see: P. K. SINGH, R. P. SINGH, P. SINGH, R. L. SINGH, *Food Hazards: Physical, Chemical, and Biological, in Food Safety and Human Health* (Chapter 2), in *Food Safety and Human Health*, Cambridge (U.S.), 2019 (1st edition), 15-65, referring to: a) Physical toxicants as generally harmful extraneous matter that are not commonly part of the food. When these materials reach the body, they lead to a number of injurious health effects. The physical hazards are easy to identify as they immediately can cause injury (e.g. extraneous materials which are usually dangerous due to their hardness, sharpness, size, or shape); b) Chemical toxicants used as food additives (e.g. colorants, sweeteners, flavors, preservatives, antioxidants) and agricultural residues (pesticides, fungicides, herbicides, heavy metals); c) Biological toxicants such as organisms, or substances produced by living beings, that represent a danger to human well-being. They are a noteworthy concern in food processing because they cause most foodborne illness outbreaks. Biological hazards can be introduced to food from the environment or from poor sanitation practices and cross-contamination during transportation, handling, processing, and storage of foods (e.g. pathogenic bacteria, fungi, parasites, viruses, etc.). With regard to how the classification of pathogens based on the analysis results and machine learning methods can provide beneficial support for clinical auxiliary diagnosis and treatment of foodborne diseases, Cf. H. WANG, W. CUI, Y. GUO, Y. DU, Y. ZHOU, *Prediction of Foodborne Diseases Pathogens: A Machine Learning Approach*, in *JMIR Medical Informatics*, 9, 1, 2021, 4-27.

[3] The World Health Organization emphasizes in many of its interventions, the need and the commitment to bring to the attention of public and political governments the issue of foodborne diseases, too often neglected despite its importance for the protection of human life, https://www.who.int/ (accessed on January 01, 2021).

[4] Some of the most relevant international food safety measures of the 20th century include: the Marrakech Agreement - signed on April 15, 1994 and entered into force on January 1, 1995 - which in addition to establishing the World Trade Organization (WTO), led among others to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and to the Agreement on Technical Barriers to Trade (TBT Agreement) available on: https://www.wto.org/; and the Codex Alimentarius, a collection of internationally recognized standards on food safety drawn up by the Joint Food and Agriculture Organization (FAO) and World Health Organization (WHO) Commission in 1963. These standards are divided into general standards, applicable to all foods, and commodity standards, for specific products. For references, see: http://www.fao.org/fao-who-codexalimentarius/en/.

[5] See. H. FOLKERTS, H. KOEHORST, *Challenges in international food supply chains: vertical co-ordination in the European agribusiness and food industries*, in *British Food Journal*, 100, 8, 1998, 385-388, referring to the food supply chain as "*a set of interdependent companies that work closely together to manage the flow of goods and services along the value-added chain of agricultural and food products, in order to realize superior customer value at the lowest possible costs.*"

demands.[6] As a result this leads to a significant negative global impact on food safety and consumer health.

In this regard, the food traceability system (FTS) assumes particular importance in meeting the complexities of the food system. In fact, as we will see, traceability responds to a recent need for consumer protection, which has driven and still is driving policies of major world powers in the food industry and beyond, such as the European Union, the People's Republic of China and the United States of America. All this should take into account the potential offered by the use of emerging technologies such as blockchain, responding with an innovative approach for consumers and business operators within the food supply chain.

2. Traceability principles within the food supply chain

Among the numerous definitions of traceability, which often turn out to be incomplete or even misleading, we can describe this as "*the ability to access specific information about a food product that has been captured and integrated with the product's recorded identification throughout the supply chain.*"[7] Based on this definition, in this paper we will outline the cardinal principles of traceability as the essential characteristics of a system that reflect the purpose and its effective operation.[8]

The first principle is represented by *product identification*. This should be understood as the identification of the smallest unit of product that can be traced (so-called "traceable resource unit" or "TRU").[9] The components of a given product depend on TRUs. The more "granular" the product is, and therefore composed of multiple units, the more information will be required to be identified and recorded.

[6] See.: J. QIAN, L. R. GARCIA, et. al., *Food traceability system from governmental, corporate, and consumer perspectives in the European Union and China: A comparative review*, in *Trends in Food Science & Technology Journal*, 99, 2020, 402-412, stressing how "*climate change, land degradation, pesticide use, the development of antibiotic-resistant microorganisms, and residual animal growth hormone in human food all contribute to food supply challenges*."

[7] See.: S. ISLAM, J. M. CULLEN, *Food traceability: A generic theoretical framework*, in *Food Control Journal*, 123, 2021, 1-12, that through a comparative analysis of the definitions of food traceability, summarizes the salient features of traceability emphasizing both the product identification (e.g. through unique codes), and the capture of data and their integration within a system suitable to contain them. Among others, at an international level: The FAO/WHO Codex Alimentarius defines traceability or product tracing as "*the ability to follow the movement of a food through specified stage(s) of production, processing and distribution*", and again "*a tool that may be applied, when and as appropriate, within a food inspection and certification system in order to contribute to the protection of consumers against foodborne hazards and deceptive marketing practices and the facilitation of trade on the basis of accurate product description.*" (Codex Procedural Manual and Codex Principles for Food Import and Export Inspection and Certification CAC/GL 20).

[8] G. ALPA, *General Principles of Law*, in *Annual Survey of International & Comparative Law*, 1, 1994, 1-38. The multidisciplinary nature of food traceability, and the attempt to give theoretical definitions from practical experience, have created great confusion within the academic literature; hence the need to better define the founding principles of food traceability.

[9] See.: H. M. KIM, M. S. FOX, M. GRUNINGER, *An ontology of quality for enterprise modelling*, in *Proceeding's 4th IEEE Workshop on Enabling Technologies: Infrastructure for Collaborative Enterprises (WET ICE '95)*, 1995, 105-116, holding that traceability in a food system hinges on the definition of what is the smallest unit of the product to trace or "traceable resource unit" (TRU).

Some authors distinguish three main types of TRU: batch, trade unit (TU), and logistics unit (LU).[10] Batch represents the total amount of material undergoing one process operation (e.g. all salmon harvested from one farm in a day). Trade unit represents the divided batches in smaller TUs ready to be sold (e.g. processed salmon portions in packaging in a retail shop). And finally, we have logistic units for transportation or storage of the TUs (e.g. many salmon portions transported in boxes on a pallet). If batch identifiers are usually locally generated by food business operators (FBOs), trade and logistic units must be explicitly labeled using globally standardized unique identifiers.

For identification purposes, once the TRU level has been identified, it is necessary to assign a unique identification code. This is the so-called "secondary identification" that constitutes the link between the "primary identification"[11] and operational information about a specific product. The most common secondary identification methods are barcodes, radio frequency identification tags (RFID), and near-field communication systems (NFC).[12]

The second principle of traceability is *data recording*. In fact, once we have a way to get the information, it is necessary to have a reliable means where to record it.[13] The first medium is represented

[10] See.: K. M. KARLSEN, K. M. DONNELLY, P. OLSEN, *Granularity and its importance for traceability in a farmed salmon supply chain*, in *Journal of Food Engineering*, 102, 1, 2011, 1-8. Among others, see.: M. BORIT, P. OLSEN, *Evaluation framework for regulatory requirements related to data recording and traceability designed to prevent illegal, unreported and unregulated fishing*, in *Marine Policy*, 36, 1, 2012, 96-102, stressing how batch level TRUs are normally used for internal traceability within a single company, whereas TUs and LUs, are subject to global standards of identification, and are required for external traceability among companies. Internal and external traceability are two concepts created in literature. Internal traceability refers to the product traceability within a single "link" or food business operator in the supply chain. External traceability occurs among several links or companies. The combined process of internal and external traceability constitutes the whole traceability chain. In this regard, see.: S. ISLAM, J. M. CULLEN, *Food traceability: A generic theoretical framework*, cit., 7; T. MOE, *Perspectives on traceability in food manufacture*, in *Trends in Food Science & Technology*, 9, 5, 1998, 211-214.

[11] See: M. LEES, *Food authenticity and traceability*, Cambridge, 2003, 480 ff., and I. SMITH, A. FURNESS, *Improving traceability in food processing and distribution*, Cambridge, 2006, 10 ff., referring to "primary identification" as the analytical measurements of source component/s using techniques, such as DNA-based analysis, and Nuclear Magnetic Resonance (NMR) spectroscopy. This is a technique that allows information to be obtained on the metabolic profile of samples, both in a liquid and a solid state, in order to define the guarantee of traceability, origin, quality and preservability of food products. Another technique is Near-Infrared (NIR) spectroscopy, a method of analysis that exploits some physical properties of matter and in particular its interaction with near infrared radiation. This interaction contains information about the chemical composition of the sample.

[12] See.: P. THANAPAL, J. PRABHU, J. MRIDULA, *A survey on barcode RFID and NFC*, in *IOP Conference Series: Materials Science and Engineering*, 2017, 1-10. The Barcode is an effective technology for labeling products and maintaining a database. Barcode scanners are the ones that have been around for a long time and are going to be replaced during time by mobile scanning devices (e.g. QR Codes). RFID technology, based on a radio-frequency technique, consists in a passive tag which contains a transceiver antenna and a transponder. Compared to barcode technology, RFID has greater perceptibility in supply chain networks, faster product velocity, more resourceful inventory management, reduced labor costs, and reduced human error. And finally, NFC technology works in the electromagnetic field as a short-range wireless RFID communication technology.

[13] ISO 12877, *Traceability of finfish products – specification on the information to be recorded in farmed finfish distribution chains*, 2011, 1-41, identifies three categories of data to be recorded: 1) data required for TRU ("*shall*" category); 2) data required to fulfill legal, certification, standardization and commercial requirements ("*should*" category); 3) other data not included in the first two categories ("*may*" category).

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by simple paper-based records,[14] still widely used, especially by companies involved in primary production. Although this way of record keeping is not expensive in terms of both infrastructure and expertise, it is not a secure way of managing and integrating information that could easily be altered or lost.

Technological development has led many companies to equip themselves with database-driven computer systems or cloud-based systems, which despite higher infrastructural and competency costs, perform more efficiently in storing, managing and analyzing data in both forward and backward directions.[15]

The third principle is represented by *information integration*, consisting in the ability to link and share collected data both within a single company[16] (internal traceability) and among different FBOs[17] (external traceability) involved within a specific food supply chain.

In the first case we refer to the product and process data linking within a single FBO, for instance product ID, process timing, temperatures, etc., whereas in the latter to the sharing of data among different enterprises. As we will see, there are different ways and approaches of integrating information thanks to technological innovations such as blockchain technologies.

The last principle involves *data accessibility*. This principle faces three different needs: one is legislative, due to the obligations imposed by the legislator on FBOs; the second is confidential, due to the fact that competitors or partners within the supply chain cannot have access to all the information; and the third is related to the need for transparency in order to ensure consumer protection.[18]

All these needs require a valid ecosystem that can provide security and transparency in the best possible way within the food supply chain.

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[14] See.: M. T. UDDIN, *Value chains and standards in shrimp export from Bangladesh and Thailand to Japan: A comparative study on safety compliances*, in the *Asia-Pacific Journal of Rural Development*, 19, 1, 2009, 89-108, stating that Thailand's shrimp industry ensures traceability through both "movement document" and "fry movement document" whereas Bangladesh starts to execute it by a "shrimp suppliers' certificate" and a "farmers and region code"; and M. HERNÁNDEZ-JOVER, N. SCHEMBRI, et al., *Evaluation of the implementation of new traceability and food safety requirements in the pig industry in eastern Australia*, in the *Australian Veterinary Journal*, 87, 10, 2009, 387-396, stating that the "PigPass national vendor declaration" (NVD) is a paper-based traceability system for groups of pigs, whereby the person responsible for the pigs declares that veterinary chemical use and treatments are undertaken in accordance with legislation and/or industry standards.

[15] See.: J. MCENTIRE, A. W. KENNEDY, *Food Traceability: From Binders to Blockchain*, in *Food Microbiology and Food Safety*, 2019, 1-12, referring to traceability as the ability to follow and understand the movement of information flowing backwards and forwards through the supply chain in order to have historical data about a specific product; and S. ISLAM, J. M. CULLEN, *Food traceability: A generic theoretical framework*, cit., 10.

[16] In this regard, see.: R. Y. CHEN, *An intelligent value stream-based approach to collaboration of food traceability cyber physical system by fog computing*, in *Food Control Journal*, 71, 2017, 124-136; and G. ALFIAN, J. RHEE, H. AHN, et al., *Integration of RFID, wireless sensor networks, and data mining in an e-pedigree food traceability system*, in *Journal of Food Engineering*, 212, 2017, 65-75, stressing the importance of new technologies such as Wireless Sensor Network (WSN) and Internet of Things (IoT) to enable real time data linking and product monitoring for an efficient internal traceability system.

[17] S. ISLAM, J. M. CULLEN, *Food traceability: A generic theoretical framework*, cit., 10, holding that external traceability is enabled when food business operators communicate their recorded internal traceability information to their food supply chain partners, and that this communication can be performed via various means (e.g. transmission of information through product labels or in accompanying documentation when the product is dispatched; via electronic channels including facsimile, mail or electronically integrated systems, etc.).

[18] In this regard, see. S. ISLAM, J. M. CULLEN, *Food traceability: A generic theoretical framework*, cit., 11.

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3. European Union: Legal and biotechnological framework in the traceability system

The supranational dimension of the European food production and distribution chain has determined the urgent need for development of food law inside the European Union.

Food products, as goods[19] subject to economic evaluation and commercial transactions, are regulated by the general provisions and principles of the Treaty on the Functioning of the European Union (TFEU) which represent primary sources of the European legal system. Among the main principles, we can mention the free movement of goods[20] (arts. 28-37 TFEU) and the principle on the approximation of laws[21] (arts. 114-118 TFEU).

Towards the end of the twentieth century, major health scandals related to the food industry, led to a loss of consumer confidence and significant economic losses for the European food market.[22] The European legislator, in consideration of the critical importance of the aforementioned issue, has actively addressed the subject by adopting regulations, directives, and decisions intended to be applied in all member States.

[19] European Court of Justice, December 10, 1968, C-7/68, holding that "*by goods, within the meaning of article 9 of the EEC treaty, there must be understood products which can be valued in money and which are capable, as such, of forming the subject of commercial transactions.*"

[20] With reference to the free movement of goods, the "mutual recognition principle" takes on particular importance. Among the first relevant judgements, see.: European Court of Justice, July 11, 1974, C- 8/74, Procureur du Roi v Benoît and Gustave Dassonville (or Dassonville Case) holding that: "*Trading rules which apply equally to national products and imported products do not in principle constitute measures having equivalent effect within the meaning of Articles 30 et seq. of the EEC Treaty.*"; and European Court of Justice, February 20, 1979, C-120/78, Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (or Cassis de Dijon Case), holding that "*There is no valid reason why, provided that they have been lawfully produced and marketed in one of the Member States, alcoholic beverages should not be introduced into any other Member State; the sale of such products may not be subject to a legal prohibition on the marketing of beverages with an alcohol content lower than the limit set by the national rules.*" On the concept and forms of mutual recognition, *see*: L. A. Jiménez, *Effective judicial protection and mutual recognition in the European administrative space*, in *the Center for European Studies Luis Ortega Álvarez and the Jean Monnet Chair of European Administrative Law in Global Perspective*, 2021, No. 2.

[21] According to art. 114 TFEU: "*The European Parliament and the Council shall […] adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market*" §1 including in matters of "*health, safety, environmental protection and consumer protection.*" §3

[22] In this regard, among the first most relevant food scandals in Europe is the BSE (Bovine Spongiform Encephalopathy) crisis, commonly known as mad-cow disease, in 1986 in the United Kingdom (UK). This food crisis and the following ones, led to the need to think about new regulatory and technological systems, able to guarantee the safety of the food supply chain, in order to protect consumer confidence and the European food market. See.: A. L. MACREADYA, S. HIEKEB, et. al., *Consumer trust in the food value chain and its impact on consumer confidence: A model for assessing consumer trust and evidence from a 5-country study in Europe*, in *Food Policy Journal*, 92, 2020, 1-15.

Among these,[23] the General Food Law (GFL) Regulation (EC) No. 178/2002 stands out[24] in response to the need for consumer protection[25] in the European food market. This Regulation provides: the general and specific provisions aimed at guaranteeing the safety of each product until reaching the final consumer; and the creation of the European Food Safety Authority (EFSA)[26] to implement and enforce food legislation.

The Regulation has given a systematic approach to food law and a strong emphasis on food traceability. In fact, article 18 of the GFL introduces the issue of food traceability in the Community system. This provision in the first paragraph, indicates FBOs[27] as the ones who have the obligation to trace extensively[28] all foods and their components such as ingredients, additives, etc.,[29] at all stages of production, processing, and distribution.

[23] See.: the Green Paper on "the general principles of food law in the European Union" of April 30, 1997 (COM/97), and the White Paper on Food Safety of January 12, 2000 (COM/99) that also emphasizes the need for effective traceability systems from "*farm to table*".

[24] Regulation (EC) No. 178/2002 of the European Parliament and of the Council of January 28, 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.*" See among others: INSTITUTE OF INTERNATIONAL AND COMPARATIVE AGRICULTURAL LAW (IDAIC), *Commentario "La sicurezza alimentare nell'Unione Europea"*, in *Le nuove leggi civili commentate*, 2003; D. GORNY, *Basis-Verordnung (EG) Nr. 178/2002, Kommentar*, Germany, 2010 (2nd edition).

[25] In that regard, article 1 of the GFL stresses as the aim and scope of the regulation the "*protection of human health and consumers' interest in relation to food […] whilst ensuring the effective functioning of the internal market*."

[26] As pointed out in the White Paper on Food Safety of January 12, 2000 (COM 1999), the creation of EFSA was considered necessary to regain consumer confidence following the food crises of the 20th century. Regulation 178/2002 (recital 40 and Articles 29 ff.) and Regulation 1304/2003 outline the essential characteristics of EFSA. As a scientific and technical advisory authority of reference for European and national institutions, EFSA's main features include independence (both from the Commission, unlike the scientific and technical committees, and from any other political, ethical or economic influence) and scientific excellence.

[27] Paragraph 3 and Paragraph 6 Article 3, Reg. No. 178/2002 referring respectively to "food business operator" as "*the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control*" and to "feed business operator" as "*the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control.*"

[28] This obligation extends to all territories within the European Union. In the extra-territorial sphere exporting third countries are not required to comply with European traceability obligations, for which the European importer must act as guarantor. See, Article 11, Reg. No. 178/2002 stating: "*Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognized by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.*"

[29] *See*, Article 2, Reg. No. 178/2002 defining "food" as "*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.*" Moreover "*includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.*" From the definition and from art. 18 of the Regulation, packaging materials and all materials intended to come into contact with the foodstuff are excluded. In fact, they are regulated differently in: Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of October 27, 2004 on materials and articles intended to come into contact with food repealing Directives 80/590/EEC and 89/109/EEC and Commission Regulation (EC) No. 2023/2006 of December 22, 2006 on good manufacturing practice for materials and articles intended to come into contact with food (text with EEA relevance).

The second and third paragraphs identify the main obligations consisting in a "one up-one down" or "one step back one step forward" approach[30] whereby FBOs must be able to communicate immediately their direct upstream suppliers and downstream customers, e.g. name and address of the supplier/customer; nature and quantity of the goods inbound and outbound; date of reception/delivery, etc.,[31] at the request of the competent authorities.

This requirement for "external traceability" is expressed in terms of results. In fact, the provision does not force FBOs to adopt specific means of recordkeeping, thus leaving them free and responsible in choosing their own organizational procedures, as long as they are suitable for the required purpose.

Moreover, Regulation No. 178/2002 omits any requirement for "internal traceability", aimed at recording every step within a company. Nevertheless, the internal processes of every company must follow the Hazard Analysis and Critical Control Points (HACCP)[32] regulations, currently contained in the so-called Hygiene package,[33] aimed at guaranteeing quality and safety of all food products placed on the market.

[30] See.: T. BHATT, G. BUCKLEY, J. C. MCENTIRE, *Proceedings of the August 2011 traceability research summit*, in *Journal of Food Science*, 78, 2, 2013, B9-B14, describing this approach as flexible, easy to implement, and requiring less data standardization. The first approach incrementally improves upon the current "one up/one down" system by requiring electronic records and tracking internal as well as external critical tracking events. The benefits of this approach are its similarity to existing regulatory requirements and low cost of implementation; resulting in a higher probability of adoption. The major disadvantage to this process is the longer response time required during a trace (back or forward).

[31] In this regard, see.: D. DONGO, *Sicurezza Alimentare e Rintracciabilità*, Trento, 2005, 78, stressing as in article 18, paragraph 3, the FBO is required to identify its direct customer, excluding the final consumer. Moreover, the rule does not oblige the FBOs to know the next phases of transformation/marketing of their products up to the final sale/administration.

[32] Introduced by Council Directive 93/43/EEC of June 14, 1993, on the hygiene of foodstuffs, repealed by Regulation (EC) No. 852/2004 of the European Parliament and of the Council of April 29, 2004, on the hygiene of foodstuffs, the HACCP system is based on some fundamental principles that can be summarized as follows: conduct hazard analysis; determine critical control points; establish critical limits; establish monitoring procedures; establish corrective actions; establish verification procedures; establish record-keeping procedures.

[33] Including, Regulation (EC) No. 852/2004 of the European Parliament and of the Council of April 29, 2004, on the hygiene of foodstuffs; Regulation (EC) No. 853/2004 of the European Parliament and of the Council of April 29, 2004, laying down specific hygiene rules for food of animal origin; Regulation (EC) No. 854/2004 of the European Parliament and of the Council of April 29, 2004, laying down specific rules for the organization of official controls on products of animal origin intended for human consumption and Regulation (EC) No. 882/2004 of the European Parliament and of the Council of April 29, 2004, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, both repealed and replaced by Regulation (EU) No. 2017/625 of the European Parliament and of the Council of March 15, 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.

The fourth paragraph of art. 18, without imposing further obligations, refers to the application of all those rules relating to the hygienic and sanitary protection of foodstuffs, consumer information,[34] customs and tax regulations,[35] aimed at facilitating traceability systems within the food supply chain.
Finally, the fifth paragraph of the article in question outlines the discipline to be followed in the event of the introduction of further rules on food traceability.[36] Despite the fact that the article is open to national regulations, it is strictly forbidden for national regulators to impose further obligations in addition to those established by art. 18 of the Regulation No. 178/2002, which would therefore be in contrast with the Regulation itself and with the principle of free movement of goods expressed by article 28 TFEU.
A subject of significant importance, for which specific provisions on traceability are foreseen, is that of genetically modified organisms (GMOs).[37] The current European regulatory framework on GMOs consists of: Directive 2001/18 EC[38] concerning the deliberate release into the environment of genetically modified organisms; Regulation 1829/2003[39] on genetically modified food and feed; Regulation (EC) 1830/2003[40] concerning the traceability and labeling of genetically modified organisms and the

[34] In this regard, it is important to specify that traceability concerns food safety and is therefore different from labeling. In fact, a product is safe not in relation to what is indicated on the label, but in relation to how the operators who participated in its creation are able to promptly provide the competent control Authorities with the documents certifying its origin and destination. Labeling, regulated by Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of October 25, 2011 on the provision of food information to consumers, has therefore only an informative and commercially strategic value. See: M. HAGENMEYER, *Food Information Regulation: Commentary on Regulation (EU) No. 1169/2011 on the provision of food information to consumers*, Berlin, 2012; and A. FRANSVEA, G. CELANO, et al., *Food Labelling: A Brief Analysis of European Regulation 1169/2011*, in *Italian Journal of Food Safety*, 3, 2014, 151 ff.

[35] On customs rules and tariffs, see.: Regulation (EU) No. 952/2013 of the European Parliament and of the Council of October 9, 2013, laying down the Union Customs Code.

[36] Regulation No. 178/2002 (article 58, §2) referring to the Council Decision of June 28, 1999, No. 468, laying down the procedures for the exercise of implementing powers conferred on the Commission (in particular to the articles 7 and 8 thereof), repealed by Regulation (EU) No. 182/2011 of the European Parliament and of the Council of February 16, 2011, laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

[37] Article 2, Directive 2001/18/EC, defines a genetically modified organism as "*an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.*"

[38] Directive 2001/18/EC of the European Parliament and of the Council of March 12, 2001 on the deliberate release into the environment of genetically modified organisms, repealing Council Directive 90/220/EEC and amended by various measures including Directive (EU) 2015/412 of the European Parliament and of the Council of March 11, 2015 regarding the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, and Commission Directive (EU) 2018/350 of March 8, 2018, regarding the environmental risk assessment of genetically modified organisms.

[39] Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of September 22, 2003 on genetically modified food and feed, repealing regulations EC 1139/98, 49/2000, 50/2000, and amending regulation EC 258/1997.

[40] Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, and amending Directive 2001/18/EC

traceability of food and feed products produced from genetically modified organisms; and Directive 2009/41/EC[41] on the contained use of genetically modified microorganisms.

Regulation (EC) 1830/2003 on traceability and labeling of GMOs aims to create, based on a "concept of coexistence",[42] two distinct supply chains between GMOs and conventional food. This is due both to guarantee the "right to know"[43] of European consumers who have become increasingly skeptical of GM foods, and the respect of the precautionary principle[44] considering the wide debate on the risks associated with the cultivation and consumption of genetically modified products.[45]

[41] Directive 2009/41/EC of the European Parliament and of the Council of May 6, 2009 on the contained use of genetically modified microorganisms, replacing the Council Directive 90/219/EEC of April 23, 1990 on the contained use of genetically modified microorganisms.

[42] See.: Y. DEVOS ET AL., *Coexistence of genetically modified (GM) and no-GM crops in the European Union. A review*, in *Agronomy for Sustainable Development Journal*, 29, 1, 2009, 11 ff.; Y. BERTHEAU, *Genetically Modified and non-Genetically Modified Food Supply Chains: Co-Existence and Traceability*, New York, 2012, 1-12; N. KALAITZANDONAKES, P. W. B. PHILLIPS, et al., *The Coexistence of Genetically Modified, Organic and Conventional Foods*, New York, 2016, 71 ff.

[43] Principle introduced by the Consolidated Version of the Treaty Establishing the European Community 97/C, No. 340/02, now contained in the Consolidated version of the Treaty on the Functioning of the European Union of December 13, 2007, Article 169, §1 stating that: "*In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organize themselves in order to safeguard their interests*." Still the paragraph 11 of the preamble of Regulation (EC) No. 1830/2003 states: "*It is necessary to ensure that consumers are fully and reliably informed about GMOs and the products, foods and feed produced therefrom, so as to allow them to make an informed choice of product.*" Regulation (EU) No. 1169/2011 also represents a recent and practical regulation about consumer information. See.: F. H. DEGNAN, *The Food Label and the Right-to-Know*, in *Food and Drug Law Journal*, 52, 1, 1997, 49-60; *L. DU*, *GMO labelling and the consumer's right to know: A comparative review of the legal bases for the consumer's right to genetically modified food labelling*, in *McGill Journal of Law and Health*, 8, 1, 2014, 18-21; D. M. STRAUSS, *Genetically Modified Organisms in Food: Ethical Tensions and the Labeling Initiative*, in H.M. JAMES JR. (ed.), *Ethical Tensions from New Technology: The Case of Agricultural Biotechnology*, United States of America, 2018, 83 ff.

[44] The precautionary principle enables decision-makers to adopt precautionary measures when scientific evidence about an environmental or human health hazard is uncertain and the stakes are high. *Cf.*: D. BOURGUIGNON, *The precautionary principle: Definitions, applications and governance*, 2016, available on: https://www.europarl.europa.eu/. See.: S. PROUTHEAU, R. L. HEATH, *Handbook of Risk and Crisis Communication - Precautionary Principle and Biotechnology: Regulators Are from Mars and Activists Are from Venus*, New York, 2009 (1st edition); L. BERGKAMP, J. C. HANEKAMP, *European Food Law and the Precautionary Principle: Paradoxical Effects of the EU's Precautionary Food Policies*, in *Regulating and Managing Food Safety in the EU*, 6, 2018, 217-244; A. ANYSHCHENKO, *The Precautionary Principle Through the Viewscreen of Cost-benefit Analysis*, in *Social Science Research Network* (*SSRN*), 2019, 1-13.

[45] According to the World Health Organization (WHO), "*different GMOs include different genes inserted in different ways. This means that individual GM foods and their safety should be assessed on a case-by-case basis and that it is impossible to make general statements on the safety of all GM foods. GM foods currently available on the international market have passed safety assessments and are not likely to present risks for human health. In addition, no effects on human health have been shown as a result of the consumption of such foods by the general population in the countries where they have been approved. Continuous application of safety assessments based on the Codex Alimentarius principles and, where appropriate, adequate post market monitoring, should constitute the basis for ensuring the safety of GM foods*", available on: https://www.who.int/. On possible risks related to the environment, and human and animal health, see.: S. SHRESTHA, *Genetically Modified Organisms and Human Genetic Engineering: How Should National Policy-Makers Respond to Perceived Risks Beyond National Borders?*, in *TLI Think!*, 2017, 2 ff.; V. V. MONARKH, *GMO and health risks selected issues*, in *The Agriculture and Forestry*

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In this context in which we find labeling as a fundamental instrument to ensure the biotechnological information in compliance with the consumer "right to know", traceability assumes a central importance.[46] In fact, a product has to be considered safe not in relation to what is indicated on the label, but in relation to how the FBOs who participated in its creation and distribution are able to promptly provide the competent control authorities[47] with the documents certifying its origin and destination.[48] In particular, FBOs have the responsibility and obligation to transmit to the buyers all the information regarding the nature, presence or derivation of GMOs. In addition to specify the type of GMOs used,[49] the FBOs must also specify the unique identification code,[50] which must also be included in the documents required for each product during the transfer within the specific supply chain. Moreover, FBOs must keep track of GM product information for a total period of 5 years from the transfer to another individual or entity involved in the food chain.

The European conservative approach, based on the precautionary principle and sensitive to health and environmental risks, is aimed at protecting European food companies and consumers at the same time. As a result, the European model[51] is inspired by a policy of protectionism and information regarding the largest importers of GMOs such as the United States of America.

In this regulatory framework, as we will see, traceability combined with technological innovation, may undertake a central importance in compliance with the European purposes related to the food supply chain.

Journal, 2019, 245-254; A. HILBECK, H. MEYER, B. WYNNE, ET AL., *GMO regulations and their interpretation: how EFSA's guidance on risk assessments of GMOs is bound to fail*, in *Environmental Sciences Europe*, 2020, 1-15.

[46] Regulation (EC) 1830/2003, Article 3, §3, defines traceability as "*the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains*."

[47] Regulation (EC) 1830/2003, Article 9, highlights that Member States have the onus to ensure that inspections and other control measures (e.g. sample checks and testing), as appropriate, are carried out in compliance with this Regulation.

[48] Regulation (EC) 1830/2003, recital 3, states that "*traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects on human health, animal health or the environment, including ecosystems, are established, and the targeting of monitoring to examine potential effects on, in particular, the environment. Traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle.*"

[49] In particular, Regulation (EC) 1829/2003 provides a threshold of 0.9% for authorized GMOs and 0.5% for the unauthorized ones. Products which contain traces within these limits, due to accidental or technically unavoidable causes, are exempted from traceability rules.

[50] Regulation (EC) 1830/2003, Article 3, §4, defines unique identifier as "*a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorized transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO.*"

[51] *See.*: A. STAZI, *Genetically modified organisms and sustainable development: regulatory approaches, access to resources and traceability*, in *BioLaw Journal*, 2, 2020, 136, stressing how "*from a comparative perspective, two macro-models can be distinguished one based on the precautionary principle with respect to the use and consumption of GMOs, adopted in Europe, China, Japan and Africa, and another in which a general policy prevails, as primarily in the United States.*"

Essays

4. United States: Food law & policy to trace the food supply chain

US food law finds its regulatory sources in a "complete set of local, State, and federal laws and regulations that implement food policies."[52] Therefore, this multidisciplinary[53] matter is closely linked to institutional choices at local, state and federal levels and to the activities of specific government agencies such as the Food and Drug Administration (FDA)[54], the Food Safety and Inspection Service (FSIS),[55], the Environmental Protection Agency (EPA),[56] and the National Marine Fisheries Service (NMFS).[57]

[52] See.: P. B. HUTT, *Food Law & Policy: An Essay*, in *Journal of Food Law and Policy*, 1, 2005, 11, referring to food law as that set of "*rules to govern common behavior and shared experiences regarding the available food supply*"; and B. J. LINNEKIN, E. M. BROAD LEIB, *Food Law & Policy: The Fertile Field's Origins and First Decade*, in *Wisconsin Law Review*, 2014, 584.

[53] See.: M. T. ROBERTS, *Food Law in the United States*, Cambridge, 2016, 10, stressing that "The vastness of food law subject matter raises a legitimate question as to whether food law is not a discipline in and of itself, but merely a subsection of other forms of law – administrative, environmental, consumer protection, international, tort, zoning, animal welfare, constitutional, and intellectual property. However, the case to consider food law as a discipline in and of itself is strong. Its value lies in focusing attention on how law governs food from the field to the table."

[54] The *Food and Drug Administration* (FDA) is part of the *Department of Health and Human Services* (DHHS) and governed by the Federal Food Drug and Cosmetic Act of 1938. The FDA is responsible for protecting the public health by guaranteeing the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, and by assuring the safety of the Nation food supply, cosmetics, and products that emit radiation. It has jurisdiction over domestic and imported foods that are marketed in interstate commerce, except for meat and poultry products. Official website available on: https://www.fda.gov/.

[55] The *Food Safety and Inspection Service* (FSIS) is part of the *U.S. Department of Agriculture* (USDA) and governed by four legislations namely Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), Egg Products Inspection Act (EPIA), and Humane Methods of Slaughter Act (HMSA). The FSIS is responsible for monitoring meat, poultry, and eggs from pesticides, animal drugs, and environmental contaminants. Official website available on: https://www.fsis.usda.gov/.

[56] The Environmental Protection Agency (EPA) licenses all pesticide products distributed in the U.S. and establishes tolerances for pesticide residues in or on food commodities and animal feed, whose enforcement is up to other agencies such as FDA or FSIS. EPA is also responsible for protecting against other environmental chemical and microbial contaminants in air and water that might threaten the safety of the food supply. Official website available on: https://www.epa.gov/.

[57] The National Marine Fisheries Service (NMFS) is part of the U.S. Department of Commerce and is in charge of inspection of seafood processing plants, fishing vessels, and seafood products. Official website available on: https://www.fisheries.noaa.gov/.

The lack of systematicity of US law, strongly influenced by the "sociological jurisprudence"[58] and "legal realism",[59], results in a practical difficulty to provide a systematic projection of sources of law typical of civil law jurisdictions.[60]

Nevertheless, leaving aside local and State regulatory measures,[61] the main regulatory interventions at the federal level of U.S. food law are represented by the Federal Food, Drug and Cosmetic Act (FFDCA) of 1938[62] and the Food Safety Modernization Act (FSMA) of 2011[63] which largely replaced and integrated the Bioterrorism Act of 2002.[64]

With regard to traceability, the Bioterrorism Act of 2002 introduces registration with the FDA of both U.S. and foreign food manufacturing facilities that supply the U.S. market. Furthermore, it lays the groundwork for the development of a tracking system capable of documenting food distribution in

[58] Sociological jurisprudence is based on the belief that decisions made to resolve a particular legal issue, should take into account the social interests at stake at that particular time. See.: R. POUND, *The Scope and Purpose of Sociological Jurisprudence*, in *Harvard Law Review*, 24, 8, 1911, 591-619; E. EHRLICH, *Montesquieu and Sociological Jurisprudence*, in *Harvard Law Review*, 29, 6, 1916, pp. 582-600, stressing how based on the vision of the French philosopher Montesquieu, the legal processes are strictly connected and influenced by the history and the social condition of society; G. E. WHITE, *From Sociological Jurisprudence to Realism: Jurisprudence and Social Change in Early Twentieth-Century America*, in *Virginia Law Review*, 58, 6, 1972, 999-1028; J. H. MERRYMAN, *Comparative Law and Social Change: On the Origins, Style, Decline & Revival of the Law and Development Movement*, in *The American Journal of Comparative Law*, 25, 3, 1977, 457-491.

[59] School of thought according to which the legal fictions, values, and principles accepted by jurists as articles of faith but without any foundation, are to be unmasked and dissolved. This is because of the impossibility of achieving, and then the futility of seeking legal certainty. See.: K. N. LLEWELLYN, *A Realistic Jurisprudence-The Next Step*, in *Columbia Law Review*, 30, 4, 1930, 431-465; L. L. FULLER, *American Legal Realism*, in *University of Pennsylvania Law Review and American Law Register*, 82, 5, 1934, 429-462; L. L. FULLER, *Legal Fictions*, Stanford, 1970, 1-49; G. E. White, *From Sociological Jurisprudence to Realism: Jurisprudence and Social Change in Early Twentieth-Century America*, cit., 999-1028.

[60] As known, the common law system is based on the principle of *stare decisis*, according to which decisions and jurisprudential interpretations have binding legal value. Therefore, a hierarchical reconstruction of the sources of law is to be considered quite inappropriate. In this regard, see.: M. A. GLENDON, *The Civil Law Tradition: An Introduction to the Legal Systems of Western Europe and Latin America by John Henry Merryman*, in *The American Journal of Comparative Law*, 19, 1, 1971, 156-159; P. H. DUNN, *How Judges Overrule: Speech Act Theory and the Doctrine of Stare Decisis*, in *The Yale Law Journal*, 113, 2, 2003, 493-531.

[61] Among the local regulatory measures we find, for instance, those related to waste disposal (e.g. *San Francisco Department of the Environment: "Mandatory Recycling and Composting Ordinance",* available on: https://sfenvironment.org/) or support for urban agriculture activities (e.g. *Boston Municipality Code, chapter 17-10 "Permitting and Regulation of Mobile food trucks"* available on: *https://www.cityofboston.gov/*). Regulatory measures under State law include for instance, State Retail and Food Service Codes and Regulations, available on: https://www.fda.gov/food/fda-food-code/state-retail-and-food-service-codes-and-regulations-state.

[62] Enacted by the 75th United States Congress and signed into law by President Franklin D. Roosevelt on June 25, 1938, the Federal Food, Drug, and Cosmetic Act, 1934, establish standards for food, drugs, medical devices, and cosmetics manufactured and sold in the U.S., and provide for federal oversight and enforcement of the above standards. Available on: https://www.govinfo.gov/.

[63] Enacted by the 111th United States Congress and signed into law by President Barack Obama on January 4, 2011, the Food Safety Modernization Act, 2011, represents one of the major reforms in the food sector, recognizing broad powers to the Food and Drug Administration.

[64] Enacted by the 107th United States Congress and signed into law by President George W. Bush on June 12, 2002.

order to identify the immediate previous sources and the immediate subsequent recipients of food, similarly to the European "one step back one step forward" approach.[65]

Nevertheless, the mismanagement of the subsequent food outbreaks[66] demonstrated the weakness of the then-present regulations, whereby most facilities kept their records in paper files difficult to access and to correlate with those of other facilities in the short time.

The Food Safety Modernization Act (FSMA) of 2011, in addition to supplementing and expanding the FDA's powers with regard to inspection activities,[67] preventive controls,[68] product recalls,[69] importation,[70] and collaboration,[71] lays the groundwork for a process aimed at fostering the implementation of FTSs.

[65] In this regard, see.: M. ESPIÑEIRA, F. J. SANTACLARA, *Advances in Food Traceability Techniques and Technologies: Improving Quality Throughout the Food Chain*, United States of America, 2016, 242 ff.; J. MCENTIRE, A. W. KENNEDY, *Food Traceability: From Binders to Blockchain*, cit., 82 ff.; F. PERNAZZA, P. P. PICARELLI, *La tracciabilità dei prodotti agroalimentari: finalità, tecniche e modelli regolatori*, in *Cibo e diritto una prospettiva comparata*, 2, 2020, 513 ff.; S. ISLAM, J. M. CULLEN, *Food traceability: A generic theoretical framework*, cit., 10.

[66] According to the Federal Agency Centers for Disease Control and Prevention (CDC), each year 48 million people get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases in the United States. Among the worst food outbreaks in the United States, we recall: The Peanut Corporation of America (PCA) Salmonella enterica serovar typhimurium outbreak of 2009; the Salmonella enterica serovar Saintpaul in raw "tomato" outbreak of 2008; and the Escherichia coli O157:H7 outbreak in spinach in 2006. Data available on: https://www.cdc.gov/.

[67] Section 101 FSMA. *Inspections of Records*, stating that: "If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner […]"

[68] Section 103 (a) FSMA. Hazard analysis and risk-based preventive controls, stating that: "The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice." The Preventive Controls Rule in this case seems to be inspired by the European precautionary principle in order to act preventively on food safety issues rather than acting when problems have already occurred.

[69] Section 206 (a) FSMA. *Mandatory Recall Authority*. For the first time, compulsory recall authority for all food is given to the FDA in case there is a reasonable probability that an article of food is adulterated (Section 402.) or misbranded (Section 403.) or the use of or exposure to such article could cause serious adverse health consequences or death to humans or animals,

[70] FSMA - Title III--*Improving the safety of imported food* (Sec. 301., ff.), which states for instance that importers must verify foreign supplier's preventive controls to be in compliance with the U.S. food safety provisions. Moreover, FDA may engage the services of qualified third-party auditors to certify that foreign food facilities are in compliance with U.S. food safety standards.

[71] Section 109 FSMA. *Food and Agriculture Coordinating Councils*. The FSMA recognizes the importance of strengthening existing collaboration among all food safety U.S. federal, state, local, territorial, tribal, and foreign agencies, in order to reinforce the U.S. food system.

In particular, Section 204 FSMA titled "Enhancing tracking and tracing of food and recordkeeping", states that FDA, in collaboration with USDA, should develop pilot projects aimed at identifying innovative technological solutions able to efficiently track products within the food industry.[72] FDA was also required to designate high risk foods and to publish a notice of proposed rulemaking for the additional recordkeeping requirements which are considered necessary in the protection of public health.

As a consequence, on September 23, 2020, the FDA published the "Requirements for Additional Traceability Records for Certain Foods"[73] on its "Food Traceability List" (FTL)[74] recently updated on January 12, 2021.[75] Notwithstanding the onus of recordkeeping on previous and subsequent recipients (Section 204 (F) FSMA), FSMA leaves, based on a liberal approach, ample room in relation to the modalities set up by food business operators aimed at guaranteeing food traceability.

A similar approach can also be found in the regulation concerning GM foods. In fact, unlike the European model, the US has adopted a model of substantial equivalence whereby GM products are fundamentally assimilated to conventional food products.[76] Therefore, the risks associated with GM food

[72] Section 204 (c) FSMA. *Product Tracing System*, stating that: "*Prior to the establishment of such product tracing system, the Secretary shall examine the results of applicable pilot projects and shall ensure that the activities of such system are adequately supported by the results of such pilot projects.*" In this regard, see.: "*Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report*" 2012, available on: https://www.fda.gov/media/124149/download; "*Report to Congress On Enhancing Tracking and Tracing of Food and Recordkeeping Submitted Pursuant to Section 204 of the FDA Food Safety Modernization Act, Public Law 111-353*" 2016. Official document available on: https://www.fda.gov/media/102784/download; and "*The Blueprint for the New Era of Smarter Food Safety*" of July 13, 2020 outlining the FDA's vision to increase traceability promoting tech-enabled end-to-end traceability for all foods, improve predictive analytics, respond more rapidly to outbreaks, address new business models, reduce contamination of food, and foster the development of stronger food safety cultures. Available on: https://www.fda.gov/media/139868/download.

[73] At the core of this proposal is a requirement for those who manufacture, process, pack or hold foods on the Food Traceability List (FTL) to establish and maintain records containing Key Data Elements (KDEs) associated with different Critical Tracking Events (CTEs). Official document available on: https://www.fda.gov/media/142303/download.

[74] The "*Food Traceability List*" (FTL) identifies the foods for which the additional traceability records described in the proposed rule would be required. As noted in the proposed rule, the additional recordkeeping requirements would apply not only to foods specifically listed on the FTL, but also to foods that contain foods on the list as ingredients. To determine which foods should be included on the FTL, the FDA developed a risk-ranking model for food tracing ("the Model") based on the factors that Congress identified in Section 204 of FSMA. The Report "*Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223)*" identifies seven criteria which are: Frequency of outbreaks and occurrences of illnesses; Severity of illnesses; Likelihood of contamination; The potential for pathogen growth, with consideration of shelf life; Manufacturing process contamination probability and industry-wide intervention; Consumption rate and amount consumed; Cost of illness. Official documents available on: https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list and https://www.fda.gov/media/142247/download.

[75] Memorandum available on: https://www.fda.gov/media/145050/download.

[76] See.: H. MILLER, *Substantial Equivalence: Its Uses and Abuses*, in *Nature Biotechnology*, 17, 1999 , 1042 ff., argues that genetic modification (GM) is simply an extension of a "natural" process.; D. M. STRAUSS, *The international regulation of genetically modified organisms: importing caution into the US food supply*, in *Food and Drug Law Journal*, 61, 2, 2006, 182 ff., who highlights that as "substantially equivalent" the GM foods are regarded as safe as their conventional counterpart; and A. STAZI, *Genetically modified organisms and sustainable development: regulatory approaches, access to resources and traceability*, cit., 137, stressing how the US has gone from a highly politicized regulatory system in the framework of public distrust in government and skepticism about

products have to be considered identical to those arising from products obtained by traditional development techniques.[77]

This equivalence is also reflected in the regulatory framework entrusted by the "Coordinated Framework for the Regulation of Biotechnology" of 1986 to the main agencies of the US food sector.[78]

As a result, all regulations, such as the ones on labeling[79] and traceability, basically follow those for conventional foods, posing significant information problems to the prejudice of consumers.[80]

In response to the issues arising from this equivalence approach, the National Bioengineered Food Disclosure Standard[81] of 21 December 2018, seemed to represent a shift towards a more pro-consumer information approach. The rule, with mandatory compliance dated on January 1, 2022, established the new national bioengineered (BE) food disclosure standard (NBFDS or Standard) requiring food manufacturers, importers, and other entities that label foods for retail sale to disclose information about BE food and BE food ingredients.

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new science technologies, to a more sectoral and product-oriented regulatory system in support of technological and scientific innovation.

[77] Among others, see.: WHO, Food safety: 20 questions on genetically modified foods, available on: https://www.who.int/news-room/q-a-detail/food-genetically-modified (2021); INSTITUTE OF MEDICINE AND NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, Washington D.C., 2004; A. NICOLIA, et al., *An overview of the last 10 years of genetically engineered crop safety research*, in *Critical Reviews in Biotechnology*, 2013, 1 - 12.

[78] The FDA makes sure that foods that are GMOs or have GMO ingredients meet the same strict safety standards as all other foods. Moreover, under the "*Plant Biotechnology Consultation Program*" GM food developers need to inform the FDA about the potential GM food that they plan to launch in the market. The developers, then, need to submit relevant information and food safety information data to the FDA. FDA, then, evaluates the assessment data provided and if satisfied, FDA allows the developers to go ahead with the product. The EPA regulates the safety of the substances that protect GMO plants, referred to as "Plant-Incorporated Protectants" (PIPs), that are in some GMO plants to make them resistant to insects and disease. Finally, the USDA ensures that GMOs are safe for human, plant, and animal health. More information available on: https://www.fda.gov/food/agricultural-biotechnology/how-gmos-are-regulated-food-and-plant-safety-united-states.

[79] In this regard, labeling assumes a great importance. In fact, the biggest difference between the US and EU system lies in the obligation to provide information on the GM nature of food products. An example of the U.S. position may be given by *The National Bioengineered Food Disclosure Law*, passed by Congress in July of 2016 banning individual States from adopting or implementing their own GMO labeling legislation and leaving food operators free to choose their own labeling method. In this regard, see.: A. STAZI, *Genetically modified organisms and sustainable development: regulatory approaches, access to resources and traceability*, cit., 138.

[80] See.: T. O. MCGARITY, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, in *University of Michigan Journal of Law Ref.*, 35, 3, 2002, 403 ff., suggesting a more precautionary approach toward regulating GM foods that should command a higher level of public trust than the substantial equivalence approach.

[81] Available on: https://www.federalregister.gov/documents/2018/12/21/2018-27283/national-bioengineered-food-disclosure-standard (2021).

5. People's Republic of China: Enhancing food safety through traceability regulation and innovation

In the framework outlined so far, based on consumer-oriented policies in the European system and on more liberal policies in the U.S. system, our analysis focuses now on the People's Republic of China's system.

Notwithstanding its massive role in technological innovation and economic development,[82] in the food sector China is often seen by the international community as a threat to the public health of all consumers across the world.

The food scandals[83] which involved the People's Republic of China in recent times and which negatively affected the whole world, determined the need for the Chinese government to intervene massively in the sector of food law through an innovative regulatory and technological approach. This is what President Xi Jinping advocated several times.[84]

Despite the fact that the territorial complexity and the fragmentary nature of the Chinese regulatory framework[85] represent obstacles in the creation of an effective food policy, China has started a process of definition and development of food regulations[86] aimed at giving shape to a strong food system, as much as possible sufficient to national and international needs.

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[82] In this regard, see.: X. ZHOUA, Z. CAIB, K. H. TAN, et al., T*echnological innovation and structural change for economic development in China as an emerging market*, in *Technological Forecasting and Social Change*, 167, C, 2021, analyzing the existing relationship between technological progress and economic growth towards the birth of new sustainable policies and strategies that could promote structural change in China.

[83] Contamination of food by heavy metals, food poisoning by additives and preservatives, and fake foods are just some problems of a more complex scenario that causes thousands of food poisonings every year in China and worldwide. One significant scandal was the melamine powdered milk scandal in 2008. About this event, see: X. PEI, A. TANDON, A. ALLDRICK, et al., T*he China Melamine Milk Scandal and its Implications for Food Safety Regulation*, in *Food Policy Journal*, 36, 3, 2011, 412-420; and R. YANG, K. HORSTMAN, B. PENDERS, *Constructing the accountability of food safety as a public problem in China: a document analysis of Chinese scholarship, 2008–2018*, in *Journal of Chinese Governance*, 2020, 1-18, analyzing how Chinese scholarly debates co-construct public accountability for food safety as a public issue.

[84] For example in a speech on July 23, 2020, President Xi Jinping said in this regard that: "Food safety is an important foundation of national security. We need to innovate in food production, optimize production technology, implement all supportive policies, protect farmers' enthusiasm for their work, and improve the income from food production." (available on: http://www.xinhuanet.com/).

[85] The fragmentary and complex nature of Chinese food law can be seen in the multiplicity of authorities capable of regulating matters relating to food law, sometimes even overlapping: see e.g. the multiple competences of the Ministry of Agriculture (MOA), the Ministry of Commerce (MOC), the Chinese Food and Drug Administration (CFDA), the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), and other local authorities. See.: A. STAZI, *Genetically modified organisms and sustainable development: regulatory approaches, access to resources and traceability*, cit., 142; J. K. YASUDA, *Why food safety fails in China: The politics of scale*, in *China Quarterly*, 223, 2015, 745-769; Q. JIANG, Y. ZHU, *Challenges for enforcing food safety law and regulations in China: Case studies of government agencies in the Shanghai region*, in *Asian-Pacific Law and Policy Journal*, 18, 2016, 36-62; J. K. YASUDA, *On feeding the masses: An anatomy of regulatory failure in China*, New York, 2017.

[86] Provision adopted at the 7th session of the Standing Committee of the Eleventh National People's Congress on February 28, 2009, and introduced effective from June 1, 2009, containing 104 articles, repealing the Food Hygiene Law of 1995, and representing the first food safety law in the PRC history. The FSL of 2009 covered the following issues: Surveillance and Assessment of Food Safety Risks; Food Safety Standards; Food Production and Trade; Inspection and Testing of Food; Food Import and Export; Response to Food Safety Incidents; Supervision

After the melamine crisis, the new Food Safety Law (FSL, 食品安全法) 2009 was a first step toward creating a more structured food policy. Nonetheless, it presented limitations in ensuring industry compliance and law enforcement in the vast territory of China.

The need for improvement aimed at ensuring effectiveness of Chinese food policy, has therefore led to a series of revisions and amendments over the years.

The Food Safety Law (FSL) of 2015[87] represents the first and most important revision. It is the result of a process of "crossing the river by feeling the stones"[88], designed to tighten the rules against offenders by imposing numerous penalties[89] on food producers and officials who fail to respond appropriately to concerns of food safety aimed at protecting the Chinese market.

and Administration; and Legal Liabilities, available on: http://www.gov.cn/zhengce/content/2019-10/31/content_5447142.htm.

[87] Provision introduced effective from October 1, 2015, following the 14th session of the Standing Committee of the XII National People's Congress of the People's Republic of China; amended for the first time in accordance with the Decision of the Standing Committee of the NPC to Amend Five Laws Including the Product Quality Law of the People's Republic of China adopted at the 7th session of the Standing Committee of the thirteenth NPC on December 29, 2018; and amended for the second time in accordance with the Decision of the Standing Committee of the NPC to Amend Eight Laws including the Road Traffic Safety Law of the People's Republic of China (including the Fire Protection Law, the Law on Import and Export Commodity Inspection, the Advertising Law, the Grassland Law, the Civil Aviation Law, the Customs Law and the Food Safety Law) at the 28th Session of the Standing Committee of the Thirteenth NPC of the People's Republic of China on April 29, 2021. The revised food safety law of 2015 is divided in 10 chapters: General Principles; Food Safety Risk Surveillance and Assessment; Food Safety Standards; Food Production and Trading; Food Testing; Food Import and Export; Handling of Food Safety Incidents; Regulatory Work; Legal Liabilities; and Supplementary Provisions, available on: https://www.pkulaw.com/en_law/be352ba1d170a5a8bdfb.html. See.: M.T. ROBERTS, C. F. LIN, *China Food Law Update: The 2015 Food Safety Law and Social Governance on Food Safety*, in *Journal of Food Law and Policy*, 12, 2, 2016, 1-35; I. HÄRTEL, *Handbook of Agri-Food Law in China, Germany, European Union*, Switzerland, 2018, 100 ff.

[88] *Cf.*: F. SNYDER, Y. S. KIM, *China's 2015 Food Safety Law: Crossing the River but Feeling the Stones and Avoiding Low Branches?*, in *The Chinese Journal of Comparative Law*, 6, 1, 2018, 1-49, emphasizing the gradual normative progress of Chinese food safety legislation, using the metaphor of "*crossing the river by feeling the stones*" – meaning a step-by-step process characterized by gradualism, exploration, and experimentation. An example of FTS experimentation was implemented at the 2008 Beijing Olympic Games. Multiple technologies (e.g. RFID, GPS, automatic temperature recording and control, humidity control, encrypted communication) were used to track and record a range of food information, including food production, processing, transport and storage. In this regard, see.: H. J. LAN, F. Q. HUANG, Z. K. LIN, *The design of a food traceability system for 2008 Beijing Olympic Games*, in *China Storage & Transport*, 2008, 86-89.

[89] See.: Article 63, FSL 2015, §1, stating that "In the event that a food producer finds that the food being produced does not comply with food safety standards or is proven to likely endanger human health, the food producer shall immediately stop production of the food, recall the food product released to the market, notify relevant producers, distributors and consumers, and create a record on recalls and notifications."; and Article 148, FSL 2015, §2: "In the event that any manufacturer produces food that does not conform to food safety standards or distributes food while being aware of its nonconformity with food safety standards, the customer can demand the producer or distributor to pay a penalty of 10 times the paid amount or 3 times of the loss, in addition to the compensation for the loss thereof."

Article 42[90] of the FSL 2015 put the onus on the Government to set up a full traceability system in order to guarantee food safety. Furthermore, the Article provided that food producers and distributors set up a traceability system for food safety in accordance with the FSL 2015.
The state was deemed to encourage food producers and distributors to collect and retain information related to production and distribution of food, also through information technology aimed at establishing an efficient FTS.
As also confirmed by subsequent implementations[91] to FSL 2015, the determination of the basic requirements for food traceability of the entire food supply chain is up to the joint activity of the "China Food and Drug Administration" (CFDA)[92] and the Ministry of Agriculture (MOA) with the additional support of other relevant State Council departments.
It is notable that neither the FSL 2015, nor its implementing regulations, provide elaborate guidance or established principles on how traceability should be executed, marking a practical divergence from

[90] Article 42, FSL 2015: "The state shall establish a whole process food safety tracing system. Food producers and traders shall, in accordance with this Law, establish a food safety tracing system to ensure the traceability of food. The state shall encourage food producers and traders to gather and retain production and trade information by digital means to establish a food safety tracing system. The food safety supervision and administration department of the State Council shall establish a whole process food safety tracing cooperation mechanism in conjunction with the agricultural administrative department and other relevant departments of the State Council" (updated version 2021) Available on: http://www.lawinfochina.com.
[91] On August 14, 2017, China notified the World Trade Organization (WTO) of the "Regulations on the Implementation of the Food Safety Law of the People's Republic of China (Revised Draft)" as SPS 1055. The revised draft regulations are in support of the implementation of China's 2015 Food Safety Law.
[92] The CFDA is the direct agency of the State Council for the supervision and management of drugs, medical devices, cosmetics, natural foods and food safety. The CFDA is responsible for drafting laws and regulations for the supervision and management of food (including food additives and health foods); for formulating and organizing the implementation of inspection systems for the supervision and management of food, drugs, medical devices and cosmetics; and in organizing the investigation and punishment for major violations.

the EU and the US systems,[93] notwithstanding the convergences[94] also present in reference to the "international normative repertoire".[95]

This has led to the development over the years of hundreds if not thousands of subordinates' secondary level regulations, such as administrative regulations, standards[96], and local regulations often dictated by local protectionism, which have made the Chinese food system increasingly complex.

In this regard the PRC, as demonstrated by subsequent implementations such as the regulations of October 2019,[97] has followed a policy aimed at tightening up sanctions by also rewarding those who report the existence of violations in the food sector.

This tightening of sanctions contained in the FSL 2015, for example articles 63 and 148, and in its subsequent implementations, represents a key lever for the enactment of efficient FTSs. In fact, a well-organized FTS would be able to shorten the time frame in case of violations by identifying and isolating the potential issue without heavily affecting all the operators involved in the supply chain.

Finally, some specific provisions are foreseen in GM foods. With exception of the Environmental Protection Law,[98] the PRC does not have any national law specific on GMOs or GM foods.

[93] Practical differences have meant that true regulatory collaboration among PRC and trading partners has been achieved through administrative cooperation coupled with bilateral trade agreements. Among some of the most recent ones: Agreement between the European Union and the Government of the People's Republic of China on cooperation on, and protection of, geographical indications, 2020, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.LI.2020.408.01.0003.01.ENG; Economic and trade agreement between the Government of the United States of America and the Government of the People's Republic of China, 2020, available on: https://ustr.gov/countries-regions/china-mongolia-taiwan/peoples-republic-china/phase-one-trade-agreement/text.

[94] Similarities can be found regarding: the risk-based processes which are largely modeled on the EU's risk analysis system; the functional barrier doctrine borrowed from the U.S. system; specific migration limit (SML) restrictions based on the European model, etc. See.: I. HÄRTEL, *Handbook of Agri-Food Law in China, Germany, European Union*, cit., 57 ff.; E. HUANG, X. DAI, Z. LI, *A Comparative Study of Differences in Government Regulation of Food Safety between China and the United States*, in *Advances in Social Science, Education and Humanities Research*, 151, 2018, 559-564; Y. KANG, *Food safety governance in China: Change and continuity*, in *Food Control Journal*, 106, 2019, 2; J. QIAN, L. R. GARCIA, ET. AL., *Food traceability system from governmental, corporate, and consumer perspectives in the European Union and China: A comparative review*, cit., 402-412.

[95] *Cf.*: P. C. JESSUP, *Transnational Law*, in *American Journal of International Law*, 51, 2, 1957, 444-445, referring to international normative repertoire as "*all law which regulates actions or events that transcend national frontiers.*"

[96] National Standards (國家標準 or Guobiao) are secondary provisions, usually issued by the Standardization Administration of China (SAC), which define technical requirements in a specific sector usually related to technology (e.g. the Food safety electronic traceability technology research and demonstration standard No. 2015BAK36B00, which aims at research on quality control, business collaboration and focuses on key products like infant formula). See.: R. BERTI, M. SEMPREBON, *Food Traceability in China*, cit., 2018, pp. 526 ff.

[97] Regulations for the implementation of the Food Safety Law of the People's Republic of China, promulgated by Decree No. 557 of the State Council of the PRC on July 20, 2009, amended in accordance with the "Decision of the State Council on the Amendment of Certain Administrative Regulations" dated February 6, 2016 and all amended and approved Executive of the State Council dated March 26, 2019. Available on: http://www.gov.cn/.

[98] *Environmental Protection Law of the People's Republic of China*, December 26, 1989. Available on: http://www.china.org.cn/english/government/207462.htm (2021).

However, there are in place, regulations and standards overseeing GMOs in the agricultural sector.[99] The MOA and the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) are vested with the responsibility for exercising regulation on agricultural GMOs and GM foods.
Traceability requirements for any GM food in China were first observed in 2015 when the Seed Law was revised to include specific requirements of traceability of seeds produced from biotechnology and stringent punishments were introduced for illegitimate production and sale of GM seed varieties.[100]
The Law provides that all seed varieties developed need to be registered under the responsible authorities prior to propagation and the same should be ensured traceability by the relevant enterprise. Apart from the Seed Law, no specialized GM traceability regime is seen in China.
Considerations related to the potential risks of genetic modification on the entire animal and environmental ecosystem,[101] have made the Chinese model closer to the European one inspired by the precautionary principle.[102] However, the issues already mentioned, arising from the rigidity of Chinese legislation and its enforcement in practice, still pose many challenges to achieving food safety in China.

6. Blockchain: An innovative and decentralized register for a better FTS

Major global food chains are under increasing pressure to implement modern traceability systems in sync with legislative, social, economic, and technological developments.[103] This is due to growing consumer awareness of food quality and safety, and social and political demands that are increasingly focused on sustainability and innovation.[104]

[99] For instance: *Regulations on Administration of Agricultural Genetically Modified Organisms Safety*, Decree No. 304 of the State Council of the People's Republic of China, Promulgated on May 23,2001, and effective as of the date of promulgation and the Lic*ensing Measures on Livestock Genetic Materials Production* of 2010, both available on: http://www.gov.cn/.

[100] Revision of the *Seed Law of the People's Republic of China* promulgated by the Standing Committee of the National People's Congress on November 4, 2015 and effective January 1, 2016. On GMOs traceability requirements, see.: Articles 16, 17, 22, 36. Available on: http://www.linan.gov.cn/art/2020/1/3/art_1367578_41444346.html.

[101] In this regard, see: A. STAZI, *Genetically modified organisms and sustainable development: regulatory approaches, access to resources and traceability*, cit., 141; X. ZHU, M.T. ROBERTS, K. WU, *Genetically modified food labeling in China: in pursuit of a rational path*, in *Food and Drug Law Journal*, 71, 1, 2016, 41 ff.

[102] In China, as in Europe, emphasis is placed on the process of how GM products are obtained and how they are commercialized. In fact, in China mandatory labeling is mandatory to protect consumers' "right to know" about the composition of a given product placed on the market. In this regard, see.: A. STAZI, *Genetically modified organisms and sustainable development: regulatory approaches, access to resources and traceability*, cit., p. 142; G. P. GRUÈRE, S. RAO, *A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule*, in *AgBioForum*, 10, 1, 2007, 5; A. Y. T. WONG, A. W. K. CHAN, *Genetically modified foods in China and the United States: A primer of regulation and intellectual property protection*, in *Food Science and Human Wellness*, 5, 3, 2016, 124-140. E. BOZZINI, D. SICURELLI, *Precautionary authoritarianism and the contested governance of Chinese food safety*, in *Contemporary Politics*, 27, 3, 2021, 334-355.

[103] In these terms, see.: J. QIAN, L. R. GARCIA, et. al., *Food traceability system from governmental, corporate, and consumer perspectives in the European Union and China: A comparative review*, cit., 403.

[104] In this regard, see.: D. C. PETRESCU, I. VERMEIR, R. M. PETRESCU, *Consumer Understanding of Food Quality, Healthiness, and Environmental Impact: A Cross-National Perspective*, in *International Journal of Environmental Research and Public Health*, 17, 169, 2020, 1-20, identifying consumers' concerns for healthier lifestyles and environment care as driving forces for reshaping food buying intentions and perspectives on food quality.

Notwithstanding the diversity of the legal systems examined so far and without prejudice to the peculiarities of each productive sector, we believe it is appropriate to stress the opportunity of developing, on a voluntary basis, new and innovative FTS, capable of guaranteeing numerous benefits for both food business operators (FBOs) and consumers.

Innovation can be seen in the new technologies that, in continuous evolution, envisage scenarios aimed at seeking greater efficiency and effectiveness in multiple areas. On traceability, especially according to the principle of data integration, technologies such as blockchain[105] are becoming increasingly relevant.

This is also apparent from the measures adopted in the countries previously considered. In the European Union, even though there is still not a well-defined regulatory framework on blockchain technologies, multiple initiatives have been promoted by the European Commission in order to deepen the phenomenon.[106]

The European Commission in collaboration with European Blockchain Partnership[107] is planning a pan-European blockchain regulatory sandbox[108] to become operational in 2021/22,[109] which could represent the launching pad for the definition of a regulatory framework aimed at guaranteeing legal certainty and respect for the principle of technological neutrality.

In the United States, many states took legislative measures[110] aimed at regulating blockchain technologies in view of their innovative nature and especially due to their multiple applications in the business industry.

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[105] Blockchain can be defined as a computer protocol falling under the broader category of Distributed Ledger Technologies (DLT) and composed of multiple applied technologies such as: the peer to peer network that guarantees the decentralization of any information inserted within a blockchain; cryptography and hash functions that guarantee the certainty of temporally identifiable information and inserted within the distributed ledger; consensus algorithms that are the basis of the continuous updating of data uploaded on blockchain. In these terms, see.: P. DE FILIPPI, A. WRIGHT, *Blockchain and the law: the Rule of Code*, Cambridge, 2019 (1st edition), 33-57; A. STAZI, *Smart Contracts and Comparative Law: A Western Perspective*, Springer, 2021, 71 ff.

[106] S. NASCIMENTO, A. PÓLVORA, J. S. LOURENÇO, *#Blockchain4EU: Blockchain for Industrial Transformations* (EUR 29215 EN), in *JRC Publications Repository*, 2018, in which is also noted the useful application of blockchain technologies in the food industry; European Parliament resolution of 3 October 2018 on *distributed ledger technologies and blockchains: building trust with disintermediation* (2017/2772(RSP) in which it is given relevance to blockchain technology as a tool that "*can democratise data and improve trust and transparency.*"; Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "*The Future of Food and Farming*" COM(2017) 713 final, 13 - 15.

[107] The European Blockchain Partnership is an initiative to develop an EU strategy on blockchain and build a blockchain infrastructure for public services.

[108] A sandbox is a system that brings together regulators, companies, and tech experts to test innovative solutions and identify obstacles that arise in deploying them.

[109] *Council Conclusions on Regulatory Sandboxes and Experimentation Clauses as tools for an innovation-friendly, future-proof and resilient regulatory framework that masters disruptive challenges in the digital age* (2020/C 447/01), available on: https://eur-lex.europa.eu/.

[110] Among the most relevant measures see the Senate Bill 5638 – 2019 – 2020 adopted by the State of Washington, that in addition to providing a definition of *blockchain* and *distributed ledger technologies*, recognizes the validity of distributed ledger technology stating that: "An electronic record or electronic signature may not be denied legal effect, validity, or enforceability solely because it is generated, communicated, received, or stored using distributed ledger technology." In this direction move the regulations of other States, available on:

In the People's Republic of China, on the other hand, in January 2019 the Cyberspace Administration unveiled the first Administrative Provisions on Blockchain[111] laying out the basic content and registration rules for entities offering blockchain functionality as a service and establishing fines and other penalties for possible violations.

The potential of this technology applied to the food industry has led to the development of several projects[112] aimed at ensuring more efficient FTS. In fact, compared to paper records or centralized databases, blockchain presents significant structural and substantial advantages.

Structurally,[113] the main advantages arising from the use of a blockchain registry are represented by: decentralization, which determines the transnationality of the information contained therein; immutability, to be understood as a non-destructive way to enroll and track information so that each change does not erase the previous one but stands as a new one; cryptography, that guarantees the security of the information and the inalterability of the data; and transparency, due to the complete accessibility by all or certain authorized parties depending on the chosen form of governance.[114]

From a substantial point of view, the benefits that can be identified from the application of blockchain to build FTSs are innumerable. A shared digital food supply chain powered by blockchain would be able to track any product at each stage, e.g. harvest, processing, transport, storage, distribution, and sales, involving all the stakeholders (*Figure 1*).

https://www.ncsl.org/. See also: A. STAZI, *Smart Contracts and Comparative Law: A Western Perspective*, cit., 91 ff.

[111] The "Regulations on the Management of Blockchain Information Services" deliberated and approved by the National Internet Information Office came into force on February 15, 2019. Official text available on: http://www.cac.gov.cn/2019-01/10/c_1123971164.htm.

[112] Among some most relevant projects, see the IBM Food Trust, powered by Hyperledger technology and result of a collaboration between major players and institutions such as IBM, Walmart, JD.com and Tsinghua University in China. The solution provides authorized users with immediate access to actionable food supply chain data, from farm to store and ultimately the consumer. The complete history and current location of any individual food item and accompanying information such as certifications, test data and temperature data, are readily available in seconds once uploaded onto the blockchain (https://www.ibm.com/blockchain/solutions/food-trust).

[113] In this regard, see.: P. DE FILIPPI, A. WRIGHT, *Blockchain and the law: the Rule of Code*, cit., 33-57; G. SLAVIOTTI, L. M. DE ROSSI, N. ABBATEMARCO, *The Blockchain Journey*, 8 ff., who analyzes the unique characteristics of blockchain systems.

[114] G. SLAVIOTTI, L. M. DE ROSSI, N. ABBATEMARCO, *The Blockchain Journey*, 23 ff., stressing that a blockchain governance model can be classified mainly within two dimensions: "permissioned/permissionless" and "public/private." "The first one refers to the ability to take part of the consensus mechanism whereas the second one is related to the possibility for a user to access the blockchain application. In a public ecosystem, anyone can join the network and use the application even without the authorization of the service provider. There is no central authority and everyone with an Internet connection can use the service (write), read the transaction's history (read) and, eventually, participate in the consensus mechanism (commit). In a private blockchain the final users are known and vetted, and they will be able to access the blockchain service only if the service provider allows them to." See also: A. STAZI, *Smart Contracts and Comparative Law: A Western Perspective*, 73-4.

This would allow stakeholders to take advantage of an "interoperable"[115] and transparent registry through which they could collaborate with each other by exchanging information as well as complying with the regulations in force.[116]

A blockchain-based FTS would contribute to business growth through greater operational efficiency, for example in tracing the causes of problems such as detecting the origin of food fraud[117] or food related outbreaks, etc., eliminating bottlenecks and putting into place the necessary corrective measures able to handle any recall quickly and cost-effectively.

This kind of system would enable a better definition and verification of responsibilities, both within the production sector and across the entire supply chain, for the phases of their respective competences.

In fact, when something goes wrong, for instance due to inspections by competent authorities or for the spreading of diseases, etc., the responsible party, more easily identifiable within the blockchain, could be subject to restrictions, even up to the elimination of its access within the blockchain. This could depend on the sanctions imposed for the lack of due diligence.[118]

[115] To be understood as internal interoperability, since cross-chain interoperability is still one of the critical issues preventing the widespread adoption of blockchain applications. In this regard, *see*.:
M. MADINE, K. SALAH, R. JAYARAMAN, ET AL., *AppXchain: Application-Level Interoperability for Blockchain Networks*, in *IEEE*, 9, 2021, 87777-87789.

[116] The rules in compliance with the law of a particular State as well as the operating rules of the registry can be established by means of smart contracts, "computer protocols that execute themselves by applying the lines of computer code for which they have been programmed". See.: A. STAZI, *Smart Contracts and Comparative Law: A Western Perspective*, 75 ff. On the applications of smart contracts in the food industry, see.: J. FRANK, *Blockchain Functionality: How Smart Contracts Can Save Small Farms*, in *New York Law School Law Review*, 2020, 17 ff., stressing that smart contracts can orchestrate the sale of goods, manage supply chain logistics, and control the passage of ownership in real property, giving especially to small farmers an invaluable opportunity to catch up and stay on top in the dynamic agriculture industry.

[117] See.: J. SPINK, D. C. MOYER, *Defining the public health threat of food fraud*, in *Journal of Food Science*, 76, 9, 2011, R157-R163, defining food fraud as "a collective term used to encompass the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging, or false or misleading statements made about a product, for economic gain."

[118] In this sense, see.: I. HERNANDEZ, L. G. VAQUÉ, *The Blockchain Technology and the Regulation of Traceability: The Digitization of Food Quality and Safety*, in the *European Food and Feed Law Review* (EFFL), 4 ff., stressing how in terms of responsibility, the blockchain ecosystem can promote honesty behavior from all entities involved in the food chain.

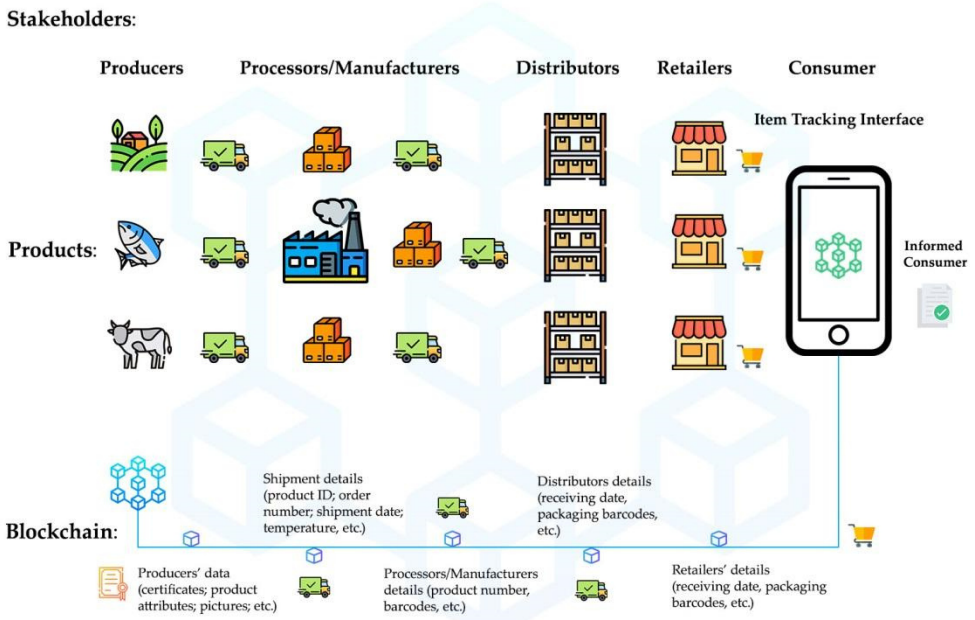

Figure 1 – Sample flow of stakeholders and products on blockchain.

The possibility for the producers of a given product to offer a practical demonstration of the management of their traceability would lead to a race to develop effective quality and sustainable systems aimed at instilling greater confidence in their brand,[119] whether it is part of a small or large company.[120] In fact, there is no doubt that there has been a tendency over time among consumers[121] and consequently retailers[122] to favor high-quality fresh products grown or raised in a sustainable manner. Sustainability, in particular, has been a strongly viewed topic in recent years due to the future challenges that await our planet. Today, in fact, many consumers believe that it is essential for food to be produced in a sustainable way with respect for the environment.[123]

[119] On a brand level, traceability increases consumers' willingness to pay in China, see.: S. JIN, Y. ZHANG, Y. XU, *Amount of information and the willingness of consumers to pay for food traceability in China*, in *Food Control Journal*, 77, 2017, 163-170; R. LIU, Z. GAO, R. M. NAYGA, et al., *Consumers' valuation for food traceability in China: Does trust matter?*, in *Food Policy*, 88, 2019, 11.

[120] In this regard, See.: J. FRANK, *Blockchain Functionality: How Smart Contracts Can Save Small Farms*, cit., 22, stressing that based on a recent shift in public perception toward favoring small farms over larger industrial agricultural businesses in the U.S., small farmers should incorporate recent innovative advancements in blockchain and digital technology to stay relevant to consumers and survive in the greater agriculture industry.

[121] J. QIAN, L. R. GARCIA, et. al., *Food traceability system from governmental, corporate, and consumer perspectives in the European Union and China: A comparative review*, cit., 407 ff., state that implementing correctly FTSs have a positive impact on consumer experience as they potentially improve consumer confidence as to the origin and quality of their product.

[122] See.: M. GARAUS, H. TREIBLMAIER, *The influence of blockchain-based food traceability on retailer choice: The mediating role of trust*, in *Food Control Journal*, 129, 2021, 1-12, highlighting how blockchain-based traceability system (as compared to a company-owned traceability system) positively impacts retailer choice; and L. DONG, P. JIANG, F. XU, *Blockchain Adoption for Traceability in Food Supply Chain Networks*, in *SSRN*, 2020.

[123] The International Food Information Council (IFIC) Foundation's 14th annual Food and Health Survey (2019) found that 54% of American consumers say "it's at least somewhat important that the products they buy be

A FTS based on blockchain technology would be an effective and transparent solution to show if a product has been produced in a sustainable manner through a process designed to decrease waste[124] and inefficiencies.

Despite the numerous benefits seen so far, the implementation of blockchain still faces some obstacles. In fact, many FBOs are still suspicious of new and complex technological systems which disrupt normality and represent an additional cost. Cross-chain interoperability is still also one of the critical issues experts are working on, preventing the widespread adoption of blockchain applications.[125]

Another challenge is represented by the veracity of the information inserted on the distributed ledger. In fact, although blockchain can be considered as a valid tool for collecting and integrating data, the proof of the veracity of the same requires the integration of additional technologies such as the internet of things[126] or artificial intelligence[127] that would corroborate the use of blockchain as a valid tool for traceability.

In such a constantly changing environment, legislative policies on food traceability aim to prevent the occurrence of threatening events through the imposition of detailed information obligations and at the same time allow a wide scope for the implementation of these obligations.

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produced in an environmentally sustainable way. Among those 54%, many look for specific labels or attributes to assess whether they believe a product is environmentally sustainable: 51% perceive products that are locally produced as environmentally sustainable, followed by products literally labeled as sustainably produced (47%), labeled as non-GMO/not bioengineered (47%), labeled as organic (44%), having recyclable packaging (41%) and having minimal packaging (35%)." Official survey available on: https://foodinsight.org/wp-content/uploads/2019/05/2019-Food-and-Health-Survey-release-FINAL.pdf (2021). The European Consumer Organization's Survey on European consumers attitudes towards sustainable food states that over half of European consumers say that "sustainability concerns have some influence (42.6%) or a lot of influence (16.6%) on their eating habits. Over one third of consumers (38.9%) would support regulations obliging farmers and food producers to meet more stringent sustainability standards. Even more (53%) agree that farmers should be given incentives (e.g. through subsidies) to produce food more sustainably. And finally most consumers (57%) want sustainability information to be compulsory on food labels." Official survey available on: https://www.beuc.eu/publications/beuc-x-2020-042_consumers_and_the_transition_to_sustainnable_food.pdf (2021).

[124] See.: M. P. MARIN, I. MARIN, L. VIDU, *Learning about the reduction of food waste using Blockchain technology*, in *INTED2019 Proceedings*, 2019, 1-4.

[125] See.: M. MADINE, K. SALAH, R. JAYARAMAN, et al., *AppXchain: Application-Level Interoperability for Blockchain Networks*, cit., 87777-87789. In this regard, the Cyberspace Administration of China, in the Blockchain Information Management Regulations 2019, has declared its readiness to standardize blockchain-related services, support a "healthy" development of the technology, and address security risks, such as the spread of illegal and harmful information or the conduct of illegal and criminal activities through this technology. Available on: https://digichina.stanford.edu/news/translation-blockchain-information-service-management-regulations-2019.

[126] In this regard, see.: A. IFTEKHAR, X. CUI, M. HASSAN, et al., *Application of Blockchain and Internet of Things to Ensure Tamper-Proof Data Availability for Food Safety*, in *Journal of Food Quality*, 2020, 1-12; J. LIN, Z. SHEN, A. ZHANG, et al., *Blockchain and IoT based Food Traceability for Smart Agriculture*, in *ICCSE'18: Proceedings of the 3rd International Conference on Crowd Science and Engineering*, 1-6.

[127] In this regard, see.: M. DORA, A. KUMAR, S. K. MANGLA, et al., *Critical success factors influencing artificial intelligence adoption in food supply chains*, in *International Journal of Production Research*, 2021, indicating that technology readiness, security, privacy, customer satisfaction, perceived benefits, demand volatility, regulatory compliance, competitor pressure and information sharing among partners are the most significant critical success factors for adopting AI in food supply chains.

However, even if it is understandable to have a somewhat restrictive legislative policy to regulate the traceability information content, the same cannot be applied to the instrument of that information. Indeed, it would be improper to force FBOs to adopt certain tools rather than others by failing to comply with the principle of technological neutrality, which is at the basis of the unceasing evolution of technology and innovation.

As a result, regulatory technology, or "RegTech", policies should favor the development of innovative technologies and education on technologies/tools whose potential still has to be perceived.[128]

In this way, it would be possible to adequately promote innovative systems aimed at guaranteeing greater advantages for companies, whether large or small, consumers, and the environment, while respecting the legislations in force in different legal systems.

[128] In particular, on food traceability, legislators could help with regard to the related problem of additional costs for the development/adoption of technological tools by the FBOs through the provision of loans, as well as support training programs on the new technological tools.