

Commenti e note

Private standards, uncertainty and liability.

The Sudan I saga

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1.- Food law, private standards and uncertainty

Uncertainty, both factual and scientific, is spread across many different domains and the food industry is no exception. At the same time, risks represent the epiphanies of uncertainty¹; thus, public authorities and professional operators within the food industry have to implement tools and processes to deal with them². Uncertainty, as mentioned, can be scientific and/or factual. The first refers to a situation in which science does not have enough data to confirm or exclude the presence of a risk; the latter to a situation in which it is scientifically clear that a substance poses a risk, but it is unclear whether such a substance is present in a given product. The analysis will focus on the interplay between some of the tools employed to govern the risks originating from uncertainty and the law of civil liability. The tools I am referring to consist of a particular type of norms, posed by private subjects, called conventionally private standards.

Private standards are widely used in food industry in order to set (safety, quality, nutritional, etc.) requirements that foodstuffs must present before being put into commerce³. According to this first meaning,

standards are specific and detailed rules, posed by private subjects, that establish how a foodstuff must be. Even if these represent the bulk of the standards used in the food industry, some private standards perform a different function.

In particular, this second type of standards provides for principles, procedures and operational tools to manage risks that can arise during the manufacturing and distribution of foodstuffs. Differently from adopting a 'command and control' approach, imposing directly on the producer how to manage risks, they try to put producers in a position to enable them to self-manage the risks, i.e. to organize their production processes in a way to minimize the risks that their activities pose. These standards apply to all the types of risks, regardless their nature, magnitude and source. As to the latter respect, it is irrelevant whether the risks originate in a situation of scientific or factual uncertainty: in both the cases the producer can apply the standards to govern these risks.

There is another aspect deserving some attention at this stage, namely how private standards are enforced. The task of controlling if standards are complied with by food producers is usually entrusted to specific subjects, the so called certification bodies, who, in most of the cases, are private firms. Certifications consist of processes by which auditors, who are agents of the certification bodies, check if producers have correctly fulfilled all the requirements provided for by private standards. When this is not the case, auditors can issue either a so called non-compliance warning (when the violation is a minor one), under which the producer is

(¹) UNI ISO 31000, *Risk management – Principles and guidelines*, 2010, where risk is defined as the output of a situation of uncertainty.

(²) On the relationship between regulation and risks in the specific context of the food industry, F. Di Porto, *Regolazione del rischio, informazione e certezza giuridica*, in *q. Riv.*, www.rivistadirittoalimentare.it, n. 4-2011, 34.

(³) On the use of standards in the food industry: E. Fagotto, *Private roles in food safety provision: the law and economics of private food safety*, in *European journal of law and economics*, 2014, 37, 83; F. Albisinni, *Sicurezze e controlli: chi garantisce cosa?*, in *q. Riv.*, www.rivistadirittoalimentare.it, n.4-2011, 4, 12, 15 ff. With regard to the interplay between private standards and contract F. Cafaggi, P. Iamiceli, *Supply chains, contractual governance and certification regimes*, in *European journal of law and economics*, 2014, 37, 131. In general, on standards: N. Brunsson, B. Jacobsson, *A world of standards*, Oxford, 2000; G. Smorto, *Certificazione di qualità e normazione tecnica*, in *Digesto delle discipline privatistiche – Sezione civile – Aggiornamento*, I, Torino, 2003, 205; F. Ancora, *Normazione tecnica, certificazione di qualità ed ordinamento giuridico*, Torino, 2000.

obliged to take corrective actions; or refuse/withdraw the certification (when the violation is a major one)⁴.

The creation of food standards, as well as the certification process, is largely influenced by large retailing chains⁵. They control a major share of the distribution of foodstuffs and, more in general, have a huge market power⁶. This power finds expression, among other things, in the ability to impose many requirements on producers as to the characteristics that foodstuffs must have in order to be sold in the supermarkets. The phenomenon is exacerbated by the so called private labeling: the expression refers to the practice by which retailing chains use their own trademarks and brands to market foodstuffs produced by other manufacturers. In other terms, these producers operate as suppliers of the retailing chains, producing and labeling their products as they were produced directly by the supermarket. The retailing chain is able to loyalize their customers; the producers to place their products to a customer/retailer who can guarantee the purchase of large volumes of goods. The role played by private standards is pivotal in private labeling: the processes, including risk management procedures, by which foodstuffs must be produced are provided for in standards, along with some specific requirements in terms of composition and packaging that the final product must fulfill. Thus, standards, as well as their enforcement pendants, certifications, represent the technical tools by which retailing chains guarantee that the products they market are safe and of good

quality: what the retailing chains fear more, indeed, is losing reputation in the case of a scandal concerning the foodstuffs they sell⁷. In this vein, standards should be conceived as a way to minimize such a risk, imposing on producers to comply with some requirements which should reasonably guarantee the safety and quality of the final product.

2.- Standards for governing risks deriving from uncertainty

As mentioned above, some private standards are conceived as risk management tools, including cases where risks derive from situations of uncertainty. Simplifying our analysis, these standards can be divided in two categories: standards providing for an ex ante governance of risks; standards providing for an ex post governance of risks.

The first type of standards aims at putting into place an array of elements capable to prevent the occurrence of given risks. An example is offered by HACCP⁸ procedures as specified in various private standards, such as manuals of good practices, ISO 22000⁹, BRC¹⁰ and IFS¹¹ standards. HACCP is a management system employed to guarantee the safety of foodstuffs: it is characterized by seven steps, which range from the identification of the hazards which can affect the products' safety to the implementation of measures to eliminate, or limit, such hazards. Most of the legal systems require food producers to adopt a food safety management

(⁴) A. Benedetti, *Certezza pubblica e "certezze private". Poteri pubblici e certificazioni di mercato*, Milano, 2010; C. Poncibò, *Private certification schemes as consumer protection: a viable supplement to regulation in Europe?*, in *International journal of consumer studies*, 2007, 31, 656. On the interplay between private standards, certifications and liability see E. Bellisario, *Certificazioni di qualità e responsabilità civile*, Milano, 2011.

(⁵) Albisinni, *Sicurezze e controlli: chi garantisce cosa?*, cit., 16; T. Havinga, *Private regulation of food safety by supermarkets*, in *Law & Policy*, 2006, 28, 515.

(⁶) L. Di Via, L. Marciano, *Le relazioni tra Industria Alimentare e Grande Distribuzione Organizzata tra tutela della concorrenza e contenimento di interessi economici*, in *q. Riv.*, www.rivistadirittoalimentare.it, n. 3-2008, 31.

(⁷) See the Commission Communication - EU best practice guidelines for voluntary certification schemes for agricultural products and foodstuffs, 2010/C 341/04, according to which "large players in the food supply chain in particular often rely on certification schemes in order to satisfy themselves that a product meets the requirements and to protect their reputation and liability in the event of a food safety incident".

(⁸) The acronym stands for Hazard Analysis and Critical Control Points.

(⁹) International Organization for Standardisation - Food Safety Management: <https://www.iso.org/iso-22000-food-safety-management.html>.

(¹⁰) British Retail Consortium Global Standards: <https://www.brcglobalstandards.com/>. These standards concern different areas, such as, for example, food safety: <https://www.brcglobalstandards.com/brc-global-standards/food-safety/>.

(¹¹) International Featured Standards - Food: <https://www.ifs-certification.com/index.php/en/standards/251-ifs-food-en>.

system based on HACCP; this is, for example, the case in Europe, with the Regulation 852 of 2004¹², and in the USA, with the enactment of the Food Safety Modernization Act of 2011¹³. Thus, adopting HACCP principles is a requisite imposed by law; at once, legal systems leave plenty of space to food operators in implementing HACCP. This is probably the main reason why HACCP is often defined as a system which allow producers to self-manage their risks; each firm is in principle free to translate the quite generic steps provided for by HACCP into their own specific procedures, in order to achieve a high level of food safety¹⁴.

But this picture would not be complete without taking into consideration the role that private standards have in integrating the legal obligation to implement HACCP principles¹⁵. Standards fill those spaces that are left empty by the law; if, on one hand, the law does not specify how to implement HACCP principles, on the other hand standards intervene in this respect, providing detailed rules on the procedures, types of infrastructures, operational tools, documents and the like that the firm must put in place. An example of ex ante standards integrating HACCP procedures is offered by the identification of routine (mostly chemical) analyses to be implemented to test the products and verify their safety. Per se the law does identify neither which specific analyses should be implemented, nor their frequency or methodology to be used. The standards intervene in this respect, often detailing how analyses must be conducted, who should perform them, how to set their frequency, etc.

A further level of details is represented by the inter-

pretation of these standards. As mentioned before, certification bodies play a pivotal role, since they check if private standards are correctly implemented. In performing their control functions, often auditors further specify what the standards provide for: they can go so far to dictate which specific analyses must be conducted and which ones can be omitted. In other terms, through certifications we assist to a standardization of the standards¹⁶. If legal rules and private standards seem to leave some flexibility to operators on how to deal with risks, the way they are implemented in everyday life seem to severely limit this discretionary space.

The second type of standards are aimed at creating an ex post governance of risks. In this case the goal is to minimize the consequences deriving from the occurrence of a given risk. More than avoiding the risk, thus, these standards try to limit the damages which can derive from it. A good example is offered by traceability. Traceability refers to the ability to trace back all the ingredients that have been used in the production of a given foodstuff (inward traceability), as well as the passages that characterize the product's life once it leaves the producer's premises (outward traceability)¹⁷. Traceability can be considered a tool for governing risks ex post since it facilitates, for example, the recall of products that are unsafe; more in general, it allows to single out the specific batches for which a risk has been identified and, then, to take corrective actions with regard to those specific batches.

As for HACCP, also traceability is a legal requirement imposed on food operators by many legal systems: in Europe it is provided for by art. 18 of

⁽¹²⁾ Art. 5 of Regulation No 852 of 29 April 2004; the same article exempts primary production from HACCP principles.

⁽¹³⁾ The Food Safety Modernization Act applies only to the food producers who are subject to the Food and Drug Administration.

⁽¹⁴⁾ Art. 5.2 of Regulation (EC) No 852 of 29 April 2004; see E. Sirsi, *L'H.A.C.C.P. nel settore agricolo*, in L. Costato (diretto da), *Trattato breve di diritto agrario italiano e comunitario*, Padova, 2003, 677 ff. On the so called food hygiene package L. Salvi, *Traceability and hygiene package*, in L. Costato, F. Albisinni (eds.), *European and global food law*, Padova, 2016, 281; C. Losavio, *Le regole comunitarie e nazionali relative all'igiene dei prodotti*, in L. Costato, A. Germanò, E. Rook Basile (a cura di), *Trattato di diritto agrario. 3. Il diritto agroalimentare*, Torino, 2011, 183.

⁽¹⁵⁾ Sirsi, *L'H.A.C.C.P. nel settore agricolo*, cit., 679.

⁽¹⁶⁾ Another way by which this process of standardization of standards takes place is through the activities of professional consultants, who assist food operators in implementing HACCP procedures and, more in general, in obtaining food safety certifications, such as BRC, IFS and ISO 22000 ones.

⁽¹⁷⁾ In addition to the inward and outward traceability, there might also be the so called internal traceability, which refers to the capability to record all the passages and transformations the product is subject to within the producer's premises.

Reg. 178 of 2002; in the USA by the Food Safety Modernization Act of 2011¹⁸. And, similarly again to the HACCP case, also traceability requirements are integrated by private standards, such as BRC, IFS and ISO 22000 standards. The dynamics which arise from the interaction between legal requirements and private standards are similar to what has been described before: usually the integration occurs via either the setting of detailed procedures, embodied into private standards, or the interpretation of such standards by certification bodies. What is partly different is that in some cases we have the creation of private standards over (more general) private standards. An example is offered by the traceability standards created by the wine industry, further specifying the traceability standards set in ISO 22000, BRC and IFS¹⁹. The reason of this additional specification is due to the fact that the ISO, BRC and IFS traceability standards apply to the production of all the kinds of foodstuffs and beverages: the wine industry asked for more specific standards, tailored on the products they manufacture.

Before turning to the analysis of the interplay between standards and liability rules, it is apt to underline one of the paradoxes characterizing the type of standards described so far. Even if they were born as flexible tools to self-manage risks, they have become more and more detailed, going back to the specific, detailed type of private standards mentioned at the beginning of this paper. This process happened either through the specification of the initial standards or by customs, implemented by certifiers and auditors, which de facto identify in details what is needed in a given situation to mana-

ge a given risk. An example is offered both by the further standardization of the food safety standards operated by certification bodies in the HACCP realm; and by the traceability case, where we assist to the creation of standards over standards.

3.- Types of liability

Civil liability provisions represent an important means by which governing the risks deriving from situations of uncertainty. They are usually conceived as an ex post tool of risk management, since their main purpose is to compensate those who suffer a damage because of the occurrence of a risk, provided that some conditions are met; but, at the same time, they also play a role as an ex ante instrument, capable, through deterrence, to determine the adoption of conducts aimed at reducing the occurrence of risks in the future²⁰.

In the specific domain of food safety, different forms of liability come at play. The most intuitive reference is to the basic distinction between liability in tort and in contract; but also the type of subjects involved can play an important role, as the case of product liability shows²¹. From a contractual perspective, and especially in the B2B (Business to Business) context, one fundamental problem liability rules must deal with is identifying who has to be considered responsible for the damages caused by the sale of unsafe foodstuffs²². This implies finding who must bear the risks that lie behind these damages, i.e. who should prevent and/or minimize these risks and suffer the consequences if they take place. In addi-

⁽¹⁸⁾ The Food Safety Modernization Act applies only to the food producers who are subject to the Food and Drug Administration.

⁽¹⁹⁾ See for example *Linee guida per la rintracciabilità nel settore vitivinicolo*, 2005, published by Unione Italiana Vini. On the relationship between UNI standards and traceability, see L. Costato, *La rintracciabilità degli alimenti*, in L. Costato, A. Germanò, E. Rook Basile (a cura di), *Trattato di diritto agrario. 3. Il diritto agroalimentare*, Torino, 2011, 533.

⁽²⁰⁾ On the deterrence function of liability for unknown risks M. Faure, L. Visscher, F. Weber, *Liability for unknown risks: a law and economics perspective*, in *Journal of European tort law*, 2016, 7, 198.

⁽²¹⁾ For a recent survey of the different forms of liability in case of defective foodstuffs S. Masini, *Vizi, difetti e rischi nel consumo di alimenti: profili di responsabilità*, in *Diritto agroalimentare*, 2016, 463; see also L. Paoloni (a cura di), *Alimenti, danno e responsabilità*, Milano, 2008.

⁽²²⁾ Another crucial problem is represented by the burden of proof, especially from the consumers' perspective. Indeed, it can be very difficult to prove that a) they bought a specific food and b) that specific food was the cause of the damage they suffered. On one hand, we do not usually keep trace of the food we consume; on the other hand, we consume many different foodstuffs, so it can be difficult to single out which one was the source of our health problems, taking also into account that some problems do not emerge immediately, but after a few days.

tion, the damages I am referring to can have different nature in their own: some damages concern the health and well-being, while others consist of pure economic and/or reputational losses.

The relation between civil liability and standards is complex and presents several facets²³. Standards are often considered to represent the state of the art and, as such, are used as a benchmark to assess if defendants breached their duty of care or acted with negligence. While this does not create peculiar problems in the case of public standards, i.e. standards set by public bodies, given their public nature, the use of private standards is more troublesome. The reason is intuitive: these standards are created by private subjects, without any democratic legitimization or delegation of regulatory power. The problem is quite clear in the agro-food context, where many of these private standards are created by large retailing chains, thus favoring specific interests and potentially generating inequalities.

Since the broad scenario characterizing liability for unsafe foodstuffs, the analysis will be limited to a specific issue, namely the interplay between con-

tractual liability rules in B2B relations and ex ante private standards. Tort law in general (including product liability)²⁴, as well as contractual liability in the B2C (Business to Consumer) domain²⁵, will be omitted. In the light of this selection, the questions that will be tackled are the following: how is the liability for risks originating from situations of uncertainty apportioned along the B2B contractual chain? And how do private standards, conceived to manage food safety risks ex ante, interact with contractual liability?

A case study on the so called Sudan I saga will provide a first, tentative answer to these questions.

4.- The Sudan I saga

4.1. The scientific and factual background

Sudan I is an organic compound used as a dye, in particular to color different products, such as waxes, oils, solvents. It is considered to be a genotoxic carcinogen, even if it is not clear its level of carcinoge-

⁽²³⁾ As to the interplay between standards and product liability for defective foodstuffs see Masini, *Vizi, difetti e rischi nel consumo di alimenti: profili di responsabilità*, cit., 501-503; E. Al Mureden, *I danni da consumo di alimenti tra legislazione di settore, principio di precauzione e responsabilità civile*, in *Contratto e impresa*, 2011, 1495, 1503 ff.; more in general, U. Carnevali, *La norma tecnica da regola di esperienza a norma giuridicamente rilevante: ricognizione storica e sistemazione teorica; ruolo dell'UNI e del CEI*, in *Responsabilità civile e previdenza*, 1997, 257.

⁽²⁴⁾ On product liability for defective foodstuffs M. Giuffrida, *Liability for defective products*, in L. Costato, F. Albisinni (eds.), *European and global food law*, Padova, 2016, II ed., 263; F. Sangermano, *L'imputazione della responsabilità tra impresa agricola, industria e commercio*, in L. Paoloni (a cura di), *Alimenti, danno e responsabilità*, Milano, 2008, 15; G. Nicolini, *Danni da prodotti agroalimentari difettosi: responsabilità del produttore*, Milano, 2006; F.S. Sesti, *La responsabilità dell'imprenditore agricolo. Lineamenti civilistici*, Milano, 2004, 39 ss.; F. Albisinni, *Commento all'art. 21*, in Aa. Vv., *La sicurezza alimentare nell'Unione Europea. Commentario a cura dell'Istituto di diritto agrario internazionale e comparato (IDAIC)*, in *Le Nuove Leggi Civili Commentate*, 2003, 1-2, 284; A. Germanò, *La responsabilità del produttore*, in L. Costato (a cura di), *Trattato breve di diritto agrario e comunitario*, Padova, 2003, 743; O. Prospero, *Sicurezza alimentare e responsabilità civile*, in *Rivista di diritto agrario*, 2003, I, 351; A. Tizzano, *Tutela del consumatore e responsabilità civile del produttore e del distributore di alimenti in Europa e negli Stati Uniti*, in *Europa e diritto privato*, 2001, 685; C. Martorana, *La responsabilità per prodotti agricoli difettosi*, in *Riv.dir.agr.*, 1992, I, 400; E. Capizzano, L. Petrelli, *L'attuazione in Italia della Direttiva 85/374 con riferimento alla responsabilità del produttore agricolo e nella prospettiva dell'agricoltura c.d. biologica*, in S. Patti (a cura di), *Il danno da prodotti in Italia, Austria, Repubblica Federale di Germania, Svizzera*, Padova, 1990, 161; M. Cubeddu, *La responsabilità del produttore per prodotti naturali*, in S. Patti (a cura di), *Il danno da prodotti in Italia, Austria, Repubblica Federale di Germania, Svizzera*, Padova, 1990, 193.

⁽²⁵⁾ On the use of civil liability in B2C relations see M. Tamponi, *La tutela del consumatore di alimenti nel momento contrattuale: valore delle indicazioni obbligatorie e volontarie nella formazione del contratto*, in L. Costato, A. Germanò, E. Rook Basile (a cura di), *Trattato di diritto agrario. 3. Il diritto agroalimentare*, Torino, 2011, 579; M. D'Addezio, *La responsabilità civile dell'«impresa agroalimentare»*, in *Rivista di diritto agrario*, 2011, I, 41. Another important perspective neglected in this paper is represented by how the type of organizations and the structure of the contractual relationships influence food safety: see G. Martino, E. Rossetti, *Sicurezza degli alimenti ed economia delle strutture ibride*, in L. Paoloni (a cura di), *Alimenti, danno e responsabilità*, Milano, 2008, 97. On hybrid organizations C. Ménard, *On clusters, hybrids, and other strange forms: The case of the French poultry system*, in *Journal of institutional and theoretical economics*, 1996, 152, 155.

nicity to humans and, therefore, it is not possible to set a tolerable daily intake²⁶.

On 9 May 2003 France sent a communication about the presence of Sudan I in some foodstuffs through the Rapid Alert System for Food and Feed (RASFF)²⁷. In particular, traces of Sudan I were found in hot chilli and hot chilli powders, as well as in other foodstuffs containing the powders as ingredients²⁸. The origin of the contamination had not been clearly determined; nonetheless, it has been ascertained that the products tainted with Sudan I came from outside the European Union. Also the number of products tainted with the dye was not clear; anyway, contamination seemed quite widespread. For example, on 313 food products analyzed in Piemonte (Italy) in October 2003, 99 were found positive to Sudan I²⁹.

The news about the presence of Sudan I in some foodstuffs triggered a host of reactions in the media which, in their turn, increased the level of alarm up to the point to transform it in a food scare. France was not only the first country to send information about the carcinogenic dye, but it was also the first to enact interim protective measures in June 2003. Following the French initiative, the European Commission published the Decision no. 460 of 20 June 2003³⁰, providing for specific measures to deal with the Sudan I contamination at EU level.

In February 2005 Sudan I was at the center of newspapers' headlines again. The UK's Food Standards Agency found traces of the dye in different food products, ranging from ready meals to sauces, and ordered a massive recall of more than 400 products³¹. Contamination involved also other countries outside Europe, as far as China³².

Sudan I sparked not only mass medias' attention in a time where food scares were prominent in consumers' minds, but also a host of litigation concerning who should be liable for the losses caused by the contaminated foodstuffs.

4.2. The regulatory framework

The regulatory history of Sudan I must be analyzed by distinguishing two different periods: the first, preceding Decision 460/2003; the second, corresponding to the enactment of the 2003 Decision. There is also a third period, following the 2003 Decision, but this is not relevant for the issues we are dealing with in this article³³.

Before Decision 460/2003, it was already illegal to use the Sudan I dye in foodstuffs. Under EU regulation, additives can be used in foodstuffs only if they have been expressly authorized³⁴: since Sudan I was not present in such a list, its use was not

(26) Sudan I has been classified as category 3 carcinogens, i.e. as not classifiable as to its carcinogenicity to humans, by the International Agency for Research on Cancer.

(27) The RASFF is a mechanism, provided for by art. 50 of Regulation 178/2002, which allows for the (rapid) notification of a direct or indirect risk to human health deriving from food or feed. See G. Maccioni, *Il "Sistema" di allarme rapido*, in *q. Riv.*, www.rivistadirittoalimentare.it, n. 2-2011, 18; L. Petrelli, *Il sistema di allarme rapido per gli alimenti ed i mangimi*, in *q. Riv.*, www.rivistadirittoalimentare.it, n. 4-2010, 14; P. Lattanzi, *La sicurezza alimentare nell'Unione europea - Commento all'art. 35*, in *Le nuove leggi civili commentate*, 2003, 1-2, 363.

(28) See Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission to Review the toxicology of a number of dyes illegally present in food in the EU, in *The EFSA Journal* (2005) 263, 1, 3.

(29) M. G. Molinaro, *Contaminazione delle varie filiere produttive in seguito all'impiego di ingredienti di largo utilizzo (SUDAN I nel peperoncino)*, paper presented at Istituto Superiore di Sanità, Focus su sicurezza d'uso e nutrizionale degli alimenti, Roma, 21-22 novembre 2005, available at: http://www.iss.it/binary/cnra/cont/CONTAMINANTI%20CHIMICI%20DEGLI%20ALIMENTI_Molinaro_Sudan.1135854768.pdf.

(30) Commission Decision 460 of 20 June 2003 on emergency measures regarding hot chilli and hot chilli products.

(31) See, for example, D. Derbyshire, *Food dye scare sparks largest recall in history*, *The Telegraph*, 22 February 2005.

(32) See, for example, *KFC found using banned dye Sudan I*, *China Daily*, 17 March 2005; C. Liu, *The Obstacles of Outsourcing Imported Food Safety to China*, 43 *Cornell Int'l L. J.* 249 (2010), 299-300.

(33) Commission Decision 92 of 21 January 2004 on emergency measures regarding chilli and chilli products has extended the measures provided for in the Decision of 2003 also to Sudan II, Sudan III and Sudan IV. Commission Decision 402 of 23 May 2005 on emergency measures regarding chilli, chilli products, curcuma and palm oil has further extended the measures provided for in the two previous Decisions also to curcuma and palm oil.

(34) Regulation 1333 of 16 December 2008 on food additives. Art. 4 provides that "only food additives included in the Community list in Annex II may be placed on the market as such and used in foods under the condition so use specified therein". See I. Trapè, P. Lattanzi,

allowed. The problem under the 'positive list' system is that the fact that an additive is not mentioned in the list does not mean that the substance is actively monitored in order to look for its presence. In particular, except for a few cases, producers, importers, retailers, public authorities and other players in the food chain do not perform chemical tests to discover the presence of a substance which is not in the list; such a practice would amount to finding a needle in a haystack, since it would require to test for a wide array of additives, without any specific target substance. Under a 'negative list' system things might be different: since only the additives listed would be banned, it is possible to imagine routine tests aimed at identifying only those substances which are in the list, since all the others should be presumed to be legitimately in the foodstuff.

The EU is aware of the limits that a positive list system for additives poses and tries to correct some of these deficiencies. In particular, the EU expressly bans some specific additives in selected foodstuffs, imposing to conduct chemical analyses to assess if they are present in these particular products. What originates is, thus, a positive list system along with a partial negative listing: the Decision 460/2003 represents an example of this middle-ground approach. Under the decision, Sudan I is not only expressly defined as a prohibited additive; it is also established that all the hot chilli and hot chilli products (the products mostly affected by the Sudan I contamination) cannot be imported in the EU if they are not accompanied by an analytical report demonstrating that the product does not contain Sudan I³⁵. It should be noted that this analytical report is not required any more. Regulation 669 of 24 July 2009 has repealed the Decisions imposing the issue of the analytical report; instead, Sudan dyes are now included in the list of substances referred to in Annex I of the Regulation, for which an increased level of control at the point of entry applies.

The obligation to issue the analytical report has to be read, among other things, in the light of a duty falling on food operators, i.e. the duty to implement an HACCP system, as mentioned before. In particular, after the 2003 Decision Sudan I monitoring was included into the HACCP plan. To be clear, Decision 460/2003 does not impose per se to include Sudan I tests in HACCP plans; it does not even mention HACCP. But a reasonable coordination between the HACCP duty and what was provided for in the 2003 decision required to include Sudan I into the HACCP system, either by imposing to use only those chilli products which were accompanied by an analytical certificate proving the absence of Sudan I or, in the case such certificate had not been provided, by adopting those analytical measures needed to test the ingredient for the presence of Sudan I. In addition, Member States had to conduct random sampling and analysis of the abovementioned products to test the absence of Sudan I³⁶. Art. 5 provided that in the case a batch of products was found to be tainted with Sudan I, it had to be destroyed. There are two points to be highlighted. First, the Decision does not mention the methodology of analysis to be used to monitor the presence of Sudan I. This has given rise to many problems, since there are different methodologies of analysis for Sudan I, each one with its pros and cons. These problems find echo in the litigation: parties are often on opposite sides as to the methodology to be used, as well as to the tolerance limits that such methodologies imply.

The second point concerns the interplay between the public regulatory framework governing the use of Sudan I and some private standards which provides for principles and operational tools to guarantee the safety of foodstuffs. On one hand, there is some overlapping between public and private norms, especially with regard to the identification of routine chemical analyses to detect the presence of prohi-

Food additives and contaminants, in L. Costato, F. Albisinni (eds.), *European and Global Food Law*, Paova, 2016, II ed., 505; G. Bivona, *L'impiego di additivi nella realizzazione dei prodotti alimentari trasformati: il regime di ammissione alla libera pratica*, in L. Costato, A. Germanò, E. Rook Basile (a cura di), *Trattato di diritto agrario. 3. Il diritto agroalimentare*, Torino, 2011, 103.

⁽³⁵⁾ Art. 2, Decision 460/2003. As mentioned in the footnote 29, the duty to provide an analytical report has been extended in 2004 also to Sudan II, III and IV and, in 2005, to curcuma and palm oil.

⁽³⁶⁾ Art. 3, Decision 460/2003.

bited substances. On the other hand, the two types of norms can be considered complementary, with private norms filling some gaps left open by the public regulatory framework. In particular, there is one provision, almost invariably included in all private standards, that sheds light on the interaction between public norms and private rules, namely the duty to validate suppliers. This duty consists in a process by which buyers check the trustworthiness of their suppliers through a series of parameters, such as for how long they had a business relationship, the presence/absence of any complaints, the adoption of certified management systems, etc. Among the variables that producers take into account there is also the provision of assurances about the safety of the products supplied: thus, the presence of an analytical report proving the absence of Sudan I was not only a duty imposed by the EU law, but it became also part of the process to validate a supplier of chilli products.

The interaction between public norms and private standards can affect the way liability is apportioned in those cases where a defective product has been supplied. The litigation occurred in the aftermath of the Sudan I scare illustrates these complex dynamics.

4.3. *The litigation on Sudan I*

As mentioned, the Sudan I scare gave rise to a number of cases in different jurisdictions³⁷. The attention will be focused on two of them, both decided by Italian courts of first instance. These two decisions will then be compared to a relatively recent decision by the Italian Corte di Cassazione. In all the three cases, the plaintiff is either a producer, who used chilli powder tainted with Sudan I for manufacturing his products, or a retailer, who displayed his name/trademark on the tainted pro-

duct's label (private labeling); the defendant is invariably an importer, who imported chilly or curry powder from countries such as India and sold them to European producers/retailers. The time-line of the cases is the same. The decisions concern the sale of chilli powder contaminated with Sudan I occurring before the EU Decision 460/2003. The courts had thus to decide if the importers had a duty to test the products they imported for Sudan I even before the 2003 Decision.

The cases present further points of convergence. Firstly, the courts apply contractual liability provisions; in particular, the decisions concern sale contracts³⁸. Secondly, the real issue at stake concerns whether the contamination with Sudan I can be considered a defect for which the importer is liable or, on the contrary, has occurred without any fault on the importer's side. Last but not least, judges make reference to private standards employed in risk management procedures, even if the reference to standards is often more implicit than explicit.

The most clear example at this regard is offered by the case decided by the Tribunale di Parma in 2011³⁹. The judge starts by considering that even if it is with the Decision 460/2003 that the European Union expressly imposed to test chilli products for Sudan I, such an additive was already illegal according to the 'positive list' framework in place. The fact that there was no express duty to conduct chemical analyses on Sudan I does not imply that there was no obligation to check the composition of chilli products. In particular, the private standards implemented by the importer required the validation of the suppliers which, in their turn, implied to verify the composition of the products to be imported. The judge defines these private standards as 'precautionary norms', in this way highlighting that they are used to fill a gap in risk management left open by (European) public norms⁴⁰. At once, taking also into consideration the presence of risk management

⁽³⁷⁾ See, for example, in England *Hazlewood Grocery v. Lion Foods*, Queens Bench Division, 27 July 2007, [2007] EWHC B5 (QB); in South Africa *Freddy Hirsch Group v. Chickenland*, 17 March 2011, [2011] ZASCA 22.

⁽³⁸⁾ The article does not deal with the implications that the Sudan I litigation can have for the transnational governance of food supply chains: see F. Cafaggi, P. Iamiceli, *Supply chains, contractual governance and certification regimes*, cit.

⁽³⁹⁾ Trib. Parma, 13 aprile 2011, unpublished.

⁽⁴⁰⁾ On the relationship between civil liability and the precautionary principle in general see U. Izzo, *La precauzione nella responsabilità civile*, Padova, 2004; with specific reference to the liability for defective foodstuffs G. Vaccaro, *Il principio di precauzione e la responsabilità delle imprese nella filiera alimentare*, in *q. Riv.*, www.rivistadirittoalimentare.it, n. 4-2015, 50.

measures based on private standards, the Tribunale di Parma states that the importer was the subject in the best position to verify the presence of the illegal dye.

This supplementary use of private standards seems to represent not only an integration of the public regulatory framework, but also an integration of the contractual duties existing between the parties. It is not clear in the decision if the contract contained clauses imposing the importer to implement private standards for risk management; if this was not the case, it would represent a curious instance of contractual integration. This type of integration can be partly justified by the fact that the adoption of risk management standards amount to routine in the food industry; nonetheless, it raises some perplexities once such a *de facto* routine is transformed in a contractual duty without indicating the normative basis to justify such an operation.

The second case was decided by the Tribunale di Monza in 2007⁴¹. The solution adopted is opposite to the one reported above. The Monza judge states that the importer cannot be considered liable for the contamination of chilli powder with Sudan I since the duty to test the powder arose only after the Decision 460 of 2003, while the sale of the product occurred before such a date. Formally, the judge refers to art. 1494 of the Italian civil code, requiring the seller to prove his lack of negligence in order to avoid liability⁴². In particular, since the duty to provide an analytical report excluding the presence of Sudan I arose after June 2003, the seller was not negligent for having failed to monitor such a dye in products marketed before the referred date. In this way, the judge seems implicitly to downplay the fact that Sudan I was an illegal additive even before Decision 460/2003.

The decision by the Tribunale di Monza can be better understood by considering the use that the judge

makes of private standards. At this regard, the reference to private standards is more nuanced in the Monza decision than in the Parma one: there are some references to the HACCP procedures, as well as to the quality parameters usually employed in food hygiene testing, but these elements do not represent the main focus of the decision. Even if standards play a smaller role in the 2007 decision than in the 2003 one, nonetheless the Tribunale di Monza makes reference to the fact that the state of the art and the standards usually applied did not require to test the products for Sudan I. Based on these findings, the Monza decision denies the importer's liability. The judge goes a step further, affirming that it was the producer who had the burden to verify if the product contained Sudan I or other not-authorized additives. This result is justified by taking into consideration that the news about the risks of Sudan I had to be known by the producer, since the information was in public domain. Once the producer knew about the Sudan I risks, he should have conducted chemical tests to verify if the additive was present in those foods for which he had the suspect that could be tainted (or, more simply, for which he ignored whether they were contaminated or not).

It should be noted that the two decisions do not deal with the case in which both the importer and the buyer have risk management procedures in place. Indeed, we can imagine the case in which the importer and the producer have equally implemented risk management procedures based on private standards: in such an instance, who would be responsible?

In 2014, the Italian Corte di Cassazione decided a case concerning the sale of hot chilli peppers contaminated with Sudan Red⁴³. Even if the judges have not dealt with the interplay between public rules and private standards, nonetheless the deci-

⁽⁴¹⁾ Trib. Monza, 31 July 2007. The decision has been published in G. Coscia (a cura di), *I rapporti commerciali nel settore alimentare*, Alessandria, 2010, appendice giurisprudenziale.

⁽⁴²⁾ The same kind of rationale has been used by the Trib. Parma, 14 November 2011, available in the database DeJure. In the case chilli contaminated with Sudan I had been supplied after the enactment of the Decision 460/2003, the supplier is liable according to art 1494: Trib. Monza, 4 November 2008, available in the database DeJure.

⁽⁴³⁾ Corte di Cassazione n. 15824, 10 July 2014, in in *q. Riv.*, www.rivistadirittoalimentare.it, n. 4-2015, 50; see G. Vaccaro, *Il principio di precauzione e la responsabilità delle imprese nella filiera alimentare*, *ivi*.

sion is important because it tries to partition the liability between the supplier and the buyer. In order to split the liability between the two players of the supply chain, the court makes recourse to article 1227, second paragraph, of the Italian civil code, providing for contributory negligence⁴⁴. The judges state that when both the supplier and the buyer are professional operators, they equally have the duty to perform those controls that are necessary to guarantee the safety of the final product. Therefore, the Corte di Cassazione poses on all the professional players of the supply chain the duty to adopt those risk management measures and procedures which are apt to guarantee the safety of the final product. This outcome is achieved by employing a variety of different legal tools⁴⁵, such as the contractual duty to cooperate, the precautionary principle and the nature of the good produced. Each of them deserves a short comment.

First, the duty to cooperate is heavily influenced from the “from farm to fork” approach, imposing on all the parties of the food chain to collaborate in producing and marketing safe foodstuffs. In its turn, this approach contributes to shape the liability rules to be applied in the food realm⁴⁶. This kind of solution seems to be consistent with the approach adopted by the European Court of Justice in the case C-

443/13. The Court stated that a retailer can be strictly liable for the non-compliance of a foodstuffs even if his activities were limited merely to the distribution stage. The reason justifying the decision is that one of the fundamental goals of food law is to guarantee the safety of the foodstuff at all stages of distribution; thus, a national law providing that all players will be jointly liable if the foodstuff put into commerce is unsafe, is compatible with the achievement of such a goal⁴⁷.

With regard to the precautionary principle, the impression is that such a principle has been invoked without any merit for the simple reason that in the case of Sudan I we are not facing a situation of scientific uncertainty⁴⁸; rather, this seems a case of factual uncertainty. In other terms, there is no scientific doubt that Sudan I is dangerous for human health; the situation of uncertainty concerns the presence (or absence) of such a dye in chilli and chilli powders. It can also be added that the precautionary principle applies per se to lawmakers and that its use to govern relations between private parties is debatable⁴⁹. The suspect is that the precautionary principle has been used to justify the high level of care imposed on the all the parties of the food chain; but the justification could have more simply been based directly on the specific obligations

⁽⁴⁴⁾ The decision by Trib. Milano, 31 July 2014 (available in the database DeJure) concerns a case in which the supplier had provided a specific assurance about the absence of Sudan I in the chilli products supplied. Because of such a statement, the court states that art. 1227 of the Italian civil code, providing for contributory negligence, is not applicable.

⁽⁴⁵⁾ A. Barba, *Garanzia e precauzione nella vendita di sostanze alimentari*, in *Nuova giurisprudenza civile commentata*, 2014, I, 1207, 1210, speaks of three essential elements the Corte di Cassazione refers to in order to justify the need to apply contributory negligence in the instant case.

⁽⁴⁶⁾ D'Addezio, *La responsabilità civile dell'«impresa agroalimentare»*, cit., 52; I. Canfora, *Sicurezza alimentare e nuovi assetti della responsabilità di filiera*, in *q. Riv.*, www.rivistadirittoalimentare.it, n. 4-2009, 14.

⁽⁴⁷⁾ European Court of Justice, 13 November 2014, C-443/13, paragraphs 28 and 41. For a comment F. Lotta, *The liability of retailers in case of infringement of food safety law*, in *European food and feed law review*, 2015, 3, 227. See also European Court of Justice 23 November 2006, C-315/05. For an analysis of the liability of the retailers P. Lattanzi, *La responsabilità nei rapporti di filiera*, in L. Paoloni (a cura di), *Alimenti, danno e responsabilità*, Milano, 2008, 57, 61 ss. and I. Trapè, *La responsabilità del distributore di alimenti*, in L. Paoloni (a cura di), *Alimenti, danno e responsabilità*, Milano, 2008, 119.

⁽⁴⁸⁾ See art. 7 of Regulation (EC) 178/2002 of 28 January 2002 and Communication from the Commission on the precautionary principle, COM(2000) 1 final 2 February 2000, 13-14, both pointing to the fact that the precautionary principle requires a situation of scientific uncertainty. On the improper use of the precautionary principle, and its vagueness, see P. Borghi, *Il rischio alimentare e il principio di precauzione*, in L. Costato, A. Germanò, E. Rook Basile (a cura di), *Trattato di diritto agrario. 3. Il diritto agroalimentare*, Torino, 2011, 53; M. Mazzo, *Il principio di precauzione*, in L. Costato (diretto da), *Trattato breve di diritto agrario italiano e comunitario*, Padova, 2003, 750.

⁽⁴⁹⁾ G. Vaccaro, *Il principio di precauzione e la responsabilità delle imprese nella filiera alimentare*, in *q. Riv.*, www.rivistadirittoalimentare.it, n. 4-2015, 50, 52 ff.; V. Cintio, *Art. 1494 c.c. e principio di precauzione quali rispettivi criteri di responsabilità del venditore e del compratore-produttore nella circolazione dei beni alimentari*, in *Giur.it.*, 2015, 301, 306; Al Mureden, *I danni da consumo di alimenti tra legislazione di settore, principio di precauzione e responsabilità civile*, cit., 1519.

posed on professional operators by food law⁵⁰.

At this regard, the nature of the good produced is able to dictate the level of diligence required. The fact that the production and marketing of foodstuffs is characterized by a detailed regulatory framework shapes the contents of the liability rules, imposing on operators duties that are specific to the food domain⁵¹.

Thus, some authors make reference to the specialization of professional diligence in the case of food operators⁵², with the further consequence that it would be possible to speak of a subsystem of liability in sale contracts of foodstuffs⁵³.

The only exception to the idea that both the supplier and the buyer are responsible is represented by the instance in which the supplier expressly guarantees the buyer about the absence of a particular and specific ingredient, such as, in this case, Sudan I. Since in the case at stake there was no such a warranty, the court states that the buyer's compensation must be curtailed because he contributed to the causation of the damage⁵⁴.

5.- Final remarks

The Sudan I litigation offers the possibility to advance some remarks concerning the intersection between civil liability rules and private standards employed for risk management. The first regards the role of these type of standards: courts seem to use them to apportion liability in those grey areas where the information about a risk began to circulate, but the public authority had not enacted any

norm to deal with it yet. At this regard, judges make recourse to standards to distribute risks and responsibilities among the food chain's players, employing them in a complementary way with respect both to the duties imposed by the public regulatory framework and to the apportionment of risks specified in the contracts⁵⁵. This is particularly clear in the case of the validation of suppliers; such a measure is perceived by judges as a safeguard that buyers must adopt in order (also) to circumscribe some safety risks in a situation of uncertainty. But it should be stressed that this is a *private* measure: the law *per se* does not impose to validate suppliers. Courts, through a reasoning that it is not always straightforward, broaden the contractual duties in order to encompass also this kind of private measures. In other words, the obligation to validate suppliers seems to be contractual, but the reason why the contract should encompass this duty is not explained.

More in general, the Sudan I saga helps focusing our attention on the crucial role that standards have in molding liability rules in the food chain⁵⁶. While, in the case of contractual liability, the traditional perspective was centered on the final product, now the attention shifts on the food production process, as well on the roles and duties that contractual parties have in such a process.

This change is due not only to the fact that the public regulatory framework is characterized by a "from farm to fork" approach, where processes play a crucial role⁵⁷, but also to the fact that private standards are primarily conceived as tools to govern processes more than products.

⁽⁵⁰⁾ G. Vaccaro, *Il principio di precauzione e la responsabilità delle imprese nella filiera alimentare*, cit., 53.

⁽⁵¹⁾ Corte di Cassazione n. 15824, cit., 233-234.

⁽⁵²⁾ F. Cafaggi, P. Iamiceli, *Responsabilità del fornitore alimentare tra colpa professionale e concorso del produttore finale*, in *I contratti*, 2015, 896, 899 ff.; V. Rubino, *Comparative negligence e regole di sicurezza alimentare: la Corte di Cassazione fa il punto sulla responsabilità degli operatori della filiera*, in *q. Riv. www.rivistadirittoalimentare.it*, n. 2-2014, 234, 237.

⁽⁵³⁾ F. Cafaggi, P. Iamiceli, *Responsabilità del fornitore alimentare*, cit., 911.

⁽⁵⁴⁾ F. Cafaggi, P. Iamiceli, *Responsabilità del fornitore alimentare*, cit., 903, note that the use of art. 1227 by the Corte di Cassazione goes beyond the bilateral logic traditionally characterizing the contributory negligence rule and it is transformed into a duty of cooperation.

⁽⁵⁵⁾ F. Cafaggi, P. Iamiceli, *Responsabilità del fornitore alimentare*, cit., 905, note that standards cannot substitute public regulation; rather, their function is to integrate it.

⁽⁵⁶⁾ On the relationship between standards and certifications, on one side, and the structure of the food supply chain, on the other side, see R. Saija, *Standards e contratti di certificazione*, in *q. Riv. www.rivistadirittoalimentare.it*, n. 1-2013, 47; Canfora, *Sicurezza alimentare e nuovi assetti della responsabilità di filiera*, cit.

⁽⁵⁷⁾ S. Masini, *Vizi, difetti e rischi nel consumo di alimenti: profili di responsabilità*, cit., 503-504.

The second remark concerns the different operational results that the two first instance courts have reached notwithstanding the many commonalities in their reasoning⁵⁸. In both the Parma and Monza decisions, private standards had some role in apportioning liability, implicitly or explicitly: but their application led to opposite consequences. Courts seem to have adopted an “all or nothing” approach, by which the reference to private standards is capable to impose liability on one party, excluding the liability of the other. But the impression is that such an approach is not completely satisfying. Almost all the players in the agro-food chain apply some kind of risk management processes in general, and private standards in particular, for governing food safety risks. The question, thus, is not on who should fall the onus to apply these processes/standards (and to be liable in the case of their negligent implementation); rather, the real issue is how to subdivide liability among all the subjects who, to a greater or lesser degree, implement them⁵⁹.

In this vein, the judges could have more carefully scrutinized the liability of the different parties, apportioning it in the light of different factors, such as the technical and economic capabilities of plaintiffs and defendants or their market power. For example, a factor which is often downplayed is represented by what has been referred before as the standardization of standards conducted by certification bodies. If the process of further standardization constrains operators’ discretion in implementing standards, does this dynamic have an impact on liability issues? Can we blame small producers/importers for not having properly implemented standards when the ways to implement

these same standards are de facto imposed by certification bodies? The recent decision by the Italian Corte di Cassazione can be seen as an important step in adopting a more balanced and nuanced approach to the liability within the food supply chain. Even if some passages of the decision are not fully persuasive⁶⁰, what should be welcomed is the principle by which, first, all the professional players within the supply chain have a duty to cooperate in order to keep the food safe and, second, that breaching such a duty can determine their liability. Private standards can contribute to better define the duty to cooperate parties have.

The last remark tries to critically review the use of private standards in apportioning liability in the B2B domain: who is really benefitting from such use? In a context where large retailing chains have a huge market power and are able to unilaterally mold contractual relationships, the risk is that private standards will be employed to systematically shift liability on the weak party. Risk management standards would thus represent those measures allowing retailing chains to discharge liability in situations of uncertainty: a sensitive issue in what have been previously called the grey areas occurring when the information about a risk begin to circulate, but the public authority has not enacted any specific norm to deal with it yet. This outcome is not inescapable, as the Corte di Cassazione decision shows. But the complexities and imbalances that characterize contractual relationships in the agro-food industry requires to be aware that private standards can be tactically used to further favor strong market players⁶¹.

⁽⁵⁸⁾ The diverging results are confirmed also by the analysis of other cases concerning Sudan I, even if these cases do not refer explicitly to the role of private standard in apportioning liability between contractual parties.

⁽⁵⁹⁾ F. Cafaggi, P. Iamiceli, *Responsabilità del fornitore alimentare*, cit., 904, who differentiate between the case where a consumer is involved from the case in which both parties are professional. While in the first case a “all or nothing” approach can be sensible, in the B2B context more attention should be paid to factors that can justify the apportionment of liability between the contractual parties.

⁽⁶⁰⁾ V. Rubino, *Comparative negligence e regole di sicurezza alimentare*, cit., 239-240 criticizes the outcome of the decision, since it can alter the structure of the supply chain, with the consequence to generate additional costs on contractual parties.

⁽⁶¹⁾ With regard to the protection of consumers A. Sciaudone, *Tecniche di tutela dei diritti del consumatore di prodotti agricoli*, in *Riv. dir. agr.*, 1994, I, 28, 41-42 highlights the imbalances existing between large retailers and consumers, arguing that the retailer should be subject to a high degree of diligence due to the market power retailers have nowadays.

ABSTRACT

The article aims at analysing the interrelations existing between private standards, certifications and the law of civil liability in situation of uncertainty. The questions that will be tackled are the following: how is the liability for risks originating from situations of

uncertainty apportioned along the B2B contractual chain? And how do private standards, conceived to manage food safety risks ex ante, interact with contractual liability? Using the Sudan Red saga as a case study, the article tries to provide an answer to such questions, showing how private standards are able to broaden contractual duties and to shape liability rules.

