



# Food additives and the future of health: An analysis of the ongoing controversy on titanium dioxide

Sophie Boutillier<sup>a</sup>, Sophie Fourmentin<sup>b</sup>, Blandine Laperche<sup>a,\*</sup>

<sup>a</sup> Centre de recherche sur l'Innovation et les Stratégies Industrielles (ISI) / Lab.RII, Université du Littoral Côte d'Opale, 21 quai de la Citadelle (MRSH), 59140 Dunkerque, France

<sup>b</sup> Unité de Chimie Environnementale et Interactions sur le Vivant (UCEIV), SFR Condorcet FR CNRS 3417, Université du Littoral Côte d'Opale, 145 avenue Maurice Schumann (MREI 1), 59140 Dunkerque, France

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## ABSTRACT

This article studies the current controversy about the food additive titanium dioxide (E171), marked by the French decision to temporarily suspend the placing on the market of foodstuffs containing it, beginning on January 1st 2020. It aims to understand the scientific and technological content of the controversy, which implies a better assessment of the impact on health of E171. We also study its nature, understood through the identification and study of the positions of stakeholders. Finally, our third aim is to contribute to a better understanding of public decision-making. This research combines concepts used in sociology of controversy and in innovation studies (organizational routines), and is based on interviews and on the analysis of secondary data. Results show that the controversy over E171 emerged and developed when evidence of its nanoparticle content was highlighted. This leads to an analysis of the nature of controversy as a confrontation of stakeholders' organizational routines, which may contribute to a process of sensemaking, essential for decision-making in a context of uncertainty. French public decision-making does indeed appear to be a compromise between all the stakeholders' positions, where the questioning and precautionary principles play a major role. This controversy is still ongoing and is surrounded by legal and scientific uncertainties.

## 1. Introduction

The use of technological food additives is currently the subject of a controversy related to the potential impacts these can have on human health. In this paper, we focus on titanium dioxide (TiO<sub>2</sub>), and more precisely on its use as a food additive (E171). France is the first European country to suspend for one year, beginning on 1st January 2020, the placing on the market of foodstuffs containing the additive E171 (Article 53 of the Egalim law, 1st November 2018; Order 17th April 2019<sup>1</sup>).

The aims of this paper are first to analyze the content of this controversy: Why is there a controversy, especially in France, since food grade TiO<sub>2</sub> was approved by the Food and Drug Administration in 1966<sup>2</sup> and in 1969 (JECFA 1969) by the European Union? Answering this question means understanding the potential impact on health of the oral ingestion of E171. Our second objective is to

\* Corresponding author.

E-mail addresses: [sophie.boutillier@univ-littoral.fr](mailto:sophie.boutillier@univ-littoral.fr) (S. Boutillier), [lamotte@univ-littoral.fr](mailto:lamotte@univ-littoral.fr) (S. Fourmentin), [blandise.laperche@univ-littoral.fr](mailto:blandise.laperche@univ-littoral.fr) (B. Laperche).

<sup>1</sup> Egalim Law: <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000037547946&categorieLien=id>; Order of April 17, 2019: <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000038410047&categorieLien=idr>

<sup>2</sup> Federal Register. Color additives. Washington (DC) USA: Federal Register part 8, Title 21 31: 1065 (1966) cited in Bettini et al. (2017), p.11.

shed light on the nature of the controversy, understanding controversy as a learning process where negotiation plays a central role (Callon, 2006), with the aim of identifying the main stakeholders and their positions on the subject. To do this, we combine this traditional sociological analysis of the controversy with the concept of organizational routines mainly used in innovation studies. As a matter of fact, “(...) organizational routines are a crucial part of any account of how organizations accomplish their tasks in society” (Becker, Lazaric, Nelson, & Winter, 2005, p.775). The use of this concept allows us to scrutinize the position of the organizations involved in the controversy. Our third aim is to understand the way public decisions are taken regarding risk assessment related to food safety and health. In this matter, public makers have to pay attention to the emergence of new technological health-related risks. These risks, when confirmed, can affect people well-being and can weigh heavily on healthcare systems, which would have to support the economic burden of the increase of diseases. An analysis of the process of expertise might help to understand the influence of the main stakeholders (regulatory agencies, research organizations, public administration, professional organizations, NGOs) on public decisions. This analysis is important for policy makers to anticipate and take the best possible decisions.

Our analysis contributes to the literature by combining approaches and concepts used in sociology of controversy and in innovation studies. It is based on a literature review and on an investigation conducted over the period January 2019–February 2020 in France. This investigation consisted in a series of interviews with the main stakeholders in the controversy. The rest of the paper is organized as follows. Part 1 presents the literature review and the main objectives and hypothesis of our research. Part 2 introduces the methodology used. Part 3 analyzes the results on controversy and public decision making and discusses their implications. Finally, we conclude and highlight the contributions and the limits of our work and define its future steps.

## 2. Literature review and hypothesis

### 2.1. The use of TiO<sub>2</sub> in food and the genesis of the controversy

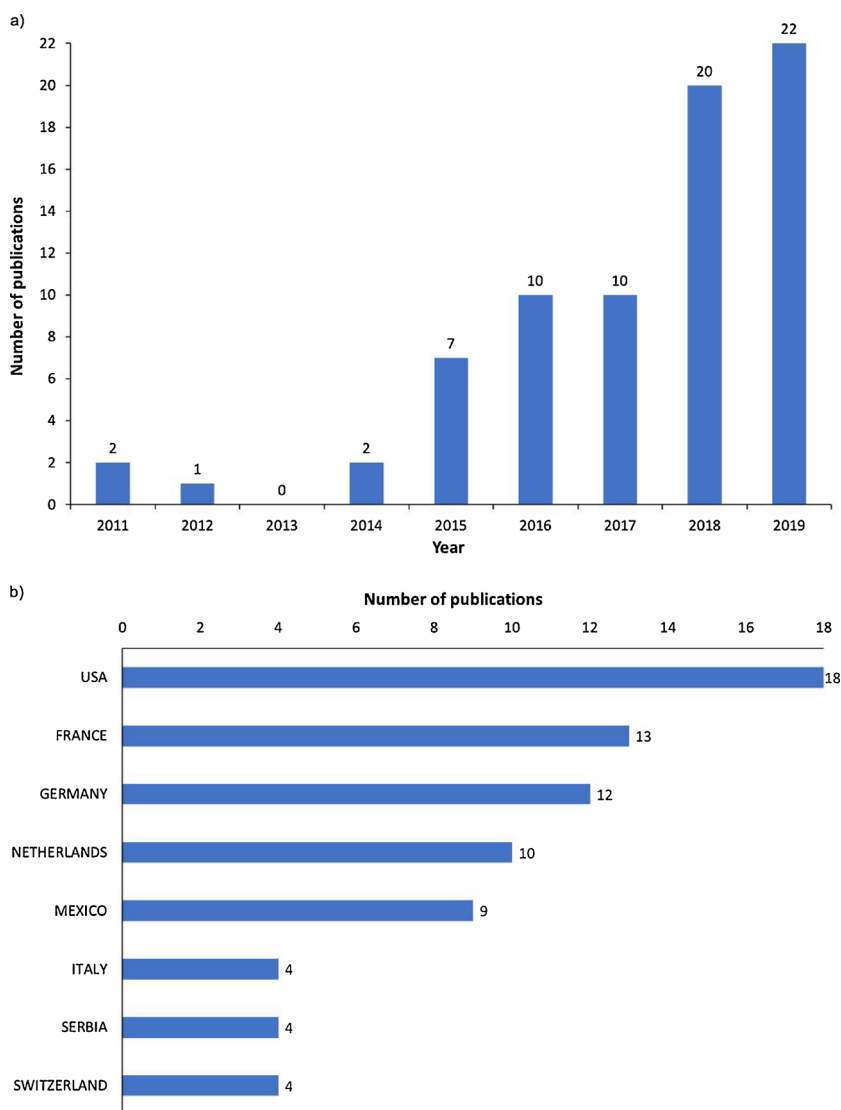
Titanium dioxide (TiO<sub>2</sub>) is the only naturally occurring oxide of titanium at atmospheric pressure. Crystalline forms of TiO<sub>2</sub> include rutile, anatase, and brookite. Its size can vary from a few dozen to several hundred nanometers, therefore it exists as microparticles or as nanoparticles (i.e. particles with at least one dimension less than or equal to 100 nm according to the European definition of nanomaterials<sup>3</sup>). The features of TiO<sub>2</sub> depend on the crystal phase, size and shape of particles. TiO<sub>2</sub> is mainly used as a powder and has two main applications, either as a pigment (scattering of light is maximized in particles that are 200 – 300 nm in diameter) or as a photocatalyst (with a mean primary particle size of 10 – 50 nm) in a great variety of finished products such as paints, cosmetics (including sun creams), drugs, toothpaste, food products and construction products (Weir, Westerhoff, Fabricius, Hristovski, & Goetz, 2012; Peters et al., 2014).

When used as a food additive, TiO<sub>2</sub> is referred to as E171 in the European Union (EU). Food additives depend on European Regulation (EC) n° 1333/2008 of December 2008. Its forms essentially consist of pure anatase and/or rutile. It is commonly used as a whitening and brightening agent in confectionary (candies and chewing gum), white sauces and icing (Bettini, Boutet-Robinet, & Cartier, 2017). To act as a whitening agent, the size distribution is expected to be centered on a mean size of 250 nm to obtain an optimal effect. Therefore, E171 should not contain nanoparticles (NPs) to obtain an optimal effect. However, data from the literature indicated that the proportion of particles considered as NPs within some E171 samples can vary from 0 to 39 % by number and from 0 to 3.2 % by mass (EFSA, 2016). This creates an uncertainty regarding the consideration of E171 as a nanomaterial. As a matter of fact, according to its NPs content and to the European Commission definition of nanomaterials (2011/696/EU), E171 can be not considered as a nanomaterial<sup>3</sup>. But according to other regulations, the existence of NPs, whatever the amount, should be indicated on products. Indeed, article 18 of European Regulation n° 1169/2011 (INCO regulation) indicates that “all ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients”. According to Novel Food Regulation (2015/2283), in the agro-food sector, the INCO regulation prevails on the European Commission definition of nanomaterials.

Another aspect to take into account is the potential impact on health of TiO<sub>2</sub>. Based on experimental evidence from animal inhalation studies, TiO<sub>2</sub> NPs are classified as “possibly carcinogenic to humans” by the International Agency for Research on Cancer (IARC) since 2006. This is the case of P25, a kind of TiO<sub>2</sub> commonly used in photocatalytic applications. P25 is advertised as “titanium dioxide without pigment properties”. This kind of TiO<sub>2</sub> is a mixture of 80 %/20 % anatase/rutile characterized by 100 % NPs with a mean size of 23 nm (Ropers, Terrisse, Mercier-Bonin, & Humbert, 2018). E171 is not classified by IARC but has recently aroused the attention of scientists.

Bibliometric analysis shows that the term “Titanium dioxide” produced around 69,400 responses in the Web of Science (WOS) in October 2019. Among these responses, only 74 contain the term “E171”, while more than 20,600 are dedicated to catalysis or photocatalysis. The oldest record dealing with E171 dates from 2011 and is entitled “Titanium dioxide in our everyday life; is it safe?” (Skocaj, Filipic, Petkovic, & Novak, 2011). From 2011–2014 few papers dealt with E171 (around two/year), while from 2015 the number of publications exponentially increased to reach 22 in 2019 (see Fig. 1a). Around 10 % of these papers are dedicated to

<sup>3</sup> According to the definition of the European Commission (2011/696/EU), “A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness, the number size distribution threshold of 5% may be replaced by a threshold between 1 and 50%. By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials”. [https://ec.europa.eu/environment/chemicals/nanotech/faq/definition\\_en.htm](https://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm)



**Fig. 1.** a) Number of publications about E171 and b) Country of origin of the publications (occurrence  $\geq 4$ ). (Source Web of Science in October 2019).

regulation, 30 % to the physicochemical characterization of E171, and the other 60 % to its impact on living systems and in the environment. France is the second country of origin of these studies, after the United States (see Fig.1b). The main research group in France is Toxalim (UMR1331, INRAE, ENVT).

Before 2011, numerous studies focused on  $\text{TiO}_2$  toxicity. However, these studies mainly used a nanoparticulate  $\text{TiO}_2$  like P25 to perform these evaluations. As stated before, P25 and E171 are two different kinds of  $\text{TiO}_2$  with different physicochemical properties (surface area, crystalline phase, isoelectric point and size). Recent studies concluded that P25 does not appear to be the most suitable reference material for toxicity studies by ingestion (Ropers et al., 2018). Moreover, it is not the most relevant material to represent the NP fraction of E171. Testing should therefore focus on E171 to obtain relevant results, as well as in the food matrix.

As can be seen from this literature survey,  $\text{TiO}_2$  corresponds to various chemical species. Therefore, one must be clear when dealing with  $\text{TiO}_2$ : are we talking about  $\text{TiO}_2$  NP (like P25) or about E171? Therefore, further studies are actually necessary to characterize and assess the toxicity of E171. More recent papers are actually undertaking this expertise, working on food grade  $\text{TiO}_2$  (E171) samples from various suppliers.

The existence of various kinds of  $\text{TiO}_2$  and their various nanoparticle content instill doubts about the safety of E171. The part of NPs in E171 underlined by research studies raised uncertainties on their potential impact on health through ingestion, especially since P25, which contains 100 % NPs, is classified as possibly carcinogenic to humans through inhalation.

**Hypothesis 1.** *The controversy on E171 ensues from the evidence of the significant part of nanoparticles it may contain, which involves technological risks/consequences to/for human health.*

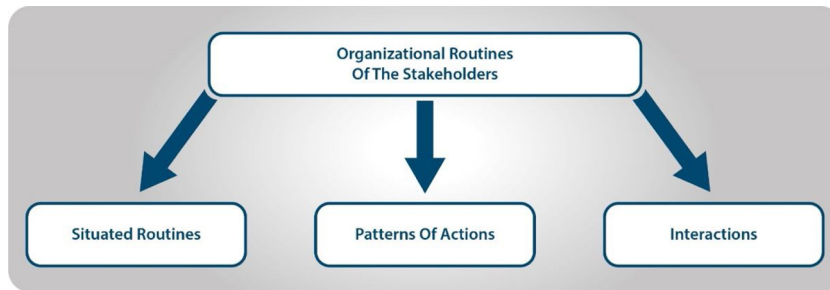


Fig. 2. Content of Organizational Routines (Source: authors based on Feldman et al., 2016).

## 2.2. The controversy: definition and approach

Knowledge production is a social process which is not linear and includes a large range of stakeholders who defend various theories and points of view. Works on the sociology of controversy put forward several important points to define a controversy, especially technological ones (Callon, 2006): they concern a technical object; various solutions can be envisaged; social groups with various interests meet, are opposed, excluded and/or reintroduced in the debate; the controversy remains open in the sense that the forces that are opposed in the controversy permanently balance each other out (Todt, 1997). The controversy represents a learning process between various stakeholders where “negotiation” plays a central role. Our subject corresponds well to this approach of the controversy. It concerns a technical object: food additives and in particular titanium dioxide; various solutions exist: using them, not using them since they have no real usefulness, finding substitutes; various stakeholders confront their points of view - we will analyze these in detail later - and it is an open controversy since the final decisions have still not been taken.

Indeed, another interesting point regarding controversies is that this is a dynamic phenomenon. Social reality is constantly constructed and changed by social groups who defend their own interests. Not all the social groups play the same role, and they do not have the same influence regarding their own resources (financial, scientific, capacity to access the media). Technical rationality is always ongoing. Scientific truth does not exist by itself; it is the product of the balance of power between the various social groups (Latour, 1994).

In this paper, we propose to consider the controversy as a confrontation of stakeholders’ routines. Routines are commonly defined as “repetitive, recognizable patterns of interdependent actions, carried out by multiple actors” within an organization (Feldman & Pentland, 2003, p.95). Our approach to routines comes from the evolutionary theory of organizations, developed by Nelson and Winter (1982), who define routines as a key element of both organization’s stability and evolution: “They are a persistent feature of the organism and determine its possible behavior” (Nelson & Winter, 1982, 14). Routines are an organizational memory, resulting from the replication of actions, a stock of knowledge, produced by learning and mobilized by the firm (the typical organization studied in this field) in its activity; they contribute to defining the firm and differentiating it from other companies. Routines are also viewed as a source of inertia, locking the organization into a specific trajectory and hindering its evolution. But routines also constantly evolve according to organizational external and internal pressures, and due to their internal dynamics. Recent approaches of organizational routines highlight their “internal dynamics” (Feldman & Pentland, 2003; Feldman, Pentland, D’Adderio, & Lazaric, 2016). Feldman et al. (2016), show, among other aspects, how routines are enacted in specific times and spaces (they are *situated*), how they are *patterns of actions* (patterns are related to the tasks being accomplished from the organization through a routine, such as hiring, budgeting, pricing... and in our case “expertising”), and how they *interact* (meaning how routines affect one another and how they work together to support stability and change). Routines are mostly used in empirical research to study change, outcome and performance of organizations (Becker, 2005), and the larger part of the literature is based on the case of firms. However, some works have operationalized the concept of routines in different types of organizations like hospitals (Edmondson, Bohmer, & Pisano, 2001), public nursing homes (Royer & Daniel, 2019) and research organizations (Franczak & Mote, 2018).

We propose to operationalize the concept of routine to study the controversy considering that each of the stakeholder (being organization) has routines that will establish its position. We do not focus on performance or outcome of each stakeholder, but we use the concept of organizational routine as a unit of analysis of their position in the controversy. Our objective is thus to understand the nature of the controversy, through the definition of the main organizational routines of each stakeholder, viewed or broken down in three main elements (see Fig. 2): *situated routines* (including past actions), *patterns of actions* (the norms and procedures guiding the accomplishment of tasks through a routine), and *interaction of routines*. On this last point, we go a step beyond recent works that emphasize the interaction of routines within the organization (intra-organizational interaction of routines) since we try to analyze the mutual influence of stakeholders’ routines (inter-organizational interaction of routines).

As a result,

**Hypothesis 2.** The controversy is defined as the confrontation of stakeholders’ organizational routines.

### 2.3. Understanding the procedures of public decision-making and the role of expertise

Our third objective is to better understand the way public decisions are taken, and in our case the French decision to suspend the use of E171. Currently, public decisions in the field of technology analysis and risk assessment are seen as being strongly linked to scientific expertise. Historically, expertise is the implementation of specific knowledge for public action (Barbier, Cauchard, Joly, Paradeise, & Vinck, 2013). Scientific expertise is “a set of activities necessary to analyze a problem based on the state of knowledge, demonstrations and experience of experts. It generally leads to the drafting of a document (expert report) which can be concluded, depending on the request, with interpretations or even recommendations” (CNRS, 2005).

According to Joly (2012), since the 1990s in France and Europe, there has been a transformation of scientific expertise, marked by the transition from a period when expertise was embedded in the structures of administrative and political power, to a new era, that of regulatory agencies affirming competence, transparency and independence as the key words of expertise. Carried out mainly within autonomous agencies (as is the case with ANSES or EFSA, see Table 1), the scientific opinions they provide meet very specific standards, charters and norms. A term was proposed to define the type of knowledge that is produced by these agencies: regulatory science. As stated by (Demortain 2017, p.140) “Regulatory science covers the testing of technologies and their risks and the interpretation of a test results in a mixed industrial, bureaucratic and academic environment, to legitimize the adoption of policy measures (marketing authorization, labeling, withdrawal, definition of thresholds for exposure, use conditions...)”. Scientific expertise is thus considered as a “technology of power” (Jasanoff, 1990), in the sense that public decisions are based on it.

However, there are many criticisms of this regulatory science (Demortain, 2017; Joly, 2012). The concepts and protocols used are subject to criticisms. The independence of experts, their conflicts of interest and the role of lobbyists are regularly highlighted. For example, Jasanoff (1990), studying the role of experts in the United-States, showed that they are not independent of government and large enterprises in various sectors. More recently the revelations of the Monsanto papers on the roles of industrial lobbies support this idea (Laperche, 2018).

Thus, a number of other studies argue, as Joly (2012) points out, for a democratization of expertise and its opening up upstream, to stakeholders other than professional scientists, to include not only the holders of scientific knowledge but also those linked to experience. These experts are “lay-members” (Estades & Remy, 2003; Wynne, 1998). In this context, think tanks and social networks play an increasingly important role in a process of controversy. Academic and non-professional rationalities are considered as legitimate in terms of expertise and the borders between them no longer exist (Callon & Rip, 1991). In this “advocacy model”, nobody has a monopoly of resources on expertise (Goebel, 1996; Hilgartner, 2000). The expertise process, which represents the decentralized expression of opinion, is defined as an exploration process between various kinds of experts (governments, academics and lay persons). It therefore becomes possible to build a map of controversies gathering together the various kinds of stakeholders. But this approach is also not without criticism, since strategic manipulations can also have their place and be used by lobbies and “merchants of doubts” (Oreskes & Conway, 2010) to delay the time of action. Excessively broad debates can also lead to an inability to stabilize knowledge for decision-making (Collins & Evans, 2002).

In our opinion, the temporality of the controversy must be added to this debate. In our case, the controversy is ongoing and it is therefore difficult to make a definitive decision on the role of regulatory agencies or on the influence of any other stakeholder. In an ongoing controversy, we will seek to show in which direction the temporary compromise associated with public decision-making is heading.

**Hypothesis 3.** Public decision-making stems from the interactions between stakeholders' decisions, and the relative power of each of them.

## 3. Methodology

### 3.1. Review of literature

To reach our objectives and test our hypotheses we carried out a review of literature, associating different types of documents. Our bibliometric analysis (see Point 1.1) helped us to date the interest of researchers on this subject. We also used academic literature in various fields to define and test our hypothesis: food toxicology, sociology of controversies, and innovation studies.

The other sources of literature are also grey literature: reports from agencies, non-governmental organizations, blogs<sup>4</sup>, and articles from the scientific and economic press<sup>5</sup>. These sources of information are all the more crucial in our case as the controversy had significant media coverage in France with the enactment of the Egalim Law.

According to the basics of the sociology of technological controversies, this review of literature helped us to map the controversy which involves: 1/ Defining the problem; 2/ Identifying the stakeholders; 3/ Identifying the relationships between these different stakeholders: how scientists or various experts may or may not be linked to firms, or how NGOs help to raise awareness of a problem that has hitherto been ignored.

<sup>4</sup> Blogdroiteuropéen (<https://blogdroiteuropeen.com/>), Tomorrow's Food and Feed (<https://tomorrowsfoodandfeed.khlaw.com/>), MedicalXpress (<https://medicalxpress.com/>), Avicenn (<http://avicenn.fr/wakka.php?wiki=PagePrincipale>), veillenanos (<http://veillenanos.fr/wakka.php?wiki=PagePrincipale>)

<sup>5</sup> *Le Monde, Le Figaro, Les Echos, 60 millions de consommateurs, UFC-Que choisir, Le Point, L'Express, Capital, Libération...*

**Table 1**

List of stakeholders (interviews and secondary data).

Type of Stakeholder	Date of the interviews	Identification of the interview	Brief description
Regulatory Agency (ANSES)	04/19/2019	IA1 (Interview Agency n°1)	The French Agency for Food, Environmental and Occupational Health and Safety (ANSES). Created on 07/01/2010, it is an administrative public establishment accountable to the French Ministries of Health, Agriculture, the Environment, Labor and Consumer Affairs ( <a href="http://www.anses.fr">http://www.anses.fr</a> )
Regulatory Agency (EFSA)	11/04/2019	IA2	EFSA (European Food Safety Authority) is a European agency funded by the European Union that operates independently of the European legislative and executive institutions and EU Member States. It was set up in 2002 following a series of food crises in the late 1990s to be a source of scientific advice and communication on risks associated with the food chain. The agency was legally established by the EU under the General Food Law-Regulation 178/2002 ( <a href="http://www.efsa.eu">http://www.efsa.eu</a> ).
Research Organization (INRAE)	11/12/2019 02/21/2020	IR1	INRAE (Institut national de recherche pour l'agriculture, l'alimentation et l'environnement) is a French public scientific research organization, under the dual supervision of the Ministries of Research and Agriculture. Its purpose is to provide ways to enlighten societal choices and to innovate. It was created in 1946, and restructured in 2020 ( <a href="http://inrae.fr">http://inrae.fr</a> )
Research Organization (Academy of Agriculture)	04/15/2019	IR2	Toxalim team: <a href="https://www6.toulouse.inrae.fr/toxalim">https://www6.toulouse.inrae.fr/toxalim</a> The French Academy of Agriculture is a public learned society which reports to the Ministry of Agriculture. It was created in 1761. Its main objective is to study agricultural development according to economic, technical, social, cultural, juridical, scientific and political aspects ( <a href="http://www.academie-agriculture.fr">http://www.academie-agriculture.fr</a> )
Public administration (DGCCRF)	12/26/2019	IPA	Within the Ministry of the Economy, the DGCCRF (Direction générale de la concurrence, de la consommation et de la répression des fraudes) ensures the proper functioning of markets to the benefit of consumers and businesses. It was created in 1985 ( <a href="http://www.economie.gouv.fr/dgccrf">http://www.economie.gouv.fr/dgccrf</a> )
Professional organization (ANIA)	11/18/2019	IP1	The National Association of the Food Industries (ANIA, Association nationale des industries alimentaires) brings together 40 trade unions and 16 regional associations. ANIA represents French food companies, major world leaders, ETI and VSE-SMEs. It was created in 1968 ( <a href="http://ania.net">http://ania.net</a> )
Professional organization (Confédération des chocolatiers et des confiseurs de France)	04/24/2019	IP2	The mission of the Confederation of Chocolatiers and Confectioners of France is to represent the profession, to promote the trades of chocolatiers and confectioners, and to defend the interests of artisans, manufacturers and traders in the manufacture of chocolate, confectionery and biscuits. ( <a href="https://www.chocolatiers.fr/">https://www.chocolatiers.fr/</a> )
Professional organization (CGAD)	04/09/2019	IP3	The General Confederation of Food Retail (CGAD: Confédération générale de l'alimentation de détail) is the representative organization of trades, crafts, local food trade and hotel and catering ( <a href="http://www.cgad.fr">http://www.cgad.fr</a> )
Non-Governmental Organizations (Foodwatch)	05/27/2019	IN1	The NGO Foodwatch was created in France in 2013 (created in 2002 in Germany by Thilo Bode who was the international director of Greenpeace after mad cow disease). Foodwatch is a non-profit campaigning organization that fights for safe, healthy and affordable food for all people. ( <a href="http://foodwatch.org">http://foodwatch.org</a> )
Non-Governmental Organizations (UFC Que Choisir)	05/05/2019	IN2	Que choisir was created in 1951. The UFC-Que Choisir is a non-profit organization dedicated to meeting the needs of consumers, protecting their rights and interests through its campaigns, surveys, collective actions and group purchases ( <a href="https://ufc.quechoisir.org/">https://ufc.quechoisir.org/</a> )

### 3.2. Analysis of stakeholders' position

The main stakeholders in the controversy, identified by our review of literature, are the targets of the study: Regulatory Agencies, Research Organizations, Public administration, Professional Organizations, Non-Governmental Organizations (see Table 1). The nature of our research question led us to choose a qualitative methodology (Yin, 2003).

To drive our investigation, we elaborated an interview guide for each kind of stakeholder: It is divided into four parts: identity of the respondent, stakeholder's actions concerning E171, relations between stakeholders and open questions.



Regarding stakeholders' actions, the questions are related to past and current activities and interest about E171: main scientific opinions published by regulatory agencies and explanations of the protocol of assessment; functioning and type of actions of public administration, professional organizations, NGOs, regarding food additives; main publications, scientific results and methodology for research organizations.

Regarding relations between stakeholders, for each of them, questions are related to the existence and the nature of the relations (exchange of information, funding, common research program, and common actions). In doing so, we identify the networks of information circulation, debates and common knowledge production.

The final part proposes open questions: future steps about the implication of each stakeholder on the subject of E171 and more largely on food additives, for example future research programs, planned scientific opinions, new strategies developed by companies (substitutes, etc.), international actions, opinion regarding the French decision to suspend the use of E171.

We contacted 20 potential stakeholders and selected 10 stakeholders to study through interviews. The selection of stakeholders was based on the importance of their role in the controversy (defined by the frequency of appearance of their names in our literature review). The acceptance of interviews often was the result of an administrative process. For example, for regulatory agencies, we first obtained an authorization from the direction and were then oriented toward the most specialized person in the field. Interviews took place over the period January 2019 - February 2020. This is a crucial period since it is that of the "ongoing controversy" (after the enactment of the Egalim law, the French Ministry hesitated to publish the Order and requested some new advice from ANSES; The Order was finally published on April 17, 2019<sup>6</sup>). The interviews lasted from 50 min to 2.5 h. All of them were recorded, transcribed and verified by all the participants to the interview.

#### 4. Controversy and public decision making: analysis of the results

##### 4.1. Content and origin of the controversy: nanoparticles and their impacts on health

Our investigation led us to consider that the main central element of the controversy is associated to the fact that E171 contains nanoparticles and to the impacts of nanoparticles used in food on health.

Some nanoparticles are present in food in their natural state, or may be intentionally produced, while nanoparticles may be unintentionally generated as a result of manufacturing processes. This is the case with TiO<sub>2</sub> (E171), where nanoparticles are generally produced by a so-called "top-down" manufacturing process, which consists in extracting the substance from an ore and then reducing it to powder to the desired size (Houdeau, Lamas, Lison, & Pierre, 2018).

The use of nanotechnologies has developed in many fields over the last thirty years (electronics, aeronautics, medicine, agriculture, food industry). In the food industry, and packaging sectors, research focuses on their role in improving the preservation of products, their sanitary quality, or the maintenance of the organoleptic qualities of food. According to He and Hwang (2016), they can protect against biological deterioration (antimicrobials, increasing bioavailability), protect against chemical ingredients (antioxidants, flavor), enhance physical properties (color additives, anticaking agents). They would then be useful for targeted feeding (sick, elderly, athletes). They can also enhance the physical and mechanical properties of packaging.

However, there are potential risks from nanotechnologies in the food industry (He & Hwang, 2016). These risks concern health and the environment. We focus here on possible health effects. One of the risks concerns the route of nanomaterials through the human body, after ingestion, and their access to various organs through the intestinal barrier, cells, blood vessels and pulmonary pathways (Ministère de l'agriculture et de l'alimentation (MAA, 2018). According to Houdeau et al. (2018), the size effect allows these agents to pass through biological barriers and diffuse into the body, until they accumulate in systemic organs (liver, spleens, gonads, etc.) and up to the fetus, where their high chemical reactivity can be a source of toxicity. The studies focus on the impact of nanoparticles on the intestinal microbiota, on the intestinal immune system, and on the risk of colorectal carcinogenesis.

On cancer risk, as mentioned before, for occupational air exposure, the IARC already classified TiO<sub>2</sub> as a possible carcinogen (category 2B) in humans at the pulmonary level. There are fewer data for the oral route. In 2017, the study by Bettini et al. (2017) demonstrated an initiator effect (i.e. spontaneous development) of the first stages of colorectal carcinogenesis in nearly 40 % of rats exposed for 100 days to E171 at a low dose, representative of human exposure, as well as a promoter effect on existing pre-cancerous lesions (Houdeau et al., 2018).

Indeed, the content of the controversy is associated with the perception of technological risks, in this case the potential impacts of nanotechnology on human health. Initially TiO<sub>2</sub> was accepted for food use, under specific conditions (Jovanović, 2014). The evidence regarding the risks associated with TiO<sub>2</sub> (catalytic use) when inhaled aroused attention. Then doubts concerning the impacts of nanotechnology contained in E171 were put forward by academic research and disseminated in public debate by the actions of NGOs, supported by the media, as explained in more detail below.

<sup>6</sup> As stated by the European Commission, "This Order was preceded by a note from the French authorities sent to the European Commission on 15 February 2018, which requested the adoption of interim protective measures provided for by Article 53 of Regulation (EC) No 178/2002. Such protective measures are to be taken when it is evident that food or feed originating in the Union or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment" ([https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com\\_toxic\\_20190513\\_sum.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_toxic_20190513_sum.pdf))

## 4.2. Nature of the controversy: a confrontation of organizational routines

Based on the data collected and interviews, we define the organizational routines which guide the position of each stakeholder (identified in Table 1) within the controversy on E171. These organizational routines are based on their past actions (*situated routines*), the norms and procedures guiding the accomplishment of tasks through a routine, the task here being “expertising” (*patterns of actions*) and *interaction of routines* (see Fig. 2)

### 4.2.1. Regulatory agencies: organizational routines based on the proof principle

We consider that organizational routines of regulatory agencies are based on the search for “proofs”, based on the certain type/quality of data. The proof principle is identical for all regulatory agencies and aims at demonstrating the safety of food additives (in our case)<sup>7</sup>. This type of routine can be read in their past actions (*situated routines*), especially on the “scientific opinions” they published.

Under EU legislation from 2008, the safety of all food additives authorized for use in the EU prior to 20th January 2009 have to go through a new risk assessment<sup>8</sup>. It is in this context that in 2016 the EFSA, which is in charge of this evaluation, published a scientific Opinion (EFSA, 2016) (IA1). They found that data concerning values and the exposure of humans to E171 by way of food consumption did not raise concerns. However, with regard to the insufficiency of research data, the admissible daily intake of E171 was not determined.

Meanwhile, and after publication of the research of Bettini et al. from INRAE in 2017, the French Authority for Health and Food Safety (ANSES) was asked to advise the French Government. Thus, ANSES published their “avis” (ANSES, 2017) and underlined that, if the results of INRAE’s analysis do not entirely undermine the safety assessment made by EFSA, they show the necessity to carry out new research to understand the potential carcinogenic effects of such food additives, especially due to the lack of data on reprotoxicity (which prevent the definition of an admissible daily intake).

Then came the French Egalim Law (2018) which, in Article 53, indicated the suspension of the use of E171 in France. The French Minister of Economy (Bruno Le Maire) thus asked a specific question to ANSES: Do you confirm your opinion of 2017 or are there new elements regarding toxicological impacts in the oral use of E171? (IA2). A new “avis” from ANSES was thus published in 2019 (ANSES, 2019) based on a review of the literature (25 new studies identified). The conclusion is that even if recent research identifies signals of toxicity, this is based on various methods and not on standard tests used for evaluation, which complicate its interpretation. It also recalls the lack of data on reprotoxicity, for which further studies are required<sup>9</sup>. Pending the decision of the European Commission that will evaluate a potential ban of E171 at EU level, EFSA confirmed on May 13 2019 that “the ANSES opinion published in April 2019 does not identify any major new findings that would overrule the conclusions made in the previous scientific opinions on the safety of TiO<sub>2</sub> (E 171) as a food additive issued by the EFSA Panel”. Therefore, EFSA confirmed that E171 used as a food additive is not carcinogenic after oral administration. A new scientific opinion from EFSA is foreseen at the end of 2020, as confirmed by our interview (IA2).

The *patterns of actions*, i.e. the norms and procedures guiding the accomplishment of tasks through a routine, are indeed based, in the case of the regulatory agency, on the search for proofs. To reach a scientific opinion, the process at EFSA is as follows (IA2): a panel of experts is constituted (selected for their private capacity and their independence, verified through the screening of their declaration of interest). This panel is supported by working groups. The scientific opinion is based on a review of the literature and on the public call for data published by the European Commission<sup>10</sup>. This data may come from all stakeholders and to a larger extent from enterprises, since the burden of proof is placed on companies. To be considered, the data need to conform to internationally accepted specific norms and standards. According to the OECD protocol<sup>11</sup>, toxicology studies must involve 100 animals (50 males and 50 females) for two years until formation of the tumor (IR1).

The organizational routines of regulatory agencies are indeed based on the *interactions* between the main stakeholders. These interactions take place mainly through the call for data and through interviewing stakeholders when they have specific information or expertise.

#### organizational routines based on the proof principle

Situated routines	Pattern of action	Interaction of routines
Scientific opinions from EFSA and ANSES since 2016	Standard test assessment	Call for data
- No proof of toxicity	Panel of experts	Stakeholder interviews
- Lack of data		

<sup>7</sup> However, the process of obtaining this proof is not strictly identical. For EFSA, which scientific opinions are the basis of decisions taken by European institutions, the proof of food additive safety is the result of the analysis of the calls for data published by the European Commission and from the work of the committees (experts committees and working groups). National regulatory agencies (like ANSES) also publish scientific opinions “avis” (for example on the demand of their government) ensuing from the works of committees (expert committees and working groups). These opinions can influence national decisions (like the suspension of E171 in France) but the decision to ban the food additive can only be taken at the European level. The opinions of national regulatory agencies can be a first step for further investigation by the European regulatory agency.

<sup>8</sup> Commission Regulation (EU) No 257/2010 set up a program for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008.

<sup>9</sup> <https://www.anses.fr/fr/system/files/ERCA2019SA0036.pdf>

<sup>10</sup> see in the case of E171 [https://ec.europa.eu/food/sites/food/files/safety/docs/fs\\_food-improvement-agents\\_reeval\\_call\\_20170130\\_e171\\_data.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_reeval_call_20170130_e171_data.pdf)

<sup>11</sup> <https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm>



#### 4.2.2. Research Organizations– organizational routines based on the questioning principle

Our work leads us to consider that the organizational routines of academics are based on the questioning principle. According to Bourdieu (1980), the work of scientists is based on scientific rules but it is also linked with social facts, since scientific development is always located socially and culturally. The primary function of a scientist is to produce knowledge to understand the physical, biological, chemical or social environment. The objective is to satisfy his/her intellectual curiosity and to attain recognition by peers (Merton, 1973). Studying current controversies and questioning the effects of chemical substances on people illustrates these various objectives.

Concerning E171, the bibliometric analysis shows that publications on E171 have increased, particularly over the last ten years (*situated routines*). The multiplication of major health scandals (mad cow disease, dioxin chickens, bird flu, etc.) since the end of the 20th century did indeed increase suspicion of the food industry and led many scientists to work on these issues and question the presumed safety of chemical substances.

The first important publication on E171 was Weir's publication in 2012 (Weir et al., 2012). He provided evidence on the existence of nanoparticles in E 171. After this date, many studies were published. It is in this context that the INRAE-Toxalim study was launched. "The question of nanoparticles in E171 did not exist before the 2010s. Production methods have changed and highlighted their existence" (IR1). The resulting publication (Bettini et al., 2017) questioned the impact of the oral ingestion of titanium dioxide and thus the latest scientific opinion of the time (EFSA, 2016). This study has been widely publicized and acted as a signal which led to new scientific assessments from the regulatory agencies. This was indeed an essential milestone in the current controversy on E171.

The *pattern of action* of academics is based on experiments either *in vivo* or *in vitro*. In the case of E171, these experiments are usually performed on rats (*in vivo*). However, academics are free to choose the methodologies they wish to use (respecting the legal frameworks), and these might not correspond to the ones used by regulatory agencies (Demortain, 2017). For example, the INRAE team has its own protocol (the INRAE protocol) and for reasons of cost, time and availability of human resources, does not follow the OECD protocol. Their study was based on 50 animals over a period of a hundred days to identify "pre-cancer" tumors (IR1). This is why regulatory agencies consider scientific works as "signals" but usually not as "proofs". "Regulatory science and academic research are thus complementary" (IA1)

One of the major limitations of the experiments is that they are often *in vitro* and not *in vivo*, which is required in order to have a complete analysis of the impacts on health. Many papers published on E171 are based on *in vitro* experiments, or when they are *in vivo* they are usually based on small samples or a short period of time. This is mainly due to the cost of large *in vivo* experiments: "The cost of carrying out this type of study amounts to approximately 400,000 euros" (IR2). These studies are thus led by companies (answering public calls for data), which, however, are not obliged to disseminate the results since "the companies have incurred the expenses to carry them out" (IR2). Another limitation of academic papers, according to agencies, is that we do not always know what kind of TiO<sub>2</sub> (NP-like P25 or E171) was used to assess the impact on health, as explained earlier (1.1). However, publication is crucial for academics in the context of the competitive market of the science (Menger, 2009). This "publish or perish" context may contribute to explain the exponential number of publications on this subject, which do have the same impact.

Of course, research organizations *interact* through publications, conferences etc. They also interact with other stakeholders. Academics can be interviewed by agencies, as was the case with the Toxalim team from INRAE (IR1). Research can also be funded by agencies, especially for ANSES, which has a specific program for this, which the INRAE Toxalim team benefited. NGOs also carry out a monitoring activity on scientific work and, in the case of E171, highlighted and disseminated the results of the INRAE study within their networks. The "signal" raised by this study on the possible negative impact of E171 thus reached the general public.

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#### Organizational routines based on the questioning principle

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Situated routines	Pattern of action	Interaction of routines
Studies in Toxicology from 2015	Free choice of methodology (respecting the legal frameworks) In vitro experiments In vivo experiments usually on a small sample or on short periods of time	Academic research as a signal for agencies and other stakeholders like NGOs Funding of research (ANSES)

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#### 4.2.3. Non-Governmental Organizations (NGOs)– Organizational routines based on the precautionary principle

In Europe, the first consumers' organizations were created after the Second World War (Dumas, 2018). The argumentation of NGOs is based on a dilemma between the positive impacts of technical progress and their negative consequences on human health. They favor the precautionary principle, emphasizing that it is a constitutional principle (Article 5 of the Charter for the Environment annexed to the French Constitution in 2005). Past actions (*situated routines*) are based on this precautionary principle with the aim of banning substances that are potentially dangerous for health. For Foodwatch this includes, for example, pesticide residues, as well as mineral oils and other endocrine disrupters, and controversial food additives (IN1).

NGOs have played an important role in French public debates on food (in particular the General Food Congress -Etats Généraux de l'Alimentation- which took place in 2017/2018, in preparation for the Egalim law<sup>12</sup>). For example, Foodwatch reports that it actively

<sup>12</sup> The Etats généraux de l'alimentation organized by the French government (the first in 2000, the second in 2017) brought together representatives of the agri-food industry, farmers, consumer organizations and NGOs. See for more information: <https://www.egalimentation.gouv.fr/>

participated in Workshop 8 on the topic of food safety: “Foodwatch has been campaigning with its allies for stricter regulation of potentially harmful substances for health in food; the subjects of food safety and of nanomaterials have been widely discussed” (IN1).

Moreover, on December 24, 2018, 22 NGOs, including UFC Que Choisir and Foodwatch, published a call in the newspaper *Le Monde* to ask Bruno Le Maire to suspend E171 in the name of the precautionary principle; this in the context of the hesitation of the government to publish the Order enabling this measure to be effective. They consider in their call that “The false suspense around this suspension has lasted too long. As in the case of bisphenol A, there is enough scientific evidence to suspend titanium dioxide in the diet”<sup>13</sup>.

The *patterns of actions* of NGOs are based on gathering information from enterprises, agencies and research organizations to inform consumers on the quality and the risk of using several food products, but also about enterprises’ practices. They organize meetings and various media actions to inform consumers. They also participate in public debates and carry out inquiries in shops or enterprises to (informally) control food products and the presence of food additives. Some actions are spectacular, showing that food products do not contain what they should contain.

The *interactions* with other stakeholders are strong. Consumer organizations consider that cooperation is necessary to increase their power to defend consumers’ rights. They develop a cooperation network, despite strong competition between them (IN2). Foodwatch works with other NGOs. But it has no direct relation with agencies and research organizations, even if its positions are forged based on the results of academic research and the “scientific opinions” published by regulatory agencies. NGOs can also be auditioned by regulatory agencies and ask “open questions to Parliament” (in the case of UFC Que Choisir, IN2), trying to influence public decisions. But they declare that they have no relations with enterprises in order to remain independent (IN2).<sup>14</sup>

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#### Organizational routines based on the precautionary principle

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Situated routines	Pattern of action	Interaction of routines
Participation in public debates (Etats généraux de l’Alimentation)	Gathering information from enterprises, agencies and academic works	Common actions of NGOs
Publication of a call in <i>Le Monde</i> asking the Ministry to suspend the use of E171	Communication actions to inform consumers	No direct relation with agencies, nor with enterprises
	Actions aimed at putting pressure on public decisions	Open questions to Parliament
	Online Petition	

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#### 4.2.4. Professional organizations. Organizational routines based on the efficiency principle

Our research leads us to consider that the organizational routines of professional organizations are based on the efficiency principle. First, we need to mention that we did not obtain direct interviews with companies but with professional associations which represent them and which are very involved in this subject of food additives: the National Association of the Food Industries (ANIA), the General Confederation of Food Retail (CGAD) and, the Confederation of Chocolatiers and Confectioners of France.

The efficiency principle that rules the behaviors of professional organizations is based on a cost/benefit analysis of using one or the other substances. On this matter, different aspects of the issue need to be considered. E171 is only a coloring agent with no nutritional value and therefore it is possible to do without it. Moreover, media coverage of their carcinogenic potential damages the image of the food industry. This is certainly the reason why some producers and distributors of food products (e.g. Carambar, Haribo, Mars, Picard, William Saurin, Carrefour, Super U, Leclerc) voluntarily undertook to suspend the use of E171 before the law comes into force. By the same token, in 2018 the French confectioners’ union also adopted a charter of ethics including the decision to ban E171 by 2020, “to meet the expectations of civil society” (IP1). However, for small and even bigger producers, changing the production process is not always that simple and may be costly: “these alternative processes must be able to benefit from a collective knowledge and appreciation of the subject, involving all stakeholders. They are long, expensive and complex” (IP1). In the case of chocolate, since the 2008 regulation, additives have been banned in chocolate. E171 was mainly used for white decorations and to make the colors more vivid. And it was tolerated for a long time. However, DGCCRF increased controls in 2018 and companies were told not to use it anymore, which they did: “Just look at the catalogues of chocolate confectioners. The white decorations are more cream, cocoa butter color, and the other colors are less bright, more pastel” (IP2). But they feared a negative impact on sales. The professional organizations have therefore encouraged companies to carry out commercial campaigns to promote the idea of good quality chocolate and the natural composition of the products; it is also a question of consumer education (IP2). Concerning products for which there is not yet a ban on the use of E171, the position of professional organizations is more complex: “It is difficult to tell a professional not to use a product as soon as it is authorized, on the pretext that an alert, however legitimate it may be, will be diffused in the media” (IP3). However, “all companies are organizing themselves to comply with the suspension order for titanium dioxide effective January 1, 2020” (IP1).

The *patterns of actions* of professional organizations are mainly based on the diffusion of information, they have a role as “information givers” (IP3) contributing to the sensitization of professionals on specific questions.

The CGAD interacts with its members, which are professional organizations (like the Confederation of Chocolatiers) and with

<sup>13</sup> [https://www.lemonde.fr/idees/article/2018/12/24/l-appel-d-associations-a-bruno-le-maire-pour-suspendre-l-additif-e171\\_5401706\\_3232.html](https://www.lemonde.fr/idees/article/2018/12/24/l-appel-d-associations-a-bruno-le-maire-pour-suspendre-l-additif-e171_5401706_3232.html)

<sup>14</sup> Other works have however shown the relations that may exist between NGOs and enterprises, see for example Binnering and Robert (2007).

other ones like ANIA. It also interacts with regulatory agencies, since CGAD is a member of their administration council. These interactions are mainly based on information sharing.

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#### Organizational Routines based on the Efficiency Principle

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Situated routines	Pattern of action	Interaction of routines
Anticipation of some food producers (ban of the use of E171 in their recipes)	Sensitization of professionals	Information exchange and sharing with professional organizations and agencies
Charter of ethics	Incentives to develop a marketing campaign	

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#### 4.2.5. Public administration: organizational routines based on the regulation principle

Organizational routines of public administration, here studied through the French Directorate for Competition, Consumption and Fraud Control (DGCCRF), can be considered as being based on the regulation principle. As a matter of fact, one of the missions of DGCCRF is the economic protection and security of consumers. The Food Products, Agricultural and Food Markets Branch is in charge of food quality. Regarding food additives and nanomaterials, since 2016 DGCCRF has developed specific and innovative methodologies enabling the detection of nanoparticles in food and cosmetic products: “The analyses carried out by the DGCCRF showed that 39 % of the 74 food products analyzed (confectionery, pastry decorations, spices,..) contain nanoparticles”<sup>15</sup>. The presence of nanoparticles was hardly mentioned on the labeling.

The public administration acts at the request of the respective Ministry. Regarding its *patterns of actions*, the DGCCRF ensures the quality that consumers are entitled to expect from a product - food or non-food - or a service. It investigates and observes infringements and breaches of consumer protection rules (e.g. false advertising) and checks that the rules on price advertising are properly applied. Information diffused on the web (as for example all regulatory text for additives) and in publications is also a way to enhance consumer protection. Regarding consumer security, the DGCCRF operates on all products, both food and industrial, and at all levels (production, import, distribution), as well as on services. At European level, the dangerousness indices of products communicated by the Member States of the European Union are followed, and companies are monitored to ensure that their actions comply with regulations. In the event of non-compliance, the DGCCRF implements coercive action that begins with the injunction to bring labels into compliance and may go as far as the imposition of penalties.

The DGCCRF interacts with professional organizations to inform them about new regulations and controls companies to ensure that these are enforced. It also interacts with agencies and NGOs in terms of exchange of information (IPA).

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#### Organizational Routines based on the Regulation Principle

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Situated routines	Pattern of action	Interaction of routines
Tests on the content and labeling of food products	Investigations and observation of infringements Publication of information and of reports	Information exchanges with regulatory agencies, NGOs and with professional organizations Compliance monitoring towards companies

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#### 4.3. Public decision-making: the role of compromise and discussion on its implications

The French decision to suspend the use of E171 appears to be a compromise between the main stakeholders' positions, here studied through their organizational routines (see Fig. 3). This compromise appears to be mainly based on the questioning principle (academic works) and the precautionary principle (NGOs). The academic works questioned the scientific opinions published by EFSA on E171 and the media coverage of their results justified the precautionary principle argument.

However, the compromise is not stabilized; E171 is only suspended in France for one year. The justification for this is that France is not allowed to ban E171; this kind of decision is taken at the European level. We recall that risk governance is based on a separation between risk assessment (based on the work of regulatory agencies) and risk management (decision-making) (Millstone, 2009). The French Order suspending E171 was notified to the European Commission on April 26th 2019. The Summary Report of the Standing Committee on plants, animals, food and feed held in Brussels on May 13th 2019 mentions that “all the Member States highlighted the importance of keeping harmonized rules for food additives in the Union and therefore the relevance of reaching a common position with respect to the French measure on E171. They also indicated that the advice of EFSA (the risk assessor) on the safety of titanium dioxide as a food additive should serve as a reference”<sup>16</sup>. New scientific opinions by EFSA will be provided, based on additional toxicological data which is currently being generated (in particular with respect to reproductive toxicity, including developmental neurotoxicity and developmental immunotoxicity, and carcinogenicity). A vote is expected to take place at a later date on the extension, repeal or amendment of the French measure.

Meanwhile, as recalled by *veille.nanos.org*, several European NGOs have questioned their respective governments about the risks and uncertainties that the use of E171 pose to the future of human health (in Belgium, Italy, Netherlands, Germany, Spain). A petition

<sup>15</sup> [https://www.economie.gouv.fr/files/files/directions\\_services/dgccrf/presse/communique/2018/cp-298-Bruno-Le-Maire-reuni-cnc.pdf](https://www.economie.gouv.fr/files/files/directions_services/dgccrf/presse/communique/2018/cp-298-Bruno-Le-Maire-reuni-cnc.pdf)

<sup>16</sup> [https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com\\_toxic\\_20190513\\_sum.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_toxic_20190513_sum.pdf)

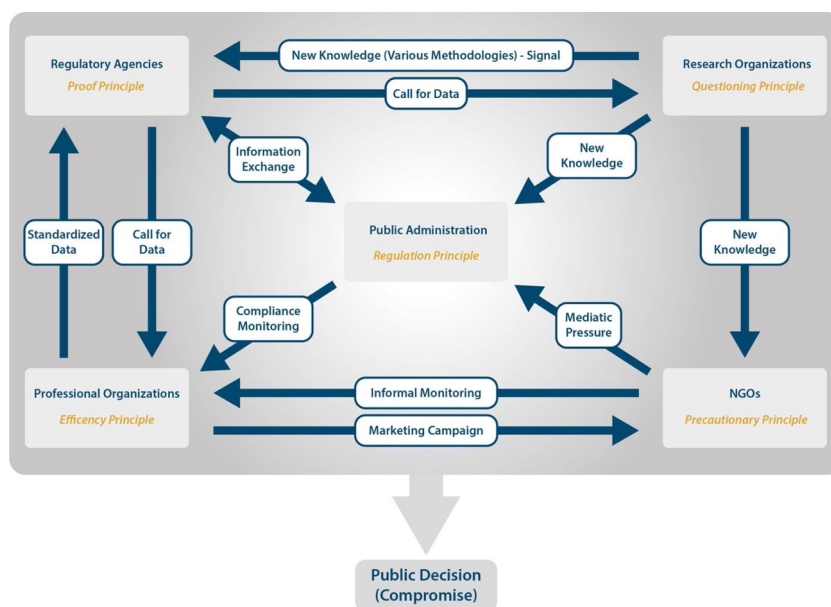


Fig. 3. Map of the controversy on E171 in France (source: authors).

launched by the NGOs Safe and other NGOs asking for a ban on E171 at the European level gathered more than 80,000 signatures in November 2019. For their part, some professional organizations (from Germany or Sweden) are opposed to the French decision to reduce or ban the use of this additive. In France, ANIA considers that “this national decision, which is not in line with EFSA’s recommendation to wait for additional opinions to assess the risk, undermines the European harmonization principle and the fundamentals of risk management in Europe” (IP1).

The uncertainties that weigh on health are largely related to the nanoparticles that could be contained in E171. E171 is therefore part of the more general debate on the regulation of risks related to nanotechnologies. At the European level, a European scale regulatory policy for nanotechnology risks has been developed since 2004 (Justo-Hanani & Dayan, 2015), which led to the European definition of nanomaterials (see Note 3). However, in the agro-food sector, according to the INCO Regulation (EU no 1169/2011), the identification of a nanomaterial is stricter without any notion of threshold. This creates significant uncertainty for manufacturers: “On the one hand (according to INCO), as soon as a nanometric form is present in the food chain, the product in question must be discarded. But they can also consider that they are not subject to this obligation, if there are less than 50 % nanoparticles (according to the European definition)” (IR1). Finally, regarding nanomaterial in food (as in other products), there is an effect of transfer of responsibility from manufacturers and governments to consumers, who are however less aware of the risks (Lacour, 2016).

Uncertainties also concern scientific work. Current research is not yet clear whether the health effects of E171 identified in recently published studies are related to the dose of ingested nanoparticles or to particle size. Similarly, knowing whether the impacts are associated with nanoparticles or with the chemical characteristics of E171 is also not a question for which researchers have provided definitive answers (IR1). All of these uncertainties show that this controversy is still an ongoing one.

Innovation, especially technological, has long been considered as a solution to major economic, social and environmental challenges like competitiveness, well-being, health and climate change (Joly, 2017). However, the use of technological innovation is not neutral and induces potentials risks, which impose scientific expertise. As shown in this paper, scientific expertise benefits from its democratization, based on the participation of various stakeholders. They develop antagonistic positions based on their organizational routines. Antagonism can be considered as a resource that feeds the debate and a process which enriches the analysis of positive and negative impacts of technologies (Bellion & Robert-Demontrond, 2020). This illustrates the necessity for public policy to analyze controversies, since they define the field of possibilities of the use of technologies. This analysis is particularly important for policies in the sectors of food and of healthcare, which are intertwined. Taking the measure of the emerging health risks associated to the use of food additives containing nanoparticles can help to define adapted policies to avoid burdening healthcare systems in the future, by greatly increasing the costs related to the care of potential patients. Similarly, a better understanding of the controversies may lead to the development of incentives for manufacturers to change their organizational routines to produce healthier food products.

## 5. Conclusion

Our research shows that the controversy on the food additive E171 emerged and developed when evidence of its nanoparticle content was highlighted and has crystallized around the risks that nanomaterials pose to human health. This validates our hypothesis 1. Our second aim was to better understand the position of each stakeholder in the controversy. Our research allows us to validate

hypothesis 2, which assumed that controversy could be defined as a confrontation of stakeholders' organizational routines. The analysis of stakeholder interactions contributes to better understanding how positions are forged and transformed. It also allows us to understand public decision-making, i.e. the suspension in France of E171. Indeed, the French public decision to suspend the use of E171 was a compromise between all the stakeholders' positions, where the questioning and precautionary principles play a major part (hypothesis 3 is validated).

The first contribution of this article is to lead to a better understanding of the ongoing controversy about E171, but it also results in the proposition of new way of analyzing controversies, as a confrontation of organizational routines. Indeed, the literature on controversies highlights the role of actors, without going deeper in the analysis of their behavior. Combining the sociological approach of controversies with the analysis of organizational routines allowed us to understand their behaviors and how they are shaped by their interactions with others. It thus contributes to better "sensemaking" at the interorganizational level. Sensemaking is usually defined as a social process during which members of an organization interpret their environment in and through the interactions with others, thus constructing observations that allow them to comprehend the world around them and to act collectively. This process is often studied at the level of an organization and used in decision-making in a context of future uncertainties (Dortland, Voordijk, & Dewulf, 2014). Our approach thus contributes to another way of analyzing the sensemaking process in inter-organizational routines. It can be useful to actors in charge of risk assessment and management. Moreover, the analysis of the emergence of controversies between stakeholders and the management of such controversies about this topic can provide insights for orienting the sense-making and the debates within the healthcare and the food sector.

Our work also contributes to research on dynamic routines, which so far have focused on how routines are created, changed or sustained over time. As stated by Howard-Grenville, Rerup, Langley, and Tsoukas, 2016(p.19), the challenge for scholars is now "to attend, empirically and conceptually, to interactions between routines in an 'ecology', that is, the idea that no routine is ever enacted in a vacuum of other routines". Our work, especially studying the interactions between routines, enriches literature and shows that routines are surrounded by and entangled with other routines.

A first limitation of our work lies in the fact that we focused on the French case, where the controversy erupted in 2017/2018. The next steps of our research will thus be to compare the French position with other European countries. Studying the next stages of the controversy will allow us to highlight and compare the arguments and organizational routines of different stakeholders in different countries. This will make it possible to identify (or not) different forms of governance of technological risks related to health among European countries. Another limitation is that the material we have gathered did not allow us to detail the behavior of companies. Our aim is to understand the impact of the decision taken (on the particular date in France) on their innovation trajectory and the creation of their knowledge capital (Laperche, 2017). Further research and new interviews will provide new elements on the evolution of the firms' strategies (new recipes, new substitutes), and the incentives and barriers relating to such change. Future developments will also consist in studying the evolution of regulations about the other uses of TiO<sub>2</sub> for example in medicines and cosmetics. As a matter of fact, we can consider that the current controversy on the E171 will also concern this form of TiO<sub>2</sub>. Companies from the healthcare sector could then be affected in the near future if the risk of ingestion of this form of TiO<sub>2</sub> is confirmed and could have to change the composition and in particular the coating of medicines. They could learn from the behavior of companies from the food sector in the current step of this ongoing controversy. We will also apply this framework of analysis to other food additives which are the subject of a controversy, like E250 (sodium nitrite) and E252 (potassium nitrate), used as preservatives. This will allow us to understand whether the connections between actors of the controversy are of the same nature and to improve our analytical framework.

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