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Food Safety Policy in a time of technofoods: risk, governance and legal issues relating to nanofoods

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1. THE LEGAL BASIS OF FOOD SAFETY POLICY

On reading the information supplied by the European Commission Directorate-General for Health and Consumers (DG SANCO),¹ one could (at least, in jest) present the long list of topics covered by Food Safety Policy as follows:²

A stone, two houses, three ruins, four gravediggers, a flower garden, a raccoon, a dozen oysters, a lemon, bread, a ray of sunshine, a groundswell, six musicians, a door with her mat, a gentleman decorated with the Légion d’Honneur, another raccoon .

Food Safety Policy is indeed directed to diverse fields of application, such as: foodstuffs; veterinary checks; food hygiene; traceability; genetically modified organisms (GMOs); animal nutrition, welfare and health; and plant health. And, to continue the Prévert-style inventory, the various fields of application may themselves be broken down into their constituent parts: for example, the regulation of foodstuffs encompasses, *inter alia*, organic products, geographical indications and designations of origin, food information to consumers and food labelling.

Moreover, under the same heading of Food Safety Policy may be employed a broad sweep of measures which are different both in their nature and in their scope, including principles or standards, procedures (which may be of great complexity), framework legislation and detailed rules. Moreover, it is often difficult to unravel what exactly are the principles which form the foundation of judicial interpretation and what exactly is the guidance given to Member States when implementing EU legislation. It is also often a delicate matter to make the necessary links and cross-references between legislation.³

¹ Part of the list may be found at http://ec.europa.eu/food/site_map_en.htm.

² The authors’ translation of an extract from J. Prévert, ‘Inventaire’, in *Parole* (Gallimard, First published 1946, Folio 2007) 208–10: ‘[u]ne pierre, deux maisons, trois ruines, quatre fossoyeurs, un jardin des fleurs, un raton laveur, une douzaine d’huitres, un citron, un pain, un rayon de soleil, une lame de fond, six musiciens, une porte avec son paillason, un monsieur décoré de la légion d’honneur, un autre raton laveur ...’.

³ For example, by reason of its earlier enactment, the Novel Food Regulation (Regulation (EC) 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, [1997] OJ L43/1) is not clearly linked to the Food Law Regulation (Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying

But one should not be deceived: despite the wide range of measures and their diversity, it would not be correct to speak in this context of legal chaos and disorder. The first reason is that European Food Safety Policy is closely bound up with meeting the key objective clearly laid down in the Food Law Regulation, namely to assure consumers that what they are eating presents no danger to health: ‘[t]he EU integrated approach to food safety aims to assure a high level of food safety, animal health, animal welfare and plant health within the European Union through coherent farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market’.⁴ The second reason flows from the fact that Food Law, and with it Food Safety Policy, has become a separate legal discipline whose precise contours are in the course of development. Albissini has shown how progressively the rules of Food Law have acquired their own independence and structure.⁵ More specifically, he has identified three stages in this process: the separation of food policy from the Common Agricultural Policy (CAP); the intervention of the judiciary, who have laid down guidelines relating to foodstuffs since *Cassis de Dijon* in 1979;⁶ and, finally, legal initiatives which have been prompted by food safety crises (such as those relating to Bovine Spongiform Encephalopathy (BSE) and Dioxin) and the *White Paper on food safety*.⁷

On these grounds, it is possible to affirm that European Food Safety Policy forms a significant constituent of European Food Law and that it henceforth falls under the umbrella of the same horizontal measures which seek to define the relevant legal principles and their monitoring and the provision of information to consumers,⁸ with these horizontal measures being complemented by specific regimes and/or derogations.⁹

down procedures in matters of food safety, [2002] OJ L31/1). However, this will be remedied in the future: European Commission, COM (2013) 894, *Proposal for a regulation of the European Parliament and of the Council on novel foods*.

⁴ See European Commission, *Health and Consumers: Food – Overall Mission* (available at http://ec.europa.eu/food/intro_en.htm). See also Food Law Regulation, (above n 3) Articles 1 and 5; and TFEU, Article 168: ‘[a] high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities’.

⁵ For an historic perspective, see, e.g., F. Albissini, ‘The Path to the European Food Law System’, in L. Costato and F. Albissini (eds.), *European Food Law* (CEDAM, 2012) 17.

⁶ Case C-120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* [1979] ECR 649.

⁷ European Commission, COM (1999) 719 (which introduced, in particular, the ‘from farm to table’ approach).

⁸ See, e.g., Food Law Regulation, (above n 3); Regulation (EC) 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, [2004] OJ L165/1; and Regulation (EC) 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, [2011] OJ L304/18 (Food Information Regulation).

⁹ For example, Novel Food Regulation, (above n 3); and Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, [2003] OJ L268/1. A French initiative has divided this area into six categories: (1) the basic rules (such as those which govern monitoring); (2) the rules applicable to food additives and processing aids; (3) the rules applicable to biotechnology (whether general in their application or specifically directed to GMOs); (4) the rules governing information to consumers and nutrition and health claims; (5) the rules applicable to quality indications; and (6) the rules which cover specific foodstuffs: see F. Collart Dutilleul and P. Nihoul (eds.), *Code de Droit Européen de l’Alimentation* (Bruylant, 2012).

2. TECHNOFOOD AND RISK

All these rules engage a common issue: the risk of injury to health.¹⁰ And this risk is exacerbated by the fact that the foodstuffs in question are derived from complex technological processes involving new scientific knowledge. In other words, Food Safety Policy, like so many socio-political phenomena today, must be adapted to the acceleration in scientific innovation,¹¹ in a context where the contribution of science to the human good is often contested.¹² This implies a constant reinterpretation of the regulatory regime; and one could thus argue that the sea-change in scientific knowledge has led to, and continues to lead to, a sea change in the law.¹³ In the realm of Food Safety Policy, big questions have therefore emerged: how to make decisions when there is a risk, on what basis and by whom? Such questions have given rise to incomplete answers in terms of both the analysis and governance of risks from foodstuffs; and it is this uncertainty which will be the focus of the chapter, with reference to Table 17.1.

¹⁰ See, e.g., the Food Law Regulation, (above n 3) Article 3(9): “‘risk’ means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard’.

¹¹ On the acceleration of scientific innovation and the need for adaptation of the law, see, e.g., M. Delmas-Marty, ‘L’Ambivalence des Nouvelles Technologies’, in E. Vergès (ed.), *Droit, Sciences et Techniques: Quelles Responsabilités?* (Lexis Nexis, 2011) 3–4.

¹² On the question of ‘speaking truth to power’, the initial basis of the contribution of scientific experts to the decision-making process, see, e.g., M. Tallacchini, ‘La Construzione Giuridica dei Rischi’, in G. Comandé and G. Ponzanelli (eds.), *Scienza e Diritto nel Prisma del Diritto Comparato* (G. Giappichelli Editore, 2004) 340.

¹³ Sheila Jasanoff often refers to parallel advancement of science and law: see, e.g., *The Fifth Branch: Science Advisers as Policymakers* (Harvard University Press, 2009) 6. Sometimes, however, the law appears to lag behind, but this should not necessarily be taken as a lacuna in or failure of the law, in that there remains scope for judicial activism.

Table 17.1 Food safety and technofood

FOOD SAFETY and TECHNOFOOD				
MAJOR UNCERTAINTIES ON HEALTH RISKS		Development of Science: Rapidly increasing scientific and technological knowledge Limitations of science		
GOVERNANCE Multi-actor Multi-scale		Changes to EU Law: More horizontal More procedural than substantial Less traditional regulation		
Who?	What is in the Law?			Main Issue
EU/Member States	EU and national law EU and national decisions	Prior authorization/positive lists/substantial equivalence	Mandatory information and labelling	Risk analysis (science-based and other factors)
			Rapid alert system	
		Control	Emergency measures: precautionary principle	
Scientists	Scientific risk assessment	Independent experts	Transparency of assessment and results	Validated science
Businesses	Self-regulation	Self-assessment, monitoring and control	Good practices	Disguised 'command and control'
Public	Participation	Consultation	Information	Level of participation Civil disobedience leading to paralysis of formal law
International Organizations	Harmonization	Standards (Codex Alimentarius etc.)	Certification: ISO	Disguised 'command and control'

2.1 Technofood and Risk Analysis

The anticipation of risks from the ingestion of food lies at the heart of Food Safety Policy and all the legal measures are directed to reducing or at least controlling such risks in order to assure consumers that what they eat will not cause them harm.¹⁴ In this context, EU law is so constructed as to provide a concrete guarantee of risk assessment (namely, the evaluation of any risks), risk management and risk communication.¹⁵

Such an approach is relatively effective when the risks at issue are known and capable of detection. In these cases, under Food Safety Policy, there is a commitment to risk prevention, namely avoiding the presence or development of the agents whose effects have been identified and recognized as harmful to human, animal or plant health. However, the position is not always so simple. Food Safety Policy also responds to unknown risks encountered in crises, those coming out of the blue and those considered remote or which may lurk concealed in some corner of science. The position is even more difficult where the source of the risk is to be found in something of such complexity as ‘technoscience’,¹⁶ with its inextricable mix of science and technology.¹⁷ This uncertainty is graphically illustrated by biotechnology and, in particular, GMOs. Whether they create risk at all has been considered controversial,¹⁸ with various research reports on their effects repeatedly contradicting each other;¹⁹ and this pattern looks likely to be followed

¹⁴ It may be recalled that, under Article 14(1) of the Food Law Regulation, (above n 3), ‘[f]ood shall not be placed on the market if it is unsafe’.

¹⁵ See *ibid.*, Article 3(10): “‘risk analysis’ means a process consisting of three interconnected components: risk assessment, risk management and risk communication”; Article 3(11): “‘risk assessment’ means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation”; and Article 3(12): “‘risk management’ means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options”; and Article 3(13): “‘risk communication’ means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions’. On this topic, see generally, e.g., P. Nihoul and S. Mahieu (eds.), *La Sécurité Alimentaire et la Réglementation des OGM : Perspectives Nationale, Européenne et Internationale* (Larcier, 2005); and S. Mahieu and K. Merten-Lentz (eds.), *Sécurité Alimentaire: Nouveaux Enjeux et Perspectives* (Bruylant, 2013).

¹⁶ On this concept, see, e.g., B. Makanga, *Nature, Technosciences et Rationalité* (L’Harmattan, 2012) 150–61.

¹⁷ See, e.g., R. Marc, ‘Un Modèle Parfait de Technoscience’, in C. Lafontaine (ed.), *Nanotechnologie et Société* (Boréal, 2010) 79.

¹⁸ For a legal discussion, see, e.g., K. Morrow, ‘Genetically Modified Organisms and Risk’, in L. Bodiguel and M. Cardwell (eds.), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (Oxford University Press, 2010) 54.

¹⁹ Contrast, e.g., C. Snell, A. Bernheim, J.-B. Bergé, M. Kuntz, G. Pascal, A. Paris and A.E. Ricroch, ‘Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: a literature’, (2012) 50 *Food and Chemical Toxicology* 1134 and G.-E. Séralini, E. Clair, R. Mesnage, S. Gress, N. Defarge, M. Malatesta, D. Hennequin and J. Spiroux de Vendômois, ‘Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize’, (2011) 50 *Food and Chemical Toxicology* 4221 (retracted and republished at (2014) 24 *Environmental Sciences Europe* 14).

in the case of nanotechnologies and nanofoods, which as yet are relatively unknown to the general public.²⁰ In the words of Stokes:²¹

We are still at the stage when there is some evidence to indicate the potential for hazard but it is too early to say with any degree of precision how this translates into risk. The problem extends beyond one of a lack of information; it is also unclear that the methods currently used to characterize and assess the potential health and environmental effects of nanotechnologies are fit for purpose.

But the debate is undoubtedly wider, extending beyond genetically modified (GM) foods and nanofoods. Indeed, we could argue that there is a greater risk factor in the case of all ‘technofoods’, which one could define as foodstuffs which have been subjected to an innovative and complex technological process whereby their structure or composition may have been modified and where the consequent risks on health (and the environment) either have not yet been definitively determined or remain subject to scientific or societal debate.

Faced by such uncertainty,²² where doubt dominates to the extent that one can legitimately ask whether there can be accommodation by the law,²³ it is well known that the legal approach adopted by the EU is the precautionary principle.²⁴ In the food context, this finds expression, for example, in the Food Law Regulation itself (both as a general principle and in the information network and alert system),²⁵ in the assessment procedures for specific products,²⁶ and in ‘safeguard clauses’ authorizing temporary measures on the basis of new or additional scientific information (with these having special resonance in the case of GMOs and novel foods).²⁷

In practice, the approach inherent in the precautionary principle is not to ban the production of a foodstuff when there is a potential risk to health, but rather to determine whether the level of risk considered to be acceptable for society has been exceeded, so prompting its management by the public authorities.²⁸ In this regard, it may be highlighted

²⁰ Agence Nationale de Sécurité Sanitaire de l’Alimentation, de l’Environnement et du Travail (ANSES), *Évaluation des Risques Liés aux Nanomatériaux: Enjeux et Mise à Jour des Connaissances* (2014) (available at <http://www.anses.fr/>).

²¹ E. Stokes, ‘Demand for command: responding to technological risks and scientific uncertainties’, (2013) 21 *Medical Law Review* 11, 20.

²² See, e.g., N. de Sadeleer, *Environmental Principle: From Political Slogans to Legal Rule* (Oxford University Press, 2002) 91; A. Di Lauro, ‘Scienza, tecnica e diritto agrario’, (2007) *Rivista di Diritto Agrario* 576; and I. Canfora, ‘Le informazioni scientifiche agroalimentare tra disciplina legale e autonomia privata’, (2007) *Rivista di Diritto Agrario* 643.

²³ Di Lauro, (above n 22).

²⁴ However, in the TFEU, express reference to the precautionary principle is made only once, in Article 191 (under the Environment title); and the Court of Justice of the European Union has been reluctant to recognize it as a general principle of EU law: see, e.g., N. de Sadeleer (ed.), *Implementing the Precautionary Principle: Approaches from the Nordic Countries, the EU and USA* (Earthscan, 2007).

²⁵ Food Law Regulation, (above n 3) Articles 7, 35–6 and 50–54.

²⁶ See, in particular, Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, [2001] OJ L106/1, Article 1 and Annex II-B.

²⁷ See, e.g., *ibid.*, Article 23; Regulation 1829/2003, (above n 9) Article 34; and the Novel Food Regulation, (above n 3) Article 12.

²⁸ This is well illustrated by Case C-601/11 P *France v Commission* (Judgment of 11 July 2013, European Court Reports 2013-00000, ECLI identifier: ECLI:EU:C:2013:465). See also D. Gadbin, ‘Principe de précaution et assouplissement des mesures à prendre en

that the acceptability of the risk is not defined by law in any general or abstract manner, but by the authorized body under the terms of the relevant legislation (with this often in the final instance being the Commission).²⁹ Consequently, the jurisprudence of the Court of Justice of the European Union (CJEU) reflects the idea that ‘zero risk’ does not exist: the law allows risks to be taken so long as they are acceptable according to the criteria of the moment.³⁰

This issue of the acceptability of risk is the more resonant in the context of ‘technofoods’, since the opaque process and inaccessibility of the science involved takes them into the realm of alchemy and exacerbates fears. Further, food crises (such as BSE, Dioxin and ‘Horsegate’) and failures in medical technology (such as PIP (Poly Implant Prothèse) implants) have destroyed the quasi-religious belief in science which had held sway since the Age of Enlightenment, calling into question the capacity of the traditional public decision-makers to manage such situations. These peculiar sensitivities relating to ‘technofoods’ will now be examined.

2.2 Technofood and the Governance of Risk

Here is not the place for a general examination of the governance of risk. Eminent authors have written learned works on the subject, including the regulation of the risk and technology.³¹ We wish rather to focus on specific points which, in our view, should operate as lighthouses sending out their beams to sea, illuminating the way for the law so that sight is not lost of the democratic will amid the fog – and siren voices – of nanofoods. Accordingly, this chapter will be directed to: first, the question of public participation; and, second, the adoption of a ‘science-based’ approach. And, in any event, it is readily appreciable that in the context of technofoods, steeped in complexity and pregnant with risk, any discussion of governance must be conducted with delicacy.

présence d'EST chez les ovins et caprins’, (2014) 419 *Revue de Droit Rural* 12–16. See also Canfora, (above n 22) at 649.

²⁹ See again, by way of illustration, Case C-601/11 P *France v Commission*, (above n 28).

³⁰ For discussion by the CJEU of the impossibility of ‘zero risk’, see, e.g., Case T-13/99 *Pfizer Animal Health SA v Council of the European Union* [2002] ECR II-3305.

³¹ See generally, e.g., C. Noiville, *Du Bon Gouvernement des Risques. Le Droit et la Question du Risque Acceptable* (PUF, 2003); and see also, more particularly, e.g., M.-A. Hermitte, ‘La nature du Projet de Coexistence entre Filière OGM et Filière non-OGM: Pluralisme Technologique et Liberté du Commerce et de l’Industrie’, in *Cahiers Droit, Sciences et Technologie, Dossier Thématique Droit et Nanotechnologie*, No. 1 (CNRS, 2008) 179 (who argues that the debate on coexistence is not susceptible of any easy resolution so long as the science remains contested); M. Lee, ‘Multi-level Governance of GMOs in the European Union: Ambiguity and Hierarchy’, in Bodiguel and Cardwell (eds.), (above n 18) 101; and Stokes, (above n 21).

2.2.1 Governance, acceptability and the public

When a decision can lead to the creation of risk (notably, a risk to health), the participation of civil society is considered central to the successful accommodation of social issues and the proper application of the law,³² so promoting the social acceptability of the decision.³³ As to how best to incorporate the public into the decision-making process, we will suggest two ways forward.

In the light of extensive experience, public participation is a process which may be both lengthy and costly, which is understood (in principle) to provide groups of individuals with the means to contribute to, or even to take, a decision freely. Both juries composed of members of the public and focus groups may provide genuine illustrations of this participation at work, with particular reference to the governance of GMOs.³⁴ However, the law does not go very far. By way of illustration, the Food Law Regulation does seek to promote principles of transparency through public consultation and public information.³⁵ Yet, analysis of more detailed provisions such as the consultation rights provided under Article 9 of the Deliberate Release Directive reveals that they have limited effect.³⁶ Consequently, there is an element of paradox in the manner in which the intervention of civil society is comprised within the decision-making process: participation does indeed form part of the legislative framework, but the detailed provisions accord to the general public only limited access. In other words, civil society is essentially a spectator, at least in the context of GMOs. And, more generally, the public is not a true actor on the stage of technofoods.

However, what is not delivered by legislative process can be obtained by the public in its own way, outside or even contrary to that process. Thus, as is well known, in several Member States, civil disobedience movements have become so successful that they have almost joined the ‘mainstream’,³⁷ with mass rejection of GM foods provoking a virtual paralysis of the law as Member States seek through recourse to moratoria to align their national stance with their ‘public opinion’. Although these moratoria may not formally be legal,³⁸ they enjoy a ‘legitimacy of fact’ which could perhaps be categorized as ‘participative’. And, while there can be no hard and fast proof that the development of

³² See, e.g., Noiville, (above n 31) 120 (who argues that it is through the prism of debate that a law acquires its legitimacy).

³³ These ideas have been developed in large part by Jasanoff, who refers to the need to incorporate ‘a socio-politically coloured judgment about the acceptability of risk’: Jasanoff, (above n 13) 232.

³⁴ See, e.g., P.-B. Joly, C. Marris and M.-A. Hermitte, ‘À la Recherche d’une “Démocratie Technique”’. Enseignements de la Conférence Citoyenne sur les OGM en France’, (2003) 11 *Nature Science Société* 3; P. Roqueplo, D. Donnet Kamel and D. Boy, ‘Un exemple de démocratie participative: la “conférence de citoyens” sur les organismes génétiquement modifiés’, (2000) 50 *Revue Française de Science Politique* 779.

³⁵ Food Law Regulation, (above n 3) Article 9 (on public consultation) and Article 10 (on public information).

³⁶ See, e.g., L. Bodiguel and M. Cardwell, ‘Genetically Modified Organisms and the Public: Participation, Preferences, and Protest’, in Bodiguel and Cardwell (eds.), (above n 18) 11.

³⁷ L. Bodiguel, ‘Conclusion’, in Bodiguel and Cardwell (eds.), (above n 18) 375; L. Bodiguel and M. Cardwell, ‘Les juridictions pénales britanniques et françaises face aux Anti-OGM: au-delà des différences, une communauté d’esprit’, (2011) *Revue Juridique de l’Environnement* 267; and L. Bodiguel, ‘Droit des OGM: contestations ardentes, tiède réforme’, (2012) 554 *Revue du Marché Commun et de l’Union Européenne* 51.

³⁸ See, e.g., Case C-165/08 *Poland v Commission* [2009] ECR I-6843.

these movements is a consequence of the absence of a true participatory system, the absence of such a system does at least strengthen the argument to that effect.

2.2.2 Governance, complexity and science

Confronted by these sensitive and complex issues whose consequences are of fundamental importance for society, the political decision-maker is often ill-equipped to unravel their implications, understand their risks and, ultimately, take a decision. Accordingly, assistance must be sought from experts in technofoods (whether specialists or generalists), who can intervene in the public process through advice and guidance. For some, this institutionalization of governance is regarded as legislative capture by the sole guarantor of the public interest, namely the state. In calmer tones, one could question, as Bellivier and Noiville, the degree of autonomy enjoyed by politicians when confronted with a plethora of agencies and assessment procedures.³⁹ This is the more so when there is a shift in at least ‘the rules of game’ such that it is the ‘all-knowing’ experts who may guide the decision – or even lay down the decision (a sort of ‘scientist advise and command system’). In any event, much weight is being placed on the ‘science-based approach’,⁴⁰ fostered throughout world trade regimes,⁴¹ and much contested in the context of GMOs. Moreover, some measures, whether for considerations of efficiency and pragmatism or to enhance corporate responsibility,⁴² advance self-regulation by enterprises in the technofood sector (a sort of ‘corporation advise and command system’); and yet this form of governance of risk can disguise a delegation of power and control to non-state entities, which does not accord well with the idea of a democratic society where the only formal sources of law are parliament, the executive and the judiciary.

To take a stark hypothetical example, already entertained by numerous scriptwriters,⁴³ one could imagine circumstances where the formal sources of law in the technofood sector are replaced by a ‘pragmatic’ model which emphasizes the incompetence of the public decision-makers and under which ‘experts’ as well as their economic allies (such as life-science companies) effectively take control. Democracy would become a ‘technocracy’, not in the administrative or bureaucratic meaning of the word, but in the sense that those who owned the technology would have the power. More realistically, in legal terms such an eventuality is unlikely. Even if the traditional development of the law is disturbed by these new technologies, it would not appear that its formal legitimacy is called into question.⁴⁴ In addition, the long-established role of executive power would seem to be maintained: to date, for example, it is the executive which has the final say as to the acceptable level of risk in the case of EU authorizations

³⁹ F. Bellivier and C. Noiville, ‘Jeux d’Acteurs, Jeux de Miroirs, Comment Prendre une Décision Politique Responsable?’, in Vergès (ed.), (above n 11) 15–19.

⁴⁰ See, e.g., Food Law Regulation, (above n 3) Article 6(2): ‘[r]isk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner’; Article 6(3): ‘[r]isk management shall take into account the results of risk assessment ...’; and Article 7(1): ‘[i]n specific circumstances ... provisional risk management measures ... may be adopted, pending further scientific information for a more comprehensive risk assessment’.

⁴¹ L. Bodiguel, ‘Genetically Modified Organisms’, in F. Collart Dutilleul (ed.), *Legal Dictionary of Food Security in the World* (Larcier, 2013) 197–203.

⁴² Food Law Regulation, (above n 3) Articles 17–21.

⁴³ See, e.g., F. Bourgeon and C. Lacroix, *Le Cycle de Cyan* (Casterman, 1993).

⁴⁴ Stokes, (above n 21): ‘[t]his is not to say that the role of the state, or indeed of hierarchy, has become obsolete; rather that regulation need not always involve state action’ (at 18).

for the growing of GM crops or the marketing of GM foods, with the strength of its decision being bolstered by the fact that the research upon which it relies is as independent as possible (being conducted by the European Food Safety Authority (EFSA)).⁴⁵ It would be different if the Member States relied only on the studies conducted by the applicants or if there was a requirement that the final decision must comply with the advice of EFSA.⁴⁶

The ‘science-based’ approach may therefore appear somewhat ‘Janus-like’: one face proposes a legal regime which permits the decision-makers to legislate without forcing them into a techno-scientific discourse; and the other proposes a ‘regime change’ to the benefit of those with greater knowledge and, possibly, greater power. In either case, the role for the public is circumscribed. As for technofoods (with nanofoods and GMOs to the fore), this constant ambiguity is of considerable importance, since only a limited number of companies have the requisite ‘know-how’ (based upon their patents and investment capacity) and these companies enjoy an economic and social power which exceeds that of some European states.⁴⁷ To give them the chance effectively to make law would be a major failure in our democratic system. The key issue therefore is the control of these ‘deregulated powers’; and it is not clear that careful research into flexible modes of governance and ‘soft law’, as suggested for the EU in the field of nanotechnologies,⁴⁸ would be the best option for the management of both health risks and political risk.

⁴⁵ Food Law Regulation, (above n 3) Article 22(2). On the other hand, this notion of independence is without doubt an ideal theoretical construct by reason of the relationship between those who conduct research into new technologies and the companies which finance them. Thus, EFSA (as is the case with other scientific institutions) has been criticized for the link between some of its members and companies submitting applications: see, e.g., Report from Corporate Europe Observatory, *Unhappy Meal: The European Food Safety Authority’s Independence Problem* (2013) (available at http://corporateeurope.org/sites/default/files/attachments/unhappy_meal_report_23_10_2013.pdf).

⁴⁶ It should be emphasized that law can create a relatively balanced system, but at any time government may upset that balance. Thus, in the context of GMOs, the quasi-systemic inability of the Members of the Council to reach a decision on authorizations has historically had the effect of granting competence to the Commission (which is arguably more sensitive to issues of free trade and commercial development).

⁴⁷ A graphic illustration of such power has been the ‘Monsanto Protection Act’ in the United States.

⁴⁸ Stokes, (above n 21): ‘[i]t would also seem preferable, given this situation, to temper the rigidity of more traditional governance techniques with a regime that fosters experimentation and knowledge creation, instils greater flexibility and revisability, and allows for more diversity and decentralization’ (at 21).

3. LEGAL ISSUES RELATING TO NANOFOODS

The terms ‘nanoscience’ and ‘nanotechnology’ are often used together to indicate the extent to which research in this area is so closely intertwined with its application; and frequently reference is made in the plural to ‘nanosciences’ and ‘nanotechnologies’ to reflect the fact that there are numerous areas of research and numerous modes of its application. Huge advances are being made in the case of foods; and the inventory of products containing nanomaterials has become ever larger.⁴⁹ Knowledge of the subject is opening the way in the food sector for the development of substances capable, inter alia: of giving the sensation of satisfying hunger; of improving the way in which ingredients combine; and of providing novel forms of material intended to come into contact with food (such as plastic films).

Nanotechnologies are therefore already on our plates,⁵⁰ both by reason that they have been employed intentionally in food production and by reason that they occur as residues from other applications (such as in the chemicals, medical or electronic sectors). Moreover, the whole question of indirect ‘contamination’ by nanomaterials remains relatively unexplored: there has as yet been no serious analysis of the presence of ‘nanoresidues’ in food, or of their being ‘captured’ by animals and plants, or in the soil, the water or the air, where they may come into contact with, migrate to, or be absorbed by humans.⁵¹ However, research into the regimes which govern the intentional use of nanotechnologies in food production leads to a worrying conclusion: we are in an area characterized by both clamour and silence (Section 3.1), with a regulatory framework which is far from perfect (Sections 3.2 and 3.3).

⁴⁹ See, e.g., the recent inventory of the Woodrow Wilson Institute, *Project on Emerging Nanotechnologies* (available at www.nanotechproject.org).

⁵⁰ A. Di Lauro, ‘Les Nanotechnologies dans l’Assiette : Les Règles sur les Nanofoods’, in F. Collart Dutilleul (ed.), *Penser une Démocratie Alimentaire Vol. 2* (INIDA, 2014) 251.

⁵¹ For a general discussion of one of the most studied areas, see M. Carrière and S. Lanone, ‘Que Savons-Nous des Risques Toxicologiques et Écotoxicologiques Liés aux Nanotubes de Carbone?’, in S. Lacour, S. Desmoulin-Canselier and N. Hervé-Fournereau (eds.), *De l’Innovation à l’Utilisation des Nanomatériaux. Le Cadre Normatif des Nanotubes de Carbone* (Larcier, 2012) 17.

3.1 Nanofoods: Clamour and Silence

For some years, there has been a plethora of commissions and working groups on nanosciences and nanotechnologies.⁵² However, at present the debate remains largely ‘off the radar’ of the general public and the measures which have been initiated, especially those based on *soft law*, are often incoherent, full of lacunae and, in all cases, ill-adapted to the management of the uncertainties which are attached to risks generated by the use of nanomaterials.

In addition, there have been warning voices on the theme of ‘nanopoverty’,⁵³ in other words fear that there will be unequal access to the new nanotechnologies in the various regions of the world. Yet, concerns related to differences in levels of knowledge between countries and to the consequences in terms of democracy and food sovereignty⁵⁴ would not appear to have been sufficiently taken into account by governments. Thus, as shown by some European documentation,⁵⁵ the imperative of preserving a technological and competitive edge, and of not falling behind in the development of nanotechnologies, would appear to have trumped all other considerations.

3.2 Nanofoods and the Regulation on Novel Foods

Many would have expected that the emerging phenomenon of nanotechnologies used in the food sector to be covered by the Novel Food Regulation.⁵⁶ The Regulation provides for a prior authorization procedure for the placing on the market of novel foods and novel food ingredients not hitherto used for human consumption to a significant degree within the EU, among which may be found, first, ‘foods and food ingredients with a new or intentionally modified primary molecular structure’; and, second, ‘foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable

⁵² For a preliminary, and incomplete, list of the various reports which have been issued, see, e.g.: European Commission, COM (2004) 338, *Towards a European strategy for nanotechnology*; European Commission, COM (2005) 243, *Nanosciences and nanotechnologies: an action plan for Europe 2005–2009*; Commission Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research, C(2008) 424; European Commission, COM (2008) 366, *Regulatory aspects of nanomaterials*; European Commission, COM (2009) 607, *Nanosciences and nanotechnologies: an action plan for Europe 2005–2009: second implementation report 2007–2009*; and European Commission, COM (2012) 572, *Second regulatory review on nanomaterials*. See also, for national and international reports on ethical issues: Comitato Nazionale per la Bioetica Italiano, *Nanoscienze e Nanotecnologie*, 9 June 2006 (Italy); Comité Consultatif National d’Éthique pour les Sciences de la Vie et de la Santé, *Questions Éthiques Posées par les Nanosciences, les Nanotechnologies et la Santé*, Avis 96, 7 March 2007 (France); House of Lords, Science and Technology Committee, *Nanotechnologies and Food: First Report – Session 2009–2010*, HL 22; and UNESCO, Commission Mondiale d’Éthique des Connaissances Scientifiques et des Technologies, *Éthique de la Nanotechnologie*, Kuala Lumpur, Malaysia, 16–19 June 2009 (available at http://www.unesco.org/new/fileadmin/MULTIMEDIA/HQ/SHS/pdf/Ethique-de-la-Nanotechnologie_FR.pdf).

⁵³ This argument is most directly addressed by the various committees which have examined the ethical questions linked to the development of nanosciences and nanotechnologies: see *ibid*.

⁵⁴ See generally the literature generated by the Projet Lascaux (available at http://www.droit-aliments-terre.eu/pages/menu3/bibliotheque_lascaux.html).

⁵⁵ See, e.g., European Commission, COM (2004) 338, *Towards a European strategy for nanotechnology*, 3.

⁵⁶ S. Rizzioli, ‘Novel Foods’, in Costato and Albissini (eds.), (above n 5) 393.

substances’.⁵⁷ On the other hand, the precise wording of the Novel Food Regulation would not seem adequately to capture nanofoods, at least in so far as it allows the producer a significant role in notifying the Commission of the placing on the market of new products.

Under the proposed reforms of the Regulation, the Commission has provided for the introduction of a specific definition for ‘food containing or consisting of “engineered nanomaterials”’.⁵⁸ On first reading, the European Parliament opted for greater protection, calling for the submission of nanomaterials used in the food sector to new tests, the application of the precautionary principle, the drawing up of a list of nanomaterials which may be used in contact with food and a general labelling obligation for ingredients as ‘nano’. The European Council, although generally favourable to the position adopted by the European Parliament, did not share its enthusiasm for labelling. After a period of conciliation, the proposal was dropped.

3.3 Nanotechnologies and Food Additives

In the food sector, there is already express reference to nanotechnologies in the regime governing food additives.⁵⁹ It is a reference which, in some ways, could be considered satisfactory in that, where a food additive is already included in a Community list and ‘there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology’, then it ‘shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market’.⁶⁰ This provision is more incisive and clearer than one might expect from Recital 13 of the same Regulation, whose rather unfortunate use of the conditional leaves the field open to doubt: thus, in the English version (and the Italian, but not the French which is more affirmative), it is recited that ‘[a] food additive already approved under this Regulation which is prepared by production methods or using starting materials significantly different from those included in the risk assessment of the Authority, or different from those covered by the specifications laid down, *should* be submitted for evaluation by the Authority’. By contrast, the wording of Article 12 is unequivocal. Unlike what happens so often under other regulatory regimes (such as the rules relating to chemicals or materials intended to come into contact with food), in the governance of food additives a bright-line distinction is drawn between nanomaterials and other materials and it is expressly required that the nanosubstance should be submitted to a new authorization procedure, even if the conventional ‘parent’ has already been authorized.

As yet, therefore, it is in the context of food additives that the phenomenon of nanotechnologies finds clearest recognition. And the regulatory regime has become more and more rigorous: the general authorization procedure for not only food additives, but

⁵⁷ Novel Food Regulation, (above n 3) Article 1(c) and (f).

⁵⁸ European Commission, COM (2013) 894, *Proposal for a regulation of the European Parliament and of the Council on novel foods*, Article 2(a)(ii).

⁵⁹ Regulation (EC) 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, [2008] OJ L354/16.

⁶⁰ *Ibid.*, Article 12 (emphasis added).

also food enzymes and food flavourings, as established by Regulation 1331/2008,⁶¹ has since been implemented by Commission Regulation 234/2011;⁶² and now that this latter Regulation is in force, it will not be easy for applicants to demonstrate the safety of their products and to furnish the necessary elements for the risk assessment in light of the great uncertainty which reigns in the field of nanotechnologies and their risks.

Nonetheless, even if the rules governing additives has the ‘nanoworld’ directly in its sights, there are still legislative gaps through which the use of nanotechnologies can slip. In this regard, one may think of the rules governing additives which have already been authorized which are subject to their own procedure (under Regulation 257/2010),⁶³ and also of the difficulties in distinguishing between additives, enzymes and flavourings.

3.4 Nanofoods and the Provision of Food Information to Consumers

It must be emphasized that, notwithstanding its lack of clarity and its imperfections, the Food Information Regulation has attempted a precise definition of ‘engineered nanomaterial’, by reference to dimensions of the order of 100 nm or less.⁶⁴ Further, in a great stride forward, it has established a requirement that the presence of engineered nanomaterials must be clearly indicated on the labelling, with every such ingredient being followed by the word ‘nano’ in brackets.⁶⁵ This legislative initiative is considered appropriate to guarantee transparency and informed choice for consumers, and the Regulation would indeed seem to tend in this direction.⁶⁶

Nevertheless, there are still legitimate questions whether the definition of nanomaterials adopted by the Regulation and the ‘highlighting’ on labels of the presence of nanomaterials can guarantee genuine information for consumers. The inclusion of definitions is not in itself sufficient. The European legislator has accustomed us to see them inserted in regulations to inform users and to create a form of common dictionary for the Member States; and they are also present in other fields of science. Against this background, and notwithstanding that the definition in the Food Information Regulation

⁶¹ Regulation (EC) 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, [2008] OJ L354/1.

⁶² Commission Regulation (EU) 234/2011 implementing Regulation (EC) 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings [2011] OJ L64/15.

⁶³ Commission Regulation (EU) 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives, [2010] OJ L80/19.

⁶⁴ The full definition is as follows: ‘any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale’: Food Information Regulation, (above n 8), Article 2(2)(t). See also Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, [2009] OJ L342/59. These two regimes, while based upon regulations which are clearly very different and follow their own course, are both directed to permitting consumers an informed choice.

⁶⁵ Food Information Regulation, (above n 8) Article 18(3).

⁶⁶ E. Stokes, ‘You are what you eat: market citizens and the right to know about nano foods’, (2011) 2 *Journal of Human Rights and the Environment* 178.

may be far from satisfactory, it does at least constitute an attempt to set parameters which has been matched in few of the other sectors that closely engage with nanotechnologies.⁶⁷ To give a classic example, there is considerable confusion of definition in the field of carbon nanotube production, where genuinely common classifications are yet to be found.⁶⁸

That said, across several areas of activity it is possible to observe a common focus on size and, more precisely, reference to a ‘nanometric scale’. On the other hand, such form of definition (which one could categorize as the ‘lowest common denominator’) is neither very explicit nor generally accepted. In addition, it is certainly insufficient to constitute a valid element in risk management, since other criteria should undoubtedly be taken into account (such as the method of production, form and effect). In sum, to speak only of a ‘nano’ scale turns out to have its limitations, as confirmed by all research undertaken into the risks flowing from nanotechnologies.⁶⁹ And the food sector does not escape this difficulty by establishing a definition which allows many products to slip through the net. In other words, even if the definition in the Food Information Regulation does set boundaries to what constitutes ‘nanotechnology’, it does so at the expense of failing to capture much that is relevant.

Moreover, in the relatively recent report from EFSA, *Guidance on the Risk Assessment of the Application of Nanoscience and Nanotechnologies in the Food and Feed Chain*, it was concluded (in the paragraph specifically addressing the term ‘engineered nanomaterial’) that ‘[i]t is not [the] intention of this ENM Guidance to provide any definitions’.⁷⁰ Further, in the same report nanomaterials are divided into six categories which engage different toxicity testing procedures,⁷¹ with any search for a general definition being abandoned. The difficulties associated with the adoption of a

⁶⁷ EFSA Scientific Committee, *Guidance on the Risk Assessment of the Application of Nanoscience and Nanotechnologies in the Food and Feed Chain* (2011), para 1.1 (available at <http://www.efsa.europa.eu/en/efsajournal/doc/2140.pdf>).

⁶⁸ A.-J. Attias, B. Bartenlian and S. Desmoulin-Canselier, ‘Réflexion Interdisciplinaire sur les Définitions Scientifiques et Juridiques: Application aux Nanosciences, Nanomatériaux et Nanotubes de Carbone – Le Cadre Normatif des Nanotubes de Carbone’, in Lacour, Desmoulin-Canselier and Hervé-Fournereau (eds.), (above n 51) 41.

⁶⁹ *Ibid.*

⁷⁰ See EFSA Scientific Committee, *Guidance on the Risk Assessment of the Application of Nanoscience and Nanotechnologies in the Food and Feed Chain* (2011), para 1.1 (available at <http://www.efsa.europa.eu/en/efsajournal/doc/2140.pdf>), which followed on from EFSA Scientific Committee, *The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety* (2009) (available at <http://www.efsa.europa.eu/en/efsajournal/pub/958.htm>). It should also be observed that, in Recital 16 of Commission Recommendation 2011/696/EU on the definition of nanomaterial, [2011] OJ L275/38, it was stated that: ‘[t]he definition set out in this Recommendation should not prejudice nor reflect the scope of application of any piece of Union legislation or of any provisions potentially establishing additional requirements for those materials, including those relating to risk management’.

⁷¹ EFSA Scientific Committee, *Guidance on the Risk Assessment of the Application of Nanoscience and Nanotechnologies in the Food and Feed Chain* (2011), para 5.2: ‘[t]he toxicity testing strategy is determined by the presence of ENM in the food/feed matrix and if appropriate, by available information on a non-nanoform of the same substance. This toxicity testing strategy is illustrated by six general cases and the toxicity tests are indicated in table 2 and figure 3’; and the six general cases are as follows: Case 1 – No persistence of ENM in preparations/formulations as marketed; Case 2 – No migration from food contact materials (i.e. no exposure); Case 3 – Complete ENM transformation in the food/feed matrix before ingestion; Case 4 – Transformation during digestion; Case 5 – Information on non-nanoform available; and Case 6 – No information on non-nanoform available.

definition are likewise evident in Commission Delegated Regulation (EU) 1363/2013,⁷² which was at once retracted.⁷³

As for improving consumer information so as to ensure informed choice, it is helpful to note that, in light of the large number of identifiable problems in the area (with problems of definition being very much to the fore), it is perhaps somewhat of a surprise that an obligation could be introduced to indicate on labels the presence of nanomaterials. Yet questions arise as to whether the consumer can really benefit from this new information. First, one must bear in mind that the majority of consumers would not read these details: despite the limitations of labelling which have been exposed in the case of GM food,⁷⁴ the legislator has persisted with the same 'solution'. One could therefore say that, unfortunately, consumer protection continues to be associated with the amount of information made available to consumers, on the basis that the appearance on a label of the relevant data in itself constitutes 'understanding'.

Second, it should be observed that the legal regime for nanotechnologies remains substantially imperfect. Several lacunae and gaps have already been identified in this chapter and to these should be added those arising in the context of materials which have contact with food and those arising in the chemical sector under the REACH Regulation.⁷⁵ In all these cases there would seem to be the same difficulties encountered in the Novel Food Regulation, with no specific engagement with technologies 'nano'.

⁷² Commission Delegated Regulation (EU) 1363/2013 of 12 December 2013 amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers as regards the definition of 'engineered nanomaterials', [2013] OJ L343/26.

⁷³ Corrigendum to Commission Delegated Regulation (EU) 1363/2013 of 12 December 2013 amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers as regards the definition of 'engineered nanomaterials', [2013] OJ L346/89. See also European Commission, COM (2012) 572, *Second regulatory review on nanomaterials*.

⁷⁴ A. Di Lauro, 'Nuove regole per le informazioni sui prodotti alimentari e nuovi analfabetismi: Verso la costruzione di una responsabilità del consumatore', (2012) *Rivista di Diritto Alimentare* No. 2, 4; and A. Di Lauro, 'Nanotecnologie e Nanoscienze negli Alimenti: Informazioni ed Incertezze', in Slovak University of Agriculture in Nitra, *Proceedings of the XII World UMAU Congress: Legal Aspects of Sustainable Agriculture* (2013) 149 (available at http://old.fesrr.uniag.sk/en/sites/default/files/Umau_proceeding_volume.pdf).

⁷⁵ Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, [2006] OJ L396/1. For example, the Regulation leaves it to the discretion of producers whether carbon nanotubes are chemical substances equivalent to existing substances. On this aspect, see, e.g., É. Juet, S. Lacour, N. Leca, 'Les Nanotubes de carbone dans REACH: les NTC sont-ils des Substances Chimiques Comme les Autres?', in Lacour, Desmoulin-Canselier and Hervé-Fournereau (eds.), (above n 51) 229.

4. CONCLUSION

In a field such as nanotechnologies which is characterized by a high degree of uncertainty over the risks for health and the environment,⁷⁶ the imposition of an obligation to indicate on labels the presence of nanomaterials could be used as a reason to abandon other regulatory avenues which may be more effective. In particular, through labelling should the responsibility for decisions be increasingly left to individual persons as opposed to being assumed collectively? And this reasoning could certainly be extended to all technofoods, as defined. Information is without doubt necessary, but it does not guarantee understanding by consumers and it can be no substitute for strict procedures for both risk assessment and risk management. The unfortunate lessons recently learnt in the field of GMOs provide a warning, with Member States having taken the lead in the governance of the cultivation of GM crops in the absence of new initiatives for risk assessment.⁷⁷ This only goes to show further how delicate a subject is the governance risk, always open to challenge and to twists and turns; and the net effect is a brake on the development of a clear EU policy which opens up research and submits all technofood to a long and rigorous analysis.

⁷⁶ ANSES, *Évaluation des Risques Liés aux Nanomatériaux: Enjeux et Mise à Jour des Connaissances* (2014) (available at <http://www.anses.fr/sites/default/files/documents/AP2012sa0273Ra.pdf>).

⁷⁷ See <http://www.europaforum.public.lu/fr/actualites/2014/06/conseil-envi-ogm/index.html>.