Title: Getting traceability right, from fish to advanced bio-technological products: a review of legislation

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1. Introduction

Many consumers have been disturbed by recent disclosures in the media, including the presence of horsemeat in products such as beef lasagne or by the production of garments by under-paid workers or children. Over the past 20 years, the claims that many products must comply with, such as quality, security and environmental sustainability (*sensu* (Goodland 1995)) have diversified significantly following market and consumer demand. Supply chains in a number of unrelated fields must obey strict quality and safety requirements. They must also consider demands for compliance with claims involving security, animal welfare, pollution control and sustainability of natural resources and human societies (Elkington 1999). Examples of these fields include products derived from genetically modified organisms (GMOs) (Schiermeier 2004), human stem cell lines (Darnovsky & Fogel 2007), agricultural (Gebbers & Adamchuk 2010) and seafood products (Smith et al. 2010), timber (Blackburn et al. 2010), hazardous waste (Borit 2014) and toys (Hora et al. 2011).

In an attempt to reassure the public that producers' claims regarding quality, safety and sustainability, among others, are met, the European Union (EU) has assumed an active role and thoroughly legislated the production of many categories of goods. One common feature of these rules is the use of traceability as a risk management tool for the systematic gathering and recording of information on products and processes. These rules are explicitly designed to facilitate the verification of product or process claims throughout the supply chain. New products, such as bioprospecting derivatives (Arnaud-Haond et al. 2011), constantly emerge, giving rise to new concerns and demands, such as intellectual property rights assurance (Salpin & Germani 2007), biopiracy avoidance and equitable sharing of resources and their benefits (Arrieta et al. 2010). To facilitate the verification of new claims deriving from these new concerns and demands in connection with the production of these new products, it is likely that legislators will again invoke traceability as the remedial process. Recent scandals across the globe that involve traceability are reminders that ambiguities in the definition, drivers and legislation involving traceability have serious practical consequences. Most of these scandals involve food products: the presence of horsemeat in Tesco/Findus frozen beef products in Europe (NTB 2013), trade of French horse meat coming from animals used for pharmaceutical purposes (TheMeatSite News Desk 2014), and Wal-Mart (an American retailer) recalling spicy donkey meat due to traces of fox meat found in the product in China (The Lawyer 2013). Other examples involve non-food products, such as the investigations into the labour conditions in overseas factories supplying H&M, a European clothing retailer.

The conceptual underpinnings of the present work involve the principles of consistency, coherence and credibility at the core of law. Consistency, coherence and credibility rank high in the EU legal chart as constitutional principles relevant at the legislative level (Barnard et al. 2013). Consistency is defined as the absence of contradictions, whereas coherence refers to positive connections (Barnard et al. 2013) and credibility means that rules are clear and predictable (European Commission 2014). At a general level, the Treaty on the Functioning of the European Union stipulates that the EU shall ensure consistency between its policies and activities (European Commission 2012a). Such a consistency provides coherence and credibility to the respective body of law. The main purpose of this study is to assess whether EU traceability legislation (i.e., the technical wording of the legal text) is consistent with the declared objective of the law (i.e., to implement a traceability system throughout the entire product supply chain). The focus is on the words of the legislation and not on general policy arguments. It is important to perform such an analysis of the legal text because the legislature sets minimum compliance requirements that businesses will have to follow. If the legal text is flawed, traceability systems put up by less aware businesses can be ineffective, and supply chains may thus become vulnerable to opportunistic behaviour, as exemplified by those recent cases indicated above. Concurrently, consumers are likely to be confused and question their trust in a legislature that creates risk regarding different product claims (quality, safety, etc.) by using the notion of traceability inconsistently.

In addition, this study attempts to explain the inconsistencies observed in the rules. This explanation is made after examining several potentially influential factors, such as the type of product, drivers for the traceability regulation of a product, and its trade value. While focusing on the EU, this interdisciplinary study is relevant worldwide because EU traceability legislation has direct consequences on the legal systems of the countries that the EU trades with. Moreover, this study is influential across all sectors that use product traceability as a risk management tool, and provides an in-depth understanding of these industrial sectors in connection with the legislative understanding. This paper advances the scientific understanding of major issues in the area, such as what traceability is, how it is achieved through legislation, why laws addressing the same concepts do not follow the same traceability principles and how legal consistency can be achieved in a legislated domain.

In Section 2, certain major issues in this field, such as controversial perceptions about the meaning of traceability, and the connection between traceability and verification of data, are clarified. The methodology used in the analysis of the consistency of legal norms is explained in Section 3. Empirical results of the analysis of 30 EU regulations and directives covering 16 general categories of products are presented in Section 4. Implications for the present and future applicability of traceability regulations are discussed in Section 5, before conclusions are drawn in Section 6.

2. Conceptualisation of product traceability

In the last two decades, traceability has become a popular concept in industrial logistics (Opara 2003), regardless of the production regime and type of product (Flapper et al. 2002; Jansen-Vullers et al. 2003). Nevertheless, tackling the theoretical aspects of traceability seems to be difficult. In some supply chains, such as those in the food industry, the disputes begin with the definition of traceability. Different branches of the food industry have different perceptions about the meaning of traceability, despite common requirements and drivers that generally extend across industries (Jansen-Vullers et al. 2003). Thus, many researchers simply do not mention any definition of traceability in their articles, refer to at least two meanings of it or make up their own definition (Olsen & Borit 2013). A typical misconception of laypeople and many authors (for examples, see Olsen and Borit, 2013) is that traceability is only a numeric code attached to products, that it actually means place of origin, or that it is a method to ensure that information about the product is true. The professional controversy continues with the granularity and the depth of traceability – how small should the identified unit be (e.g., a crate of shrimps or one-month production of beef lasagne), and whether the entire supply chain (i.e., from field/farm/hook to plate) or only parts of the supply chain should be covered by traceability requirements, and whether this coverage should be based on risk assessment (e.g., steps in production in which pathogens are inactivated). Other points of disagreement include the breadth of traceability, i.e., the amount of information the system records (McEntire et al. 2010), and the body that should be responsible for implementing traceability, i.e., the legislature or the industry. In conclusion, traceability has been both a politically and strategically controversial issue and has acted as a major deterrent for multi-disciplinary cooperation and understanding (Vorst 2004). On a deeper level, the multiple perceptions about the meaning and applicability of traceability held by different people may be related to idiosyncratic cultural backgrounds and, therefore, to their basic notions of trust and transparency requirements (Hofstede 2004). Following this suggestion, it has been noted that transparency does not equate to traceability (Egels-Zandén et al. 2014) because the latter only sets the framework for the former.

Considering that the market for technologies related to food traceability alone will reach USD 10.6 billion in 2014 (Visiongain 2013), a clear understanding of how traceability is employed in different contexts is important for the public in general, for industries in the EU and for these industries' suppliers overseas. The present work uses the definition of traceability that incorporates all the critical properties of a traceability system as described in the scientific literature (Olsen & Borit 2013). Thus, traceability of any given product refers to "the ability to trace the origin of materials and parts, the product processing history and the distribution and location of the product after delivery by means of recorded identifications" (Olsen & Borit 2013). There are several principles (or requirements) that must be followed for the traceability system to be effective. It is critical that these recordings are interconnected and in a format that allows the product to be tracked along the entire supply chain. Thus, units that are traced (traceable resource units (TRUs), e.g., a timber log, a box of mackerel, one day's production of shampoo) and identification/numbering schemes that provide codes/numbers used for the unique identification of TRUs (e.g., GS1 barcodes) are parts of a traceability system (Borit & Olsen 2012). For this system to be effective, it is essential that the codes of a TRU (either as a raw material or semi-finished product) entering a link in the supply chain are associated uniquely with those of the same item (semi-finished or end product) leaving the link. This ability to identify products individually is the basis of product traceability (Moe 1998; Jansen-Vullers et al. 2003; Poli 2004; Kelepouris et al. 2007; Porter et al. 2011). Equally critical is maintaining accurate records of the transformations (e.g., splitting, joining) that the TRU undergoes and sharing the TRU identification code with partners in the supply chain (Kelepouris et al. 2007; Nachay 2011).

The definition used herein relates to all types of products and services and is believed to provide the basis for effective traceability (Olsen & Borit 2013). With respect to the food sector, this approach concurs with the position recently taken in the USA, the largest single food importer/exporter in the world, by the Food and Drugs Administration (FDA) in its new Food Safety Modernization Act (Nachay 2011). Based on these arguments, this study maintains that traceability is an infrastructure that can be used by control agencies for two purposes. The first purpose is to retrieve different data for various reasons (such as validation of documentation of environmental sustainability – e.g., food miles, emissions (Olsen 2009) - or contamination concerns). The second purpose is to verify these data with their specific means – including genetic identification of species such as in the seafood mislabelling cases identified by studies such as those reported in Helyar et al. 2014 (haddock labelled as cod; tilapia sushi labelled as white tuna sushi). Mislabelling in these cases “presents substantial challenges for the sustainable management of the respective fisheries” (Helyar et al. 2014). As discussed in the literature, “a traceability system is quite similar to a filing cabinet in that they both deal with systematic storing and retrieving of data. Importantly, neither a traceability system nor a filing cabinet care about what types of data are being stored” (Olsen & Borit 2013). This notion has several important consequences. For instance, there is no guarantee that the recordings are true or complete, as both error and fraud can lead to false claims about the properties of the food product, including its origin. There is a clear need to verify these claims, and in this area, analytical methods and instruments play a crucial role. Similarly, documenting traceability and documenting eco-label type chain of custody are two different concepts. Although traceability can be used as a tool in the certification process, traceability and certification are nonetheless different processes (Borit & Olsen 2012).

3. Methods and data

The aim of this study is to analyse first, whether the EU body of law addressing product traceability is consistently applying traceability requirements. Second, this study attempts to offer an explanation of the situation at hand and forecast future legal approaches to product traceability. To address the complexity of these research aims, this study employed a mixed methodological approach that involved four steps: 1) a systematic review of EU regulations and directives that refer to product traceability; 2) codification and interpretation of these laws according to traceability criteria adapted from Borit and Olsen (2012) and based on logical operations; 3) statistical analyses to reveal possible associations between the drivers, categories and trade value of products, and the traceability approach chosen by the legislature; and 4) a forecast of the traceability approach taken by the EU legislators for several new products.

3.1. Systematic legislation review

This study was undertaken as a systematic literature review based on the original guidelines proposed by specialty literature (Kitchenham 2004; Machi & McEvoy 2009; Booth et al. 2012). The steps in the systematic literature review method are documented below. To identify the EU legislation that refers to product traceability, a two-steps search strategy was implemented as follows. The on-line search looked for “traceability” in “title” and afterwards in “title AND text” in the EUR-Lex database (the EU database of EU law). All documents found in the first online search were included in a preliminary list. Only the most recent documents, *viz*. the first 100 hits (ordered by date), returned in the second search were added to this list. Inclusion and exclusion criteria for the final list were formulated as follows. Inclusion criteria were that the norms were published as a regulation or directive in the Official Journal of the European Communities and that they referred to traceability of products defined as the result of activities or processes (ISO 1994). Exclusion criteria were that the norms were published in the Official Journal of the European Communities as something other than as a regulation or directive and referred to other types of traceability (e.g., traceability in software systems or measurement traceability).

After eliminating documents that failed to meet these criteria, 16 legal rules remained for analysis. Norms implementing or amending these rules were identified and were added to the final list of documents if they fulfilled the inclusion criteria. A summary of the legislation included in the final list is given in Table 1. These 30 rules covered the following 16 groups of products: toys, timber and timber products, seal products (i.e., all products derived or obtained from all species of pinnipeds), food in general, fish and fish products sourced inside and outside the EU, beef, eggs, food and feed products produced from GMOs, organic products, explosives for civil uses, cosmetics, medicinal products, hazardous waste, human blood and blood components, and human tissues and cells. The English language version of these documents was used for analysis. The coding and interpretation procedures are detailed in Section 3.2

Table 1. Summary of documents used to evaluate the EU legislative approach to traceability in the case of 16 groups of products. For a detailed list of norms included in this study, contact the corresponding author. R = regulations; D = directives.

Groups of products	Number of norms	Legislated area
1. Beef	R: 3 D: 0	System for the identification and registration of bovine animals. Labelling of beef and beef products.
2. Cosmetics	R: 1 D: 0	Market surveillance and labelling of cosmetic products.
3. Eggs	R: 1 D: 1	Marketing standards for eggs. Registration of establishments keeping laying hens.
4. Explosives for civil uses	R: 0 D: 1	Identification and traceability of explosives for civil uses.
5. Fish and fish products sourced inside the EU	R: 2 D: 0	Control system for ensuring compliance with the rules of the common fisheries policy.
6. Fish and fish products sourced outside the EU	R: 2 D: 0	System to prevent, deter and eliminate illegal, unreported and unregulated fishing.
7. Food in general	R: 2 D: 0	General principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
8. Food and feed products produced	R: 2 D: 0	Traceability and labelling of genetically modified organisms and traceability of food and feed products

from genetically modified organisms		produced from genetically modified organisms. System for the development and assignment for the development and assignment of unique identifiers for genetically modified organism.
9. Hazardous wastes	R: 0 D: 1	Labelling and traceability of hazardous waste.
10. Human blood and blood components	R: 0 D: 2	Traceability and standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.
11. Human tissues and cells	R: 0 D: 2	Traceability and standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
12. Medicinal products	R: 0 D: 2	Measures for prevention of the entry into the legal supply chain of falsified medicinal products (e.g. identification of suppliers, labelling of products).
13. Organic products	R: 4 D: 0	Control of organic production and labelling of organic products.
14. Seal products	R: 2 D: 0	Placement on market of seal products.
15. Timber and timber products	R: 1 D: 0	Obligations of operators who place timber and timber products on the market.
16. Toys	R: 0 D: 1	Rules for ensuring safety of toys.

3.2 Codification and interpretation based on logical operations

To analyse the consistency of these legal rules, this study utilised a coding scheme based on a generalised and simplified version of the evaluation framework for effective traceability systems described by Borit and Olsen (2012). Because this framework was originally developed for analysing legal norms in a different and specific context (i.e., addressing illegal, unreported and unregulated, known as IUU fishing), it was generalised by transforming the IUU-critical traceability control points into the common links of a product supply chain (i.e., supply, manufacture, storage, transport, etc.). Only those descriptors related to effective traceability were considered, i.e., those that required that 1) TRUs were uniquely identified, such that they might be individually traced along the supply chain; 2) special measures were in place at each link of the supply chain to assure the identification of suppliers and customers of products; 3) for TRUs whose integrity can be affected under product processing, such as food, whether records of transformations (e.g., splitting or joining) were kept was also checked; and 4) the traceability provisions covered the entire supply chain. One matrix was developed for each of the 16 products and included the coding for all the legal norms regulating the respective supply chain. The provisions of the legal text were read thoroughly and coded in the respective cells of the evaluation matrix by one rater. At this step, the specific requirements of the rules, rather than general and imprecise requirements, were considered. While coding the legal text, the rater followed both the literal and purposive approaches to statutory interpretation of the EU legislation, as directed by the literature (Rösler 2012), and reported the same results regardless of the approach. During coding, the stated drivers for traceability for each product were also identified. In addition, the products were divided into four categories based on the research and development (R&D) intensities of their manufacturing industries, as defined by the Organization for Economic Co-operation and Development (OECD) (OECD Directorate for Science 2011), as shown in Table 2.

The identification of TRUs was straightforward for most product chains except for the toy industry. In this special case, the rules identified the toy prototype – rather than the production or trade units – because the TRU warranted the identification number. It is beyond the scope of this analysis to decide whether this is appropriate; for purposes of simplicity, it was considered that the first principle of traceability was fulfilled.

Table 2. Products and their respective driver for traceability stated in the legal norms (some products have two drivers). Hazardous waste (not included in the OECD taxonomy) is the 16th group of products, with pollution control as the traceability driver.

Driver for traceability	Categories of products	Products
Natural resource sustainability or	Low-technology	Fish and fish products sourced outside and outside the EU; timber and timber

animal welfare		products; seal products.
Product quality	Low-technology	Food; organic products.
	High-technology	Human blood and blood components; human tissues and cells.
Human safety or security	Low-technology	Beef; egg; food.
	Medium-low-technology	Toys.
	Medium-high-technology	Explosives for civil uses; cosmetics.
	High-technology	Medicinal products; human blood and blood components; food and feed products produced from genetically modified organisms; human tissues and cells.

The scoring of individual entries in the matrices – as well as the logical operations performed with these scores – can be explained in terms of three-valued logic (Breuer 1972). An individual entry in the matrix could only take one of three possible values, {0,?, 1}, depending respectively on whether the requirement was absent (false proposition), equivocal (fuzzy proposition) or clearly defined and addressed (true proposition). Logical operations occur when calculating the final value of supply chain coverage or traceability (e.g., requirement C) from two or more requirements (e.g., A and B). In this qualitative characterisation, the value of the requirement C for the supply chain (horizontal analysis) and traceability (vertical analysis) was the result of the logical conjunction operation, i.e., A ^ B. Thus, in the final assessment, the results of this logical operation can only take three values: true (1) if present in all requirements, false (0) if absent in any requirement, and equivocal (?) in all other cases. This calculation method rendered traceability true (effective) in eight cases and false (non-effective) in the remaining eight. To further distinguish partly effective traceability (i.e., traceability that allows for a system that would function to a limited extent) from the non-effective, the majority function was chosen to be used in all the false cases. Thus, traceability was set to false only when n/2 arguments or more were false, where n is the number of traceability conditions (Valiant 1984), and to partly effective in all other cases.

3.3 Statistical analysis and forecast

The statistical analyses employed in this study explored whether the approaches to traceability identified by this research of EU legislation were correlated with the trade value, with the driver for legislation or with inclusion into a certain category of products. To measure these associations, Spearman's rho was used. This non-parametric descriptor was considered most appropriate for measuring the concordance between sets of observations that were qualitative and ordinal in nature. The tests were performed in the statistical package SPPS 19.0, with a significance level $\alpha=0.05$ (two tailed) for rejecting the null hypothesis of no relationship between sets of descriptive variables.

The first analysis investigated the association between the stated drivers of the EU regulations and the effectiveness of the traceability systems introduced in 16 supply chains. Prior to statistical inference, the traceability approach followed by the EU legislators was coded in numerals as follows: 1 – for norms in which the traceability value was assessed to be non-effective (false); 2 – when the traceability value was evaluated as partly effective; and 3 – when the traceability value was assessed to be effective (true). The drivers for traceability were coded in numerals according to a scale that implicitly contrasted concern for nature with consumer satisfaction and, particularly, human health and safety: 1 – the main driver was natural resource sustainability or animal welfare; 2 – the main driver was product quality (including organic claims); 3 – the main driver was the safety or security of humans. The second analysis investigated whether the approach to traceability taken by the EU legislators was somehow related to the regulated category of product. The final analysis investigated whether there is a relationship between the trade value of the products and the traceability approach of the EU legislature. The sources used to extract trade data are listed in Table 3. The hazardous waste group was omitted from the last two analyses because this group is absent from the OECD taxonomy and misses trade values.

After finalising these statistical analyses, the forecast by analogy method (Green & Armstrong 2007) was used to predict the traceability approach taken by EU legislators for several new products. These are products in connection with which the requirement for traceability has been raised either by lawmakers or academics, or they are goods otherwise judged by the authors of this study as being of future interest to legislators: textiles, aquaculture feed of wild origin, non-hazardous waste from offshore oil production, waste from electrical and electronic equipment, and products derived from marine bioprospecting activities (other than medicinal products).

4. Empirical results

The main result of the analysis is that EU product traceability legislation is inconsistent in the application of traceability requirements. As detailed in Table 3, in all the legal rules except those applying to products derived from seals (marine mammals), the traceability provisions were explicitly devised to cover the entire supply chain of goods. However, only with respect to eight groups of products does the legislation correctly follow the traceability principles and provide for an effective system, that is, a system that enables the identification of the origin of the product and of its input materials, in addition to conducting full backward and forward tracking to determine its specific location and life history in the supply chain (Olsen & Borit 2013). Thus, all manufacturers in high-technology industries (food and feed products produced from GMOs; medicinal products; blood and blood components; and tissues and cells), one each in medium-high- technology and medium-low-technology (explosives and toys), and some in low-technology (beef, eggs) enterprises must employ appropriate systems and standardised procedures to identify suppliers and customers (i.e., neighbouring operators) and to record the transformations that the TRUs undergo. In addition, the TRUs related to all these products must be assigned unique identifiers. The documents with which the EU made the traceability allegation in connection with these products are listed in Table 3, together with the specific drivers for traceability mentioned in the legal norms.

In contrast with the first group of products, some goods among the remaining eight supply chains, i.e., cosmetics and organic products, meet the principles of mandatory identification of neighbour economic operators – and in the latter case, of recording transformations – but lack unique identification of TRUs. Thus, they were considered to be only partly effective. In the remaining groups of products, traceability was deemed to be not effective due to caveats in the following items: 1) identification systems for neighbour operators (seal products, hazardous waste); 2) mandatory recording of transformations (timber and timber products, fish and fish products sourced both inside and outside the EU, general food products, hazardous waste); and 3) unique identification of TRUs (all cases).

Table 3. Analysis results of the EU legislative approach to traceability: no highlight indicates legal norms that implement effective (true) traceability systems; light grey highlighted cells indicate the laws that implement a partly effective traceability system; dark grey highlighted cells indicate the rules that implement a non-effective (false) traceability system. The documents in which the EU made the traceability allegation in connection with the respective products and the drivers for addressing traceability as stated in the legal text are also shown, together with the sources used to extract trade values and the data year.

Product	**Where does the EU make the traceability allegations?**	**What kind of traceability system does the EU legislation implement? Why?**	**Legislation**	**Driver(s)**	**Trade values source**
Beef and beef products	Paragraph 4, Preamble Regulation 1760/2000 Paragraph 2, Preamble Regulation 1825/2000 Paragraph 3, Preamble Regulation 275/2007	Effective	Regulation 1760/2000 Regulation 1825/2000 Regulation 275/2007	Safety	United States International Trade Commission , 2007 (USITC 2008)
Medicinal products	Article 82, Directive 2001/83/EC	Effective	Directive 2001/83/EC Directive 2011/62/EU	Safety	Eurostat, 2009 (EUROSTAT 2013)
Eggs	Report from the Commission to the Council with regard to developments in consumption,	Effective	Directive 2002/4/EC Regulation	Safety	The Poultry Site, 2007 (The Poultry Site 2011)

	washing and marking of eggs (COM/2003/0479 final)		5/2001		
Food in general	Paragraph 28, Preamble Regulation 178/2002	**Non-effective** - no unique identification of TRUs; - no recording of the transformation the TRUs undergo.	Regulation 178/2002 Regulation 931/2011	Safety and quality	Eurostat, 2009 (EUROSTAT 2013)
Human blood and blood components	Paragraph 17, Preamble Directive 2002/98/EC	Effective	Directive 2002/98/EC Directive 2005/61/EC	Safety and quality	-
Food and feed products produced from genetically modified organisms	Paragraph 2, Preamble Regulation 1830/2003	Effective	Regulation 1830/2003 Regulation 65/2004	Safety	-
Human tissues and cells	Paragraph 28, Preamble Directive 2004/23/EC	Effective	Directive 2004/23/EC Directive 2006/86/EC	Safety and quality	-
Hazardous waste	Article 17, Directive 2008/98/EC	**Non-effective**	Directive	Pollution	Not applicable

		- no unique identification of TRUs; - no recording of the transformation the TRUs undergo; - no identification system for neighbor operators.	2008/98/EC	control	
Organic products	Paragraph 1, Preamble Regulation 344/2011 Paragraph 2, Preamble Regulation 426/2011	**Partly effective** - no unique identification of TRUs.	Regulation 834/2007 Regulation 889/2008 Regulation 344/2011 Regulation 426/2011	Organic claim	Organic Europe, 2007 (Organic Europe 2013)
Fish and fish products Sourced outside the EU	Mare A4/PS D(2009) A/12880 Handbook on the practical application of Council Regulation (EC) No. 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated	**Non-effective** - no unique identification of TRUs; - no recording of the transformation the TRUs undergo.	Regulation 1005/2008 Regulation 1010/2009	Sustainability	European Commission, 2009 (European Commission 2012b)

	fishing (The IUU Regulation)				
Explosives for civil uses	Paragraph 3, Preamble Directive 2008/43/EC	Effective	Directive 2008/43/EC	Safety and security	-
Fish and fish products sourced inside the EU	Article 58, Regulation 1224/2009 MEMO/11/234 EU press release	**Non-effective** - no unique identification of TRUs; - no recording of the transformation the TRUs undergo.	Regulation 1224/2009 Regulation 404/2011	Sustainability	European Commission, 2009 (European Commission 2012b)
Cosmetics	Paragraph 12, Preamble Regulation 1223/2009	**Partly effective** - no unique identification of TRUs.	Regulation 1223/2009	Safety	European Commission, 2009 (European Commission 2012b)
Toys	Paragraph 19, Preamble Directive 2009/48/EC	Effective	Directive 2009/48/EC	Safety	Eurostat, 2009 (EUROSTAT 2013)
Timber and timber products	Article 5, Regulation 995/2010	**Non-effective** - no unique identification of TRUs; - no recording of the transformation the TRUs undergo.	Regulation 995/2010	Sustainability	Eurostat, 2009 (EUROSTAT 2013)
Seal products	COWI Study on implementing measures for trade in seal products (2010)	**Non-effective** - no unique identification of TRUs;	Regulation 1007/2009 Regulation	Animal welfare	COWI, 2010 (COWI 2010)

	Notes for guidance, Regulation 737/2010	- no identification system for neighbor operators	737/2010

The ambiguous commitment to the basic principles of traceability clearly contrasts with the resolve shown by legislators in the eight cases in which the necessary conditions were explicitly demanded. This demonstrated an inconsistent approach to the same matter. Trying to find an explanation for this situation, a strong positive correlation between the driver for risk management in the legal norms and the effectiveness of the chosen traceability approach was detected (see Table 4).

Table 4. Matrix of Spearman's rho and number of observations (n). Significance codes: ns non-significant; * P<0.05; ** P<0.01; *** P<0.001.

	Traceability approach	**Driver(s)**	**Category of products**	**Trade value**
Traceability approach	1 (15)	0.90 *** (16)	0.67 ** (15)	-0.23 ns (10)
Driver(s)		1 (16)	0.62 * (15)	-0.09 ns (10)
Category of products			1 (15)	0.41 ns (10)
Trade value				1 (10)

When the main driver for implementing traceability relates to or can impact on human health – as opposed to product quality or environmental sustainability – legislation normally imposes effective traceability systems (see Figure 1). In addition, a moderate positive correlation was found between the category of products and the traceability approach. Goods manufactured by the high-technology industry are more likely to comply with all conditions for effective traceability. However, no correlation was found between the trade value of different products and the approach to traceability adopted by the legislature. EU regulations apparently follow traditional ethical lines. Legislation requires effective traceability mostly when human health – rather than commercial, environmental or intangible issues – are at stake.

These discrimination rules enable the forecasting of the effectiveness of norms that are being developed now or are likely to be initiated in the future (Table 5). Thus, it is expected that the traceability systems imposed for products manufactured in low-technology industries, such as textiles (EU 2011) or aquaculture feed of wild origin (Naylor et al. 2009), will fall short of effectiveness. The drivers for monitoring these products relate to product quality and nature sustainability. With pollution reduction as a driver, but addressing medium-technology products, the traceability systems for the waste of electrical and electronic equipment (WEEE TRACE Project 2012) and of offshore non-hazardous oil production waste (Borit 2014) will likely only be partly effective. This might also be the case for high-technology products based on marine bioprospecting activities when the traceability drivers are issues other than human safety and security.

Table 5. Forecast of traceability approach of the EU legislator based on its correlation with traceability drivers and the category of products.

Product	**Who mentioned traceability in connection with this product?**	**Driver(s)**	**Category of products**	**What kind of traceability system will the future the EU legislation implement? Forecast made by this study:**
Textiles	EU; Article 24, Regulation 1007/2011	Correct and uniform information for consumers	Low-technology	Non-effective
Aquaculture feed of wild origin	Academia (Weil et al. 2013)	Sustainability of natural resources	Low-technology	Non-effective
Non-hazardous wastes from offshore oil production (Borit 2014)	Likely future development, in our opinion	Pollution reduction, Correct and uniform information for consumers	Medium-low-technology	Partly effective
Wastes from electrical and electronic equipment	WEEE TRACE Project (WEEE TRACE Project 2012)	Pollution reduction	Medium-high-technology	Partly effective
Products based on marine	Likely future development, in our	IPR, biopiracy, equitable sharing	High-technology	Partly effective

bioprospecting activities, other than medicinal products	opinion	of resources and benefits from resources

5. Discussion

The traceability system applied by operators in the market does not need to be as loose as inferred from the benchmarking of the regulations performed here. In the absence of clear legal norms, some supply chains, such as specific segments of the food industry, assumed more responsibility and began to rely on private standards (e.g., ISO 22000, Bureau Veritas Certification) that include traceability provisions that are effective but only partially measurable (Olsen 2009). However, this might not be always the case, even in sectors that may be perceived by the public as tightly controlled, such as the food sector in the EU: after the beef-horsemeat scandal in Europe, agricultural experts declared that “the lack of transparency and traceability is flagrant in regard to poultry, pork and horsemeat” (Priscille 2013). It has been noted that the mislabelled beef was traced back to its original supplier due to the effective traceability implemented in the beef sector (i.e., the one who fraudulently or accidentally mislabelled the horsemeat as beef). Nevertheless, because of the non-effective traceability of the horsemeat sector, the origin of this meat could not be identified (Priscille 2013). The difficulties in following the horsemeat through its supply chain raised questions about the human health risk encountered by consumption of meat that might be improper for humans. Thus, why does the legislature, or different uncoordinated legislatures working under different contexts, make demands that are sufficiently specific for some goods but not for others, thus neglecting the principle of the consistency of laws? As indicated by the results of this study, the driver(s) for traceability and the category of products exert an important influence on this approach.

Getting traceability principles right in the case of the eight faulty product categories and in new legislation, such as the legislative package proposed by the EU in 2013 in connection with product safety and market surveillance (European Commission 2013a), is not a difficult task. Excellent examples of norms for complex supply systems have previously been implemented in the EU, as described above. Operational implementation of effective traceability is, however, chain specific. A general recommendation to the legislature is to keep track of the traceability principles: assignment of a unique identification number to each defined TRU; assurance that systems allowing the identification of neighbour operators are in place; specifications for the recording of transformations that must be performed at each production stage; and assurance that these rules cover the entire supply chain. When guided by appropriate legislation, it will be the prerogative of the industry to implement adequate technical solutions for the specific production chain and driver for traceability. With respect to the food industry, practitioners claim that there are already technical solutions available to implement effective traceability in most supply chains (conform. Petter Olsen, senior scientist, Nofima, Norway).

Moreover, the labelling industry considers that "legislation on traceability in pharmaceuticals may well be applied to foods sooner rather than later" (Smithers Pira 2014). Nonetheless, the future of truly effective traceability in some sectors, particularly those outside the health business (i.e., in all areas except cosmetics), is unclear. Some people working with traceability worry that the cost of implementing an effective system may lead operators to look for ways to avoid the rules. Others, including some European politicians (GUENGL 2013), argue that legislators have a responsibility to make any criminal act as difficult as possible. It is notable that even this view may have critics among the regulators. Some of these regulators clearly disapprove of the implementation of effective traceability on the grounds that the complexity of the matter may escape both academics and the industry (conform Jean-Pierre Vergine, Directorate-General for Maritime Affairs and Fisheries EU, during the Seafood Summit 2010 (Seafood Choices Alliance 2010)). In the end, it is only possible to predict that future safety and environmental scandals will lead authorities to be explicit and consistent about what type of product tracking systems are politically acceptable or feasible under cost/benefit analyses.

However, there is another question that arises: how important is it that traceability legislation passes the effectiveness test? The inconsistency and ambiguity in applying traceability principles can have critical consequences for risk management and for consumer support. While a traceability system alone cannot, for instance, deter the infiltration of illegally harvested wild resources into the supply chain or the mislabelling of products, it can facilitate secondary actions that do so, if supported by proper data recording requirements. These actions include identification of perpetrators, assignment of liability, and elimination of offending products from the market, thereby leading to loss of profit for non-compliant actors.

Moreover, getting traceability right would provide other far-reaching advantages, such as settling commercial disputes (e.g., the case of the EU seal products ban brought to the World Trade Organization (COWI 2010)) and providing a framework for improved transparency, as requested by academia (Weil et al. 2013) and consumers (Lye 2011). More importantly, data obtained with the help of such a traceability system would facilitate both performing product life cycle analysis (Bellon-Maurel et al. 2014) and providing a complete type III environmental declaration for any product. Such declarations are documents used to communicate environmental claims (European Commission 2013b; International EPD® System 2013), where life cycle analysis is the method used to quantify the environmental impact of any product (Bellon-Maurel et al. 2014; Stilgoe et al. 2014; Lehuger et al. 2009). However, the mere naming of non-effective systems as traceability may give both the legislature and consumers a false sense of security and hinder further action, research and effective new legislation in the field. Finally, public trust can be eroded if it becomes public knowledge that claims made regarding goods sold, some at premium prices, cannot be established with reasonable certainty.

There are solutions simpler than traceability for partial product tracking, such as when the regulator only requires operators to identify their suppliers or customers. This process is less efficient and more inaccurate because tracing product sources can only be attempted by means of a formal, and often lengthy, examination of each link in the chain. To clarify, it is appropriate to employ terms such as step-by-step or chain traceability instead of the comprehensive name of traceability. The principle of the correct denomination of traceability systems should also be complied with by certification and documentation schemes, which are also becoming increasingly common among private actors (Nilsson et al. 2004). These requirements for correct denomination of procedures also involve the responsibility to inform producers and consumers of the concepts applied and their limitations.

6. Conclusions

Following several serious threats to consumer safety posed by food and other products, the risk of contamination from infections in blood transfusions, or the threats to environmental sustainability posed by illegal fishing, the EU chose traceability as a mandatory risk management tool for different supply chains. Considering that such issues are too critical to be left to the disposition of industry alone, specific legislation was passed for implementing traceability in the supply chain of different products manufactured in low- to high-technology industries. Among these legal norms, 30 directives and regulations seeking to establish strict monitoring requirements for 16 groups of products were identified. The analysis shows that the application of traceability principles is inconsistent. With respect to eight groups of products, the legislation correctly follows traceability principles and provides an effective system. Thus, the traceability legislation in high-technology industries (food and feed products produced from GMOs, medicinal products, blood and blood components, and tissues and cells), one each in medium-high-technology and medium-low-technology (explosives and toys, respectively), and some in low-technology (beef, eggs) follows all the traceability principles. However, the traceability legislation applicable to the remaining product groups (cosmetics, organic products, seal products, hazardous waste, timber and timber products, fish and fish products sourced both inside and outside the EU, and general food products) fails to do so. To provide a wider picture of the true effectiveness of traceability in the EU, this theoretical analysis should be complemented by an evaluation of the practical performance of traceability in the various industries identified here.

Several steps can be taken to improve the consistency of the laws. These steps require that legislators always formulate the legal text by following the principles of traceability closely: assignment of a unique identification number to each defined TRU; assurance that systems allowing the identification of neighbour operators are in place; specifications for the recording of transformations that must be performed at each production stage; and assurance that these rules cover the entire supply chain. Such clear legal text will facilitate effective implementation of traceability, which in turn will enable other processes, such as product life cycle analyses, identification of illegal traders, product recall, and others. This paper advances the scientific understanding of major issues in the area, such as what traceability is, how it is achieved through legislation, why laws addressing the same concepts do not follow the same traceability principles in a similar manner, and how legal consistency in the legislated domain can be achieved.

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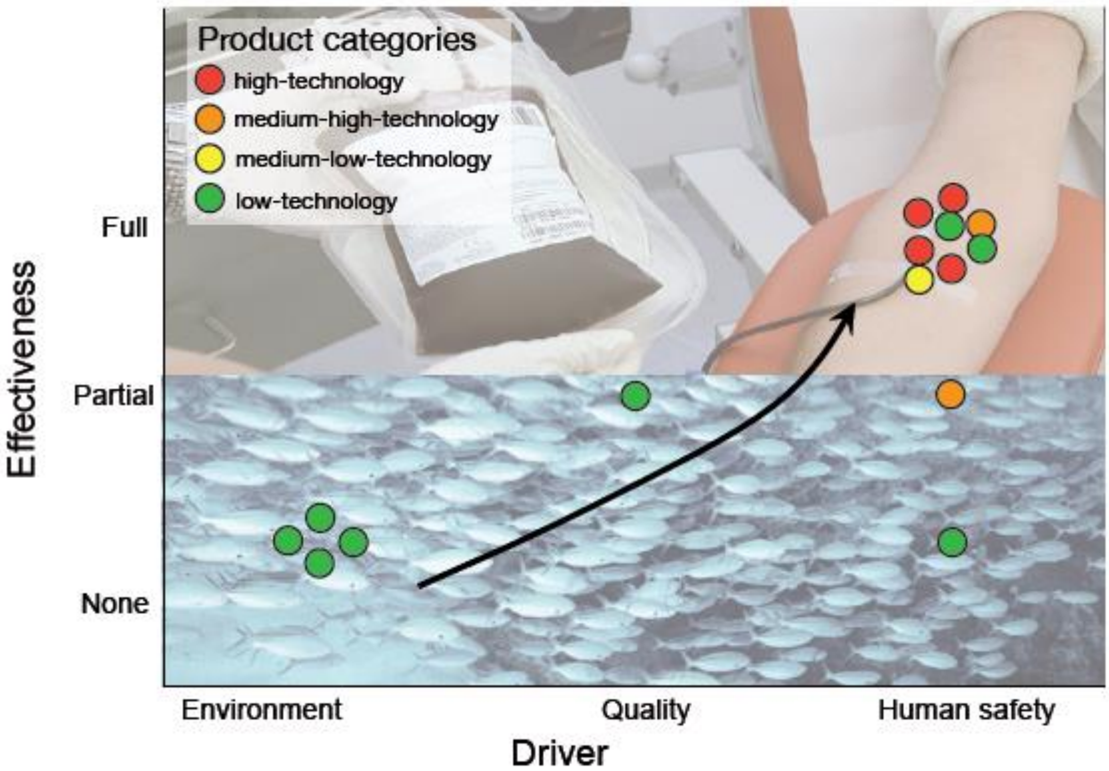

Figure 1. Environmental concerns have little leverage in traceability norms. The data points represent only legislation for the groups of products manufactured in low- to high-technology industries included in the OECD taxonomy.

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